APLICACIONES MÓVILES EN SALUD: mHEALTH

UTILIDADES DE LAS NUEVAS TECNOLOGÍAS MOVILES EN LA PRÁCTICA CLÍNICA

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Murcia, 21 de febrero de 2019

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- Reflexiones finales

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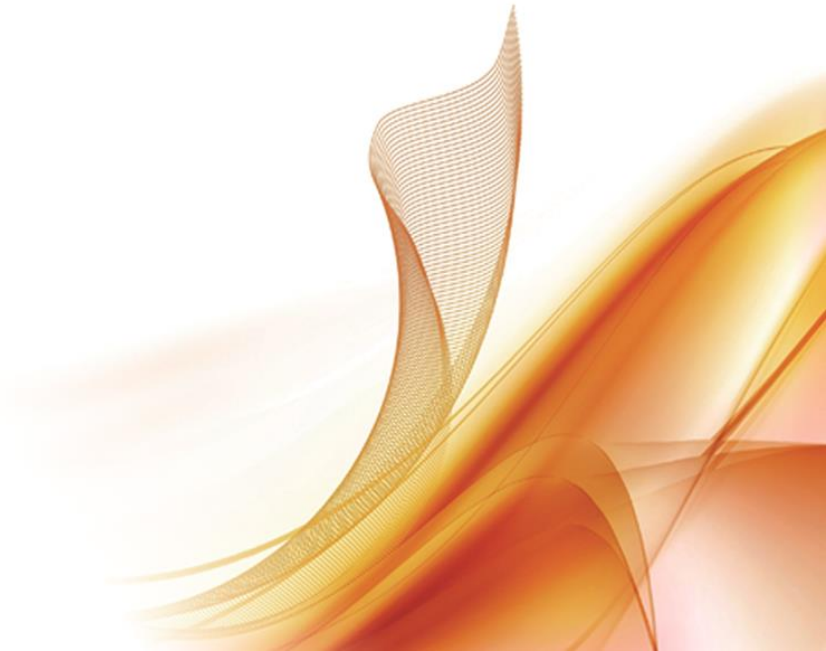
Conceptos básicos: eHealth y mHealth

Definiciones y situación actual



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eHEALTH

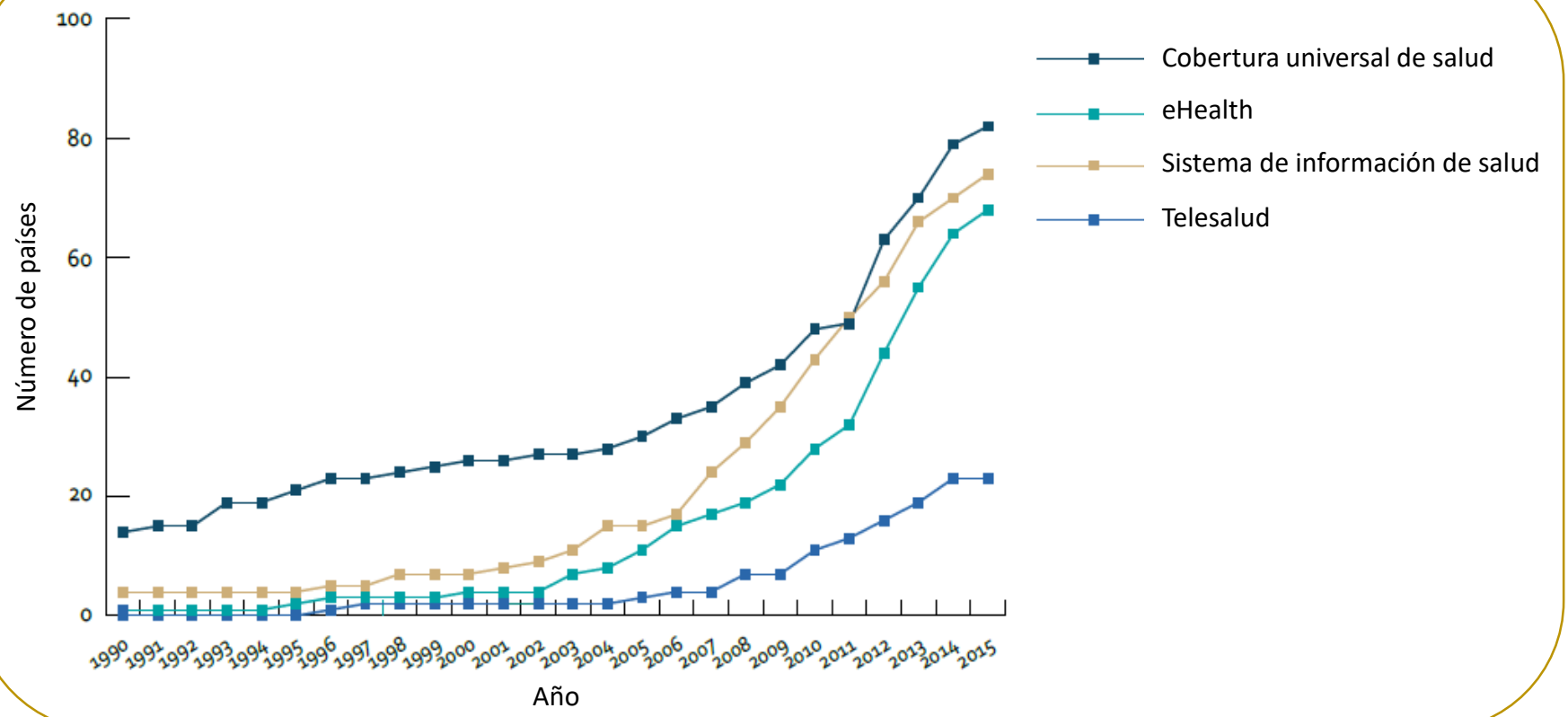
La **eHealth** es el uso **eficiente y seguro** de las **tecnologías de la información y la comunicación (TIC)** en apoyo de la **salud y de los campos relacionados con la salud,** incluidos los servicios de atención de salud, vigilancia de la salud, literatura de salud y educación, conocimiento e investigación de la salud[1].

Historia clínica electrónica, recetas electrónicas, telesalud, servicios de telecomunicación, software clínico…

1. *World Health Organization. Resolution WHA58.33. Sustainable health financing, universal coverage and social health insurance. In: Fifty-eighth World Health Assembly, Geneva, 16–25 May 2005. Resolutions and decisions annex. Geneva: World Health Organization; 2005 WHA58/2005/REC/1; [citado 5 de febrero de 2019]. Disponible en: http://apps.who.int/gb/ebwha/pdf_files/WHA58-REC1/english/A58_2005_REC1-en.pdf.*

eHEALTH

Desarrollo de estrategias de implementación de eHealth por países con el tiempo[1]



1. *World Health Organization. Global diffusion of eHealth: making universal health coverage achievable. Report of the third global survey on eHealth. Geneva: World Health Organization; 2016.*

mHEALTH

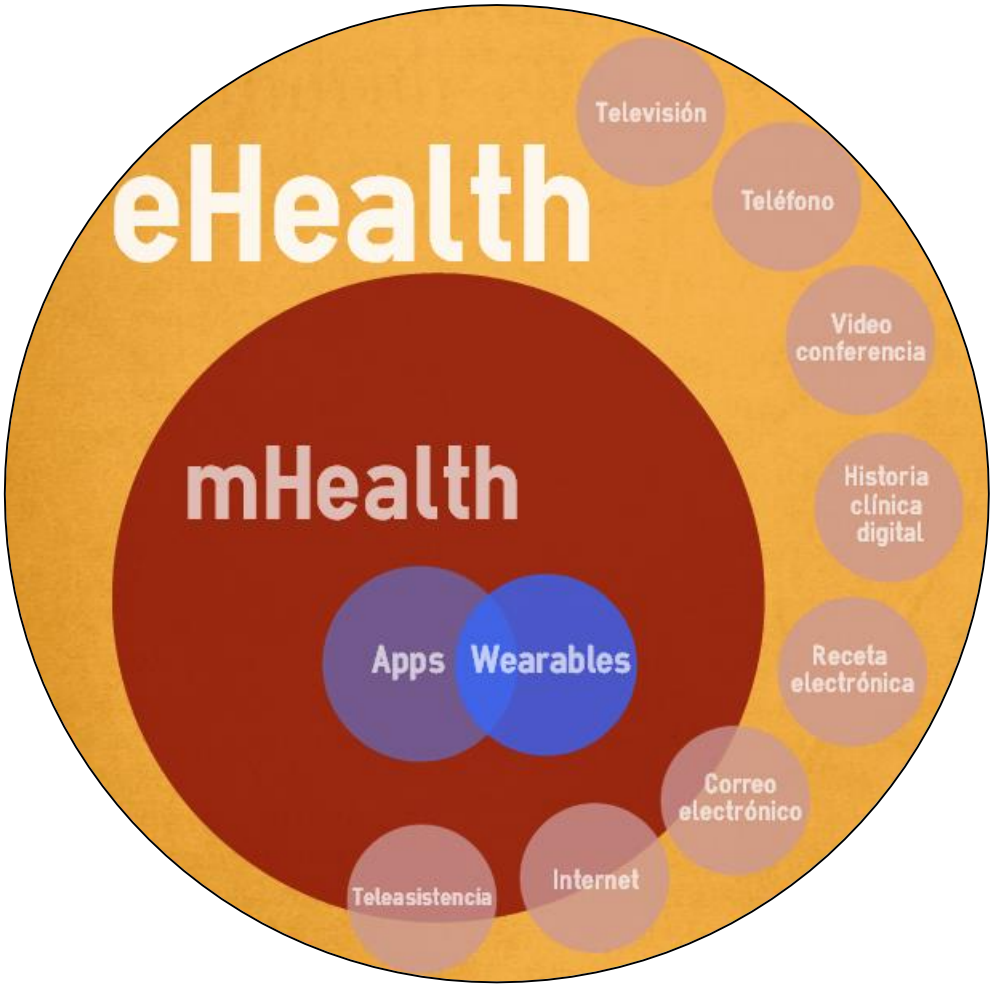
Uso de dispositivos móviles, como teléfonos móviles, dispositivos de monitorización de pacientes, asistentes digitales personales (PDA) y dispositivos inalámbricos para la **práctica médica y de salud pública[1].**

También incluye **aplicaciones de estilo de vida y bienestar** que pueden conectarse a dispositivos médicos o sensores (brazaletes o relojes), así como **sistemas de orientación personal, información de salud y recordatorios** proporcionados por SMS y telemedicina de forma inalámbrica[2].

Recordatorios de citas, telesalud móvil, acceso móvil a información electrónica del paciente, líneas telefónicas de ayuda al paciente…

1. *World Health Organization. Global diffusion of eHealth: making universal health coverage achievable. Report of the third global survey on eHealth. Geneva: World Health Organization; 2016.*
2. *World Health Organization. Green paper on mobile Health ("mHealth"). Brussels: World Health Organization, 2014.*

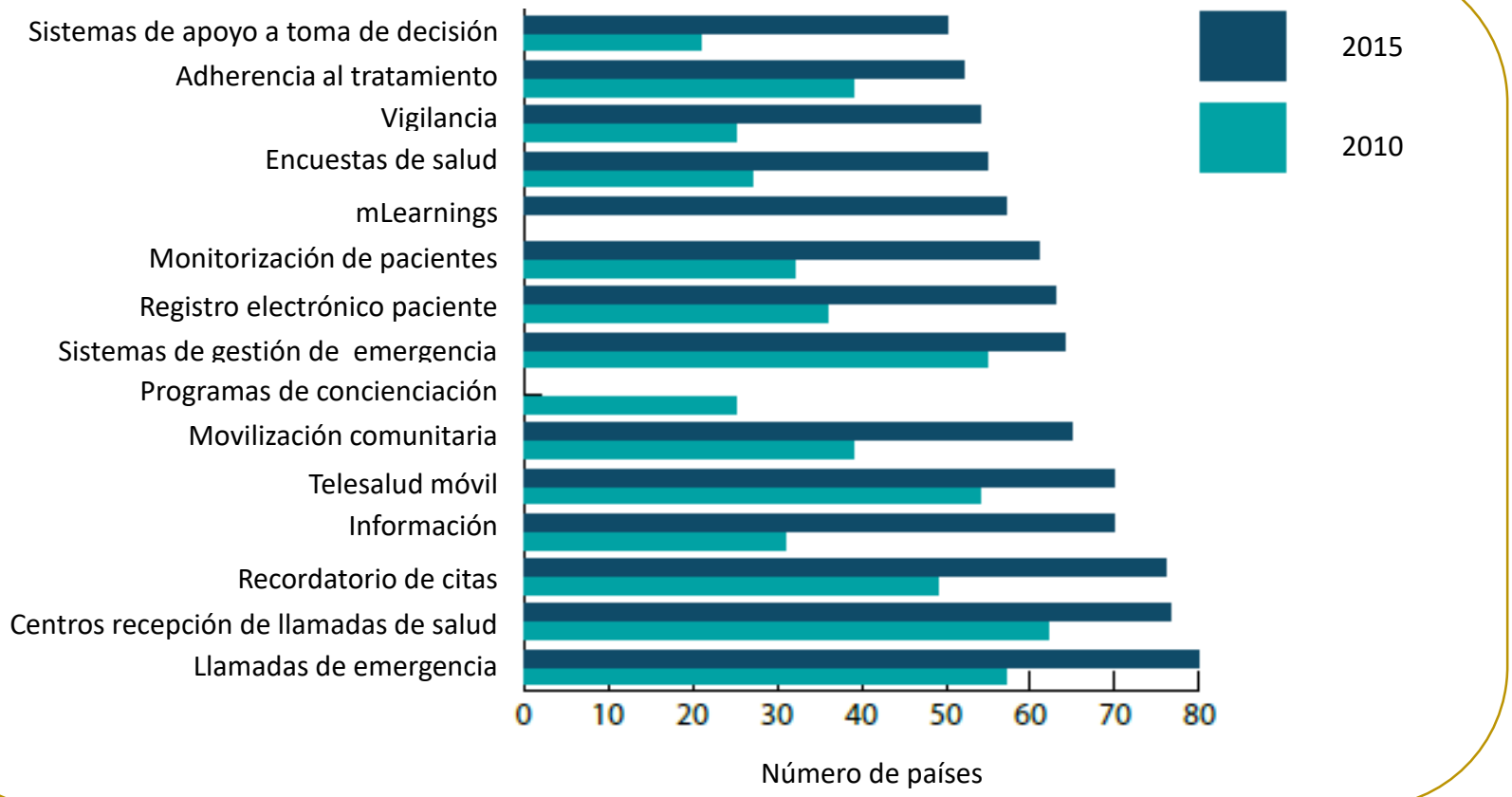
eHealth y mHealth: Visión global



1. *Extraído de: Blog del Instituto Aragonés de Ciencias de la Salud (IACS blog). eHealth, mHealth, wearables, apps… Help! [Internet]. Zaragoza: Elsa Palacios Ramos, junio 2015 [citado 5 de febrero de 2019]. Disponible en: http://www.blog.iacsaragon.es/2015/07/ehealth-mhealth-wearables-apps-help.html*

mHEALTH en cifras

Número de países que informaron de implantación de programas de mHealth por tipo, evolución 2010 y 2015, globalmente[1]



1. *World Health Organization. Global diffusion of eHealth: making universal health coverage achievable. Report of the third global survey on eHealth. Geneva: World Health Organization; 2016.*

mHEALTH en datos

Resumen de implantación de programas mHealth en España[1]:

Acceso/prestación servicios de salud	Nivel sanitario	Estado de programa
Llamadas de emergencia	Internacional, Nacional, Regional y Local	Establecido
Centros recepción llamadas de salud	Internacional, Intermedio, Nacional, Regional y Local	Establecido, informal
Recordatorio de citas	Regional	Establecido
Telesalud móvil	Regional	Establecido
Manejo de emergencias y desastres	Regional	Piloto
Control de adherencia	Regional y Local	Piloto, Establecido
Acceso/prestación información de salud	**Nivel sanitario**	**Estado de programa**
Movilización comunitaria	Regional	Piloto
Acceso a información, bases de datos	Nacional	Establecido
Registro electrónico paciente	Nacional y Regional	Piloto, Establecido
mLearning	Local	Informal
Sistemas de apoyo a toma de decisión	Regional	Establecido
Recogida de información de salud	**Nivel sanitario**	**Estado de programa**
Monitorización de pacientes	Regional y Local	Piloto
Vigilancia de enfermedad	Regional	Piloto

Nivel Internacional: entidades de salud en otros países del mundo.
Nivel Regional: entidades de salud en países de la misma región geográfica.
Nivel Nacional: hospitales de referencia, laboratorios e institutos de salud.
Nivel Intermedio: que abarca instalaciones provinciales .

Nivel Local: puestos de salud y centros de salud, que brindan un nivel básico de atención.
Informal: uso de las TIC para fines de salud en ausencia de procesos y políticas formales.
Piloto: en proceso de prueba y evaluación.
Establecido: llevado a cabo para un mínimo de 2 años y está previsto que continúe.

