



ETSI EP eHealth Open Meeting on *Health and the Internet of Things (HIT)*

*Use Cases for standards in patient-driven medicine*

20 November 2015

# User-defined guidelines to improve the quality and relevance of health apps



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Director

[myhealthapps.net/PatientView](http://myhealthapps.net/PatientView)



## About PatientView

- UK-based research, consulting and publishing company
- **Collects and analyses the viewpoints of thousands of patient groups (and their members) worldwide – since 2000**
- Has the capacity to reach out to **120,000 patient organisations worldwide**, covering over 1,000 health specialties
- Launched **myhealthapps.net** in November 2013 to help patients, carers, and health-conscious consumers find apps that have been tried and trusted by people like them

# Evolution of health apps

## The promise

1. From the consumer perspective, health apps promise much more than support with diagnosis and treatment; they also promise to promote greater self-care.
2. Healthcare policymakers are hoping that mHealth interventions could bring about significant reductions in levels of chronic disease—enough to stave off the impending crisis in over-stretched healthcare systems (and largely funded by the user).



*“In a pilot funded by the NHS Tower Hamlets Clinical Commissioning Group, webGP had 36,000 visits in six months. Some 60 per cent of the patients who visited were managed remotely and 18 per cent did not need the doctor. This saved 400 GP hours.”*

Source: “Smartphone Apps are Key for Patient Health”,  
*The Times*, Lorena Tonarelli , 23 March 2015

# Evolution of health apps

## The need

Less than half of patients with a long-term illness take exercise, *or* have a social life, *or* get enough sleep, *or* cope with stress well, *or* eat a healthy diet, *or* look for health information online—according to an April 2014 EU-wide pilot study on the opinions of patients with long-term conditions (and their carers), conducted by PatientView.

Source: PatientView study commissioned by the European Commission and the Greek Presidency of the Council of the EU: Survey of 500 respondent patients/carers on the value of services in the home to support independent living and care for people with a long-lasting illness, April 2014[1].

A PatientView survey of 500 patients and carers on the value of services in the home to support independent living and care for long-lasting illnesses/conditions

*% saying that they undertake (or help their patients undertake) the following self-care actions to look after health / wellbeing*

	Taking exercise	Eating a healthy diet	Coping well with stress	Getting enough sleep	Having a social life
Patients	27.6%	43.5%	38.2%	33.3%	29.8%
Carers	33.3%	69.4%	53.3%	46.5%	33.1%

Source: PatientView study commissioned by the European Commission and the Greek Presidency of the Council of the EU: Survey of 500 respondent patients/carers on the value of services in the home to support independent living and care for people with a long-lasting illness, April 2014[1].

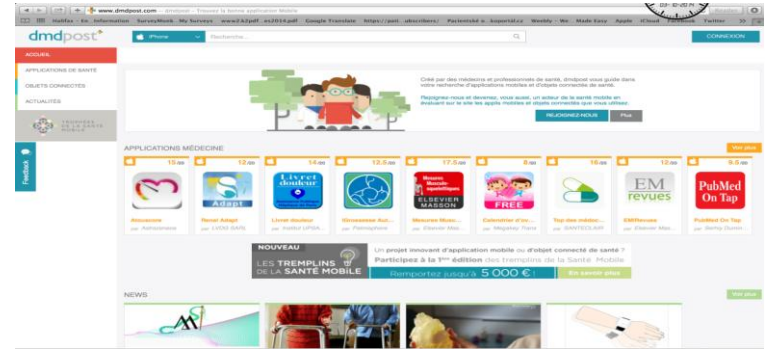


## Patients' views on health apps



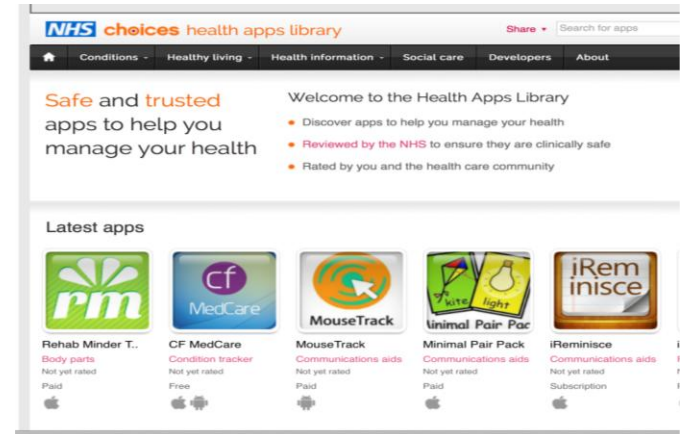
The screenshot shows the homepage of 'my health apps'. At the top, there is a navigation menu with links: ABOUT, SUBMIT APP, BROWSE BY CATEGORY, BROWSE BY PLATFORM, BROWSE BY LANGUAGE, RESOURCES, and HELP. Below the menu is a search bar labeled 'Search Health Apps' with a magnifying glass icon. The main heading 'my health apps' is accompanied by several colorful icons representing different health categories. Below this, a section titled 'Browse by Category' features seven icons with corresponding labels: Heart, Circulation and Blood; Me and My Doctor; Mental Health; Nervous System and Brain; Sexual Health; Staying Healthy; and Stomach, Bowel and Continence. To the right of these icons is a 'Support Sense: Mobility Learner' logo.

