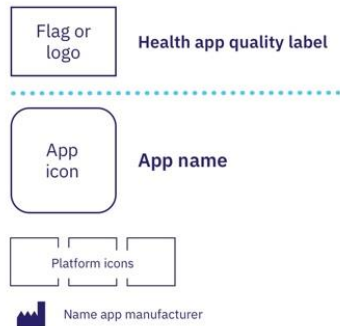


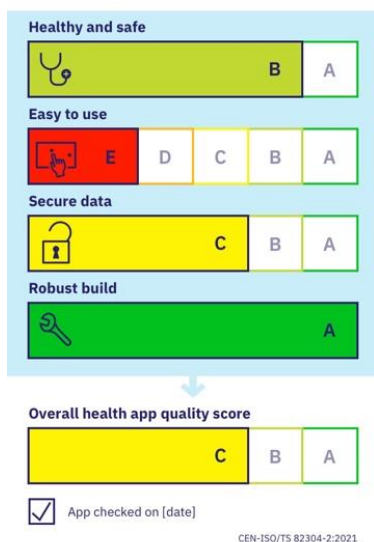
LABEL2 ENABLE 2nd workshop report



Benefit of the app

With this app [intended users] can [intended use] / With this app [x in 10] [intended users] [health effect] [if use]

Check [here] when app requires approval from a health professional before use



Preamble

On **June 26, 2023** the Horizon Europe Label2Enable consortium¹ organized its **second multi-stakeholder workshop** in a series of four workshops over the course of two years with representatives of our key stakeholders. These workshops are supporting a structured multi-stakeholder dialogue and include a backcasting exercise. Backcasting entails defining success of labelling health apps in 5 to 10 years, with a focus on the CEN-ISO/TS 82304-2 label, and how to jointly get there, in a context of the current legislative initiatives.

The presentations during the informative plenary session are available via <https://label2enable.eu/second-multi-stakeholder-workshop>. Agenda and details captured during the break-outs are found in the Annexes.

We welcomed 25 participants in person in Brussels, Belgium and another 42 online. The attendees included representatives of **patients / citizens / carers** (among others the European Patients' Forum, EuroHealthNet, Eurocarers), **healthcare professionals** (European Junior Doctors, European Medical Students' Association, HIMSS, University of Patras), **app assessors / frameworks / libraries** (DEKRA, HTCert, i~HD, INBIT, mindapps.dk, Equalis, Onco Appstore, ORCHA, Taskforce DMD), **app manufacturers** (Agoria, COCIR, Digital Therapeutics Alliance, EIT Health, Johnson & Johnson), **standard development organizations** (CEN TC 251, GS1, HL7, the Irish National Standardization Body), **regulatory service providers** (Complear), and **healthcare authorities** (the European Commission, Austria, Catalonia, Italy, Luxemburg, the Netherlands, Norway, Sweden), and multistakeholder initiative EHTEL.



Executive Summary

In this workshop we took our point of departure from the preferred future of the label as an integral part of a digital health landscape 5-10 years from now. We reflected on how thoughts and feelings of stakeholder groups in this preferred future affect labelling characteristics. More specifically, its scope (digital health / health and wellness apps), its level of enforcement (voluntary / mandatory), and type of certification (self-certification / third party certification). We then explored what changes are needed for bringing about this preferred future and who are needed to realize the changes and activities required. We further considered the in between targets and milestones, drivers and barriers and factors and trends that are assumed to be steady or cannot be influenced. We initiated an exploration of the unique role of each stakeholder group in getting to that future, a discussion however to be the main focus of the next workshop that will take place in **Brussels, Belgium** on **November 3rd, 2023**. In summary,

Thoughts and feelings in the preferred future

The vision for 2033 is that **digital health is a toolbox and apps are the tools**, fully integrated into clinical pathways and protocols. Yet strategies, policies and tools will need to be developed to make sure that the quality of the apps is assured and that the number of apps that health care professionals have to deal with will be selectively limited to a realistically manageable number. From the citizen/patient perspective the same reasoning would plea for a restriction of the number of health apps used in daily practice. The sector of wellness apps may go through a different type of development and may eventually become positioned closer to health apps and thus be part of the toolbox as well.

Examples of the range of elements to be taken into consideration in the suggested selection process are influence on the cost of care and scarce human resources time; prioritization of health care needs and integration of digital and health approaches into healthcare, and public health monitoring priorities outcomes that need to be collected.

In this process, manufacturers will need to be effectively supported in the assessment process, making the assessment efficiently available at scale. More importantly, harmonization across Europe (and beyond) will create a unified digital market. Choosing a single recognized label for all health and wellness apps across Europe and beyond will provide a major enabler.

In conclusion, there is a need for selection of fewer and better fit-for-purpose apps and with a wider application range and whenever relevant at the European level. For this we need to define more closely the relevant concepts, target groups, policies and strategies as well as reimbursement and revenue oriented models, and support their deployment for developers and health providers alike.

Although there are different thoughts as to the scope, a distinct majority thinks the label should eventually be mandatory. Hence, by implication the label should be established through regulation, and more specifically, European Regulation to achieve harmonization.

Changes needed for bringing about the preferred future

All of the above, requires a number of steps in the adoption road map which is summarized as follows:

A sustainable model for app assessment and certification scheme maintenance and continued multi-stakeholder engagement

- An entity should be established to maintain the label certification scheme, collect, and publish the evidence, including a database of labelled products; if and when mandatory and regulated, the latter will likely become a normative EU database.