1. *Adaptación de: World Health Organization. Atlas of eHealth country profiles: the use of eHealth in support of universal health coverage: based on the findings of the third global survey on eHealth 2015. Geneva: World Health Organization; 2016.*

mHEALTH; realidad tangible

≡ EL PAÍS SOCIEDAD

EDUCACIÓN MEDIO AMBIENTE IGUALDAD SANIDAD CONSUMO ASUNTOS SOCIALES LAICISMO COMUNICACIÓN

TECNOLOGÍA SANITARIA ›

Teleconsulta: el médico, ante un ordenador; el paciente, en una cabina

Un cubículo permite que el facultativo atienda y explore al paciente a distancia

EMILIO DE BENITO

Madrid - 19 FEB 2019 - 21:28 CET

"…Encerrada en una cabina de teleconsulta, la supuesta paciente –se trata de una demostración– atiende las instrucciones que le da José María Arribas, médico de familia. En el ordenador que maneja el facultativo, una pantalla muestra lo que hace la paciente, y da el resultado: **37,2 grados. Bien, no tiene fiebre,** zanja el galeno. La exploración continúa. Se puede medir la tensión, la saturación, ver los oídos y la boca, auscultar y hasta hacer un electro..."

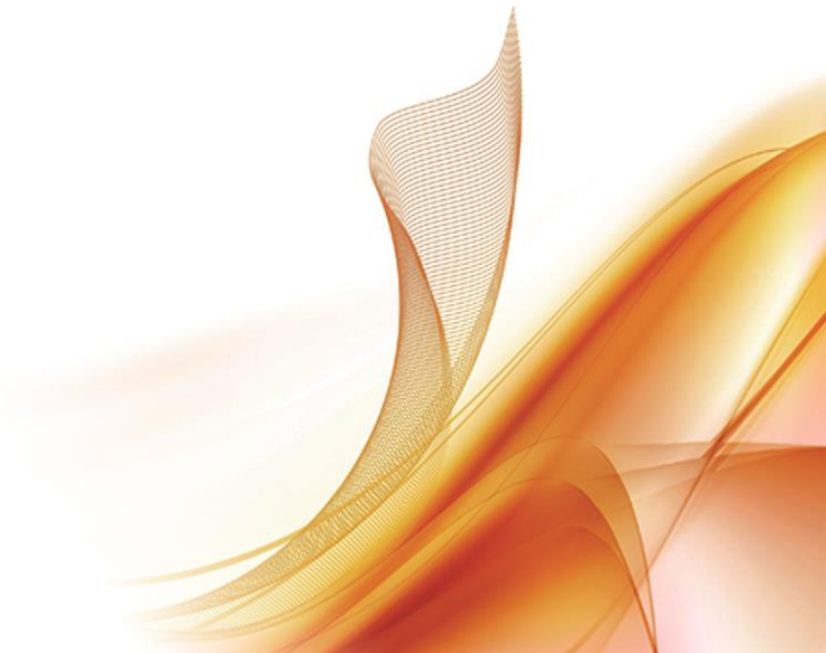
1. *Emilio De Benito. Teleconsulta: el médico, ante un ordenador; el paciente, en una cabina (Internet) El País, Madrid 19 de febrero de 2019 [citado 19 de febrero de 2019]. Disponible en: https://elpais.com/sociedad/2019/02/19/actualidad/1550588772_585170.html*

mHEALTH; realidad tangible

1. *Emilio De Benito. Teleconsulta: el médico, ante un ordenador; el paciente, en una cabina (Internet) El País, Madrid 19 de febrero de 2019 [citado 19 de febrero de 2019]. Disponible en: https://elpais.com/sociedad/2019/02/19/actualidad/1550588772_585170.html*

Marco regulador mHealth

Green paper, acreditación y marcado CE



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Green paper de mHealth

En 2014, la **Comisión Europea** lanzó una consulta pública sobre mHealth:

Green paper on mHealth[1]

Consulta abierta a:

- Autoridades nacionales y regionales
- Profesionales de la salud
- Consumidores y usuarios
- Emprendedores de webs y apps
- Agencias aseguradoras …


EUROPEAN COMMISSION

Brussels, 10.4.2014
COM(2014) 219 final

GREEN PAPER

on mobile Health ("mHealth")

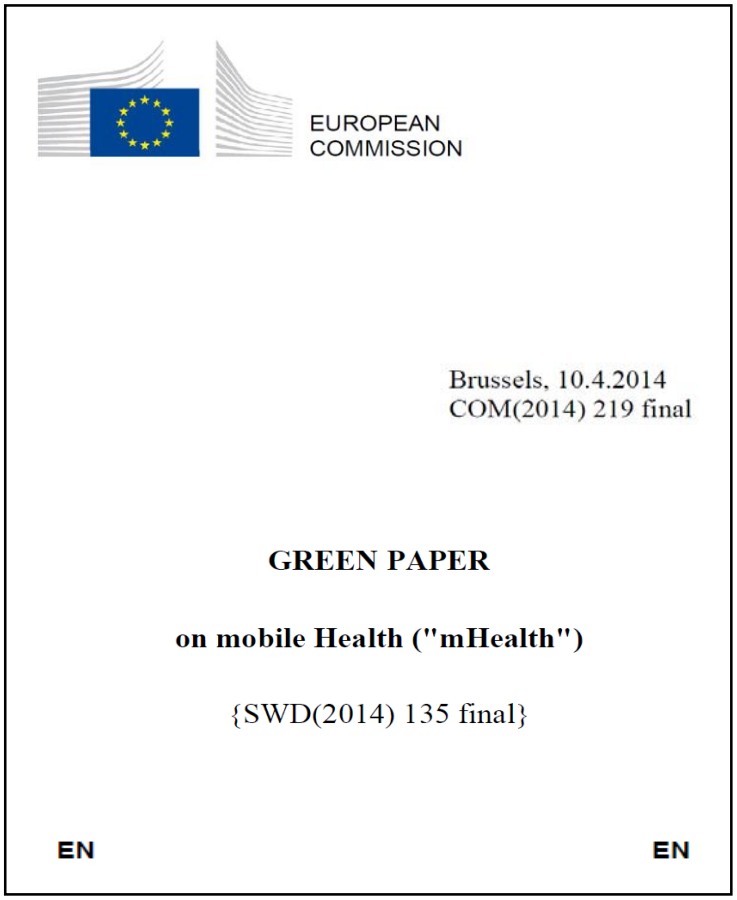
{SWD(2014) 135 final}

EN EN

Evaluar barreras existentes para identificar el camino a seguir para poder desbloquear el potencial de las mHealth.

1. *European Comission. Green paper on mobile Health ("mHealth"). [Internet]. Luxemburgo: Publications Office of the European Union 2014. [citado 5 de febrero de 2019]. Disponible en: https://ec.europa.eu/digital-single-market/en/public-consultation-green-paper-mobile-health*

Green paper de mHealth


EUROPEAN
COMMISSION

Brussels, 10.4.2014
COM(2014) 219 final

GREEN PAPER

on mobile Health ("mHealth")

{SWD(2014) 135 final}

EN EN

Green paper on mHealth[1]

- Potential of mHealth
- Potential for healthcare
- Market potential
- Issues at stake
- Data protection, including security of health data
- Big data
- State of play on the applicable EU legal framework
- Patient safety and transparency of information
- mHealth role in healthcare systems and equal access
- Interoperability
- Reimbursement models
- Liability
- Research and innovation in mHealth
- International cooperation
- Access of web entrepreneurs to the mHealth market
- Next Steps

Se establecen las bases y se realiza una primera aproximación de los elementos más relevantes a considerar en las mHealth.

1. *European Comission. Green paper on mobile Health ("mHealth"). [Internet]. Luxemburgo: Publications Office of the European Union, 2014. [citado 5 de febrero de 2019]. Disponible en: https://ec.europa.eu/digital-single-market/en/public-consultation-green-paper-mobile-health*

Green paper de mHealth

Green paper on mHealth[1]

➢ mHealth role in healthcare systems and equal access

"The **ageing population and the rising number of chronic disease** patients are increasing the burden on EU healthcare systems, resulting **in rising hospitalisations, continuous care and steep healthcare costs.**

mHealth is one of the tools that could help EU Member States **maintain sustainable healthcare systems** as it could support more **efficient delivery of care**. It should be noted that the work pressure of health care professionals is high. Introducing mHealth services may, in the beginning, require training in order to adapt and develop their digital skills.

It could keep **chronic disease patients outside of hospitals** and help tackle the shortage of healthcare professionals in Europe. It is estimated that **approximately 15% of healthcare utilisation costs could be saved through remote monitoring, using mHealth solutions.**

mHealth can contribute to a more equitable **access to healthcare as technologies spread to remote areas and people that would otherwise not have easy access to healthcare.** It could also help ease access to healthcare by people with disabilities. Such shifts in access are already noticeable in many developing countries thanks to mobile phones (in particular SMS)39.

However, mHealth **is currently not used to its full potential in the European healthcare systems**. Healthcare providers and potential payers **may need further evidence of its clinical and economic ben**efits before they scale up its adoption. In this respect, the European Commission facilitates cooperation and the exchange of scientific information among EU Member States through a voluntary network of national experts on health technology assessment.[1]"

1. *European Comission. Green paper on mobile Health ("mHealth"). [Internet]. Luxemburgo: Publications Office of the European Union, 2014. [citado 5 de febrero de 2019]. Disponible en: https://ec.europa.eu/digital-single-market/en/public-consultation-green-paper-mobile-health*

Green paper de mHealth

Green paper on mHealth[1]

➢ Reimbursement models

"One existing model is based on **reimbursement by institutional payers and national authorities**, which decide whether mHealth can be included into the nomenclature of reimbursable healthcare activities. Currently, some national legislations still provide that a medical act can only be performed with the physical presence of both the patient and his doctor, preventing the reimbursement of mHealth solutions.

National health services are beginning to implement innovative refund models, such as incentive programs. It may be in the payers' financial interest to actively support their affiliates in staying healthy. In this respect, **insurers are proposing to their subscribers specific mHealth solutions that promote healthy behaviours in return for a reward,** e.g. refund of a suggested health app or a free smartphone. The goal is to improve people's overall health through behavioural change.

Users' role in bearing the costs for these solutions needs careful assessment. As regards lifestyle and wellbeing apps, users often pay for their apps via app stores. Cases are emerging where a partner can pay for these apps (e.g. a pharmaceutical company) in the context of an existing therapy.

Creating incentives for healthcare professionals to use mHealth solutions also requires reflection, for instance by remunerating them for care activities outside of the classic consultation (e.g. request for information by e-mail).[1]"

1. *European Comission. Green paper on mobile Health ("mHealth"). [Internet]. Luxemburgo: Publications Office of the European Union, 2014. [citado 5 de febrero de 2019]. Disponible en: https://ec.europa.eu/digital-single-market/en/public-consultation-green-paper-mobile-health*

Marco regulador

No existe una normativa clara sobre el marco legal de las aplicaciones mHealth

Green paper on mHealth

"Algunas aplicaciones de mHealth pueden responder a la definición de **Producto Sanitario** o de **Producto Sanitario de Diagnóstico** ***in vitro*** y, por tanto, ser considerada como tales, teniendo que cumplir con los requisitos técnicos y de seguridad exigidos a los mismos[1]."

EUROPEAN
COMMISSION

Brussels, 10.4.2014
COM(2014) 219 final

COMMISSION STAFF WORKING DOCUMENT

on the existing EU legal framework applicable to lifestyle and wellbeing apps

Accompanying the document

GREEN PAPER

on mobile Health ("mHealth")

{COM(2014) 219 final}

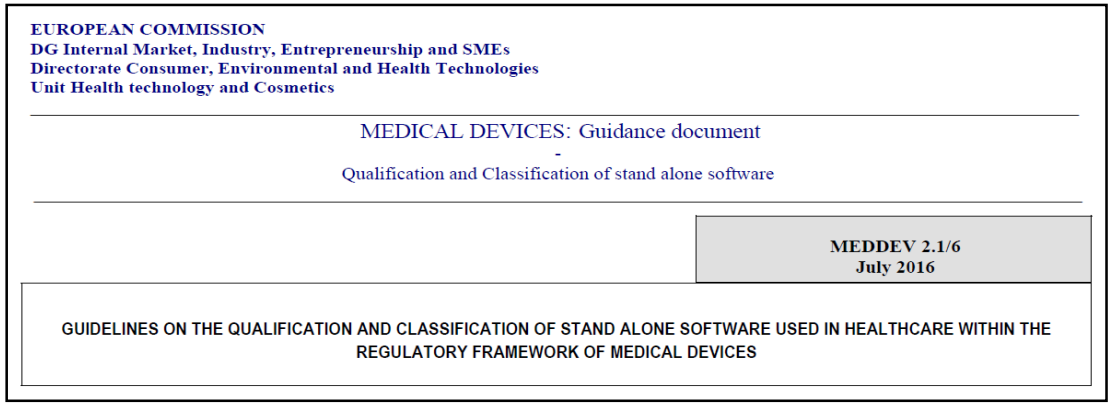
EN EN

1. *European Comission. Commission staff working document on the existing EU legal framework applicable to lifestyle and wellbeing apps accompanying the document Green paper on mobile Health ("mHealth") Luxemburgo: Publications Office of the European Union, 2014.*

Marco regulador

- **¿Cuándo se considera una mHealth como un Producto Sanitario o Producto Sanitario de Diagnóstico *in vitro*?**

No hay reglas vinculantes sobre si una mHealth es considerada una **aplicación de estilo de vida y bienestar** o es considerada un **producto sanitario/producto sanitario de diagnóstico *in vitro***[1].



EUROPEAN COMMISSION
DG Internal Market, Industry, Entrepreneurship and SMEs
Directorate Consumer, Environmental and Health Technologies
Unit Health technology and Cosmetics

MEDICAL DEVICES: Guidance document
-
Qualification and Classification of stand alone software

MEDDEV 2.1/6
July 2016

GUIDELINES ON THE QUALIFICATION AND CLASSIFICATION OF STAND ALONE SOFTWARE USED IN HEALTHCARE WITHIN THE REGULATORY FRAMEWORK OF MEDICAL DEVICES

Guías europeas para desarrolladores y fabricantes de software[2]

De forma general, **la mayoría de aplicaciones mHealth** entran dentro de la clasificación de **Productos Sanitarios Clase I (productos no invasivos)**[3], y deben contar con el correspondiente **Marcado CE**[3]

1. *European Comission. Commission staff working document on the existing EU legal framework applicable to lifestyle and wellbeing apps accompanying the document Green paper on mobile Health ("mHealth") Luxemburgo: Publications Office of the European Union 2014.*
2. *European Commission. Guidelines on the qualification and classification of stand alone software used in healthcare within the regulatory framework of medical devices [Internet]. Luxemburgo: Publications Office of the European Union; 2016. [citado 5 de febrero de 2019]. Disponible en: https://ec.europa.eu/docsroom/documents/17921*
3. *Real Decreto 1591/2009, de 16 de octubre, por el que se regulan los productos sanitarios. Boletín Oficial del Estado de 25 de julio de 2013 [Internet]. Madrid: Agencia Estatal Boletín Oficial del Estado; 2013. [citado 5 de febrero de 2019]. Disponible en: https://www.boe.es/buscar/pdf/2009/BOE-A-2009-17606-consolidado.pdf*

Producto Sanitario

Una mHealth será considerada como Producto Sanitario si responde a la siguiente definición[1,2]:

Cualquier instrumento, dispositivo, equipo, **programa informático**, material u otro artículo, utilizado solo o en combinación, incluidos los programas informáticos destinados por su fabricante a finalidades específicas de **diagnóstico y/o terapia** y que intervengan en su buen funcionamiento, **destinado por el fabricante a ser utilizado en seres humanos con fines de:**

- Diagnóstico, prevención, **control**, tratamiento o alivio **de una enfermedad**
- Diagnóstico, **control,** tratamiento, alivio o compensación de una **lesión o de una deficiencia**
- Investigación, sustitución o modificación de la anatomía o de un proceso fisiológico
- Regulación de la concepción

Y que **no ejerza la acción principal** que se desee obtener en el interior o en la superficie del cuerpo humano por medios **farmacológicos, inmunológicos ni metabólicos**, pero a cuya función puedan contribuir tales medios.

1. *Real Decreto 1591/2009, de 16 de octubre, por el que se regulan los productos sanitarios. Boletín Oficial del Estado de 25 de julio de 2013 [Internet]. Madrid: Agencia Estatal Boletín Oficial del Estado; 2013. [citado 5 de febrero de 2019]. Disponible en: https://www.boe.es/buscar/pdf/2009/BOE-A-2009-17606-consolidado.pdf*
2. *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Official Journal of the European Communities of 12 July 1993 [Internet]. Luxemburgo: Publications Office of the European Union; 1993. [citado 5 de febrero de 2019]. Disponible en: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31993L0042&from=EN*

Producto Sanitario de Diagnóstico *in vitro*

Una mHealth será considerada como Producto Sanitario de Diagnóstico *in vitro* si responde a la siguiente definición[1,2]:

Cualquier producto sanitario que consista en un reactivo, producto reactivo, calibrador, material de control, estuche de instrumental y materiales, **instrumento**, aparato, equipo o **sistema**, utilizado solo o en asociación con otros, destinado por el fabricante a **ser utilizado *in vitro* para el estudio de muestras procedentes del cuerpo humano**, incluidas las donaciones de sangre y tejidos, sólo o principalmente con el fin de proporcionar **información** relativa a un **estado fisiológico o patológico**, o relativa a una anomalía congénita, o para determinar la seguridad y compatibilidad con receptores potenciales, o para **supervisar medidas terapéuticas**.