## Doctors' views on health apps



The screenshot shows the homepage of 'dmdpost'. The top navigation bar includes 'Accueil', 'Rechercher', and 'Connexion'. Below the navigation is a banner with a cartoon illustration of a doctor and a patient, with text in French: 'C'est par des médecins et professionnels de santé, dmdpost vous guide dans votre recherche d'applications médicales et d'articles scientifiques de qualité. Partagez nous et découvrez, vous aussi, un futur de la santé mobile en produisant sur le site les apps médicales et articles scientifiques que vous aimez.' Below the banner is a section titled 'APPLICATIONS MEDICINE' with a grid of app cards. Each card includes an app icon, name, and a 'Télécharger' button. The apps listed include 'Anatomie', 'Pneumologie', 'Livre d'Anatomie', 'Mémoriser An...', 'Mémoriser An...', 'Calculateur d'...', 'Top des ind...', and 'EM revues'. A 'PubMed On Tap' app is also visible. Below the app grid is a 'NEWS' section with a 'Nouvel' announcement: 'LES TREMPAINS DE LA SANTE MOBILE' and a 'Participez à la 1<sup>re</sup> édition des tremplins de la Santé Mobile' with a '5 000 €' prize.

## Clinical views of health apps



The screenshot shows the NHS Choices Health Apps Library. The top navigation bar includes 'NHS choices health apps library', 'Share', and 'Search for apps'. Below the navigation is a 'Conditions - Healthy living - Health information - Social care - Developers - About' menu. The main content area features a 'Safe and trusted apps to help you manage your health' section with a 'Welcome to the Health Apps Library' message and three bullet points: 'Discover apps to help you manage your health', 'Reviewed by the NHS to ensure they are clinically safe', and 'Rated by you and the health care community'. Below this is a 'Latest apps' section with a grid of app cards. Each card includes an app icon, name, description, and a 'Télécharger' button. The apps listed include 'Rehab Minder T.', 'CF MedCare', 'MouseTrack', 'Minimal Pair Pack', and 'iReminisc'. The descriptions for these apps are: 'Body parts', 'Condition tracker', 'Communications aids', 'Communications aids', and 'Communications aids'. The pricing for these apps is: 'Not yet rated', 'Free', 'Paid', 'Paid', and 'Subscription'.

**Substantial support** available to help patients and doctors overcome their concerns....



## Where we are today...

- Over 450 apps
- Covering **150+ health specialties**
- Apps in **50 languages**
- **Reviews** by over **650 patient organisations worldwide**
- **Transparency**: info on and links to app developer, who funded the app, whether it was developed with a medical adviser, if it has regulatory approval (if necessary)
- **Neutral platform**: only apps recommended by patient or health consumer groups included. Myhealthapps.net/PatientView takes no money from app developers or app downloads

Patients are increasingly building a repertoire of apps to support their needs

## How apps already help people with cancer





## Pilot study with Sycamore House Medical Centre, Birmingham (UK) 4,000 patient practice

- To promote the use of health apps to patients, give online advice, electronic booking of consultations - all to support self-care and improve relations with patients

The screenshot displays the Sycamore House Medical Centre website. At the top, a blue navigation bar contains the logo and menu items: Open, Appointments, Team, Services, New Patients, Feedback, and News. Below the navigation bar is a large hero image of a woman holding a baby, with a doctor examining the baby. A search bar is overlaid on the image with the text "I would like reliable information to help me with:" and "Search Patient.co.uk". Below the search bar, a prompt reads "Please enter your main symptom / the name of your condition above". A horizontal menu below the hero image features six colored buttons: Self Help Information (green), Health Apps (green), Request Medication (teal), My Medical Records (light blue), Web Consultation (light blue), and Book an Appointment (blue). At the bottom, a dark grey footer contains a disclaimer and privacy policy link, the copyright notice "© Sycamore House Surgery 2014", and the text "Powered by CAREAXES" with the CAREAXES logo.





Two test sites offered:

**NHS Health Apps Library and myhealthapps.net**

**Sycamore House Medical Centre** Open ▾ Appointments ▾ Team ▾ Services ▾ New Patients ▾ Feedback ▾ News

## Health Apps

To better manage your health and to boost your sense of wellbeing, have you considered using a health app on your smartphone, on your tablet device, or on your computer? There is increasing evidence that health apps can be very beneficial

**Two Useful Websites :**

- [The NHS Health App Library](#)

This site provides details of NHS accredited health apps

- [The myhealthapps Library](#)

This site reviews apps which have been ranked highly by patients

**Personal Health Record**

Users of Apple iPhones and iPads can now use the [Apple Health App](#) to integrate with our practice computer systems to create a complete Personal Health Record. For more details, please click [here](#)

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# Canvassing patients' views – a few examples...

