

Adopting CEN-ISO/TS 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps.

2 March 2023 10:00 – 11:30 CET

Enabling **patients**, **citizens** and **carers** to benefit from using health and wellbeing apps

LabelRoundtable Event Series















Agenda

10:00 - 10:05	Welcome and introduction
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10:05 – 10:10 Short interactive session with the participants: experiences with using health and wellness apps

10:10 – 10:30 How Label2Enable is fostering the adoption of the CEN-ISO/TS 82304-2 and a trusted EU mHealth label for health and wellness apps

10:30 – 10:40 Citizens' views on using health and wellness apps – insights from a large-scale EU survey

10:40 – 10:50 Addressing the barrier of low health literacy for the adoption and use of health and wellness apps: best practices

10:50 – 11:00 A health app platform providing a budget to purchase preselected apps as an innovative way to support public health?

11:00 – 11:10 Short interactive session with the participants: painting the perfect future for using health apps

11:10 – 11:30 Discussion, Q&A

Webinar Housekeeping



Participants are muted by default. During the interactive parts of the webinar, organisers can unmute participants who wish to comment.



This is a recorded webinar. The recording will be published on the Label2Enable website.



Parts of the webinar require use of an interactive tool called Mentimeter. Be prepared to be given a URL to participate via the tool. Preferably use a second device (mobile phone).



Participants have two two ways of interaction: by clicking on "raise hand" and waiting for the organisers to call on them, or by submitting a comment/question via the chat.



The recording and slide deck will be made available to participants after the event, via a follow-up email.

Webinar Panelists



Petra Hoogendoorn

Label2Enable co-ordinator

Leiden University Medical Center / National eHealth Living Lab



Mariam Shokralla

Digital Health Consultant Leiden University Medical Center



Eline Heemskerk

Senior Consultant Pharos, Netherlands

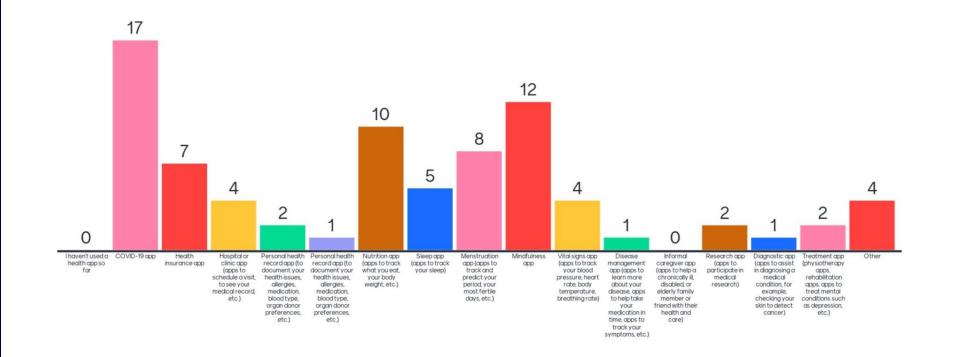


Romy Willemsen

Researcher eHealth and Project Manager Label2Enable

Leiden University Medical Center / National eHealth Living Lab Short interactive session with the participants: experiences with using health and wellness apps

Which type of health apps do you use or have you used in the past? (more than one answer possible)





How Label2Enable is fostering the adoption of the CEN-ISO/TS 82304-2 and a trusted EU mHealth label for health and wellness apps

Petra Hoogendoorn

Label2Enable co-ordinator Leiden University Medical Center / National eHealth Living Lab

LABEL2 لي ENABLE

what is 82304-2: the EU Energy label but then for health apps

Flag or logo	Health app quality label
App icon	App name

Name app manufacturer

Benefit of the app

Α

Α

B A

В

С

C B

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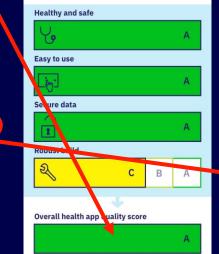
European Union

D

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



CEN-ISO/TS 82304-2:2021

App checked on [date]

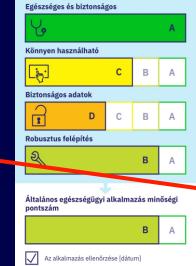
Zászló vagy logó	Egészségügyi alkalmazás minőségi címke
Alkalmazás ikon	Alkalmazás neve
Platform iko	nok

Alkalmazás gyártójának neve

Az alkalmazás előnyei

Ezzel az alkalmazással [célzott felhasználók] [tervezett felhasználás] / Ezzel az alkalmazással [x 10-ből] [célzott felhasználók] [egészségre gyakorolt hatás] [használat esetén]

Jelölje be [itt], ha az alkalmazás használatához egészségügyi szakember jóváhagyása szükséges.