1. *Real Decreto 1591/2009, de 16 de octubre, por el que se regulan los productos sanitarios. Boletín Oficial del Estado de 25 de julio de 2013 [Internet]. Madrid: Agencia Estatal Boletín Oficial del Estado; 2013. [citado 5 de febrero de 2019]. Disponible en: https://www.boe.es/buscar/pdf/2009/BOE-A-2009-17606-consolidado.pdf*
2. *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Official Journal of the European Communities of 7 December 1998 [Internet]. Luxemburgo: Publications Office of the European Union; 1998. [citado 5 de febrero de 2019]. Disponible en: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0079&from=EN*

Marcado CE

Las aplicaciones mHealth que sean consideradas bien Productos Sanitarios o bien Productos Sanitarios de diagnostico *in vitro*, precisan de la presencia del marcado CE[1,2]

- ✓ Cumplen con las disposiciones de seguridad y técnicas
- ✓ A disposición de las Autoridades Nacionales competentes

- Productos Sanitarios Clase I: fabricante o representante en Europa autocertifica el marcado CE.
- Productos Sanitarios ≠ Clase I o Productos Sanitarios de diagnostico *in vitro*: precisan un organismo notificador externo para certificar el marcado CE.

La información sobre el **marcado CE <u>debería</u>** estar disponible con la aplicación, en la sección **"Acerca de esta aplicación"** o en la **descripción de la aplicación en la tienda de aplicaciones en línea.**

1. *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Official Journal of the European Communities of 12 July 1993 [Internet]. Luxemburgo: Publications Office of the European Union; 1993. [citado 5 de febrero de 2019]. Disponible en: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31993L0042&from=EN*
2. *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Official Journal of the European Communities of 7 December 1998 [Internet]. Luxemburgo: Publications Office of the European Union; 1998. [citado 5 de febrero de 2019]. Disponible en: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0079&from=EN*

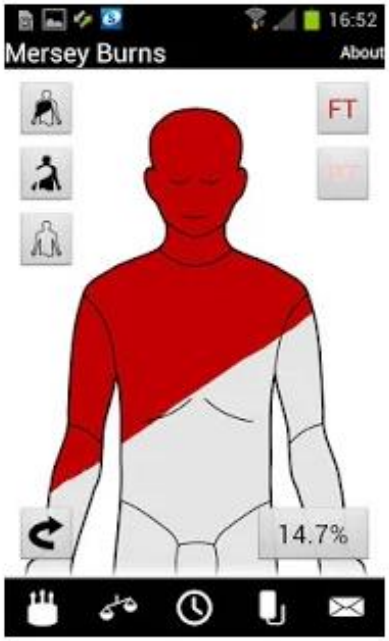
Marcado CE: Mersey Burns app

Mersey Burns

Chris Seaton Medicina

PEGI 3

- ✓ Aplicación para el cálculo del porcentaje de área quemada de un paciente



Mersey Burns is a free clinical tool for calculating burn area percentages, prescribing fluids using Parkland, background fluids and recording patients' details. It was developed by specialist and consultant plastic surgeons and experts in burns management.

Mersey Burns is regulated in the UK by the MHRA and is CE marked for conformance as a medical device.

In 2011 Mersey Burns won an Excellence in Innovation prize at the NHS North West Health Innovation Awards. It has been presented at the British Burns Association and the British Association of Plastic, Reconstructive and Aesthetic Surgeons and covered by BBC online, TV, radio, the Daily Mirror, the Universities of Manchester and Liverpool and countless technology and medical professional news sources.

1. *Mersey Burns app. [citado 5 de febrero de 2019]. Disponible enhttps://play.google.com/store/apps/details?id=com.merseyburns*

Marcado CE

"El **marcado CE** es la garantía de que una aplicación **cumple criterios esenciales, funciona y es clínicamente segura**."

"No se deben utilizar aplicaciones médicas, que no tienen marcado CE."

"Desafortunadamente, **incluso si una aplicación tiene marcado CE**, eso **no significa que** ayude a cumplir las **mejores prácticas clínicas**, que se haya probado su exactitud o los **beneficios en uso clínico**, o que **sea aplicable** al paciente para la cual se está utilizando."

1. *Royal College of Physicians. Using apps in clinical practice Important things that you need to know about apps and CE marking. [Internet] London, Royal College of Physicians. [citado 5 de febrero de 2019]. Disponible en: https://www.rcplondon.ac.uk/guidelines-policy/using-apps-clinical-practice-guidance*

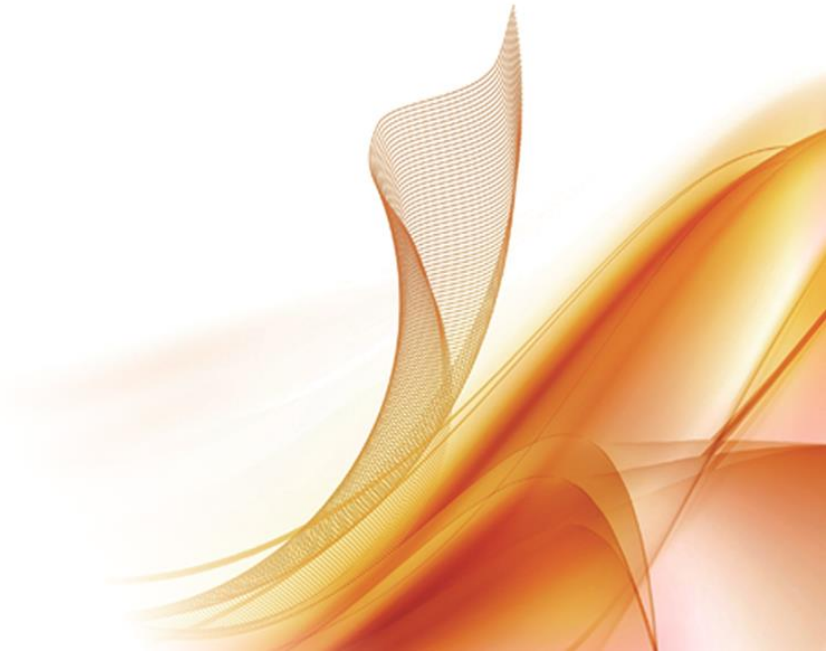
Evaluación de tecnología mHealth

Andalucia: AppSalud

Cataluña: TIC Salut Social

Inglaterra: NHS

Estados Unidos: FDA



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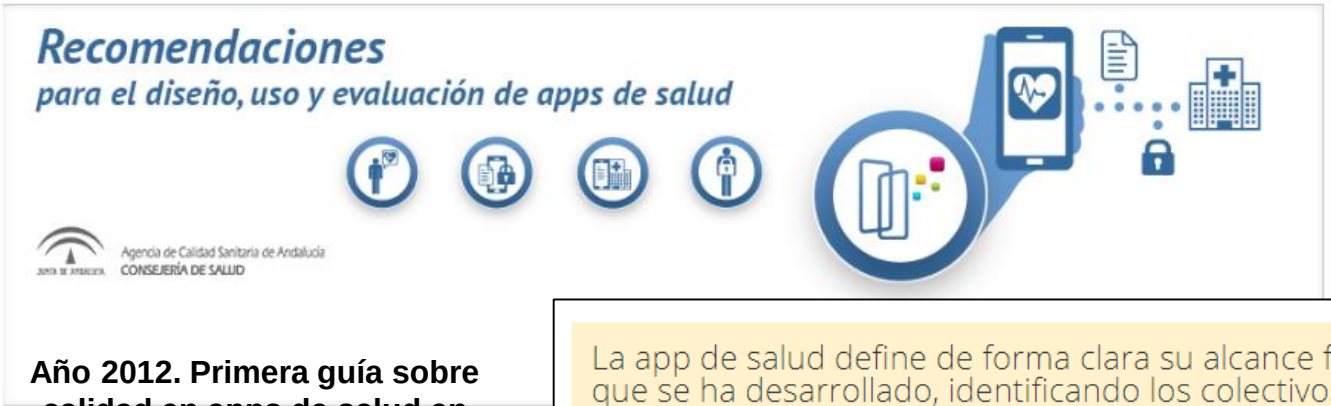
Andalucia: Calidad AppSalud

1. *Agencia de Calidad Sanitaria de Andalucía. Estrategia de calidad y seguridad en aplicaciones móviles de salud. [Internet] Sevilla, Agencia de Calidad Sanitaria de Andalucía, Consejería de Salud de Andalucia [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/serveis/mhealth/serveis-acreditacio-i-segell-tics/*

Andalucia: Calidad AppSalud



Guía de recomendaciones para el diseño, uso y evaluación de aplicaciones móviles de salud

Año 2012. Primera guía sobre calidad en apps de salud en español

Guía de recomendaciones

Distintivo AppSaluds

La app de salud define de forma clara su alcance funcional y la finalidad con la que se ha desarrollado, identificando los colectivos a los que se destina la información y los objetivos que se persiguen con respecto a estos colectivos.

[Pertinencia]

Propósito: Describir de forma explícita y objetiva el público al que se dirige, los objetivos y finalidad con la que se ha desarrollado, de manera que el usuario pueda valorar el interés de la app.

Requisitos:

1. Se matizan la finalidad y objetivos de forma concreta y bien definida, correspondiéndose con sus contenidos y servicios.
2. Se detallan las funciones que se cumplen y bajo qué condiciones, en un lenguaje claro y accesible para el usuario.
3. Se informa de que el uso de la app no sustituye la relación médico-paciente.
4. En la descripción se define a quién va destinada y se categoriza atendiendo a una clasificación normalizada de apps de salud.
5. Se adaptan los contenidos y servicios en función de la audiencia a la que se dirige.

1. *Agencia de Calidad Sanitaria de Andalucía. Estrategia de calidad y seguridad en aplicaciones móviles de salud. [Internet] Sevilla, Agencia de Calidad Sanitaria de Andalucía, Consejería de Salud de Andalucia [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/serveis/mhealth/serveis-acreditacio-i-segell-tics/*

Andalucia: Calidad AppSalud

Una guía abierta a la participación de los usuarios

1. *Agencia de Calidad Sanitaria de Andalucía. Estrategia de calidad y seguridad en aplicaciones móviles de salud. [Internet] Sevilla, Agencia de Calidad Sanitaria de Andalucía, Consejería de Salud de Andalucia [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/serveis/mhealth/serveis-acreditacio-i-segell-tics/*

Andalucia: Calidad AppSalud

- **Recomendaciones para diseño, uso y evaluación de apps de salud**

1. *Agencia de Calidad Sanitaria de Andalucía. Estrategia de calidad y seguridad en aplicaciones móviles de salud. [Internet] Sevilla, Agencia de Calidad Sanitaria de Andalucía, Consejería de Salud de Andalucia [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/serveis/mhealth/serveis-acreditacio-i-segell-tics/*

Andalucia: Calidad AppSalud

- **Recomendaciones para diseño, uso y evaluación de apps de salud**

1. *Agencia de Calidad Sanitaria de Andalucía. Estrategia de calidad y seguridad en aplicaciones móviles de salud. [Internet] Sevilla, Agencia de Calidad Sanitaria de Andalucía, Consejería de Salud de Andalucia [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/serveis/mhealth/serveis-acreditacio-i-segell-tics/*

Andalucia: Calidad AppSalud

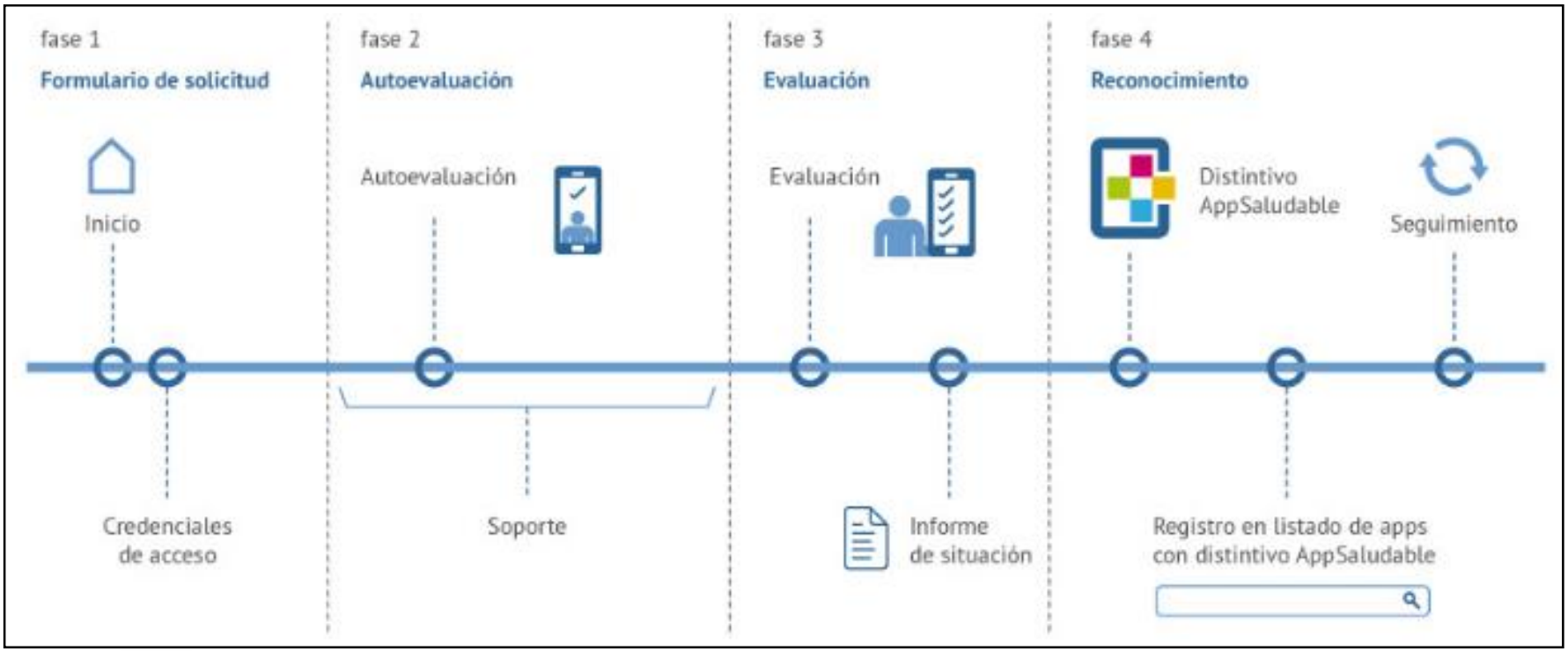
Reconoce a aquellas aplicaciones de salud que ponen en marcha las medidas necesarias para cumplir una serie de **recomendaciones de calidad y seguridad** y que, por tanto, pueden **ser utilizadas por la ciudadanía de forma fiable, minimizando riesgos**

Distintivo AppSaludable

1. *Agencia de Calidad Sanitaria de Andalucía. Estrategia de calidad y seguridad en aplicaciones móviles de salud. [Internet] Sevilla, Agencia de Calidad Sanitaria de Andalucía, Consejería de Salud de Andalucia [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/serveis/mhealth/serveis-acreditacio-i-segell-tics/*

Andalucia: Calidad AppSalud

➢ Fases del proceso reconocimiento AppSaludable



Servicio activo desde el 2013

- Gratuito.
- Abierto a iniciativas públicas y privadas.
- Apps nacionales e internacionales

1. *Agencia de Calidad Sanitaria de Andalucía. Estrategia de calidad y seguridad en aplicaciones móviles de salud. [Internet] Sevilla, Agencia de Calidad Sanitaria de Andalucía, Consejería de Salud de Andalucia [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/serveis/mhealth/serveis-acreditacio-i-segell-tics/*

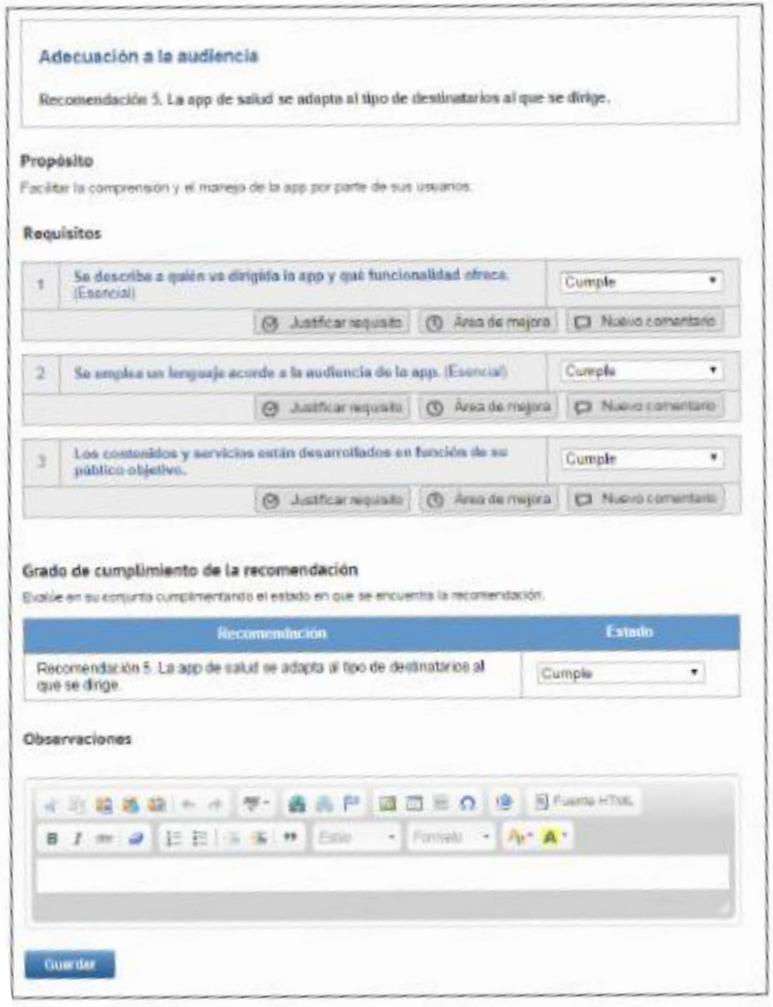
Andalucia: Calidad AppSalud

Reconocimiento AppSaludable

Distintivo AppSaludable

Para obtener el distintivo hay que pasar por una **fase de autoevaluación,** aportando pruebas, y una **fase de evaluación**.