Survey on behalf of the European Commission and the Greek Presidency (pilot study, results published in April 2014) into the attitudes of patients and carers to:

**1. Services in the home (like mobile phones, the internet, telecare, or personal health monitors) which provide support for independent living, or which communicate with the doctor, nurse or other care professional.**

- *Can these services help with the care of your long-lasting illnesses or conditions?*
- *Can they help you care for a person with long-lasting illnesses or conditions?*

**2. Supporting services based on mobile phones, the internet, telecare, or personal health monitors (which communicate with your doctor).**

- *How could they be improved to help people cope with long-lasting illnesses or conditions?*



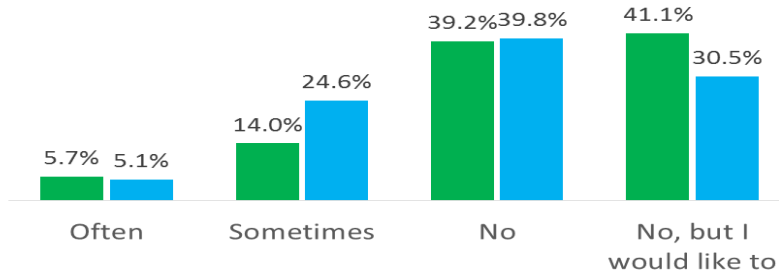
# Profile: respondents to the April 2014 Pilot Study

- **Responses from 21 EU Member States**  
majority from the UK (69%), but also from:  
Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Netherlands, Portugal, Romania, Slovenia, Spain and Sweden.
- **The majority of the patients and carers have extensive experience of coping with the medical condition**
  - **43%** of the patients and carers have been coping with the medical condition for **more than 10 years**.
  - **11%** of the patients and carers are coping with a condition that is lifelong.
- **The patients and carers were involved with diverse chronic medical conditions, notably...**
  - **Rheumatological conditions (26%)**
  - **Cancer (13%)**
  - **Diabetes (8%)**
  - **Multiple sclerosis (7%)**
  - **Rare diseases (6%)**
  - **Mobility impairments (5%)**

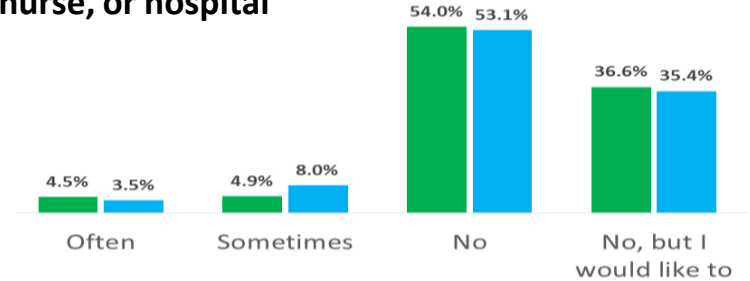


# Results: the technology is rarely used by the respondents for ...

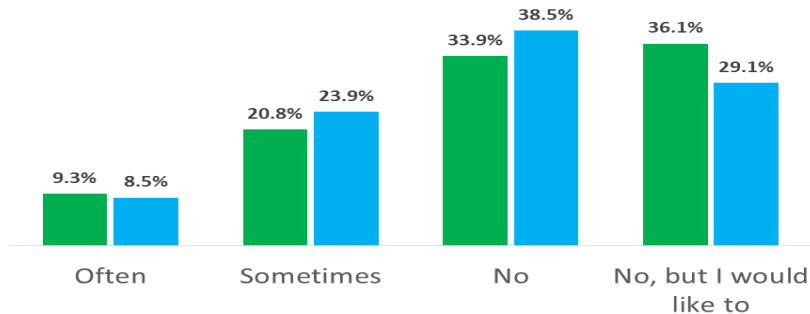
- Keeping in touch with doctors online



- Electronic home health-monitoring system collecting results to be shared with the doctor, nurse, or hospital



- Arranging medical appointments online



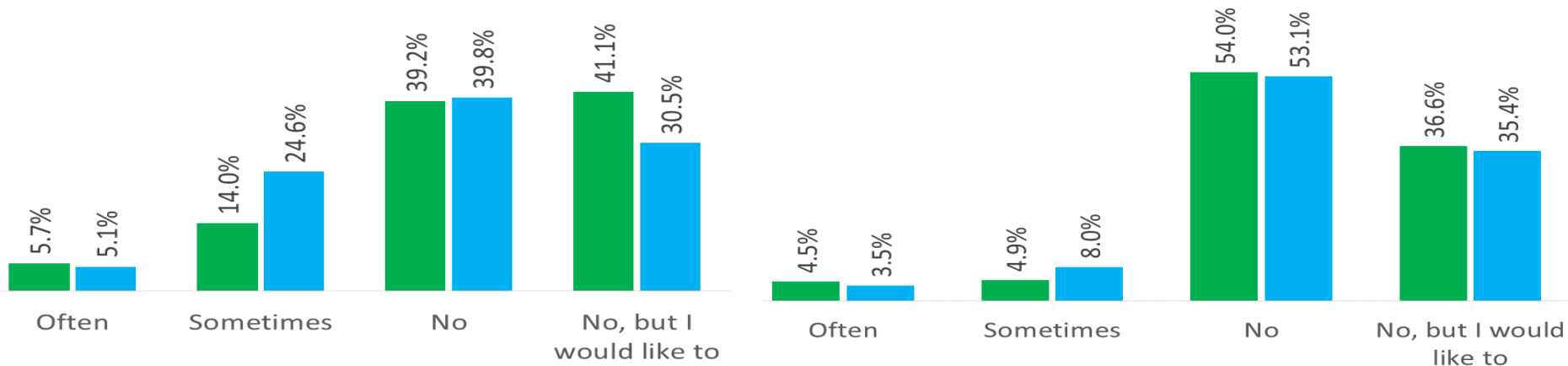
... though many of the respondents would like to do this