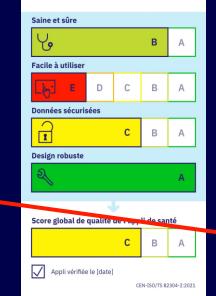
CEN-ISO/TS 82304-2:2021

Drapeau ou logo	Label qualité pour appli de santé	
Icône de l'appli	Nom de l'appli	
Icônes des plateformes		

Bienfait de l'appli

Avec cette appli, [utilisateurs prévus] peuvent [utilisation prévue] / Avec cette appli, [x sur 10] [utilisateurs prévus] [effet sur la santé] [si utilisée]

Cochez [ici] si l'appli nécessite l'approbation d'un professionnel de la santé avant d'être utilisée



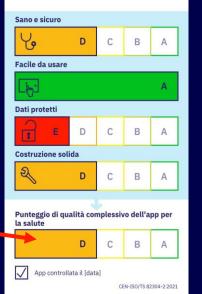
Bandiera o logo	Marchio di qualità dell'app per la salute
Icona dell'app	Nome dell'app
cone della piati	laforma

Vantaggio dell'app

Con questa app [utenti previsti] possono [uso previsto] / Con questa app [x in 10] [utenti previsti] [effetto sulla salute] [se utilizzato]

......

Controlla [qui] quando l'app richiede l'approvazione di un operatore sanitario prima dell'uso



App ikon	App navn
Platformsi	
	i leverandør af app
ordel ved a	ppen
	an [tilsigtede brugere] [tilsigtet brug] / plever [x ud af 10] [tilsigtede brugere]

Sundhedsapp

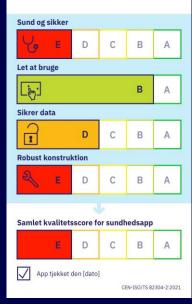
kvalitetsmærke

Flag eller

logo

Med denne app kan [tilsigtede brugere] [tilsigtet brug] / Med denne app oplever [x ud af 10] [tilsigtede brugere] [sundhedseffekt] [ved brug]

Tjek [her], når appen kræver godkendelse fra en sundhedsperson inden brug



LABEL2 U the EU Energy score



********* (91) Siemens WM14N295NL iQ300 extraKlasse wasmachine





★★★★★ (1) Whirlpool FFDBE 9638 BCEV F wasmachine

497,- Adviesprijs 629,- ✓ Op voorraad

A D

- Energieklasse D
- Vulgewicht 9 kg
- max. 1600 toeren
- 85 dB centrifugeren

Vergelijk product



AEG L8FEN96CAD OKOMix AutoDose wasmachine

866,- Adviesprijs 1.329,- ✓ Op voorraad



- Energieklasse A
- Vulgewicht 9 kg
- max. 1600 toeren76 dB centrifugeren

Vergelijk product



Miele WED 174 WPS wasmachine

1.379,- ✓ Op voorraad



- Energieklasse A
- Vulgewicht 9 kg
- max. 1400 toeren
- 70 dB centrifugeren

🗌 Vergelijk product

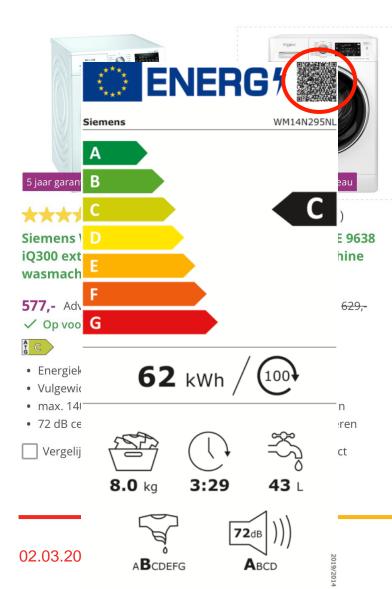


ne 02.03.2023

LABEL2 U the EU Energy label

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AEG L8FEN96CAD OKOMix AutoDose wasmachine

- **866,-** Adviesprijs 1.329,- ✓ Op voorraad
- A A
- Energieklasse A
- Vulgewicht 9 kg
 max. 1600 toeren
- 76 dB centrifugeren