Reconocimiento de aplicaciones móviles de salud para su uso de forma fiable y segura, minimizando riesgos



1. *Agencia de Calidad Sanitaria de Andalucía. Estrategia de calidad y seguridad en aplicaciones móviles de salud. [Internet] Sevilla, Agencia de Calidad Sanitaria de Andalucía, Consejería de Salud de Andalucia [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/serveis/mhealth/serveis-acreditacio-i-segell-tics/*

Andalucia: Calidad AppSalud

30 apps cuentan con el distintivo AppSaludable

1. *Agencia de Calidad Sanitaria de Andalucía. Estrategia de calidad y seguridad en aplicaciones móviles de salud. [Internet] Sevilla, Agencia de Calidad Sanitaria de Andalucía, Consejería de Salud de Andalucia [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/serveis/mhealth/serveis-acreditacio-i-segell-tics/*

AppSaludable: Numo, deshabituación tabáquica

Numo

Numo Salud y bienestar

PEGI 3

App para smartphones orientada a **controlar el estado de salud general** del paciente

1. *Numo. Numo. [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=es.numo.numo*

AppSaludable: Numo, deshabituación tabáquica

Descripción

Numo es la solución definitiva para dejar de fumar. Es una app móvil que está basada en la mejor y más reciente evidencia científica. Ha sido diseñada por personal sanitario y teniendo en cuenta la opinión de usuarios y otros profesionales. Basada en la Guía de Práctica Clínica de la SAMFYC

- Categorías: Salud y bienestar general
- Plataforma: Android. Dispositivo: Smartphone. Versión: 1.2.7
- Plataforma: iOS. Dispositivo: Smartphone. Versión: 1.1.3
- Idiomas: Español, Inglés
- Desarrollador: NUMO

Aspectos destacables

- ☑ Adecuación de los contenidos y servicios de la aplicación a la audiencia a la que se dirige.
- ☑ Aplicación testada en usuarios potenciales antes de su lanzamiento, incorporando mejoras detectadas durante el pilotaje.
- ☑ La aplicación ha sido desarrollada y coordinada por un equipo de profesionales sanitarios con experiencia en este ámbito.
- ☑ El contenido se ha desarrollado como una adaptación a la Guía de Práctica Clínica más usada en la deshabituación tabáquica: "Tabaquismo. Abordaje en Atención Primaria", editado por la Sociedad Andaluza de Medicina Familiar y Comunitaria (SAMFyC) en 2011.

Mejoras identificadas tras el proceso de evaluación

- ☑ Establecer un compromiso explícito por parte de los editores para la revisión de los contenidos y funcionalidades de la app.
- ☑ Facilitar dentro de la app, un enlace al sitio web con información complementaria.
- ☑ Establecer un compromiso para la revisión de calidad científico-técnica de los contenidos de la app y su actualización en base a la nueva evidencia científica disponible.
- ☑ Incorporar un sistema de notificaciones proactivo que alerte de nuevas actualizaciones en la aplicación.

Distintivo AppSaludable

11/12/2018

Disponible en Google play

Disponible en App Store

1. *Numo. Numo. [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=es.numo.numo*

Catalunya: TIC Salut Social

Impulsando la innovación

Impulsar el desarrollo y la utilización de las TIC y el trabajo en red en el ámbito de la salud. Ofrece servicios de **normalización y homologación de productos.**

1. *TIC Salut Social. Quienes somos. [Internet] Barcelona, Generalitat de Catalunya 2013-2019 [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/qui-som/*

Catalunya: TIC Salut Social

TIC | Salut Social

Generalitat de Catalunya

1. *TIC Salut Social. Quienes somos. [Internet] Barcelona, Generalitat de Catalunya 2013-2019 [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/qui-som/*

Catalunya: TIC Salut Social

ACREDITADA · FUNDACIÓ TIC SALUT SOCIAL ·

Garantiza que el producto reúne los requerimientos indispensables para crear una **app con garantías de calidad y fiabilidad.**

- ✓ Seguridad
- ✓ Tecnología
- ✓ Usabilidad y accesibilidad
- ✓ Funcionalidad y contenidos

1. *TIC Salut Social. Servicio de Acreditación y Sello TICSS mHealthTendenciasApps. [Internet] Barcelona, Generalitat de Catalunya 2013-2019 [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/serveis/mhealth/serveis-acreditacio-i-segell-tics/*

Catalunya: TIC Salut Social

Manuales de acreditación para Apps de salud o bienestar

mHealth Apps

Consulta estos documentos para saber qué necesitas tener en cuenta para superar el proceso de acreditación de aplicaciones de salud o bienestar de la Fundación TIC Salut Social.

- Guía del proceso de acreditación para Apps de salud o bienestar
- Precios de acreditación para Apps de salut o bienestar
- Criterios de acreditación para Apps de salut o bienestar
- Infografía de los criterios funcionales
- Manual del desarrollador
- SDK
- Certificados

1. *TIC Salut SocialManuales de acreditación para Apps de salud o bienestar [Internet] Barcelona, Generalitat de Catalunya 2013-2019 [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/es/recursos/mhealth-es/manuales-acreditacion-apps/*

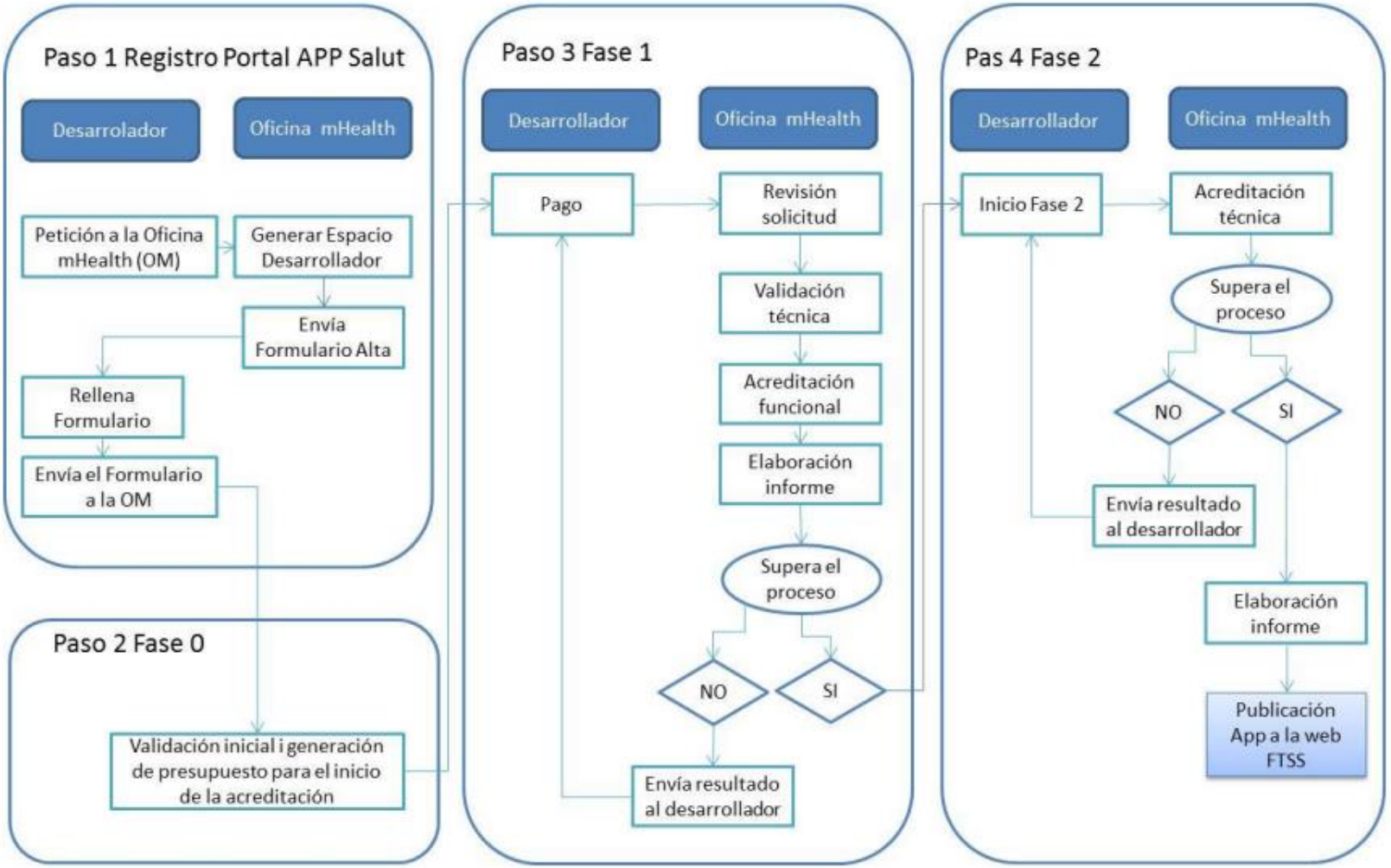
Catalunya: TIC Salut Social

Manuales de acreditación para Apps de salud o bienestar

1. *TIC Salut SocialManuales de acreditación para Apps de salud o bienestar [Internet] Barcelona, Generalitat de Catalunya 2013-2019 [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/es/recursos/mhealth-es/manuales-acreditacion-apps/*

Catalunya: TIC Salut Social

Fases del proceso reconocimiento acreditación TIC Salut Social



1. *TIC Salut Social. Servei d'Acreditació i Segell TICSS. [Internet] Barcelona, Generalitat de Catalunya 2013-2019 [citado 5 de febrero de 2019]. Disponible en: https://ticsalutsocial.cat/serveis/mhealth/serveis-acreditacio-i-segell-tics/*

Catalunya: TIC Salut Social

JMIR RESEARCH PROTOCOLS

Protocol

Prescription and Integration of Accredited Mobile Apps in Catalan Health and Social Care: Protocol for the AppSalut Site Design

Francesc López Seguí[1,2], MSc; Carme Pratdepàdua Bufill[1], BSc; Ariadna Rius Soler[1], MSc; Marc de San Pedro[3], MSc; Bernat López Truño[4], BSc; Agnès Aguiló Laine[4], BSc; Jordi Martínez Roldán[1], MSc, MD; Francesc García Cuyàs[1], MD, PhD

[1]TIC Salut Social, Generalitat de Catalunya, Mataró, Spain
[2]Centre for Research in Health and Economics, Department of Experimental and Health Sciences, Universitat Pompeu Fabra, Barcelona, Spain
[3]Universitat de Vic – Universitat Central de Catalunya, Vic, Spain
[4]IN2, Barcelona, Spain

Precedentes

"The use of new mobile technologies in the health and social welfare sectors is already a reality. The **ICT Social Health Foundation**, in accordance with the technology strategy of the Catalan government's Ministry of Health and its Ministry of Labour, Social Affairs and Families, **is leading an initiative to create a public library of apps for its AppSalut Site**."

1. *López Seguí F, Pratdepàdua Bufill C, Rius Soler A, de San Pedro M, López Truño B, Aguiló Laine A, Martínez Roldán J, García Cuyàs F. Prescription and Integration of Accredited Mobile Apps in Catalan Health and Social Care: Protocol for the AppSalut Site Design. JMIR Res Protoc. 2018 Dec 21;7(12):e11414.*

Catalunya: TIC Salut Social

Objetivo

"The objective of this paper is to **present an account of the design of the project,** with a global perspective, **applied to the Catalan ecosystem**, which can be divided into 3 areas:

1. **The framework governing the recommendation and prescription of apps**
2. **The subset of interoperability for mobile environments**
3. **The data storage infrastructure"**

Métodos

"The security and **credibility of the apps included in the catalog is ensured by submitting them to an accreditation process in the public domain that provides users with the guarantee that they are fit for purpose and trustworthy** for the management and care of their health, while **providing health care professionals with the possibility of recommending the apps in the doctor's surgery, as well as adding the information generated by the users'** mobile devices to the information systems of the various organizations concerned."

1. *López Seguí F, Pratdepàdua Bufill C, Rius Soler A, de San Pedro M, López Truño B, Aguiló Laine A, Martínez Roldán J, García Cuyàs F. Prescription and Integration of Accredited Mobile Apps in Catalan Health and Social Care: Protocol for the AppSalut Site Design. JMIR Res Protoc. 2018 Dec 21;7(12):e11414.*

Catalunya: TIC Salut Social

Retos y necesidades

Needs	Challenges
The app stores feature an enormous number of apps that are highly heterogeneous in terms of quality and type. A trusted framework is required to ensure that both doctors and patients use apps that meet certain minimum requirements.	Certify the app's relevance and added value by means of an accreditation process.
The apps also capture and record data by means of associated devices (glucometers being the most frequent).	Standardize the devices linked to mobile apps.
Every device uses its own platform, meaning that doctors who wish to access the data generated by their patients must enter the same number of platforms as devices used by their users.	Design a single platform for viewing all the collected data and adding it to the health system's information system.
The aforementioned apps and devices collect data without necessarily adhering to international standards.	Standardize the data from the apps through the use of an interoperability framework.
The collected data cover very different themes (related to lifestyle, physical activity, etc, both actively and passively) and its veracity must be proven.	Upload data solely at the doctor's discretion and distinguish it visually from the rest of the patient's medical history.
From the start, developers should become aware of the desirability and potential added value of incorporating information from the app with public information systems and that they take this into account during the app's technical design.	Support developers in the design of apps that are likely to be added to the library.
The prescription of mobile apps in the health environment is currently carried out on an informal basis: the doctors prescribe those they know or have been recommended to them by other professionals.	Create an institutional prescription process and integrate the recommendation of apps into clinical information systems.
Apps can serve to empower citizens in taking care of their health, and they can generate quality doctor-patient communication, giving a much more holistic vision of health, oriented toward promotion and prevention.	Organize the process around the Personal Health Folder.

1. *López Seguí F, Pratdepàdua Bufill C, Rius Soler A, de San Pedro M, López Truño B, Aguiló Laine A, Martínez Roldán J, García Cuyàs F. Prescription and Integration of Accredited Mobile Apps in Catalan Health and Social Care: Protocol for the AppSalut Site Design. JMIR Res Protoc. 2018 Dec 21;7(12):e11414.*

Catalunya: TIC Salut Social

1. Marco para desarrolladores, profesionales y usuarios

1.1 *Accreditation process*

"Based on a **consensus between professionals** in the sector doctors, nurses, psychologists, and social workers). A **multidisciplinary approach,** different stages are to be taken into consideration:

- New apps consideration
- Initial validation
- Classification
- Evaluation
- Result"

1.2 *Recommendation Process*

"The **starting point for these apps is primary health care physician,** where there is greater potential for the attributes of telemonitoring and the observation of chronic patients."

1. *López Seguí F, Pratdepàdua Bufill C, Rius Soler A, de San Pedro M, López Truño B, Aguiló Laine A, Martínez Roldán J, García Cuyàs F. Prescription and Integration of Accredited Mobile Apps in Catalan Health and Social Care: Protocol for the AppSalut Site Design. JMIR Res Protoc. 2018 Dec 21;7(12):e11414.*

Catalunya: TIC Salut Social

2. Interoperabilidad

"Ability to share information between components without its meaning being lost. This communication must ensure the **coherent exchange of data among departments, organizations, health care levels, or regions.**"

"This standard allows the sending of only the **relevant and/or necessary information, simplifying the exchange of health information** and adapting the methods of transmission to the mHealth environment."

3. Almacenamiento de información.

"**Information from mobile devices must be stored for later use**, either by doctors as part of health and social care systems and/or by patients themselves. Therefore, this requires a platform that can be address based on **Big Data solutions: volume, velocity, variety, veracity and value**."

1. *López Seguí F, Pratdepàdua Bufill C, Rius Soler A, de San Pedro M, López Truño B, Aguiló Laine A, Martínez Roldán J, García Cuyàs F. Prescription and Integration of Accredited Mobile Apps in Catalan Health and Social Care: Protocol for the AppSalut Site Design. JMIR Res Protoc. 2018 Dec 21;7(12):e11414.*

Catalunya: TIC Salut Social

3. Almacenamiento de información.

"The information stored on the platform must allow the following uses:

- For doctors, to **personalize the treatment** for patients, with the use of information originating from personal devices
- For patients, to **visualize the information from mobile apps** they have installed in a standard manner;
- For the current information systems, to **add the necessary information to patients' clinical history;**
- For the remaining agents in the sector, the **exploitation of the data**, creation of alerts, prevention, and prediction."