Education

- Reach out to the entire population to bridge the gap between early and late adopters of the label
 - Consider, in particular, digitally deprived citizens and otherwise disadvantaged populations
 - Embed in digital health literacy programs and in financing and quality incentivization policies
 - Facilitate access to technology and facilities
 - Train students early in their career
 - Prepare and support the workforce

Communication

- Pursue an adoption roadmap for market and consumer uptake
- An adequate understanding and trust will promote uptake by consumers and health care professions, which in turn will contribute to a path to reimbursement and other revenue based financing business models
- Market demand for certification and labeling will
 - drive establishment of a or more Certification Bodies, competition is likely to create a need for certification, which in turn will create certification capacity with Conformity Assessment Bodies
 - create demand for skilled assessors
 - create a market for supporting Certification Bodies and Conformity Assessment Bodies and training of assessors
 - eventually prepare the ground and conditions for EU level legislation

Incentives / reimbursement

- Affordable quality
- Address unmet needs and equity
- Fewer apps broader scope?
- Evidence based health app selection and acquisition choices
- Beyond reimbursement of apps also recognize health care professionals' support role and time allocated

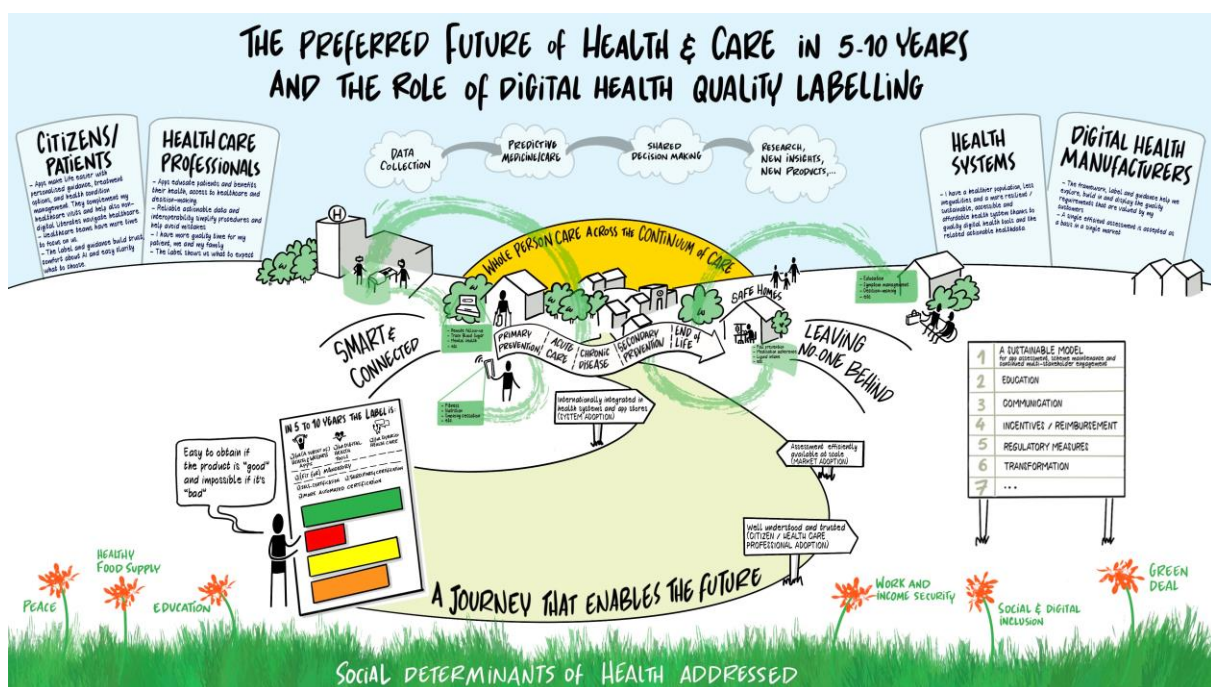
Regulatory measures

- EU harmonization implies legal intervention at EU level
 - Based on EU labeling framework in place

- Labelling may be voluntary or obligatory; likely to impose third party assessment for certain categories of apps/digital health technologies
- Member States establish oversight mechanisms
- EU level co-ordination, monitoring, and updates
- EU database of labels and labelled products
- Meet prerequisites
 - Sufficient Member State interest and demand for legislation