Vergelijk product



Miele WED 174 WPS wasmachine





- Energieklasse A
- Vulgewicht 9 kg
- max. 1400 toeren
- 70 dB centrifugeren

🗌 Vergelijk product

LABEL2 U the EU Energy product information sheet

	pean mission		
PREL - Eu	ropean Product Registry for Energy Labe	lling	
me > Washing ma	chines > 335652		
Siemens WM14N295 — General	NL		
A	Overall dimensions 85 (Height) x 60 (Width) x	63 (Depth)	cm
C A G	Energy efficiency Index (EEI)		68,6
15PA	Washing efficiency index		1,04
8 Kg		4,5	a/ka
	Rinsing effectiveness		33
	Rinsing effectiveness Energy consumption [per cycle, eco 40-60 programme]	0,624	
		0,624 62	
	Energy consumption [per cycle, eco 40-60 programme]	62	kWh
	Energy consumption [per cycle, eco 40-60 programme] Weighted energy consumption [per 100 cycles, eco 40-60 programme]	62	kWh kWh litres
	Energy consumption [per cycle, eco 40-60 programme] Weighted energy consumption [per 100 cycles, eco 40-60 programme] Water consumption [per cycle, eco 40-60 programme]	62 43 44	kWh kWh litres
	Energy consumption [per cycle, eco 40-60 programme] Weighted energy consumption [per 100 cycles, eco 40-60 programme] Water consumption [per cycle, eco 40-60 programme] Maximum temperature inside the treated textile (Rated capacity)	62 43 44 37	kWh kWh litres °C
	Energy consumption [per cycle, eco 40-60 programme] Weighted energy consumption [per 100 cycles, eco 40-60 programme] Water consumption [per cycle, eco 40-60 programme] Maximum temperature inside the treated textile (Rated capacity) Maximum temperature inside the treated textile (Half)	62 43 44 37	kWh kWh litres °C °C



LABEL2 why: how to distinguish a "good" health app?

App Store Preview

mySugr - Diabetestracker-log Suggesties voor jou Glucose Blood Sugar Dexcom Clarity Glycemische index. Diabetes:M LibreLinkUp Diabeto Log Diabetes Geneeskunde Diabetes Tracker Geneeskunde Geneeskunde Logboek Geneeskunde Geneeskunde Geneeskunde iHealth iHealth ONE an BG8 DAR DROP Glucose Buddy Dario Health iHealth Gluco-Smart iHealth Myvitals Klinio: Diabetes One Drop: Better Health Gezondheid en fitness Diabetes Tracker Geneeskunde Today (Legacy) guidance app Geneeskunde Gezondheid en fitness Gezondheid en fitness Gezondheid en fitness Diabetes DIASCICS Pal Glooko - Track Diabetes Sugarmate | Diabetes-Glucose tracker++ **Diabetes Food Tracker** Carbs & Cals: Diet & DiabetesPal Data tracker Geneeskunde ~ Fittur Diabetes Geneeskunde claims Geneeskunde Geneeskunde Gezondheid en fitness Gezondheid en fitness

Wyatt (2018) How can clinicians, specialty societies, and others evaluate and improve the quality of apps for patient use? Larsen et al. (2019) Using science to sell apps: Evaluation of mental health app store quality claims

Singh et al. (2016) Many health apps target highneed, high-cost populations, but gaps remain





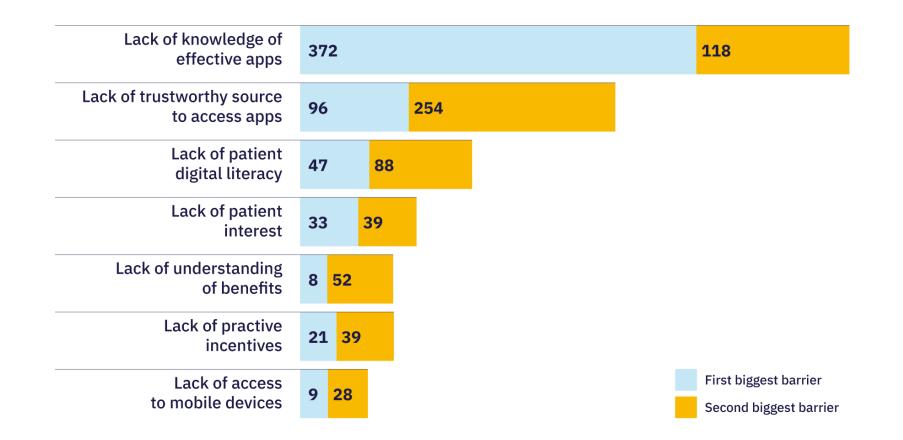
LABEL2 C choosing a 'good' health app is difficult