■ Patient  
■ Carers

# Results: the technology is rarely used by the respondents for ...

- Online counselling and support for the illness/condition

- Networking with other people who have the same illness/condition



■ Patient  
■ Carers

... but again, many respondents would like to do this

# What do patients and carers want from health apps?

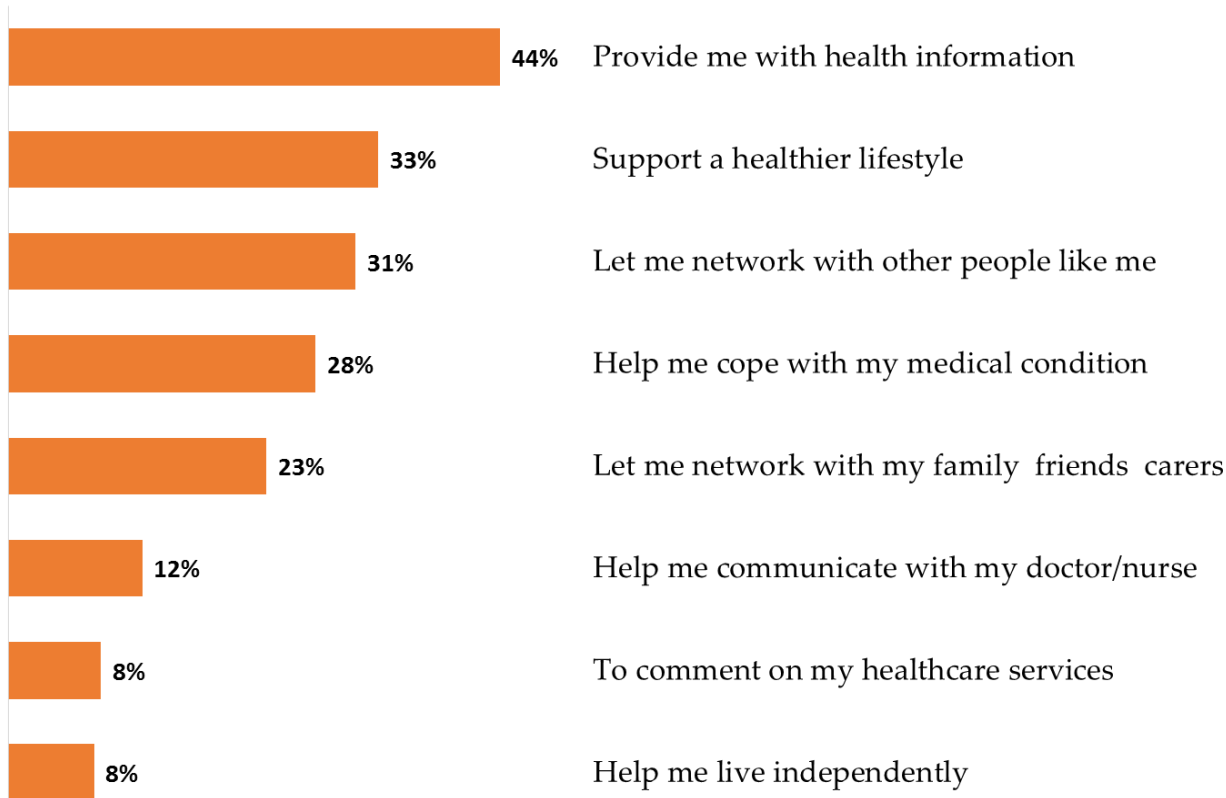
A June-Oct 2014 global survey conducted by PatientView, myhealthapps.net, and Health 2.0

- **1,130 respondents**
  - with either a long-lasting illness, or caring for someone who has one
- **From 31 countries**
  - 82.3% from Europe
- 10% with diabetes
- 9.6% with cancer
- 7.6% with arthritis
- 6.6% with a mental health problem
- 6.4% with a rare disease
- 4.9% with a hormonal disorder
- 4.8% with pain
- 4.4% with a heart condition
- 4.2% with multiple sclerosis
- Plus: 39 other conditions