Transformation

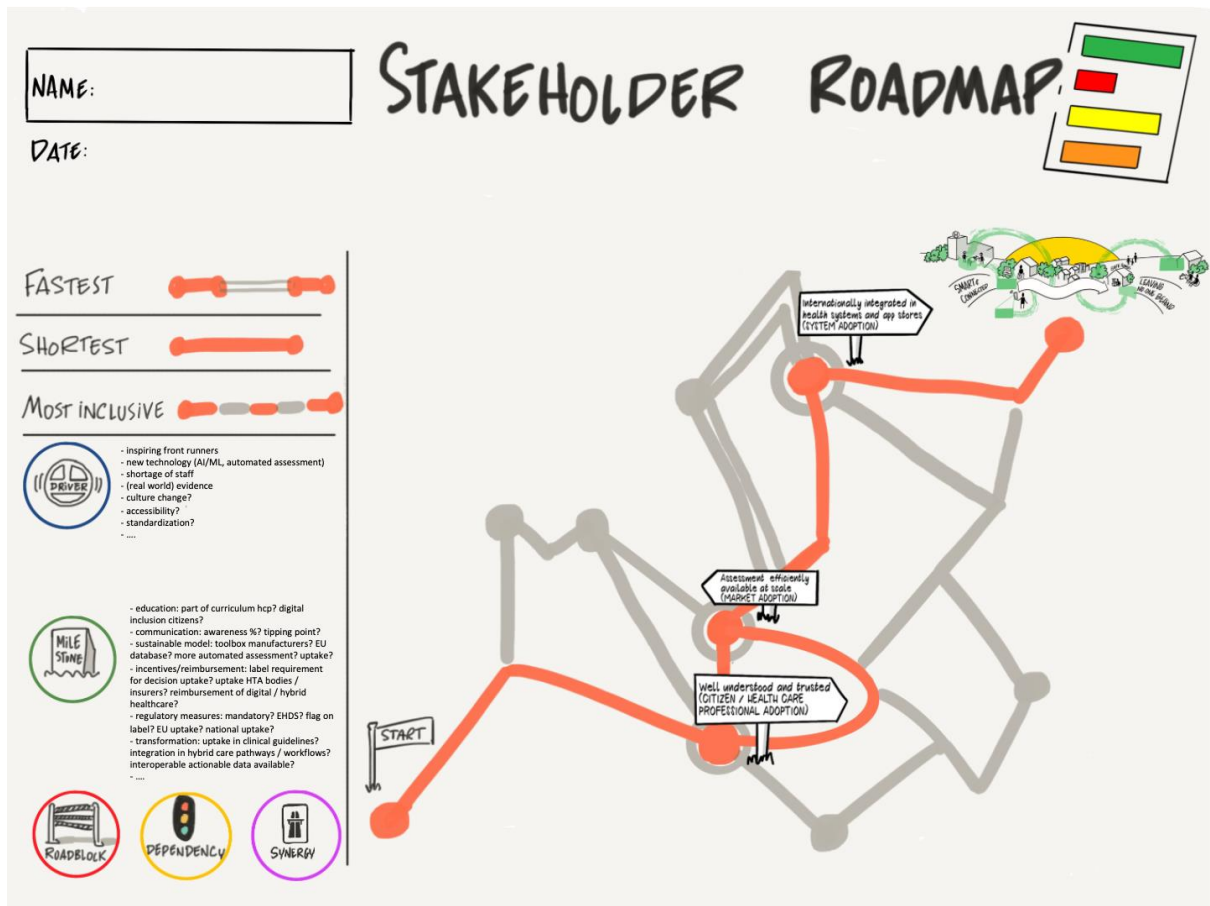
- Uptake in clinical guidelines
- Integration into clinical care pathways / workflows
- Interoperability with electronic health records



There will need to be a roadmap to making the label trusted, used and ultimately likely mandatory, departing from Label2Enable to build in the missing trust elements; operationalize certification and ensure sufficient citizen, health care professional, market and system adoption to create the needed maturity conditions for EU legislation. We need to, collaboratively with key stakeholders,

- **secure trust** in the Technical Specification and its associated trust framework i.e., its certification scheme, its proper operationalization and its stakeholder engagement enabling mechanisms
- continue to effectively **promote the TS 82304-2** for both the digital health demand and supply side actors, as a precondition to **establish** win-win relationships and **uptake**
- at the same time secure two strongly related perceptions of trust:
 - **ensure acceptance by national competent authorities**, health care administrations, HTA bodies and reimbursement agencies
 - **create a bond of trust with present and future users** to provide the digital health market with the basis to start and grow their business.

- actively **support citizen and health care providers' cultural shift**, including through early preparation of the workforce
 - this is likely to provide for sufficient scale up and evidence the need for the **European Commission and the Member States to propose relevant legislative initiatives**
- market uptake will drive **certification to become the means** and to build scale up capacity to meet increasing demand.




Annex I 2nd workshop agenda

LABEL2 ENABLE invitation

Flag or logo Health app quality label

App icon App name

Platform icons


 Name app manufacturer

Benefit of the app

With this app [intended users] can [intended use] / With this app [x in 10] [intended users] [health effect] [if use]

 Check [here] when app requires approval from a health professional before use

Healthy and safe

| | | |
|---|---|---|
|  | B | A |
|---|---|---|

Easy to use

| | | | | |
|---|---|---|---|---|
| E | D | C | B | A |
|---|---|---|---|---|

Secure data

| | | |
|---|---|---|
| C | B | A |
|---|---|---|

Robust build

| | |
|---|--|
| A | |
|---|--|

↓

Overall health app quality score

| | | |
|---|---|---|
| C | B | A |
|---|---|---|

App checked on [date]

CEN-ISO/TS 82304-2:2021

CEN-ISO/TS 82304-2 health app quality label

The Label2Enable consortium kindly invites you to participate in the **second multi-stakeholder workshop** on **June 26, 2023** at **CEN-CENELEC, Rue de la Science 23, Brussels, Belgium**. As part of our workplan, we will run a series of four workshops over the course of two years with representatives of our key stakeholders: app assessors, app manufacturers, app libraries and app stores, citizens / patients / carers, healthcare professionals, health authorities, insurers and Standard Development Organizations (SDOs). These workshops will support a structured multi-stakeholder backcasting exercise.