The sheer number of health apps makes choosing them confusing	37%
I am not sure health apps will help me	32%
I prefer face-to-face consultations with doctor/nurse	31%
I know of no health apps relevant to me	30%
I am suspicious of health apps, because I don't know who makes them	27%

Get-ehealth.eu (2015) What do patients and carers need in health apps - but are not getting? Global survey of 1,120 patients and carers



LABEL2 C choosing a 'good' health app is difficult

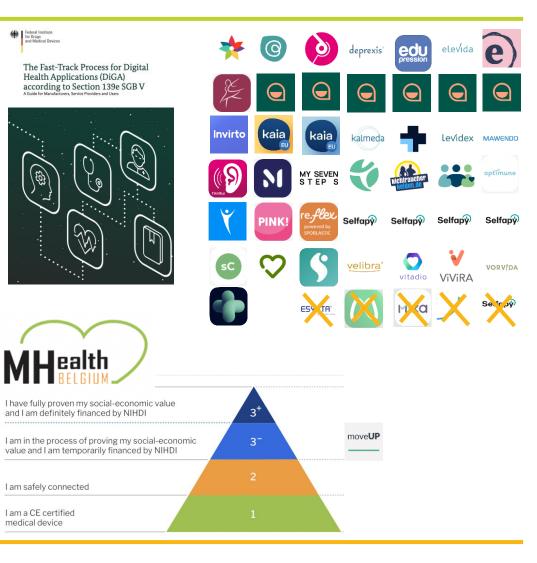


Byambasuren et al (2019) Current knowledge and adoption of mobile health apps among Australian General Practitioners: Survey study



LABEL2 U delivering a 'good' health app is difficult







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LABEL2 V reviewing a 'good' health app is difficult too

- **npj** | digital medicine Health app policy:
- Belgium
- Denmark
- England
- Germany
- Netherlands
- Norway
- Sweden
- Singapore
- United States

"There is great interest in the use of apps in all the countries evaluated, but even Belgium, Germany and the UK, which are relatively far along in their operationalization of frameworks, are struggling with efficient implementation.

Cross-national efforts are needed around regulation and for countries to realize the benefits of these technologies."

Essén et al (2022) Health app policy: international comparison of nine countries' approaches



EVABLE EU policy context

- The Green Paper on mobile health (2014) addresses the potential benefits and risks of health apps, questioning how to verify or ensure the efficacy of health apps (e.g. certification schemes) and how to better inform users on the quality and safety of these apps
- The Communication on enabling the digital transformation of health and care in the Digital Single Market (2018) highlights "digital tools and data for citizen empowerment and person-centred care" as a key priority and proposes common principles and certification to facilitate supply of these tools, also by Small and Medium-sized Enterprises
- CEN-ISO/TS 82304-2:2021 (health and wellness apps quality and reliability), an assignment from the European Commission to the European Committee for Standardization (CEN), International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), delivers a common health app assessment framework and label
- The Proposal for a Regulation on the European Health Data Space (2022) calls for voluntary labelling of wellness apps (Article 31) and a cascading effect in medical devices that aim to be interoperable with Electronic Health Record systems
- Horizon Europe project Label2Enable creates ISO 17065 EU certification scheme for CEN-ISO/TS 82304-2 aligned with EU values and EU legislation, enabling accredited app assessors (third party assessment) to issue trusted CEN-ISO/TS 82304-2 health app quality labels, scores and reports



LABEL2 U European Health Data Space alignment

Annex II

1. General requirements

1.1. achieve the performance intended by its manufacturer and designed and manufactured such that, during normal conditions of use, it is suitable for its intended purpose and its use does not put at risk patient safety.
1.2. designed and developed that it can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its intended use.
1.3. designed and developed in such a way that its interoperability, safety and security features uphold the rights of natural persons.

1.4. designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared with the EHR system.