10/11/2014



# What are the **main type** of health apps you use regularly?

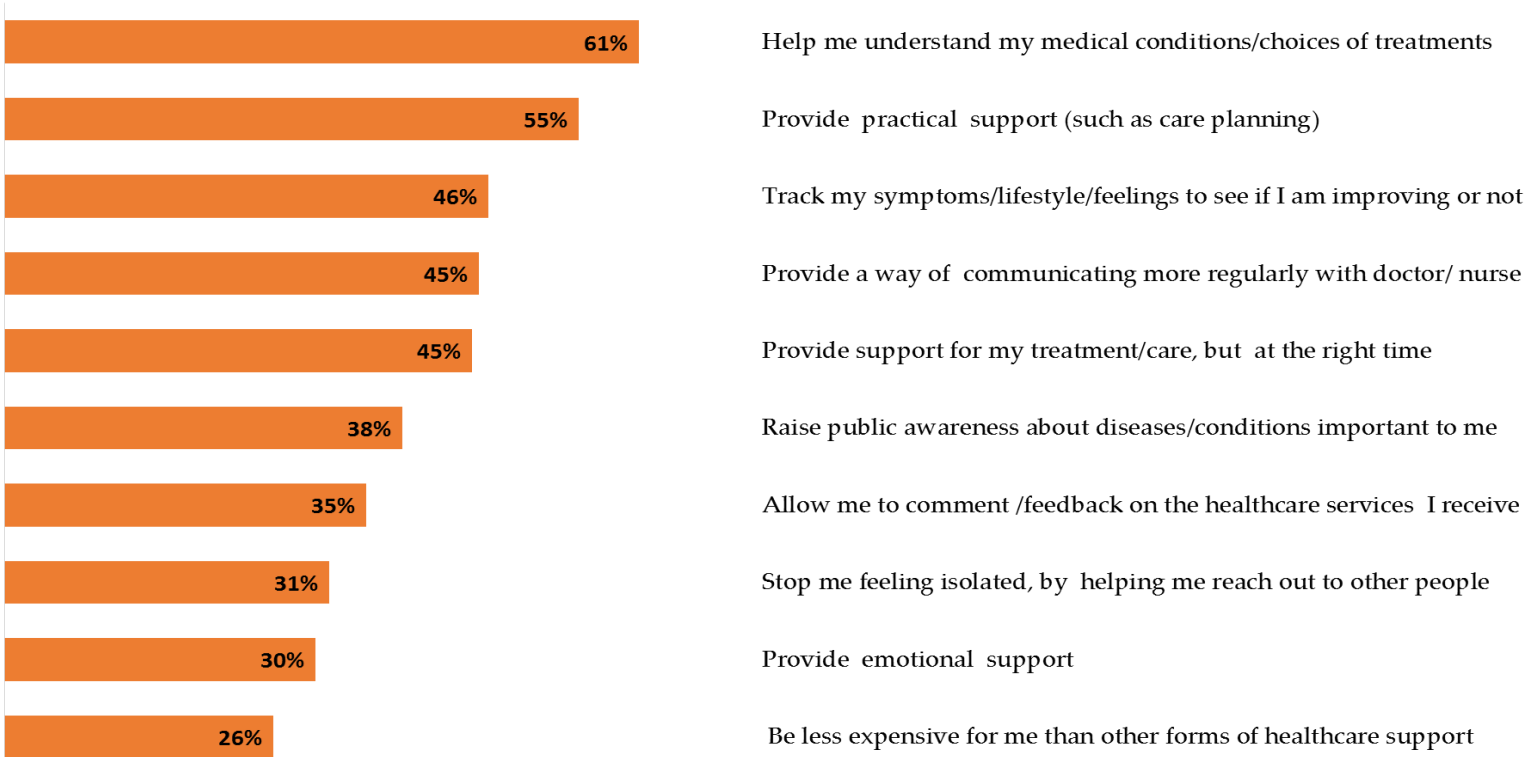


*Activities are focused on areas NOT integrated with the healthcare system; that can be undertaken alone*



# Irrespective of what health apps you are currently using, what do you **want most** from health apps?

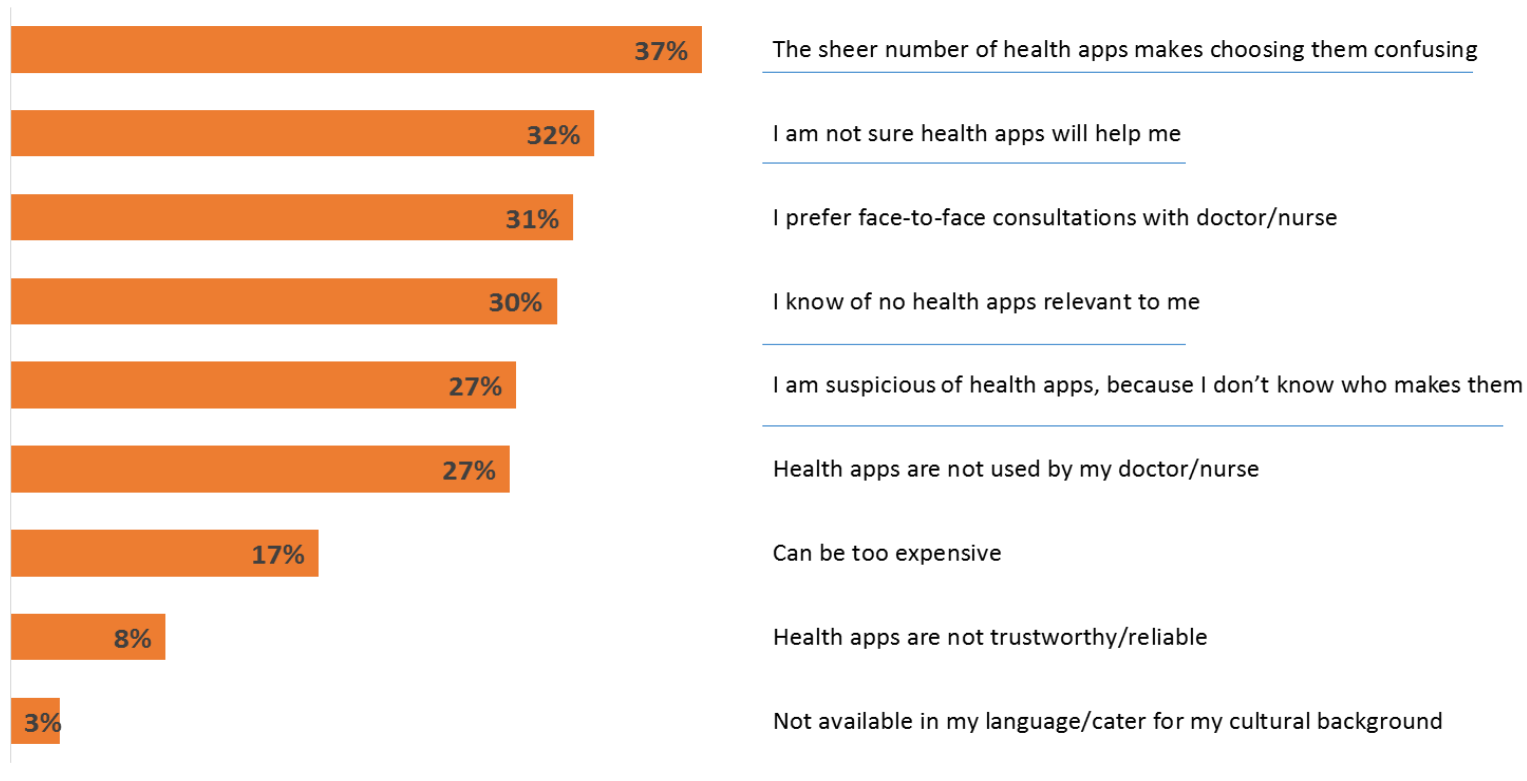
*But patients aspire to more than information*