Backcasting entails defining success of labelling of health apps in 5 to 10 years - with a focus on the CEN-ISO/TS 82304-2 label - and how to jointly get there, in a context of labelling apps as specified in article 31 of the draft European Health Data Space Regulation. In the first workshop we jointly characterized the preferred future of digital health and the role of labelling. Please find in the agenda an initial sketch of the preferred future based on these discussions, and via this link the presentation slides: <https://label2enable.eu/first-multi-stakeholder-workshop>.

We will start this second workshop with a short discussion on the sketch and subsequently detail the journey with the label to get there: What changes are needed for bringing about this future? Who are needed to realize the changes and activities required? What are in between targets and milestones, drivers and barriers, and factors and trends that are assumed to be steady or cannot be influenced? What is each stakeholders' unique role in getting there?

The Label2Enable Coordination and Support Action (Jun22-May24) is a Horizon Europe project that aims to promote the Europe-wide adoption of CEN-ISO/TS 82304-2 and its quality label for health and wellness apps. The Label2Enable consortium partners² mirror the main mHealth stakeholders. Leiden University Medical Center coordinates the Label2Enable project.



agenda

Given the topic we hope to again welcome many stakeholders in Brussels. Thank you for indicating soonest if you will participate in person and join us for dinner. Please also indicate any dietary restrictions, so we can adequately inform our suppliers. For those who cannot join in person:
Dial-In link for Label2Enable – Second Multi-Stakeholder Workshop

June 25th

| | | |
|-------|-------------------|---|
| 19h00 | NETWORKING DINNER | L' Atelier de Willy, Boulevard Emile Jacqmain 118, Brussels |
|-------|-------------------|---|

June 26th

| TIME | TOPIC | |
|-------------------------|---|---|
| 9h00-9h30 | Arrival | CEN-CENELEC, Rue de la Science 23, Brussels |
| 9h30-10h00 (30 min) | <p>Welcome remarks and introduction Petra Hoogendoorn, LUMC and Zoi Kolitsi, I~HD</p> <p>Looking back and ahead: workshop objectives</p> | |
| 10h00-10h40 (40 min) | <p>Plenary Session I: Recent developments and inspiration Moderated by Petra Hoogendoorn, LUMC</p> <p>Inspiration from the journey and results of the EU Energy label Stamatis Sivitos, DG ENER</p> <p>Labelling in the EHDS and related developments (AI Act, Pharma Act) Petra Wilson, HIMSS</p> <p>Patient /citizen / carer and Healthcare professional advisory board thoughts and feelings in the preferred future Gözde Susuzlu, EPF and Antanas Montvila, Kaunas Clinics</p> | |



| | |
|---------------------------------|---|
| 10h40-11h00 | COFFEE BREAK |
| 11h00-11h50 (50 min) | <p>Plenary Session I: Recent developments and inspiration Moderated by Petra Hoogendoorn, LUMC</p> <p>Label2Enable findings and updates</p> <ul style="list-style-type: none"> - Healthcare professional survey on recommending health apps Ieva Biliunaite, LUMC - Testing the label scheme with 24 apps and 5 assessment organisations Paul Weston, ORCHA and Menno Kok, EIT Health - Testing the label in four corners of Europe: Denmark, France, Hungary, Italy Vania Putatti, EuroHealthNet |
| 11h50-12h20 (30 min) | <p>Break-out session I: Stakeholder thoughts and feelings in the preferred future and how those thoughts and feelings affect labelling characteristics: Should the label in 5 to 10 years cover digital health / (health and wellness) apps, be voluntary / mandatory, self-certification / third party certification? Why?</p> |
| | <p>Citizens / patients / carers and healthcare professionals Moderator: Dipak Kalra / Gözde Susuzlu</p> |
| | <p>App assessors, app libraries and app stores, app manufacturers, SDOs and regulatory service providers Moderator: Petra Hoogendoorn</p> |
| | <p>Health authorities and insurers Moderator: Zoi Kolitsi</p> |
| 12h20-13h30 | LUNCH BREAK |
| 13.30 -14.00 (30 min) | Plenary Session II: Reports from break-out session I |
| 14h00-15h30 (90 min) | <p>Break-out session II: What changes are needed for bringing about this preferred future? Who are needed to realize the changes and activities required? What are</p> <ul style="list-style-type: none"> - in between targets and milestones? - drivers and barriers? - factors and trends that are assumed to be steady or cannot be influenced? <p>What is your (stakeholder group's) unique role in getting to that future in 5 to 10 years?</p> <p>3 break-outs of mixed stakeholder groups</p> |
| 15h30-15h45 | COFFEE BREAK |
| 15h45-16h30 (45 min) | <p>Plenary Session III: Reports from break-out session II</p> <p>Discussion: Input for follow-up agenda Identifying dependencies and potential synergies</p> <p>Wrap up</p> |

Annex II: Reports from break-out sessions

1. Stakeholder thoughts and feelings in the preferred future

Citizens / patients / carers and healthcare professionals

Should the label cover digital health / (health and wellness) apps, be voluntary / mandatory, self-certification / third party certification and why?