- 2. Requirements for interoperability
- 3. Requirements for security -



LABEL2 Feedback on the proposed EHDS Regulation



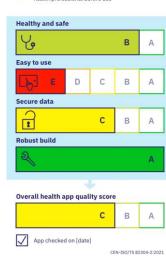
LABEL2 A how: CEN-ISO/TS 82304-2:2021 helps choose apps

Flag or logo	Health app quality label
App icon	App name
Platform icc	ons omanufacturer

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



Comprehensive For wellness and medical device apps, not duplicating the work of notified bodies

Evidence-informed Inspired by the EU energy label: used by 85% EU consumers and in 59 non-EU countries

Label tested with people with low health literacy

Score, label and report communicate quality in a glance to the needed detail

At most 81 questions, of which at most 67 score-impacting yes/no questions

Yes-answers require evidence to be assessed by accredited app assessors

Assessment framework founded in a Delphi study with 83 experts from 8 stakeholder groups



https://ec.europa.eu/commission/presscorner/detail/en/MEMO_19_1596



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Inclusive

Testable

Relevant

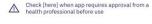
Maintained

Informative

Proportionate

LABEL2 ပြ **CEN-ISO/TS 82304-2:2021 content** ENABLE

Flag or logo Health app quality label	Healthy and safe	Health requirements, Health risks, Ethics, Health benefit, Societal benefit
App icon App name	Easy to use	Accessibility, Usability
Platform icons	Secure data	Privacy, Security
Name app manufacturer Benefit of the app With this app [intended users] can [intended use] / With this app [in 10] [intended users] [health effect] [if use]	Robust build	Technical robustness, Interoperability





CEN-ISO/TS 82304-2:2021

Original Paper

What Makes a Quality Health App—Developing a Global Research-Based Health App Quality Assessment Framework for CEN-ISO/TS 82304-2: Delphi Study



02.03.2023 **European Union**

لمع LABEL2

The Label2Enable project has made this video.

- The video explains how a new label that helps you choose a health app works.
- We use the App store and diabetes apps as an example.
- The apps you will see are real.
- The app icons and name of the app and app manufacturer are not real.
- We made up the scores, and the health benefit and date you see on the label.





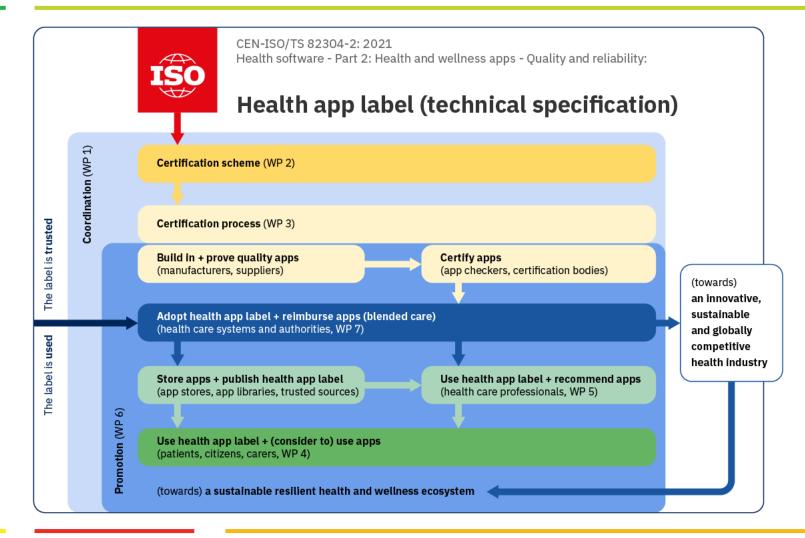


LABEL2 Who can benefit from CEN-ISO/TS 82304-2:2021?



02.03.2023

LABEL2 J fostering the adoption of CEN-ISO/TS 82304-2





02.03.2023



- Title
- Duration
- Instrument
- Type
- Grant Agreement number
- Budget
- Partners

Adopting CEN-ISO/TS 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps.

- June 2022 May 2024
- Horizon Europe
 - Coordination and Support Action
 - umber 101057522
 - 1,999.957.50 EUR





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LABEL2 Consortium partners mirror key stakeholders