1. *López Seguí F, Pratdepàdua Bufill C, Rius Soler A, de San Pedro M, López Truño B, Aguiló Laine A, Martínez Roldán J, García Cuyàs F. Prescription and Integration of Accredited Mobile Apps in Catalan Health and Social Care: Protocol for the AppSalut Site Design. JMIR Res Protoc. 2018 Dec 21;7(12):e11414.*

Catalunya: TIC Salut Social

Resultados

App accreditation

- **Functionality:** the evaluation of the quality and utility of the app's contents.
- **Usability and design:** accessibility, user experience, and visual aesthetics.
- **Technology:** technological reliability and adaptability of the app in general.
- **Security:** guarantee of data security and adherence to data management policies.

Committee	Members
Functional (in charge of the functional criteria)	• Official College of Doctors of Barcelona • Official College of Nurses of Barcelona • Catalan Society of Clinical Psychologists • Association of Family and Community Nursing • Catalan Society of Family and Community Medicine • Official Association of Graduates in Physical Education and Physical Activity and Sports Sciences of Catalonia
Technical (in charge of the usability and design, technology, and security criteria)	• Currently managed by a specialized consulting company

1. *López Seguí F, Pratdepàdua Bufill C, Rius Soler A, de San Pedro M, López Truño B, Aguiló Laine A, Martínez Roldán J, García Cuyàs F. Prescription and Integration of Accredited Mobile Apps in Catalan Health and Social Care: Protocol for the AppSalut Site Design. JMIR Res Protoc. 2018 Dec 21;7(12):e11414.*

Catalunya: TIC Salut Social

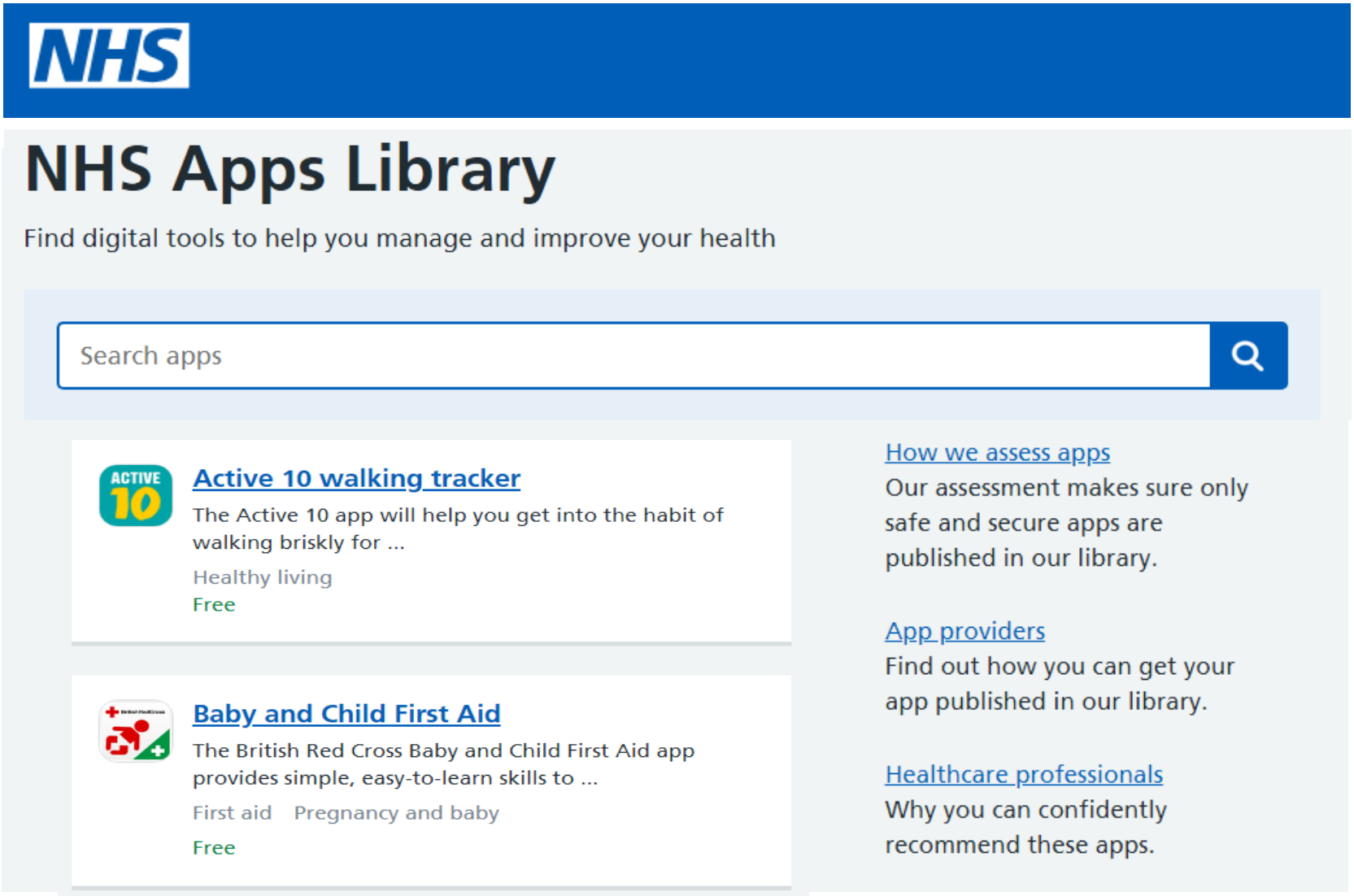
Conclusiones

"This experience illustrates that **an accreditation model is a key structural element** of the prescription and data integration process. It must be conceived in a highly dynamic fashion, **open to feedback from the agents** concerned and **adaptable to technological changes**, plus the concerns of both app developers and patients."

"The project has evolved in keeping with changes in the technological and social paradigm and responds very satisfactorily to the needs posed to it. It can be seen as a **landmark experience in mobile strategies in the fields of health and welfare of any public health system.** The experience has shown itself to be **feasible in organizational terms**, necessary in any attempt to integrate mobile technologies into public health practice, and a global **pioneer in the field."**

1. *López Seguí F, Pratdepàdua Bufill C, Rius Soler A, de San Pedro M, López Truño B, Aguiló Laine A, Martínez Roldán J, García Cuyàs F. Prescription and Integration of Accredited Mobile Apps in Catalan Health and Social Care: Protocol for the AppSalut Site Design. JMIR Res Protoc. 2018 Dec 21;7(12):e11414.*

Inglaterra: NHS Apps Library



1. *National Health Service (NHS). NHS apps library. [Internet] Leeds, NHS Department of Health and Social Care[citado 5 de febrero de 2019]. Disponible en: https://www.nhs.uk/apps-library/?page=3*

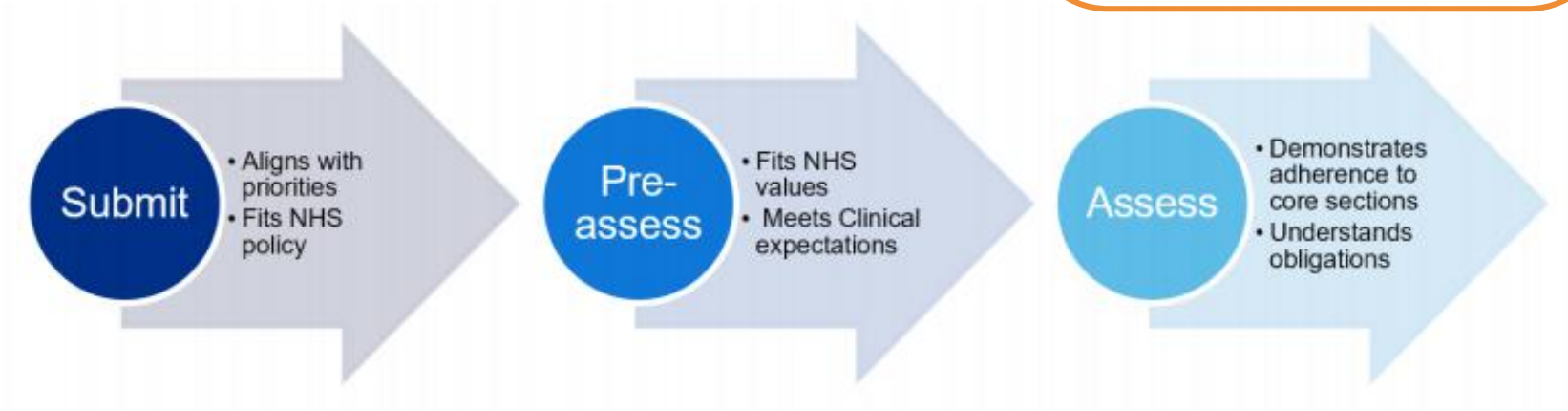
Inglaterra: NHS Apps Library

NHS

How we assess apps

Our Digital Assessment Questions make sure only safe and secure apps and digital tools are hosted in the NHS Apps Library. App providers may need to show evidence that their products pass our tests in areas such as clinical safety, data protection, security and usability, and how anyone using them could see benefits to their health and wellbeing.

- Eligibility
- Evidence of Outcomes
- Clinical Safety
- Data Protection
- Security
- Usability & Accessibility
- Interoperability
- Technical Stability



1. *National Health Service (NHS). NHS apps library. [Internet] Leeds, NHS Department of Health and Social Care[citado 5 de febrero de 2019]. Disponible en: https://www.nhs.uk/apps-library/?page=3*

NICE: estándar evidencia para mHealth

NICE National Institute for Health and Care Excellence

Evidence standards framework for digital health technologies

As digital health technologies develop at an increasing pace, we've worked with partners to develop standards that ensure new technologies are clinically effective and offer economic value.

The aim of these standards is to make it easier for innovators and commissioners to understand what good levels of evidence for digital healthcare technologies look like, while meeting the needs of the health and care system, patients, and users.

We've created these standards as part of a working group led by NHS England. The group also includes:

- Public Health England
- MedCity
- DigitalHealth.London.

NICE National Institute for Health and Care Excellence

NHS England

Public Health England

MEDCITY CAMBRIDGE | LONDON | OXFORD

DigitalHealth.London

1. *Evidence standards framework for digital health technologies (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

Guidance

Code of conduct for data-driven health and care technology

Updated 19 February 2019

Department of Health & Social Care

The principles

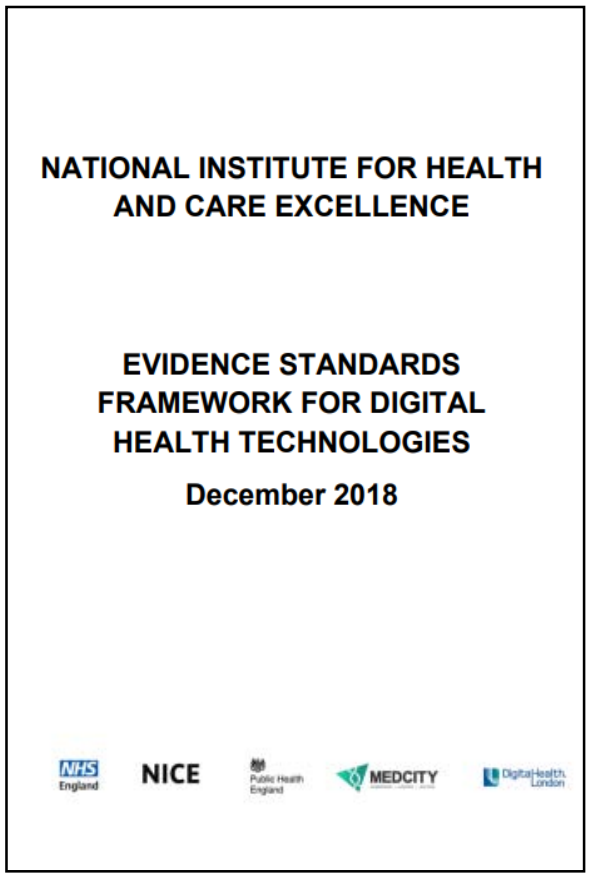
1. Understand **users,** their **needs and the context**
2. Define the **outcome** and how the **technology will contribute to it**
3. Use **data** that is in line with **appropriate guidelines** for the purpose for which it is being used
4. Be **fair, transparent and accountable** about what data is being used
5. Make use of **open standards**
6. Be **transparent about the limitations** of the data used and algorithms deployed
7. Show what type of **algorithm** is being developed or deployed, the **ethical examination** of how the data is used. Generate **evidence of effectiveness** for the intended use and **value for money**
8. Make **security integral** to the design
9. Define the **commercial strategy**

1. *Department of Hralth & Social Care (DHSC). Code of conduct for data-driven health and care technology. [Internet] London, DHSC 2019 [citado 19 de febrero de 2019]. Disponible en: https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology*

NICE: estándar evidencia para mHealth

Evidence standards framework for digital health technologies

NICE accredited
www.nice.org.uk/accreditation


NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

EVIDENCE STANDARDS FRAMEWORK FOR DIGITAL HEALTH TECHNOLOGIES

December 2018

NHS England · NICE · Public Health England · MEDCITY · Digital Health London

The aim of the standards

Provide advice to digital health innovators:

- about how the NHS makes decisions
- about the standards of evidence they will be expected to produce for different types of digital technologies.

Help NHS commissioners:

- to make more informed and consistent decisions by providing a framework for the levels of evidence they should expect to see presented to them.

Improve the approach to developing and commissioning digital health technologies:

- by making it more dynamic and value driven, with a focus on offering real value to patients.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

Evidence standards framework for digital health technologies

NICE accredited
www.nice.org.uk/accreditation

The standards

Download the evidence standards framework for digital technologies (PDF)

The evidence standards framework is made up of 2 sections:

1. Evidence for effectiveness for intended use.
2. Evidence for economic impact.

Both parts of the framework have a proportional approach to defining evidence standards. This recognises:

- the sparsity of available evidence in the field of digital healthcare
- the challenges of developing traditional clinical trials for digital health technologies
- the significant opportunities offered by digital health technologies to collect real world data to inform effectiveness judgements.

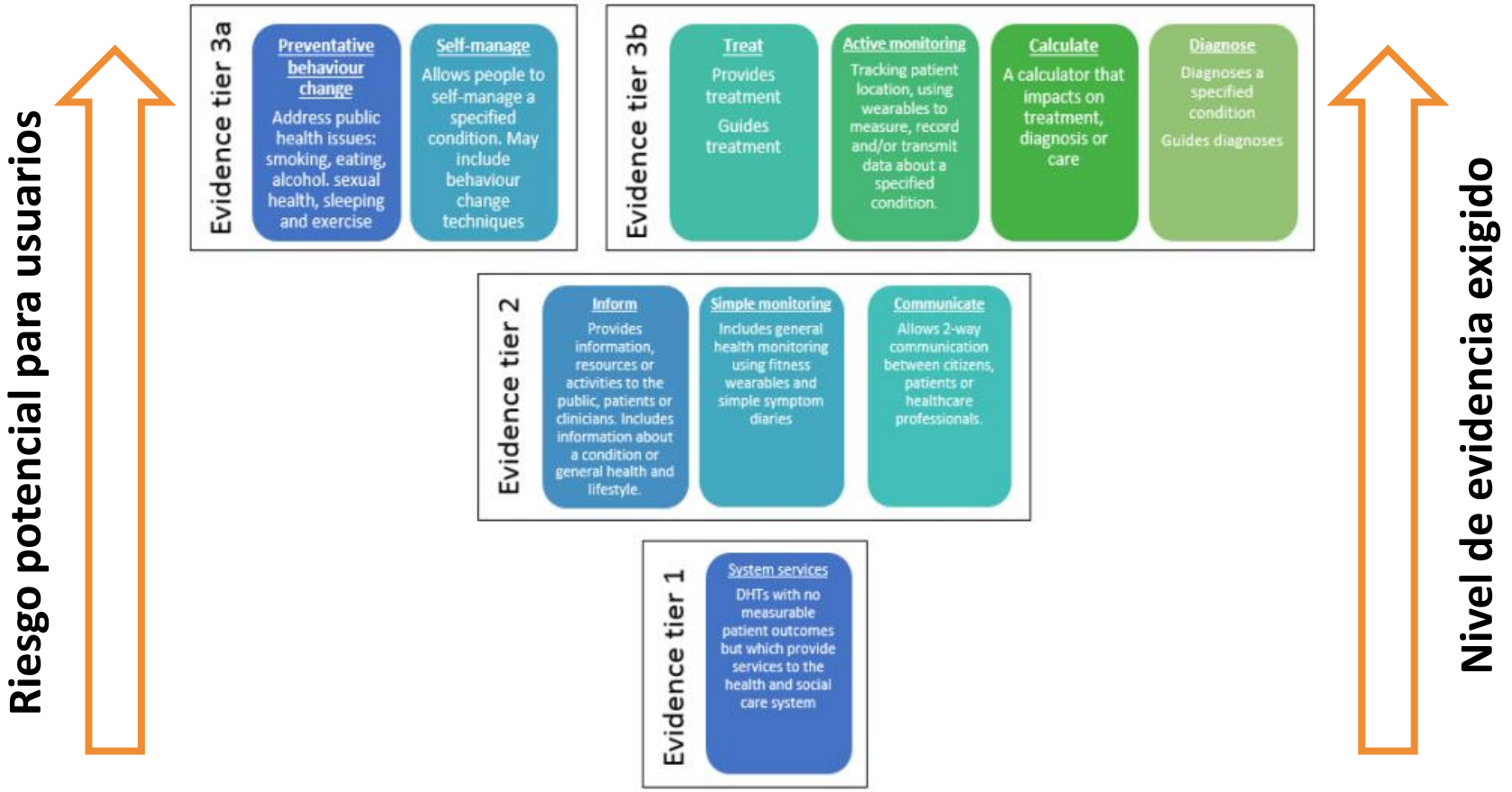
This work directly supports the relevant principles of the Department of Health and Social Care code of conduct for data-driven health and care technology. We welcome comment and feedback on the standards framework - find out how to do this in the 'tell us what you think' section below.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

1. **Evidence for effectiveness for intended use.**

NICE accredited
www.nice.org.uk/accreditation



1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

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- **Clasificación de las mHealths por tiers en función del riesgo potencial a usuarios**

Evidence tier	Functional classification	Description	Includes (for example)	Excludes (for example)
Tier 1: DHTs with potential system benefits but no direct user benefits.	System service.	Improves system efficiency. Unlikely to have measurable individual patient outcomes.	Electronic prescribing systems. Electronic health record platforms. Ward management systems.	Systems that provide treatment or diagnoses, such as early warning systems that monitor patient vital signs.
Tier 2: DHTs which help users to understand healthy living and illnesses but are unlikely to have measurable user outcomes.	Inform.	Provides information and resources to patients or the public. Can include information on specific conditions or about healthy living.	DHTs describing a condition and its treatment. Apps providing advice for healthy lifestyles (such as recipes). Apps that signpost to other services.	Tools that collect symptom data from users. Tools that provide treatment for a condition. Apps that allow communication among users, or between users and professionals.
	Simple monitoring.	Allows users to record health parameters to create health diaries. This information is not shared with or sent to others.	Health tracking information such as from fitness wearables. Symptom or mood diaries.	DHTs that share information with professionals, carers or other users. Tools that provide treatment for a condition.
	Communicate.	Allows 2-way communication between users and professionals, carers, third-party organisations or peers. Clinical advice is provided	Instant messaging apps for health and social care. Video conference-style consultation software. Platforms for communication with carers or professionals.	DHTs that provide clinical content themselves (such as cognitive behavioural programmes for depression).