There was a general feeling that labelling should be mandatory; however, a step wise approach is likely, starting from voluntary to eventually become mandatory. In terms of scope, start with those in the health domain – gradually increasing the scope, which is opposite to what the draft European Health Data Space regulation proposes, starting with [article 31] voluntary labelling of wellness applications, with [preamble - impact assessment] a cascading effect into medical devices that aim to be operable with EHR systems.

There should be a trial period of voluntary uptake. Prior consultation with stakeholders will be necessary.

- Define Conditions: who would set criteria, what is the assessment behind it, capable of filtering out less useful apps. Taking into account multiple perspectives and appropriate conditions ensure acceptance of approaches.
- Recommendation to project as a whole– try to look out for complimentary therapy apps and developers willing to use ISO standard against that – where they shine and struggle.
- Patient information apps are perceived as medical devices. Difficult to fulfil all requests on medical devices e.g., duet of cultural differences. Obligation for patient info leaflets and manual for medical devices. Information for patients should be taken into account.

Health authorities and insurers

What are the main challenges for health authorities?

The challenge for health authorities is that the **scope** they need to address in digital transformation is broad, which explains the low speed and the lagging behind in enabling policies.

Public health is more focused on data. Improving **trust, interoperability** and quality as different types of data are added is needed as more and more data is merged.

There is a challenge to further integrate digital health policies into health policies, as is the case in other sectors.

There is a risk and a challenge to prevent a **digital divide** due to varying levels of digital literacy which in turn is expressed as health care professionals being less willing to recommend apps to patients with low Socioeconomic Status (SES).

According to Roadmap 2030 (https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/europes-digital-decade-digital-targets-2030_en), in a couple of years all citizens should be able to have access to their **electronic health records**, which **should contain high quality data**. An action plan and support actions and other projects are set for building that capacity in Member States.

Recommendations

Bridge healthcare and public health, mandate secondary prevention. Socializing those ideas, finding what they already do and leverage on low hanging fruit, for example integrate remote consultations which is common amongst health authorities into care delivery.

App assessors, app libraries and app stores, app manufacturers, SDOs and regulatory service providers

ISO 82304-2 as a benchmark

The label is considered by manufacturers to provide a competitive advantage in the marketplace. They have to show somehow that their product stands out in a crowd that is enormous in size. For small companies acquiring (private-)investment is a day to day worry. They hope that acquiring ISO 82304-2 will help them convince investors (often venture capitalists) that their app has a higher than average chance to reach the market (and be reimbursed) in multiple European economies. For large companies ISO 82304-2 provides business intelligence (what is the competition doing, who is also in our market segment and what is their proposition?).

Trust as a core value

The label is associated with having earned the trust of a competent authority which is considered to add value to the company and its products. In addition, creating a bond of trust with present and future users provides a basis for the company to start and grow their business. These two perceptions of trust are strongly related.

The path to reimbursement for app manufacturers

The journey to market is a complex one requiring multiple interactions of the company staff with external parties. Often app manufacturers lack detailed insight in this “journey” and rather than following an optimized development path, they pick up individual challenges one by one. In addition, the technological development plan of the product, the business and marketing approach and the regulatory pathway would ideally be integrated, but in reality are often poorly aligned. If we could make (the application process for) ISO 82304-2 a tool for the app manufacturers to align all these internal processes more effectively, the companies would profit in more than one way from application for the label.

We need to think about introducing quick improvement cycles following up on the initial assessment process. Apps are likely to be improved regularly due to more substantial underlying data, technology improvements, additional features etc. Benefits of apps for society (in terms of direct healthcare outcomes, reduced illness, healthy employment, informal care provision etc.) were mentioned as well. Although often quite difficult to measure, societal impact may play a significant role in reimbursement decisions.

Should labeling be voluntary or mandatory (?)

There were mixed opinions about the question whether ISO 82304-2 would need to become mandatory for health apps (..eventually). The question was raised what would be needed to make it mandatory. For wellness apps the situation is different, voluntary assessment was considered the logical way to go.

2. What changes are needed for bringing about this preferred future?

(Considering the road and the label)

Participants were asked the following questions:

Q1. Who is needed to realize the changes and activities required?

Q2. What are the drivers and barriers, as well as the factors and trends assumed to be steady or cannot be influenced, that exist between targets and milestones?

Q3. What is your (stakeholder group's) unique role in reaching that future?

The outlook on the role of health and wellness apps 5 to 10 years from now

Digital health is a toolbox and apps are the tools

In 2033, digital health is a toolbox, and individual apps are the tools. All stakeholders expect health apps to be fully integrated into clinical protocols by 2033, but they agree that strategies, policies and tools will need to be developed (soon!) to make sure that quality of the apps is assured and that the number of apps that any health care professional will have to deal with will be limited! It is impossible for a General Practitioner, home care provider, physiotherapist, medical specialist (etc.) to deal with hundreds of apps, simply because one or several of their patients have selected these. From the citizen/patient perspective the same reasoning would plea for a restriction of the number of health apps used in daily practice: an elderly person with frailty cannot be expected to use more than one app to deal with his/her individual conditions. [At the same time, that is exactly what we expect in medication intake, especially in this age group and from people with multiple conditions.]

The sector of wellness apps may go through a different type of development. One trend could be that wellness apps may be relatively short lived, another that (some) wellness apps, due to ever richer data support (e.g., from Real World Data) might become positioned closer to health apps. So particularly in digital health, there is a need for selection of fewer apps with a wider application range. Elements to be taken into consideration in the suggested selection process: how does the digital health application influence (integral!) cost of care and time required from (scarce!) health care personnel? To make the case for a proper integration of digital health into healthcare, public health outcomes need to be collected.