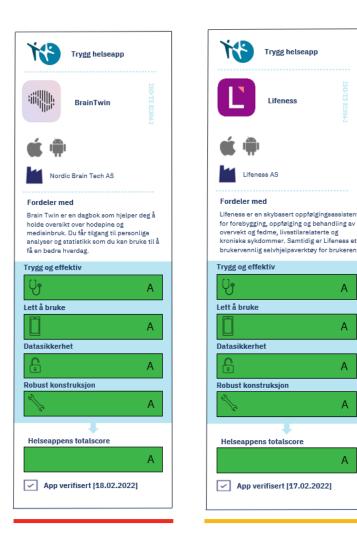
Funded by the U2 European Union

LABEL2 U trusted – used – adopted EU mHealth label

Flag or logo Health app quality label	task 2.1/2.2	Co-create a trusted ISO 17065 certification scheme for CEN-ISO/TS 82304-2	
App icon App name	task 3.1/3.2	Test the scheme with 6 app assessment organisations and 24 app manufacturers	TRUST
Platform icons	task 3.3	Assess business models for app assessments	
Benefit of the app With this app [Intended users] can [intended use] / With this app [xin 10] [intended users] [health effect] [if use]	task 4.1/5.1	Patient citizen carer / health care professional advisory group and board	
Check [here] when app requires approval from a health professional before use	task 4.2/5.2	Patient citizen carer / health care professional surveys	
Healthy and safe B A Easy to use B A A	task 4.3	Test the label with people with low health literacy in 4 corners of Europe	USE
Secure data	task 4.4/5.1	Co-create educational material label / Propose detail health app quality report	
Robust build	task 5.3	Assess how to position the label in app stores, app libraries and trusted sources	
Overall health app quality score	task 6.3/7.1	Multi-stakeholder backcasting workshops / Analyse authorities' use of 82304-2	ADOP- TION
App checked on [date] CEN-ISO/TS 82304-2:2021	task 7.2	Explore with insurers / HTA bodies value 82304-2 in their decision-making	(single market)



LABEL2 early adopters



"People are using more and more health apps. It is a desired development. There is no easy way to know that the apps are safe to use. Project "Safer health apps" wants to do something about it. The Directorate of Health, Norwegian Health Network and the Directorate for e-Health are working together on the project.

In the period January – March 2022, the project has tested an evaluation framework together with five app suppliers. The evaluation is carried out as a combination of self-completion and interviews. The self-filling forms are published together with the apps. After the evaluation, each app is awarded a quality mark that shows the quality of the app in the following areas:

Safe and effective Easy to use Data security Robust construction Quality branded apps"

> https://www.helsedirektoratet.no/om-oss/forsoksordningerog-prosjekter/tryggere-helseapper



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Email	info@label2enable.eu
Website	label2enable.eu
Twitter	@label2e
LinkedIn	linkedin.com/company/label2enable
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Citizens' views on using health and wellness apps – insights from a large-scale EU survey

Mariam Shokralla

Digital Health Consultant

Leiden University Medical Center

The survey results are not public yet, this part of the webinar cannot be shared.



Addressing the barrier of low health literacy for the adoption and use of health and wellness apps: best practices

Eline Heemskerk

Senior Consultant at Pharos, Netherlands



- Sustainable improvement of the quality, effectiveness and accessibility of care and prevention for people with limited health literacy, non-western migrants and refugees.
- Reduce existing health disparities between different groups of people.







 Personal health literacy is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.







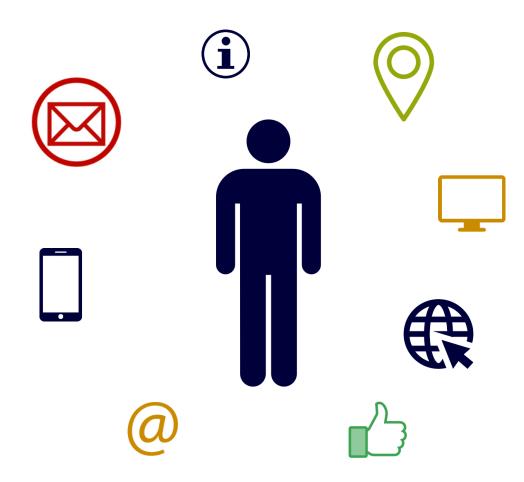
Reading and writing

- Knowlegde of health & diseases
- Knowledge of healthcare system
- Planning & organizing
- Numeracy
- Asking questions











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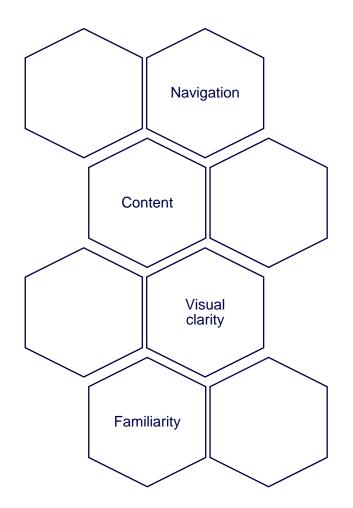


- Better understanding of health (condition)
- Personalized information
- Interactive
- Use of audio, visuals (video, images)













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LABEL2 Why is testing important?