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

1. **Evidence for effectiveness for intended use.**

		by a professional using the DHT, not by the DHT itself.		
Tier 3a: DHTs for preventing and managing diseases. They may be used alongside treatment and will likely have measurable user benefits.	Preventative behaviour change.	Designed to change user behaviour related to health issues with, for example, smoking, eating, alcohol, sexual health, sleeping and exercise. Prescribed to users by a professional.	Smoking cessation DHTs and those used as part of weight loss programmes. DHTs marketed as aids to good sleep habits.	DHTs that describe themselves as a treatment for a diagnosed condition. Apps that provide general healthy lifestyle advice.
	Self-manage.	Aims to help people with a diagnosed condition to manage their health. May include symptom tracking function that connects with a healthcare professional.	DHTs that allow users to record, and optionally to send, data to a healthcare professional to improve management of their condition.	DHTs that describe themselves as a treatment for a diagnosed condition. Apps that automatically monitor and report data to a healthcare professional or third-party organisation.
Tier 3b: DHTs with measurable user benefits, including tools used for treatment and diagnosis, as well as those influencing clinical management through active monitoring or calculation. It is possible that DHTs in this tier will qualify as medical devices.	Treat.	Provides treatment for a diagnosed condition (such as CBT for anxiety), or guides treatment decisions.	DHTs for treating mental health or other conditions. Clinician-facing apps that advise on treatments in certain situations.	Apps that provides general health advice or advice on living with a diagnosed condition. DHTs that offer general advice for clinicians such as online textbooks or digital versions of care pathways.
	Active monitoring.	Automatically records health information and transmits the data to a professional, carer or third-party organisation, without any input from the user.	DHTs linked to devices such as implants, sensors worn on the body or in the home. Data are automatically transmitted	DHTs that allow a user to choose if and when to send recorded data to a professional, carer or third-party organisation.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

1. Evidence for effectiveness for intended use.

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- **Exigencia de un nivel de evidencia en función del tier de la mHealth**

About the evidence tables

Each table corresponds to an evidence tier:

- Tier 1 evidence for effectiveness standards: table 3
- Tier 2 evidence for effectiveness standards: table 4
- Tier 3a evidence for effectiveness standards: table 5
- Tier 3b evidence for effectiveness standards: table 6

The evidence tiers are **cumulative**. This means that a DHT must meet all the standards in the previous tier(s), as well as its own tier.

The tables show 2 levels of evidence for the criteria in each tier: a minimum evidence standard and a best practice standard.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

1. Evidence for effectiveness for intended use.

Table 3 Evidence for effectiveness standards for tier 1 DHTs

Evidence category	Minimum evidence standard	Best practice standard
Credibility with UK health and social care professionals.	Be able to show that the DHT has a plausible mode of action that is viewed as useful and relevant by professional experts or expert groups in the relevant field. Either: • show that relevant clinical or social care professionals working within the UK health and social care system have been involved in the design, development or testing of the DHT, or • show that relevant clinical or social care professionals working within the UK health and social care system have been involved in signing-off the DHT, indicating their informed approval of the DHT.	Published or publically available evidence documenting the role of relevant UK health or social care experts in the design, development, testing or sign-off of the DHT.
Relevance to current care pathways in the UK health and social care system.	Evidence to show that the DHT has been successfully piloted in the UK health and social care system, showing that it is relevant to current care pathways and service provision in the UK. Also evidence that the DHT is able to perform its intended function to the scale needed (for example, having servers that can scale to manage the expected number of users).	Evidence to show successful implementation of the DHT in the UK health and social care system.
Acceptability with users.	Be able to show that representatives from relevant user groups were involved in the design, development or testing of the DHT. Provide data to show user satisfaction with the DHT.	Published or publically available evidence to show that representatives from relevant user groups were involved in the design, development or testing of the DHT and to show that users are satisfied with the DHT.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

1. Evidence for effectiveness for intended use.

NICE accredited
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Table 4 Evidence for effectiveness standards for tier 2 DHTs

Evidence category	Minimum evidence standard	Best practice standard
Reliable information content.	Be able to show that any health information provided by the DHT is: • valid (aligned to best available sources, such as NICE guidance, relevant professional organisations or recognised UK patient organisations, and appropriate for the target population) • accurate • up to date • reviewed and updated by relevant experts at defined intervals, such as every year • sufficiently comprehensive.	Evidence of endorsement, accreditation or recommendation by NICE, NHS England, a relevant professional body or recognised UK patient organisation. Alternatively, evidence that the information content has been validated though an independent accreditation such as The Information Standard or HONcode certification.
Ongoing data collection to show usage of the DHT.	Commitment to ongoing data collection to show usage of the DHT in the target population, and to report these data to commissioners in a clear and useful format.	Public reporting of both commitments in the minimum evidence standard.
Ongoing data collection to show value of the DHT.	Commitment to ongoing data collection to show user outcomes (if relevant) or user satisfaction (using non-patient identifiable information) to show ongoing value, and to report these data to commissioners in a clear and useful format.	Public reporting of ongoing data collection to show user outcomes (using non-patient identifiable information) to demonstrate ongoing value.
Quality and safeguarding.	Show that appropriate safeguarding measures are in place around peer-support and other communication functions within the platform. Describe who has access to the platform and their roles within the platform. Describe why these people or groups are suitable and qualified to have access. Describe any measures in place to ensure safety in peer-to-peer communication, for example through user agreements or moderation.	As for the minimum evidence standard.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

1. **Evidence for effectiveness for intended use.**

NICE accredited
www.nice.org.uk/accreditation

Table 5: Evidence for effectiveness standards for tier 3a DHTs

Evidence category	Minimum evidence standard	Best practice standard
Demonstrating effectiveness.	High quality observational or quasi-experimental studies demonstrating relevant outcomes. These studies should present comparative data. Comparisons could include: • relevant outcomes in a control group • use of historical controls • routinely collected data. Relevant outcomes may include: • behavioural or condition-related user outcomes such as reduction in smoking or improvement in condition management • evidence of positive behaviour change • user satisfaction.	High quality quasi-experimental or experimental studies which incorporate a comparison group, showing improvements in relevant outcomes, such as: • patient-reported outcomes (preferably using validated tools) including symptom severity or quality of life • other clinical measures of disease severity or disability • healthy behaviours • physiological measures • user satisfaction and engagement • health and social care resource use, such as admissions or appointments. The comparator should be a care option that is reflective of the current care pathway, such as a commonly used active intervention.
Use of appropriate behaviour change techniques (if relevant).	Be able to show that the techniques used in the DHT are: • consistent with recognised behaviour change theory and recommended practice (aligned to guidance from NICE or relevant professional organisations) • appropriate for the target population.	Published qualitative or quantitative evidence showing that the techniques used in the DHT are: • based on published and recognised effective behaviour change techniques • aligned with recommended practice • appropriate for the target population.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

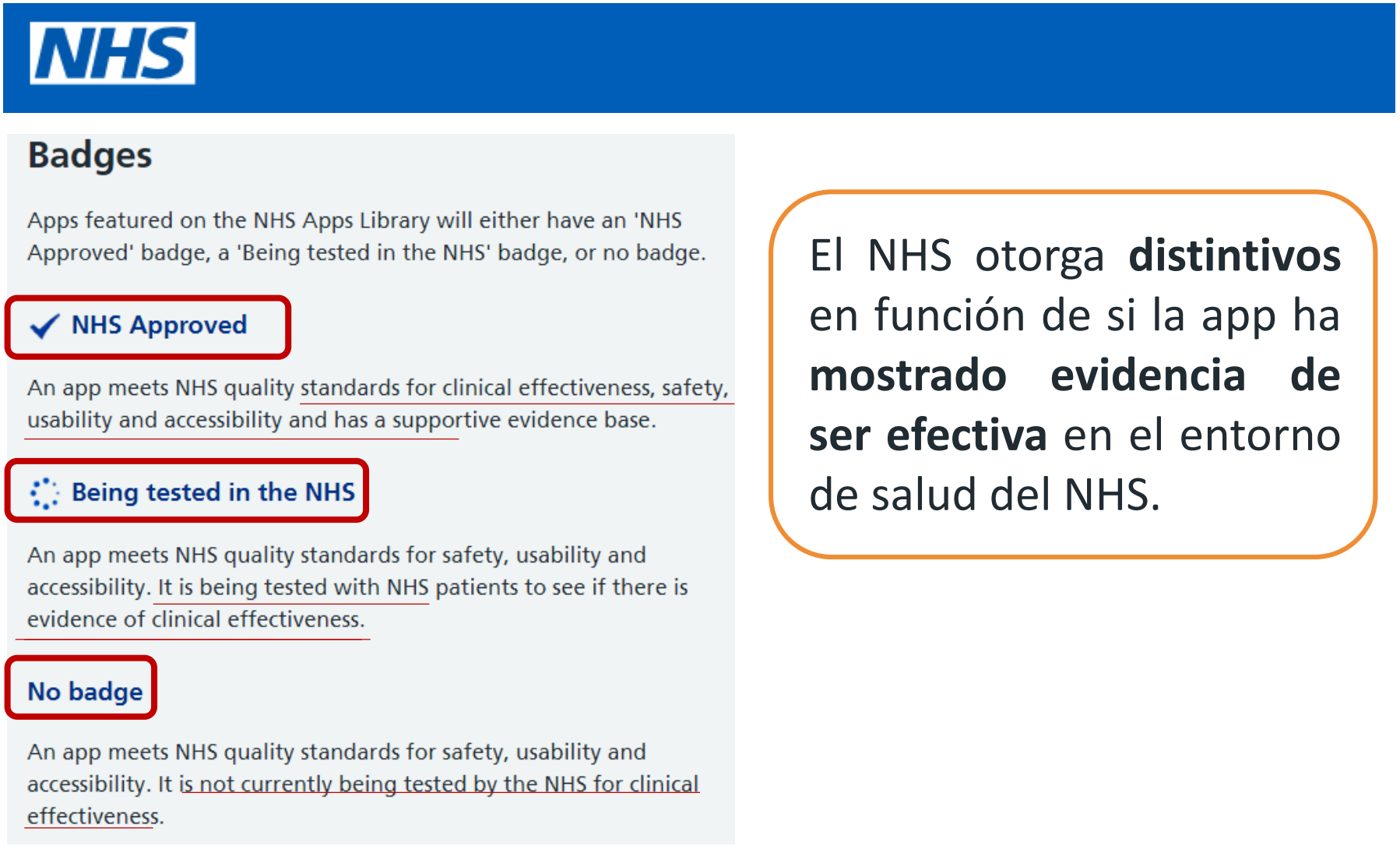
1. **Evidence for effectiveness for intended use.**

Table 6 Evidence for effectiveness standards for tier 3b DHTs

Evidence category	Minimum evidence standard	Best practice standard
Demonstrating effectiveness.	High quality experimental or quasi-experimental studies showing improvements in relevant outcomes, such as: • diagnostic accuracy • patient-reported outcomes including symptom severity or quality of life • other clinical measures of disease severity or disability • healthy behaviours • physiological measures • user satisfaction and engagement. Generic outcome measures may also be useful when reported alongside condition-specific outcomes. The comparator should be a care option that is reflective of the current care pathway, such as a commonly used active intervention.	High quality randomised controlled study or studies done in a setting relevant to the UK health and social care system, comparing the DHT with a relevant comparator and demonstrating consistent benefit including in clinical outcomes in the target population, using validated condition-specific outcome measures. Alternatively, a well-conducted meta-analysis of randomised controlled studies if there are enough available studies on the DHT.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

Inglaterra: NHS Apps Library



NHS

Badges

Apps featured on the NHS Apps Library will either have an 'NHS Approved' badge, a 'Being tested in the NHS' badge, or no badge.

NHS Approved

An app meets NHS quality standards for clinical effectiveness, safety, usability and accessibility and has a supportive evidence base.

Being tested in the NHS

An app meets NHS quality standards for safety, usability and accessibility. It is being tested with NHS patients to see if there is evidence of clinical effectiveness.

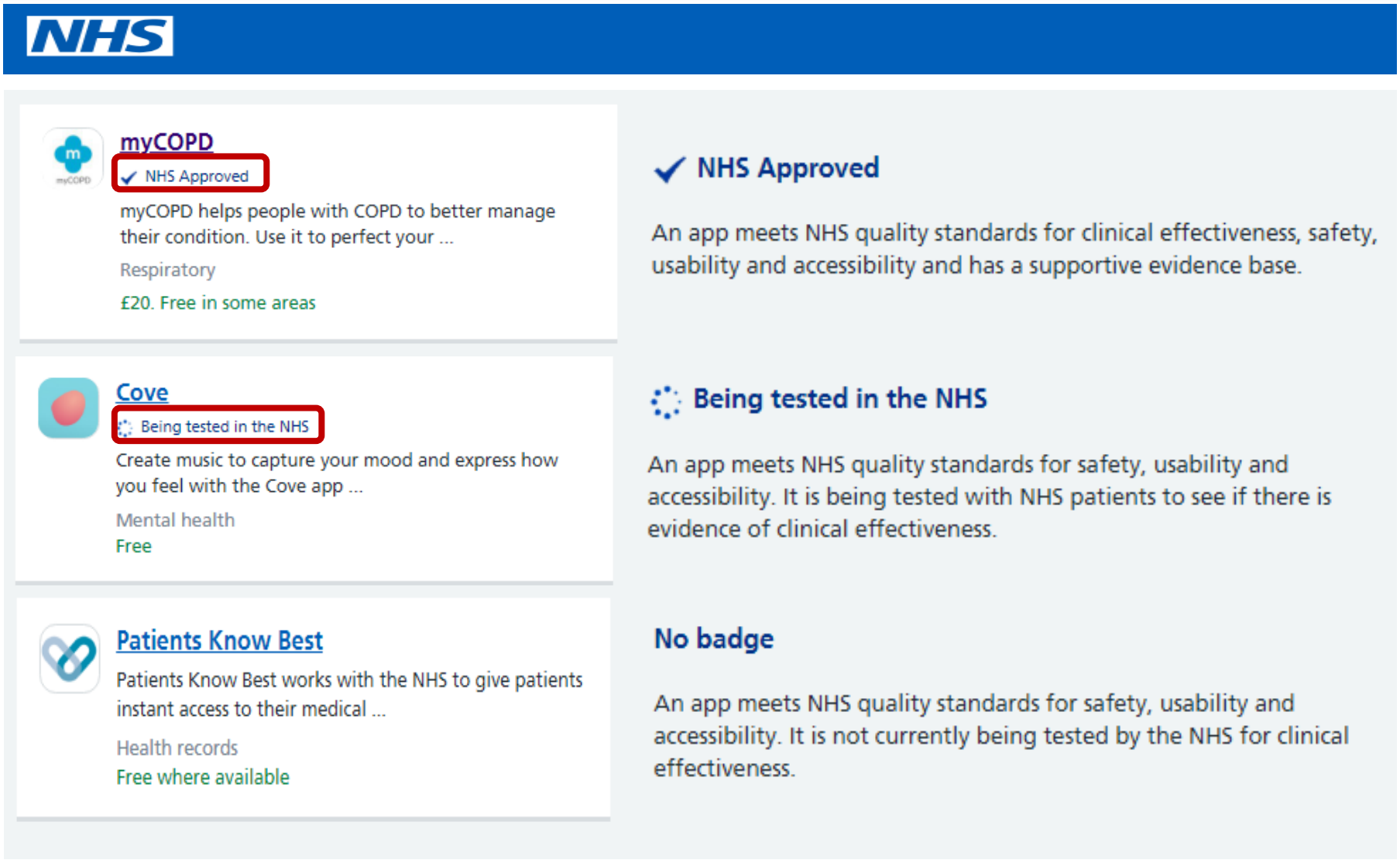
No badge

An app meets NHS quality standards for safety, usability and accessibility. It is not currently being tested by the NHS for clinical effectiveness.