Where are we today?

We need to more closely define what we're talking about, in terms of:

- Planning apps / wellness apps / health apps
- Primary target groups (e.g., general apps or disease specific apps)
- Business models (reimbursement oriented or other revenue models)

How can we reach the entire population?

The lag-time between early adopters and late adopters (including digitally deprived citizens and otherwise disadvantaged populations) may prevent successful role out of digital health solutions. All stakeholders in the digital health domain are affected by this. We should train students (as in: professionals early in their career) to deal with this problem. In addition, we need to promote health literacy (is there a role for primary education?) and facilitate access to technology and facilities.

Awareness and trust were identified as major parameters in adoption of new digital technologies. A quality label (that is recognized by the general population) would help adoption. Also, integration of apps into health care pathways will support recognition of digital technology as "trustworthy" by the general public.

How can we support manufacturers?

In the assessment process: providing opportunity for a "preapplication" (a short informal assessment of a few basic elements of the app to allow manufacturers to plan their validation strategy);

In the development process: stimulate app manufacturers to use the assessment process to guide them through the development and evidence build-up phases.

Harmonization: stimulate harmonization across Europe (and beyond) to rescue them from having to adapt their strategies to every new economy they get into. Harmonization would also imply choosing a single label for all health and wellness apps.

Needed changes

Cultural change

A cultural change is needed towards a more widespread but at the same time informed use of digital technologies to foster better health outcomes. Digital health literacy is a key element for such change, allowing for a better, safer and more effective use of technologies. Such a change should be enabled by proper legislation and the introduction of clear standardization for the use of digital health technologies.

Digital health and health equity

Digital health has the potential to both reduce and exacerbate inequalities. Therefore, it is important to introduce mechanisms that can mitigate the impact of these inequalities, specifically related to new digital health technologies, including apps. One way to achieve this is through the implementation of digital health equity impact assessments, which can drive change towards more equitable approaches to digital health. The label can also play a role in supporting these mechanisms by facilitating the identification and reduction of unmet needs in innovation, such as incentivizing and protecting apps in areas of need. Additionally, cohesion policies and other EU funds can contribute to the integration of these assessments, leading to improved delivery of quality healthcare.

Introduction of a certification scheme

The introduction of a certification scheme is key to fostering the standardization of app quality, thereby creating trust among actors in the app market. Certification bodies need to be established and should seek synergies with existing institutions. The industry should bear the expenses for the certification, although they can later claim reimbursement. The certification should be mandatory but introduced gradually, starting from a voluntary basis and transitioning to mandatory compliance over time.

Fostering harmonization

The industry and authorities need better harmonization to facilitate a smoother introduction of health apps and prevent duplication in the overall process. Building evidence for the EU can also contribute to synergistic efforts.

Discussion

At the EU level, there is competition and innovation within companies that contribute to moving the company forward and fostering an innovation basket. It is important to have competition that encourages the best ideas and legislation that categorizes met needs and unmet needs separately. It is crucial to provide extra incentives for those who innovate and address either met or unmet needs. One of the biggest challenges lies in addressing the healthcare needs of individuals from low socioeconomic backgrounds, including Roma people and marginalized groups. These groups often face barriers to accessing healthcare and may lack knowledge about even basic terminology related to organs and healthcare. They can be the costliest groups in terms of healthcare expenses. From an EU perspective, utilizing apps to address specific problems, especially unmet needs, can be incentivized and supported. Unmet needs typically have limited budget allocations. For example, there is a large market for apps that promote healthy eating and exercise, while other populations may be largely overlooked. Implementing an assessment scheme that evaluates aspects of more deprived segments of society can enrich the criteria for app evaluation. Health equity impact assessments can help determine whether an app or intervention can act as an incentive or exacerbate existing inequalities. Cross-fertilization and harmonization of assessment practices are important for ensuring a comprehensive evaluation process.

Closing remarks

When comparing similarities and identifying gaps, the goal is to reach harmonization. In this process, several synergies can emerge. Moving forward, it is suggested to organize workshops with more thematic / stakeholder focuses and establish priorities to start building a cohesive approach. It is important for stakeholder segments to take synchronized action. By the end of the process, a timeline should be established to understand what needs to be delivered and by whom. Proper stories should be developed from today's break-out sessions to create synergies.

In working towards the goal of harmonization, it is essential to consider the larger scope of things and be mindful of potential challenges or obstacles. One idea is to engage with app stores, as they hold influence in implementing the label. Pursuing discussions through letters or dialogues can be a productive approach. It is also worth considering engaging associations, although their influence may not be as significant as at the hospital level.

Annex III: Post-its

Many post-its, both physical and virtual, with answers to the questions discussed in the break-out sessions, the Patient / citizen / carer and Health care professional advisory board thoughts and feelings in the preferred future (see presentations) and a few articles³ were used alongside the discussion in the break-outs to update the visual of the preferred future and to suggest milestones and drivers for the stakeholder roadmaps in the third multi-stakeholder backcasting workshop. The content of the post-its is available in this Annex as well as the related content in the current or previous version of the visual of the preferred future or stakeholder roadmap.