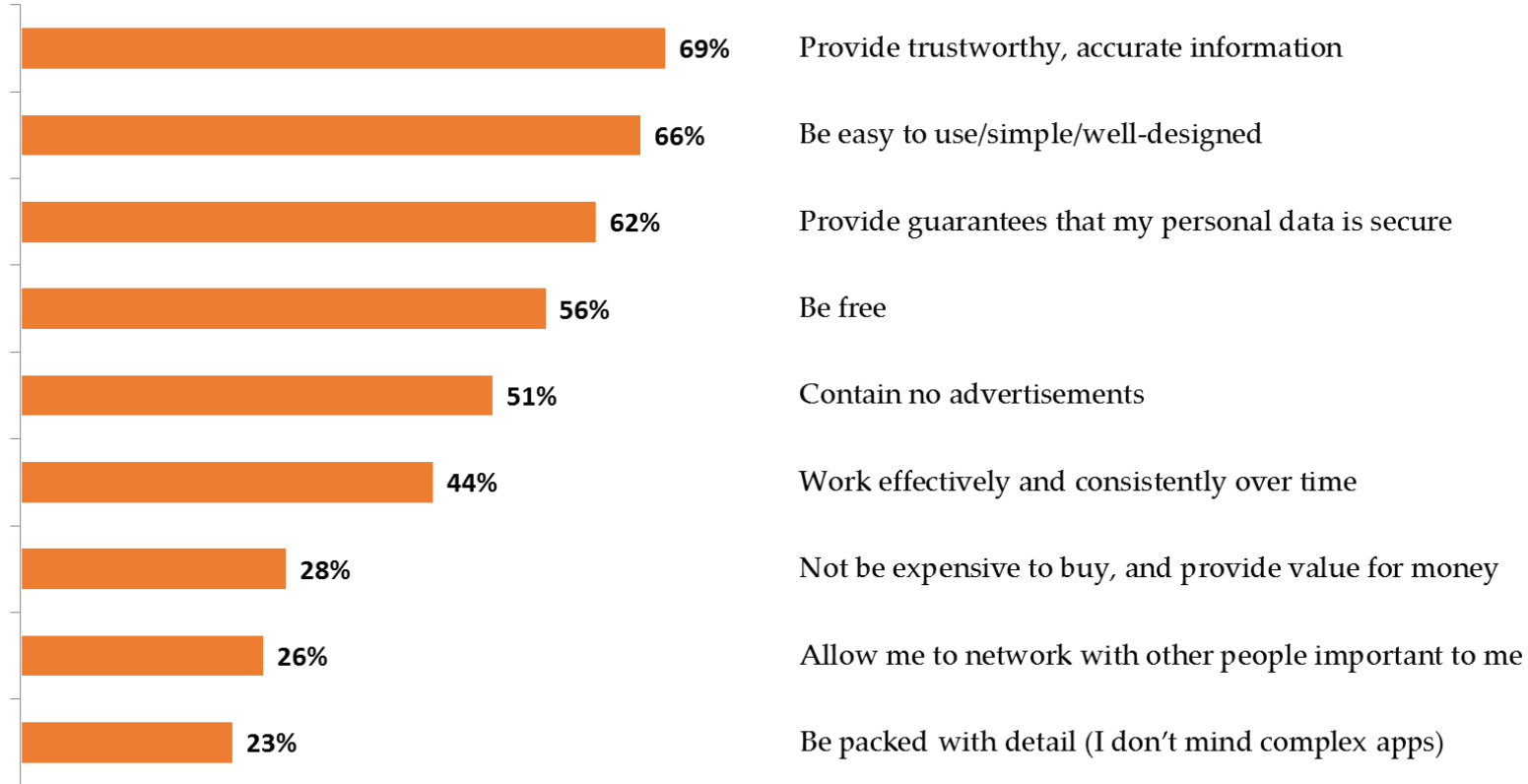
## Do any of the following **prevent you** from downloading some health apps, or using them regularly?