El NHS otorga **distintivos** en función de si la app ha **mostrado evidencia de ser efectiva** en el entorno de salud del NHS.

1. *National Health Service (NHS). NHS apps library. [Internet] Leeds, NHS Department of Health and Social Care[citado 5 de febrero de 2019]. Disponible en: https://www.nhs.uk/apps-library/?page=3*

Inglaterra: NHS Apps Library



1. *National Health Service (NHS). NHS apps library. [Internet] Leeds, NHS Department of Health and Social Care[citado 5 de febrero de 2019]. Disponible en: https://www.nhs.uk/apps-library/?page=3*

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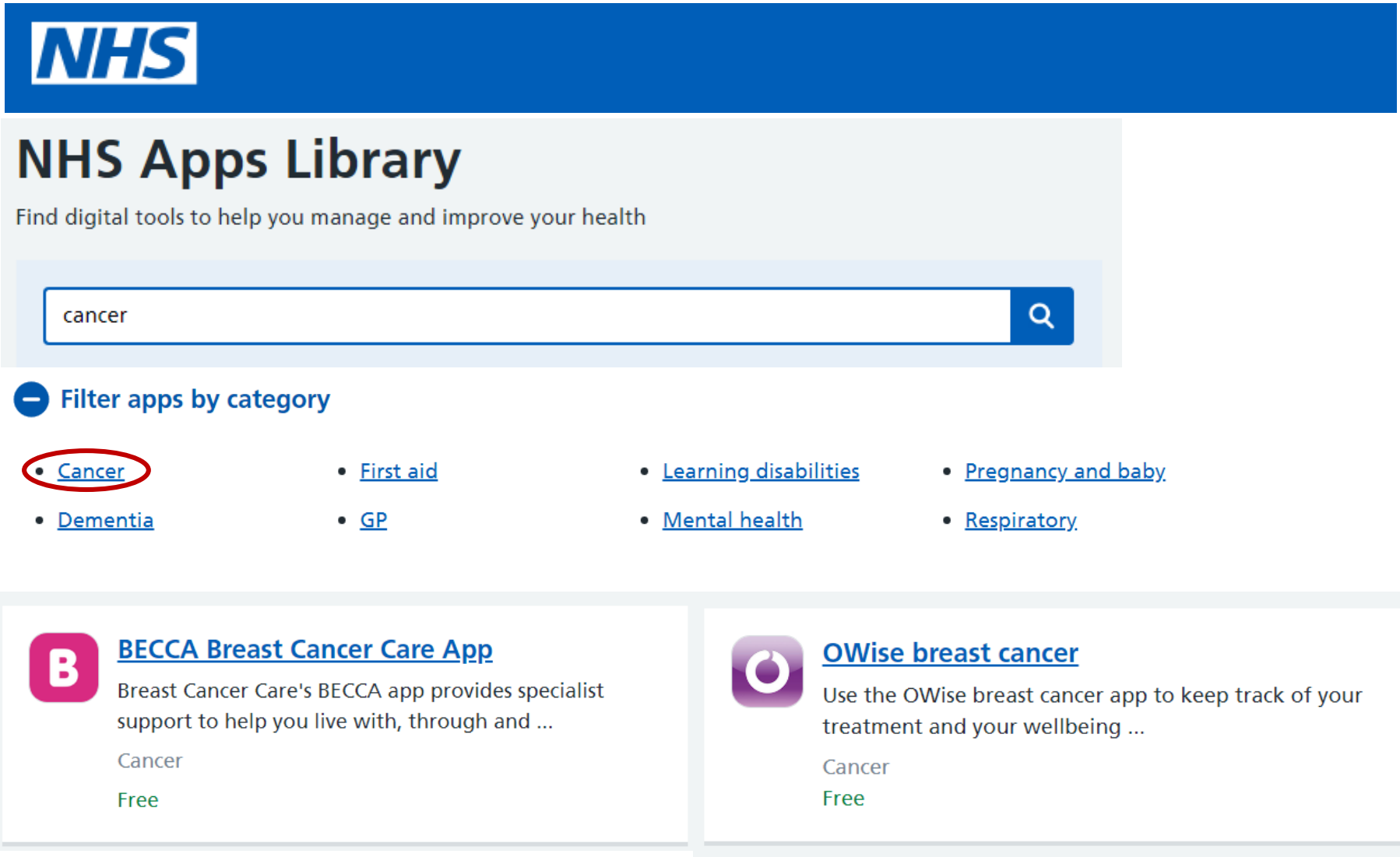


1. *National Health Service (NHS). NHS apps library. [Internet] Leeds, NHS Department of Health and Social Care[citado 5 de febrero de 2019]. Disponible en: https://www.nhs.uk/apps-library/?page=3*

Inglaterra: NHS Apps Library

NHS

BECCA Breast Cancer Care App

Download on the App Store | GET IT ON Google Play

Category: Cancer

Free

Breast Cancer Care's BECCA app provides specialist support to help you live with, through and beyond breast cancer. Easy-to-use flashcards give information, support and inspiration to anyone struggling to find their "new normal" following diagnosis.

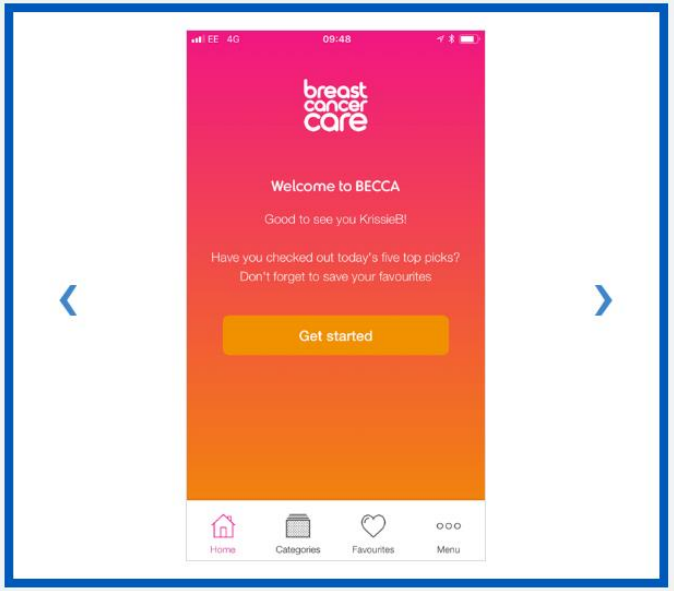
Who is it suitable for?

BECCA is for anyone finishing treatment for primary breast cancer.

How does it work?

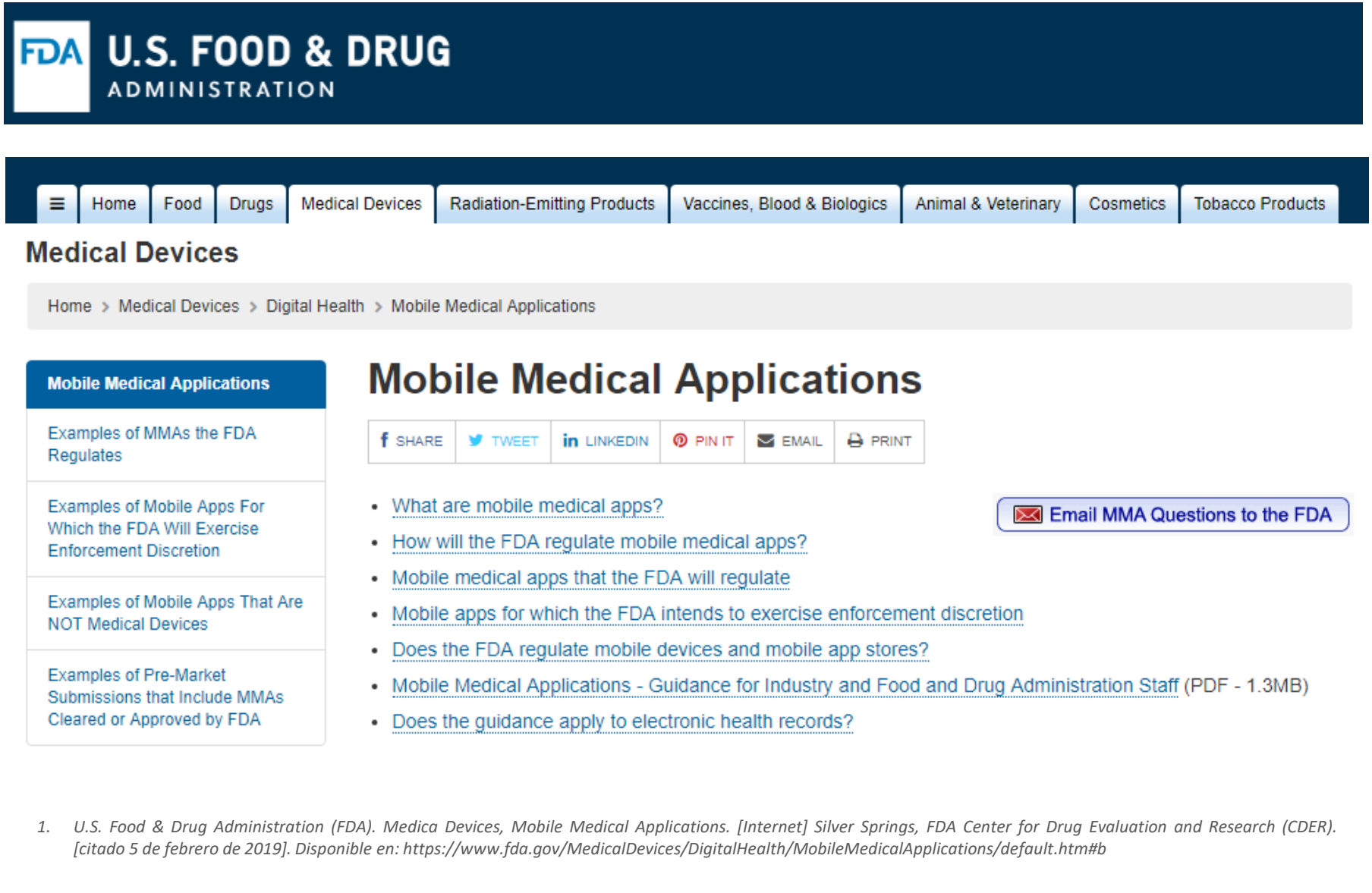
BECCA helps you adapt to life after breast cancer treatment by giving you access to relevant and trustworthy advice directly on your mobile device. You'll find tips on a range of subjects including health, exercise, food and what is now normal for you.

Daily blogs by people living with breast cancer are designed to help you understand your symptoms and feelings, and give you confidence to move forward after breast cancer.



1. *National Health Service (NHS). NHS apps library. [Internet] Leeds, NHS Department of Health and Social Care[citado 5 de febrero de 2019]. Disponible en: https://www.nhs.uk/apps-library/?page=3*

Estados Unidos: FDA



1. *U.S. Food & Drug Administration (FDA). Medica Devices, Mobile Medical Applications. [Internet] Silver Springs, FDA Center for Drug Evaluation and Research (CDER). [citado 5 de febrero de 2019]. Disponible en: https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm#b*

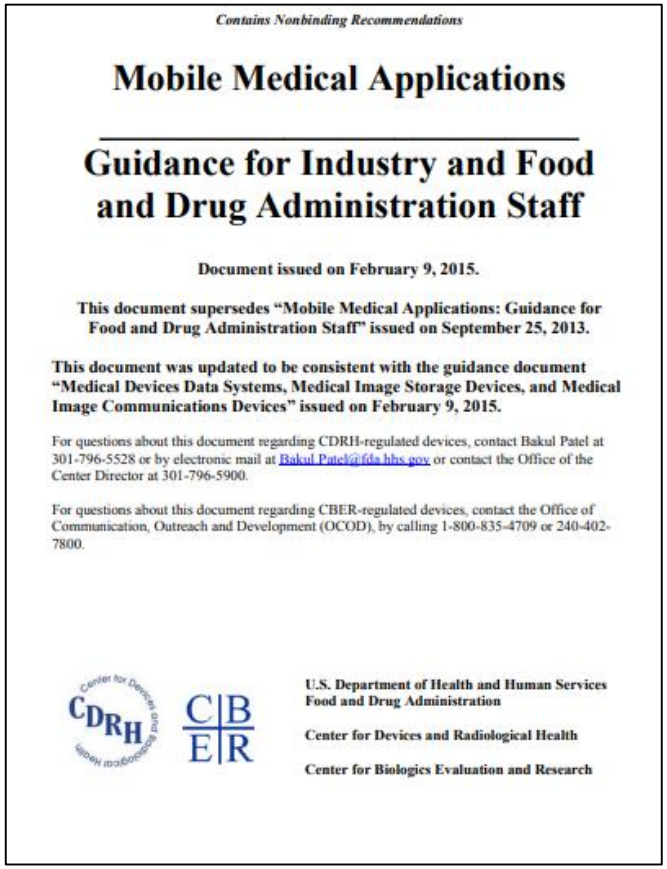
Estados Unidos: FDA

FDA U.S. FOOD & DRUG ADMINISTRATION

How will the FDA regulate mobile medical apps?

The FDA will apply the same risk-based approach the agency uses to assure safety and effectiveness for other medical devices. The guidance document (PDF - 269KB) provides examples of how the FDA might regulate certain moderate-risk (Class II) and high-risk (Class III) mobile medical apps. The guidance also provides examples of mobile apps that are not medical devices, mobile apps that the FDA intends to exercise enforcement discretion and mobile medical apps that the FDA will regulate in Appendix A, Appendix B and Appendix C.

We encourage app developers to contact the FDA – as early as possible – if they have any questions about their mobile app, its level of risk, and whether a premarket application is required.



Contains Nonbinding Recommendations

Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

Document issued on February 9, 2015.

This document supersedes "Mobile Medical Applications: Guidance for Food and Drug Administration Staff" issued on September 25, 2013.

This document was updated to be consistent with the guidance document "Medical Devices Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices" issued on February 9, 2015.

For questions about this document regarding CDRH-regulated devices, contact Bakul Patel at 301-796-5528 or by electronic mail at Bakul.Patel@fda.hhs.gov or contact the Office of the Center Director at 301-796-5900.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-7800.

CDRH CBER

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

1. *U.S. Food & Drug Administration (FDA). Medica Devices, Mobile Medical Applications. [Internet] Silver Springs, FDA Center for Drug Evaluation and Research (CDER). [citado 5 de febrero de 2019]. Disponible en: https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm#b*

Estados Unidos: FDA

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.

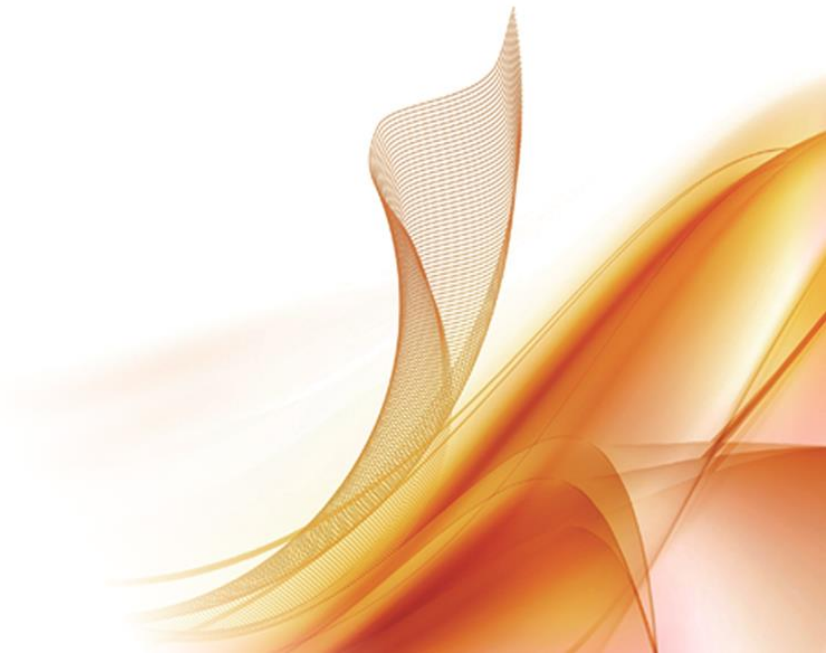
Does the FDA regulate mobile devices and mobile app stores?

FDA's mobile medical apps policy does not regulate the sale or general consumer use of smartphones or tablets. FDA's mobile medical apps policy does **not** consider entities that exclusively distribute mobile apps, such as the owners and operators of the "iTunes App store" or the "Google Play store," to be medical device manufacturers. **FDA's mobile medical apps policy does not consider mobile platform manufacturers to be medical device manufacturers** just because their mobile platform could be used to run a mobile medical app regulated by FDA.