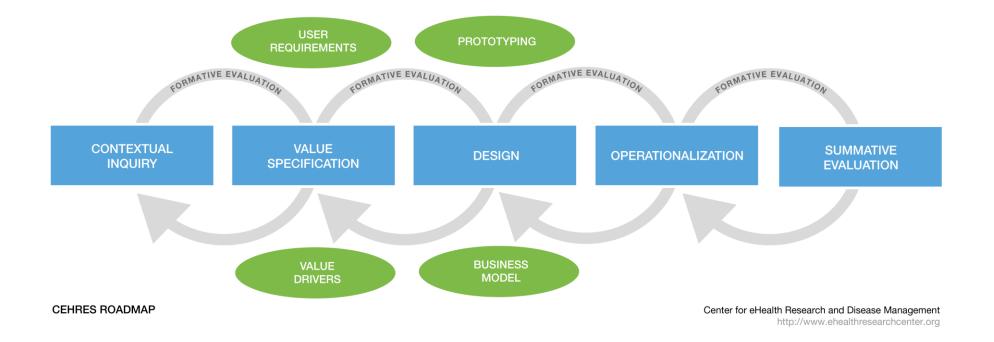
















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Adopting CEN-ISO/TS 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps.

Thank you for your attention

More information e.heemskerk@pharos.nl

Website pharos.nl



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A health app platform providing a budget to purchase preselected apps as an innovative way to support public health?

Romy Willemsen

Researcher eHealth and Project Manager Label2Enable

Leiden University Medical Center / National eHealth Living Lab

LABEL2 Barriers for uptake of health apps













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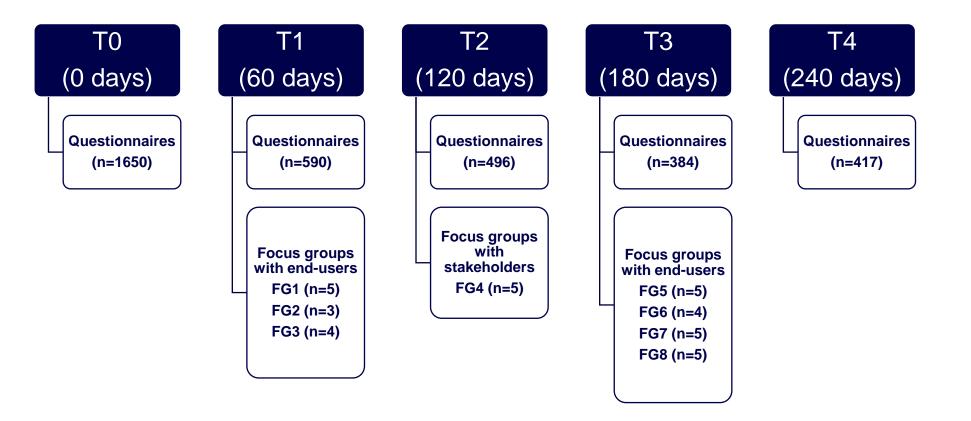
Goal FitKnip: FitKnip as an innovative tool to stimulate the uptake and usage of ehealth, ultimately supporting a healthier society



Goal of the study: To scientifically evaluate FitKnip, regarding: Feasibility Acceptability Health empowerment Health outcomes













45 years

71.3% Female

79.2% Highly educated



35.9% Diagnosis









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- Useful concept: financial barrier + preselection
- Budget
 - Satisfactory
 - Too low

'I find this an incredible initiative, since people are stimulated to use eHealth and money is no longer a barrier for using eHealth.' Female, 27 – Focus group at T1





Accontability (Madian IOP)	T1
Acceptability (Median, IQR)	N=579
Ease of payment system	8 (7-10)
Satisfaction look and feel website	7 (6-8)
Satisfaction amount of apps	6 (4-7)
Satisfaction with type of apps	6 (4-7)
Satisfaction with budget	9 (7-10)





- User friendliness
 - Motivational reminders

'I bought an application. You don't finish the program at once. Therefore it can happen that you forget about it. That is a shame. There should be a system, that if you don't log in for a week and you didn't finish the program, you will receive an app or e-mail.' Female, 63 – Focusgroup at T3





- Missing lifestyle apps
- Apps in varying levels of expertise
- Guidance towards suitable apps
 - Information applications
 - Categorization in themes
 - Personal selection

'I think it would be helpful if I could fill out a couple of questions and that based on these results, recommendations for suitable health apps are being provided' Female, 27 – Focusgroup at T1

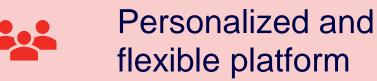




Conclusion

End-users and relevant stakeholders are enthusiastic about the idea behind FitKnip

The needs of end-users and suggestions for improvement identified





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Thank you for your attention

More information info@label2enable.eu

Website label2enable.eu



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Awareness & Discovery

Related to our general awareness about apps and how we find (discover) new apps

- Ask a friend / family • member
- Ask my doctor •
- Search myself (where? - google, app store, social media, ...)
- Ask my voice assistant •
- •

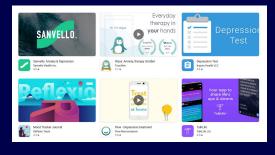
Appraisal & Selection

Related to how we judge which app is best suitable for us

- What criteria are important to you? e.g. rating/star, ease of use, security, ...
- How do you know if the • information shown is impartial and comparable across apps?
- The role of costs (e.g. free vs. freemium, on prescription)?