Post-its

Health care professionals:

Upskill; Advocate for use of quality tools - Participate in development - Participate in policy making - Be ... (novel?) - Protect needs of society

Digital health manufacturers:

Quality requirements that are valued by my customers

Data collection:

Integration and merging of health data so existing information regarding health can be used in apps or vice versa - Privacy issue

My group: - condition / data used to remove rights on medical grounds -> driving -> employment

Shared decision-making:

My group's role: complex and varied condition -> many factors to consider -> no easy answer -> cross over of areas (drug, psychological)

End of life:

"Informed decisions" "Preferences communicated" [used article instead]

Leaving no one behind:

Digital health equity impact assessment?)

Tailored apps: health literacy, age, disease types

Next to label still guidance is needed for citizens what apps fit their needs

In 5 to 10 years the label is:

Consistent labels and quality criteria across health and care products and services (not just digital)

Anyway, apps as medical device should include at least patient info leaflet or guideline

It should cover all and mandatory

Perhaps, it should only be mandatory for high risk apps. Voluntary for low risk. Not sure how risk criteria would be decided.

Yes it should be for all apps that claim to assist individuals with prevention or managing their health, not those just providing information or informal content

The label should cover both wellness and health apps; however, the latter should be labeled mandatorily.

In the first years it should be voluntary with advancement to 'mandatory' stage about covering the Digital Health, it will depend on domains of Digital Health, if mobile and web app, then Yes

Yes cover wellness apps and be on a formative path: to aid progression along from wellness to even apply to specific patient groups in the future. Thus, mandatory but on a spectrum allowing guidance

The label should take into account digital health (health care and social care). In the long run the label should be mandatory, may be of importance what individual pay and reimbursement system

³ <https://www.nature.com/articles/s41746-021-00430-7>

https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7969595/>

The label should cover all digital health and be mandatory to ensure its usability. Its integration in the App Store and Google Play would be the most useful.

Yes it should be mandatory

Yes mandatory -> informs the user of health app -> consequence: longer time to access solutions

Labelling should be voluntary if any other info exists

Mandatory – depends on who decides on criteria? How much patient feedback / medical is involved?

Mandatory

Voluntary first

Should be voluntary otherwise there is a risk that many users will not be very welcome to use the app

Yes it should be mandatory

Comparisons help push up the quality

Based on the company feedback, there is still room to improve the assessment system. For this reason, it should be voluntary first. Only after improvements it could be made mandatory..

Voluntary until a sound legal EU framework is created for the assessment scheme

Trusted 3rd party -> building trust in ecosystem, independent, cross EU, certificate

Health determinants addressed:

"Agriculture" should be "wholesome food" or "healthy food available" or some such [two articles used]

Well understood and trusted:

Patient-centric timeline: patients / citizens / carers involved in every stage of the timeline

4. Reassessment requirements

Areas for improvements: evidence based approach, reassessment required in case of changes in application areas or use of AI

Objective assessment

HA assessors: Transparency, impartial assistance and guidance to developers. Patient at center.

How: 1. Role based training + certification

HP orgs should be consulted prior labeling apps which aim to be used in therapeutic sense

Assessment efficiently available at scale:

The notified bodies could perhaps provide app assessment services, but they are rather busy with other MDR related work. Finding suitable and accredited assessors could be a barrier.

Several languages are spoken in the EU. Some apps are for one language only. There needs to be an app assessor (preferably more to avoid a monopoly) for each language for the system to work in the EU.

Scalable assessment

The next version of the 82304-2 should contain an informative annex which addresses the problems brought up by the app manufacturers by providing information about how and how much to answer.

The app evaluation infrastructure needs to be in place before the labeling can be made mandatory. If there is a queue of 18 months to get an evaluation, this is harmful to the businesses and patient

Data submission standards that make space for digital integration on existing tools (alternative to the Excel questionnaire)

Internationally integrated in health systems and app stores:

Build agreement on common pathway and care process and quality criteria

Areas for improvements: clear application areas for digital health solutions,

Better connection & communication between different healthcare professionals and related areas e.g., GPs, specialized clinics, pharmacists, social workers

2. Define standardized classes / categories to compare apps or planning,

Barrier: lack of human contact

A sustainable model for app assessment, scheme maintenance and continued multi-stakeholder engagement:

Understand & participate to: - iron out challenges in assessment process - drive trust and early adoption of the label

Role of app assessors: adopt a harmonised approach across borders where we recognize assessments from other app assessors otherwise it will be too circumstantial for manufacturers

As SDOs, we should update the 82304-2 based on obtained feedback and we should have better implementation guidance in the doc than it has now

IKEA type of affordable quality (?)

Define label life cycle along solution life cycle (?)

Interoperability and agile development that track with the developers. Compliance system.

Ensure data is used is consistent and compliant with latest data specifications

Education:

6. Inclusion!! Not only SES

A general improvement of digital literacy in the population at large seems necessary to avoid potential health inequalities correlated with different digital skills

Mobile games / apps for children can teach children to notice healthy choices at an early age

We have to start educating people early, from Kindergarten. Mobile apps are no use if people's thinking doesn't change. Already today, antibiotics will not be taken until the end...

Educating

Education at all levels, but especially to medical students across all member states universities. Young newly warranted medical doctors are the stepping stones to clear fear barriers in patients.