*Not just about the monetary cost of the health apps ... patients want support on which ones are most relevant to them*



## Which of the following would **convince you to** use health apps regularly?

*Patients/carers also need guidance on which apps to trust*



## Diabetes



→ *An intuitive app that calculates carb to insulin ratios advising on next best steps, giving feedback on how proper maintenance clearly improves my health*

*(relevant in T1 or insulin-dependent T2 diabetes only, though some aspects may be relevant to people with Type 2 diabetes that do not have to take insulin)*

### **Critical design and concept features that a diabetes app should address**

- Calculates carb ratios, based on information provided by the user
- Provides useful information for understanding carb to insulin ratios
- Tracks my blood sugar levels regularly throughout the day
- Takes data on my symptoms, treatment and lifestyle
- Works out how the food I eat affects my blood sugar
- Works out how the exercise I take affects my blood sugar
- Must be easy-to-enter data
- Secure messaging service with doctors/nurses for questions would also be of value
- Supports me in calculating ratios and insulin dosing based on personal historical data
- Permits me to communicate with other people like myself to get help and advice on how much insulin to take with food
- Provides access to nutritional information for accurate carbohydrate content of common foods

# Sustainable healthcare app

## FINANCIAL

- Sustainable business model, for example subscription, payer contribution

## TECHNOLOGICAL

- Works seamlessly over multiple platforms
- `Smooth` updates with no loss of data or negative impact on patients

## CLINICAL

- Accepted by HCPs and patients because medical content is accurate, and regularly reviewed and updated

## INTEGRATED

- Accepted as part of the local healthcare support system
- HCPs, patients and carers clear how this app fits into the person's care

## 'FOR LIFE'

- Able to adapt and target personalised support for a patient at each stage of a journey with a long-term condition

# The need for user guidelines

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There are compelling reasons why the quality of health and wellbeing apps might be improved with a set of user-designed guidelines.

Users want apps that they can trust and which meet their needs and developers need clearer guidance on how to address those needs in order to deliver better quality apps.

Jorge Gonzalez, Managing Director, TICBioMed  
[An eHealth cluster headquartered in the region of Murcia (Spain) whose members include the local public healthcare system, four private hospitals, three universities and more than 30 ICT companies]

*“One reason why the health app market has failings is that more often than not health apps are developed in isolation from their intended users—patients and the public.”*



# The need for guidelines rather than excessive regulation - better outcomes for users and developers

- Health apps transcend national geographic boundaries and it is unclear who or what has jurisdiction over them—the same app can be used in many countries.
- Technology is moving so quickly it would be hard for regulators to keep up and not stifle innovation with bureaucratic delay.
- Health apps are but one tool in the electronic delivery of medical solutions, so regulating them in isolation may not be productive.
- EU nations are finding it increasingly difficult to keep up with the transposition and application of regulation.

# US Food and Drug Administration (FDA) recently updated its guidance on regulating health apps\*

\**Medical Devices Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices*,  
9 February 2015 [www.fda.gov/medicaldevices](http://www.fda.gov/medicaldevices)

## Mobile medical apps that the FDA will regulate

The FDA is taking a tailored, risk-based approach that focuses on the small subset of mobile apps that meet the regulatory definition of “device” and that:

- are intended to be used as **an accessory** to a regulated medical device, or
- **transform a mobile platform** into a regulated medical device

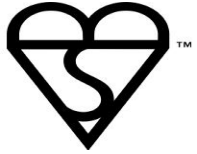
Mobile apps span a wide range of health functions. While many mobile apps carry minimal risk, those that can pose a greater risk to patients will require FDA review.

## Mobile apps for which the FDA intends to exercise enforcement discretion

For many mobile apps that meet the regulatory definition of a “device” but pose minimal risk to patients and consumers, the FDA will exercise enforcement discretions and will not expect manufacturers to submit premarket review applications or to register and list their apps with the FDA. This includes mobile medical apps that:

- Help **patients/users self-manage their disease** or condition without providing specific treatment suggestions
- Provide patients with simple tools **to organise and track their health information**
- Provide **easy access to information**
- **Help patients document, show or communicate potential medical conditions to health care providers**
- **Automate simple tasks** for health care providers
- **Enable patients or providers to interact with Personal Health Records (PHR) or Electronic Health Record (EHR) systems.**

# Examples of other app guidelines



British Standards Institution **PAS 277:2015 Health and wellness apps. Quality criteria across the life cycle. Code of practice**

**NATIONAL  
INFORMATION  
BOARD**

**WORK STREAM 1.2 ROADMAP: Enable me to make the right health and care choices. Providing citizens with access to an assessed set of NHS and social care 'apps'**

October 2015

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/467065/Work\\_stream\\_1.2\\_with\\_TCs.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/467065/Work_stream_1.2_with_TCs.pdf)



GSMA has created a set of **guidelines for app developers** that enable improvements across a number of areas including application connectivity, power consumption, network reliability and security.