•

Example: search in Play Store for "depression app"

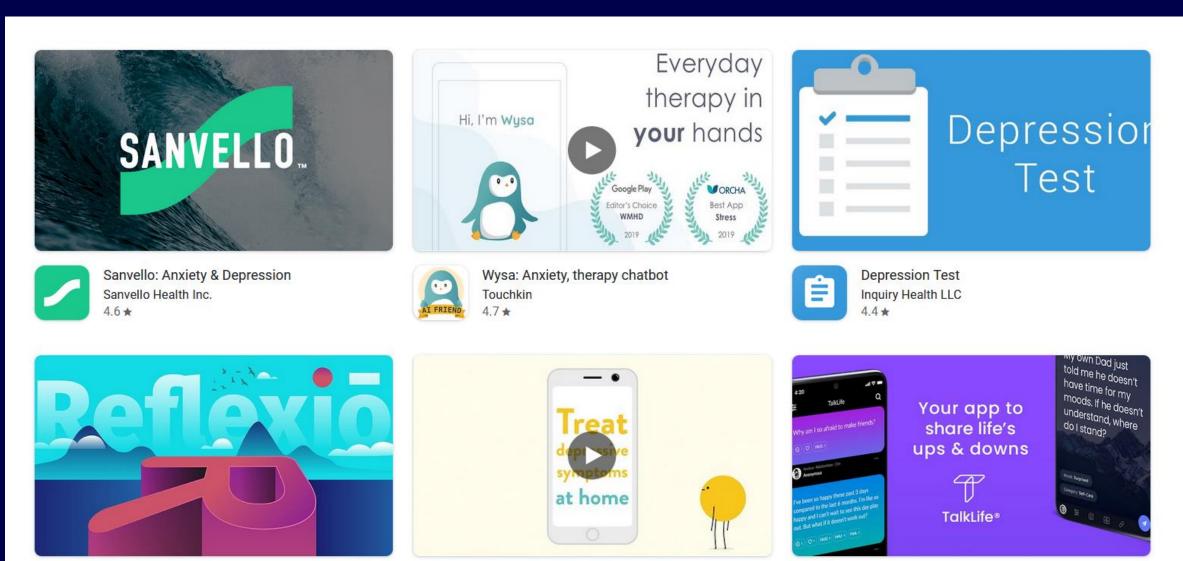


Use

Related to how we utilise the app for an extended period of time

Impact

Related to the results (or lack of results) we observe after using the app for a while





Mood Tracker Journal Reflexio Team 4.4 ★ Flow - Depression treatment Flow Neuroscience 4.0 ★



TalkLife TalkLife Ltd

Short interactive session with the participants: painting the perfect future for using health apps

What would be, for you, the ideal way of finding (discovering) apps that are good for you in 10 years?

Mentimeter

lin	k sent	to	me	by	my	health	h prof	essionals	5
-----	--------	----	----	----	----	--------	--------	-----------	---

À label and a recommendation by a HcP

Reviews and comments with a clear approval rating linked to my specific problem.

validated / officially labelled apps by the health authorities

In the future, apps may use AI algorithms and machine learning to analyze users' behavior, preferences, and interests to provide personalized app recommendations.

Al chatbot with a questionnaire to drill down my goals and recommend me only good apps based on my needs

quality label and app library for high quality apps

Scientists recomend

App store survey that then gives personalised suggestions

Professional directed

I would do a desk research on google and then assess the quality and trust among stakeholders (doctors, psychologist etc)

Would expect curated lists of Apps according to needs, symptoms, conditions provided by many organisations and bodies incl. government Short interactive session with the participants: painting the perfect future for using health apps

What barriers do you experience in selecting suitable health^{Mentimeter} apps, that should be solved within 10 years?





Adopting CEN-ISO/TS 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps.

Thank you for your attention

More information info@label2enable.eu

Website label2enable.eu



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