HCP education now

Communication:

Effective communication about the value of the label and the products that score well

5. Communication campaign

Awareness

Evangelizing energizing

Incentives / reimbursement:

Define economic value by ecosystem (HTA, hospitals, hcp) of a score on the label

Empower gate keepers to enforce label as criteria -> procurement departments -> HTA -> app market places -> clinical societies

Drivers and barriers: health authorities -> incentives - to encourage adoption - to discourage perverse motives

Drivers / barriers: - value of label

Label: value an easy visual way for lay consumers to choose good apps at the point of downloading

Label: if an app maintains its a status for some time then its price can be increased so label act as a pricing indicator

Regulatory measures (also addressed at In 5 to 10 years the label is Mandatory / Voluntary):

3. Clear roadmap on when effective and how long grace period will be,

Enabling policies

Enabling legislation on patient / consumer rights, tools for patients / citizens to exercise these rights

Move from non-reg to regulated. See these as milestones for all app assessor groups and developers alike

Transformation:

Culture change: consumer in the driver seat

Currently EU healthcare is in emergency state as delivery focuses solely on service provision rather than actual focus on health. It is important to rethink the healthcare(?) but see digital health only as a tool not a solution

Processes and service transformation

Standardized terminology to support data analytics for efficient operational management of patients.

Standardized terminology to support care across borders

Separate stakeholder roadmaps:

- Stakeholders:

Patients and citizens

I think that patient advocacy groups play a very pivotal role to encourage patients they represent to trust the regulated labelled apps. Leaders of PAGS need capacity building training to be heard.

Patients/Citizens

Patients are the end user of the label. Patients, citizens, carers are ultimately who the label is created for

4. Medical staff + caretakers that are educated in the label

Professionals

Health Care Professionals through Clinical Care Programmes

By far the most important stakeholders to realize a need are actual decision-makers, who can truly influence policy behind healthcare delivery and financing. These are key drivers for any change.

EU and local politicians

3. Local authority or EU level authority,

HTA evaluation will play a role, in order to verify the importance of the app.

policy makers, as well as the legal system including.

Policy makers

Who: 1. QP/RP like person in digital health at manufacturers

Clinical Engineers

Dialogue, push site -> health tech, government, demand site -> pat/hcp

2. Training companies + notified bodies (easy to access),

Certification body / app checkers / assessors (CAB)

Auditors - to review progress

- Drivers - Barriers (Roadblocks) - Milestones - Dependencies - Synergies:

Feeling of privacy

Barrier: - data used by insurance companies

Barriers: varying levels of literacy

Barriers: Move active and targeted work with people/patients in low SES groups - always working from

"we are only as good as our weakest link"

Areas for improvement: Digital and health literacy for population. Digital Health education for healthcare workforce, plain/adaptive/personalized language for different groups of users

Pointing of key inequity factors – accessibility

Eventually there will be a need to change - shortage of resources

Drivers: Over-crowded hospitals

Limited resources

Drivers: Positive examples e.g., energy label, positive attitude from patients

Database of issued labels

Milestone: EU wide catalogue?

First label issued in health app repository

As a driver there could be an EU wide catalogue of (assessed and approved) apps which would be "an honor" for an app manufacturer to get to. The catalogue should be maintained frequently.

For uptake targets, need to group solutions: Self-management, Chronic disease management, Acute care

First reassessment label

Registration app checkers

Cost / time

A standard that is not achievable by the app providers.

assessment orgs

Expertise

Security (?)

New technology

Security of data

(Real world) evidence

Drivers: outcomes proved by data

Work on evidence!! Are health and wellness apps effective?

Better understanding of varying patient needs -> what works for one type of illness / group might not for another

Good quality apps should be available for successful implementation of health apps in health care or public health

Ways to track the moving target that health apps will likely follow. (?)

Drivers / barriers: adoption by all

Targets: A unified front in pilot projects amongst 4-5 countries to introduce the whole concept of Label2Enable - a pilot project similar to the implementation of the EU Disability Card now acknowledged

Endorsement building - EU - national – regional

Lobbying, representation, policy making, research, testing

Targets: Have enough app providers in the market to ensure L2E is valuable. Need to be phased.

Label: act as a filtering system for healthcare providers to recommend apps to their patients

Barriers: too complicated regulations

Barriers: policies

Keep your 360° stakeholder involvement interactive (2023-2033)

Drivers: industry, patients, hcp

Champions uptake - network - good practices (*teach the teachers*)

Barriers: financing schemes

Barriers: Due to such high rates of movements of people worldwide. Truly integrated solutions MUST follow the patient/person over borders; thus, a GLOBAL collaboration is a must. Global standards.

Barriers: Too many countries/policy makers offering their own benchmark and not working together.

Barriers: fragmentation

Barriers: lack of integration and interoperability

Driver: - remote & easy access + disconnect (for some)

A barrier for adoption could be to force the national authorities to pay for the app assessment since the first results of L2E show that the app assessment as per the ISO TS was given low scores. (?)

- Factors and trends that are assumed to be steady or cannot be influenced:

Demographics, burden of disease, at least in foreseeable future, technology development, growing demand at least 10-15 years

Every patient is different -> has different needs -> label should enable patients to make the right choice for them

Be aware of the uptake curve we cannot go around, play the game (*early adopters etc.*)

Notif. Pressure to demo quality steady increase use of digital health (manufacturers working to demo compliance)

Trends: Citizen/patient expectation of having everything accessible through mobile phone as is the case for banking