<http://smarterappsguidelines.gsma.com/>



Highlighting those features of mobile devices that are beneficial to people with disabilities



# The challenges of creating assessment frameworks and guidelines....

(Consultation feedback on NIB Work Stream 1.2)

- ❖ The **definition of apps needs to be clarified**: what is an app for the purpose of this assessment?
- ❖ The scope of the assessment may be too broad: **which apps should be covered?** Some believe only apps which can put patients at risk of harm should be assessed, others that the focus should be on apps connecting to patient records. There are views that the focus should be on apps that have the potential to be cost-saving. There is also a view that **the assessment of apps should focus on nationally set priorities where there are unmet needs from the app market**. There is a general consensus that the process will fail if it does not attempt to segment the market and establish focus and some priorities
- ❖ It is **unclear who the assessment is for**: for care professionals recommending apps? For commissioners who decide to procure apps locally? Or for the end users of apps, patients, citizens or carers?
- ❖ There is a **need to clarify what the different stages of the assessment mean for users and to establish if users will be able to differentiate between different degrees of 'endorsement' or 'recommendation'**
- ❖ **Is an assessment framework the only solution? Can guidelines be developed to help developers and users alike create and choose better apps?**
- ❖ Is a yes/no result to the assessment the only solution? An alternative output could be **a rating scale based on the key dimensions of the assessment such as, for example, privacy, effectiveness, usability, cost**

# 12 January 2015 - *Summary report on the public consultation on the Green Paper on mobile health* identifies many concerns [European Commission]

## *Lots of questions for users and developers to consider ....*

**Data protection**—what is health data? What would build trust?

**Data-sharing interoperability**—how important is this to users? How important is it that data in apps are standardised?

**Big data**—should users know how their data are being gathered and used? Should users decide which of their data they want to share?

**Legal oversight**—what do users want? Should law define how personal data in apps are processed and

used? Should app developers be required to ensure any claims they make are justified?

**Liability issues**—need for code of conduct among app developers? Should there be guarantees of reliability and functionality? Should app stores be made liable for their content? Who should be liable if patients pass inaccurate medical data to one another?

**Levels of transparency** of the app/owner developer, and their partners—how much and what?

# 12 January 2015 *Summary report on the public consultation on the Green Paper on mobile health* identifies many concerns [European Commission]

## *Lots of questions for users and developers to consider ...*

**Incentives** - what would make public/patients use health apps more frequently? Should they be prescribed by doctors?

**Health outcomes** - how tangible should they be?

**Value for money** - how important?

**Levels of governance** - should there be quality labels and certification schemes? Should there be a central registry of health apps?

**Clinical input** - when?

**Public and patient safety** - how should that be protected?

**Health literacy** - how can apps be made more readily understandable to the user? Whose role is it to educate users in mHealth?

**Accessibility** - how can apps be made more readily accessible to the user? Should government help pay for health and wellness apps?

The green paper - summary of the public consultation, relevant findings to MHA Document: Summary report on the public consultation on the Green Paper on mobile health

<https://ec.europa.eu/digital-agenda/en/news/summary-report-public-consultation-green-paper-mobile-health> Published: 12 January 2015. Based on responses of 211 stakeholders to the Commission's Green Paper published on 10 April 2014.

# Improving user understanding of risk

There are several ways to classify apps.

But from the perspective of how people use health apps, and their perception of risk, myhealthapps has identified five different types of app from the research undertaken with patients and carers over the past four years.



**Disability**—health apps that enable people to cope with daily living and provide support to people with any type of disability, including physical, mental and sensory impairment. For example, text-to-speech apps that help people who have speaking difficulties or limited verbal abilities, to augment their communication skills.

**Health, wellness and care in the community** are health apps that allow us to manage our health and healthcare without the necessity for medical assistance, and which do not result in clinical decision-making by the user, or require input from a health professional. These apps include the bulk of lifestyle health apps (diet, exercise, stopping smoking etc), many informational apps, and those that enable people to gain support from carers, family, or friends.

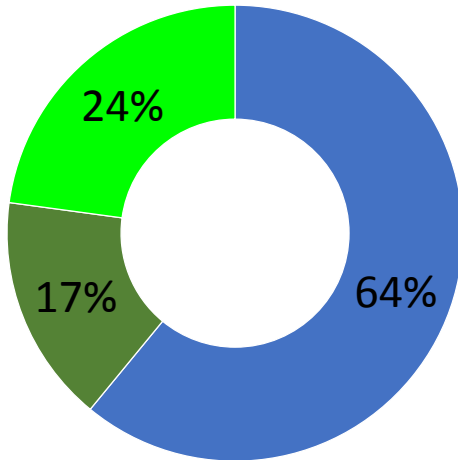
**Medical apps.** These are health apps that lead to any sort of clinical decision-making, diagnosis or treatment. Health apps that work alongside medical devices are included in this class as well.

Generally speaking, medical apps will pose more safety risks to the public and patients because they involve clinical decision-making processes (though for some patients, say with renal disease, the food they eat can mean the difference between life and death).

The above definitions hold no legal context but are drawn up as a result of the research already undertaken by myhealthapps with users and other stakeholders. They represent the users' perspective only.



myhealthapps.net ... out of 450 apps  
*(does not add up to 100%)*



- Health, Wellness and Care in the Community
- Disability
- Medical

# Next Steps

**What guidance and advice is most needed by app developers from their target users, to develop useful, effective, and sustainable health, wellness, and disability apps?**

Results of a survey of app developers, conducted with the App Quality Alliance and Research2Guidance, to be published in early 2016

**Guidelines and Indexed Directory of 100 Medical Apps**  
[Apps that provide diagnosis, treatment or are intended to be used within a clinical setting], 2016



## The myhealthapps directory 2015-2016

Featuring health apps that focus on care in the community, disability, health, and wellness – a review by patient groups and empowered consumers

With a foreword by Dr Zoran Stančić,  
Deputy Director-General, DG CONNECT,  
European Commission





# myhealthapps.net partners and research collaborators





**We would welcome your input and involvement!**

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