1. *U.S. Food & Drug Administration (FDA). Medica Devices, Mobile Medical Applications. [Internet] Silver Springs, FDA Center for Drug Evaluation and Research (CDER). [citado 5 de febrero de 2019]. Disponible en: https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm#b*

Aplicaciones de las mHealth

mHealth en el entorno clínico



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pharmacoeconomics & outcomes research iberia

Utilidad de las mHealth

¿Dónde tienen cabida las mHealth?

- ✓ Ensayos preclínicos
- ✓ Ensayos clínicos
- ✓ Estudios observacionales
- ✓ RWE
- ✓ Estudios Farmacoeconómicos

Seguridad → Eficacia → Seguridad Efectividad → Eficiencia

- Mejor control del paciente
- Medicina personalizada
- Optimización de procesos
- Generación de resultados
- Modificación de hábitos del paciente…

mHealth[1,2]

1. *Weiler A. mHealth and big data will bring meaning and value to patient-reported outcomes. Mhealth. 2016 Jan 31;2:2. doi: 10.3978/j.issn.2306-9740.2016.01.02. eCollection 2016.*
2. *Blog A un clic de las TIC. Salud móvil: la ultima revolución en medicina. [Internet] Mercedes Nuñez, blogthinkbig.com [citado 5 de febrero de 2019]. Disponible en: https://aunclicdelastic.blogthinkbig.com/salud-movil-la-ultima-revolucion-en-medicina/*

Servicios profesionales asistenciales

¿Cómo pueden ayudarme las mHealth?:

Los servicios profesionales asistenciales son actividades prestadas por profesionales sanitarios con el objetivo de **optimizar recursos, garantizar resultados y cubrir necesidades asistenciales de los pacientes**[1]

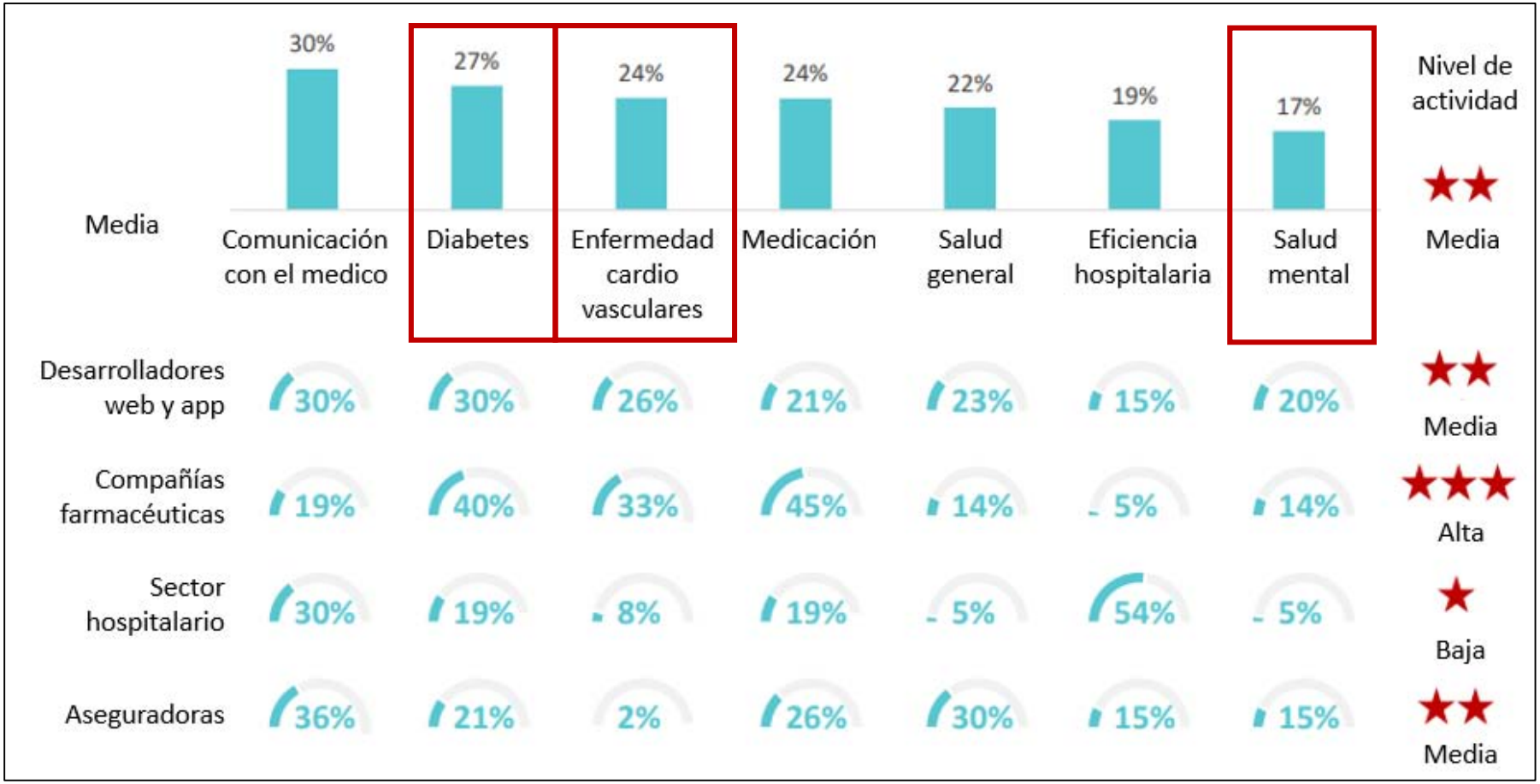
- ✓ Seguimiento farmacoterapéutico
- ✓ Sistemas personalizados de dosificación
- ✓ Programas de adherencia al tratamiento
- ✓ Revisión de medicación
- ✓ Atención domiciliaria
- ✓ Deshabituación tabáquica
- ✓ Campañas sanitarias

mHealth
herramientas de utilidad

1. *Sexto comunicado Foro de Atención Farmacéutica y Farmacia Comunitaria. Servicios profesionales farmacéuticos asistenciales. [Internet] Foro de Atención Farmacéutica y Farmacia Comunitaria [citado 5 de febrero de 2019]. Disponible en: https://www.pharmaceutical-care.org/archivos/2912/6to_comunicado_FORO_AF-FC_SPF_A_y_clasificacion_v4_160628.pdf*

Principales áreas de desarrollo

Por patología, existe un mayor interés en el desarrollo de apps de mHealth en **diabetes, enfermedades cardiovasculares y enfermedades mentales**[1]



1. *Research 2 Guidance. mHealth App Developer Economics (2016): The current status and trends of the mHealth app market [Internet] Research 2 Guidance, 2016 [citado 5 de febrero de 2019]. Disponible en: https://research2guidance.com/r2g/r2g-mHealth-App-Developer-Economics-2016.pdf*

Análisis bibliométrico mHealths

RESEARCH ARTICLE

BMC Medical Informatics & Decision Making

Bibliometric analysis of worldwide scientific literature in mobile - health: 2006–2016

Waleed M. Sweileh[1*], Samah W. Al-Jabi[2], Adham S. AbuTaha[1], Sa'ed H. Zyoud[2], Fathi M. A. Anayah[3] and Ansam F. Sawalha[1]

Abstract

Background: The advancement of mobile technology had positively influenced healthcare services. An emerging subfield of mobile technology is mobile health (m-Health) in which mobile applications are used for health purposes. The aim of this study was to analyze and assess literature published in the field of m-Health.

Methods: SciVerse Scopus was used to retrieve literature in m-Health. The study period was set from 2006 to 2016. ArcGIS 10.1 was used to present geographical distribution of publications while VOSviewer was used for data visualization. Growth of publications, citation analysis, and research productivity were presented using standard bibliometric indicators.

Results: During the study period, a total of 5465 documents were published, giving an average of 496.8 documents per year. The *h*-index of retrieved documents was 81. Core keywords used in literature pertaining to m-Health included diabetes mellitus, adherence, and obesity among others. Relative growth rate and doubling time of retrieved literature were stable from 2009 to 2015 indicating exponential growth of literature in this field. A total of 4638 (84.9%) documents were multi-authored with a mean collaboration index of 4.1 authors per article. The United States of America ranked first in productivity with 1926 (35.2%) published documents. India ranked sixth with 183 (3.3%) documents while China ranked seventh with 155(2.8%) documents. *VA Medical Center* was the most prolific organization/institution while *Journal of Medical Internet Research* was the preferred journal for publications in the field of m-Health. Top cited articles in the field of m-Health included the use of mobile technology in improving adherence in HIV patients, weight loss, and improving glycemic control in diabetic patients.

Conclusion: The size of literature in m-Health showed a noticeable increase in the past decade. Given the large volume of citations received in this field, it is expected that applications of m-Health will be seen into various health aspects and health services. Research in m-Health needs to be encouraged, particularly in the fight against AIDS, poor medication adherence, glycemic control in Africa and other low income world regions where technology can improve health services and decrease disease burden.

Keywords: Mobile Health, Bibliometric, VOSviewer

1. *Sweileh WM, Al-Jabi SW, AbuTaha AS, Zyoud SH, Anayah FMA, Sawalha AF. Bibliometric analysis of worldwide scientific literature in mobile - health: 2006-2016. BMC Med Inform Decis Mak. 2017 May 30;17(1):72.*

Análisis bibliométrico mHealths

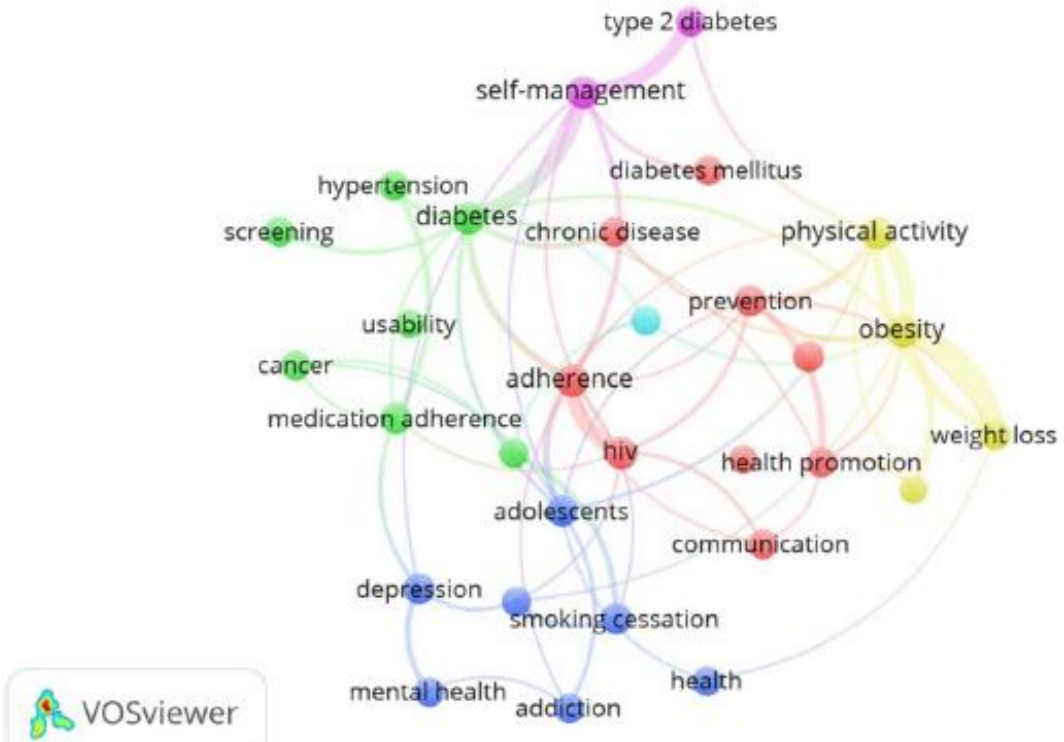


Fig. 1 Network visualization map of author keywords occurrences (i.e., keywords listed by the author). Keywords with minimum occurrences of 25 times were shown in the map. Keywords with the same color were commonly listed together. So, for example, physical activity, obesity, health behavior, and weight loss have similar color suggestive that these keywords have close relation and usually co-occur together

1. *Sweileh WM, Al-Jabi SW, AbuTaha AS, Zyoud SH, Anayah FMA, Sawalha AF. Bibliometric analysis of worldwide scientific literature in mobile - health: 2006-2016. BMC Med Inform Decis Mak. 2017 May 30;17(1):72.*

Análisis bibliométrico mHealths

El número de **publicaciones de mHealth** ha ido **incrementando en los últimos años**[1]

Table 2 Annual number of publications and citation analysis per year (2006 – 2016)

Year	Frequency	% $N = 5465$	TC	Mean ± SD of citations	Median (Q1 – Q3) of citations
2006	155	2.8	2438	15.7 ± 33.8	5 (1–17)
2007	176	3.2	3248	18.5 ± 31.5	11 (1–21.75)
2008	189	3.5	3646	19.3 ± 32.6	6 (1–20.5)
2009	234	4.3	4955	21.2 ± 42.7	6 (1–23)
2010	288	5.3	5994	20.8 ± 45.6	7 (1–24.75)
2011	343	6.3	6886	16.6 ± 39.7	4 (0–17)
2012	505	9.2	8332	20.1 ± 26.7	7 (2–21)
2013	630	11.5	8581	13.6 ± 23.4	6 (2–16)
2014	861	15.8	6179	7.2 ± 11	3 (1–9)
2015	989	18.1	3749	3.8 ± 6.7	2 (0–4.5)
2016	1095	20.0	929	0.8 ± 1.8	0 (0–1)

TC Total citations, *SD* Standard deviation, Q1-Q3 Interquartile range

1. *Sweileh WM, Al-Jabi SW, AbuTaha AS, Zyoud SH, Anayah FMA, Sawalha AF. Bibliometric analysis of worldwide scientific literature in mobile - health: 2006-2016. BMC Med Inform Decis Mak. 2017 May 30;17(1):72.*

Análisis bibliométrico mHealths

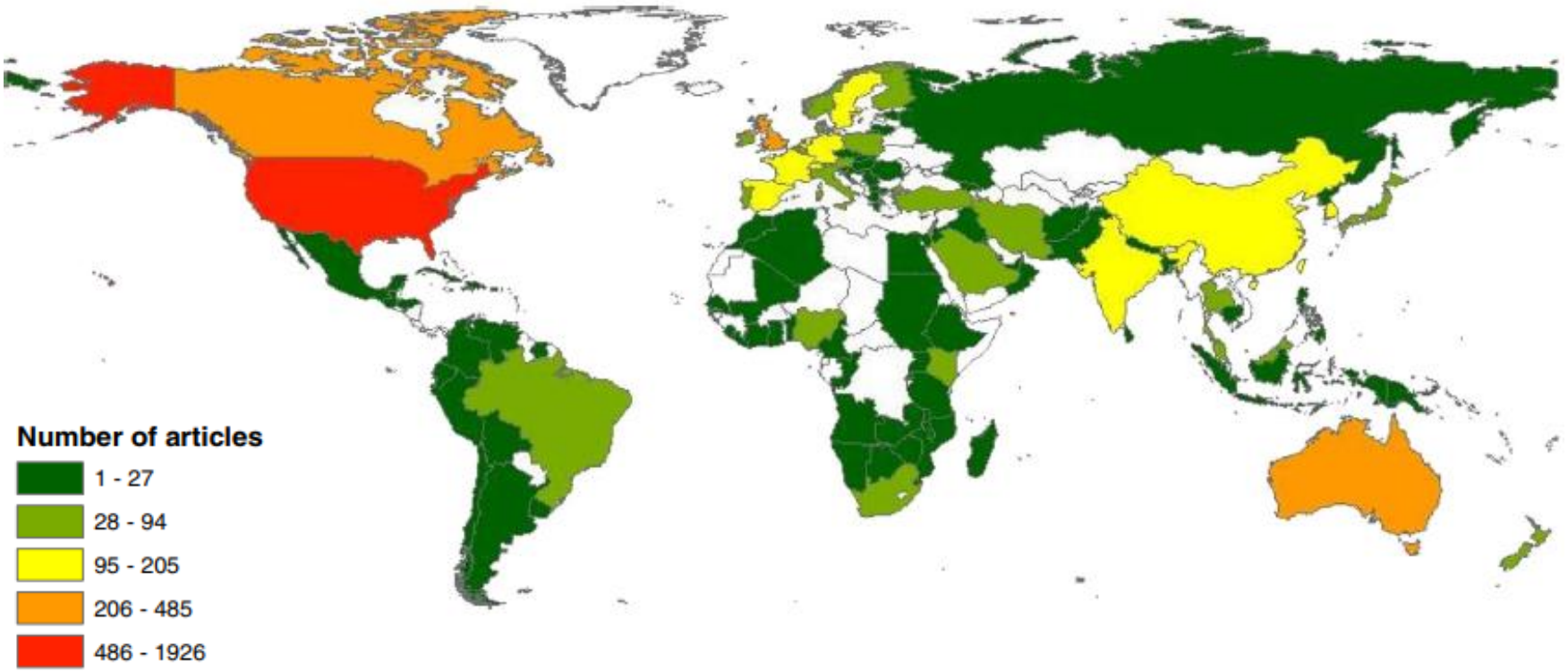


Fig. 3 Geographical distribution of publication in m-Health. The map was created using ArcGIS 10.1 software. The map is color coded where world regions with *red* color had the highest productivity while world regions with dark *green* had the lowest productivity. Areas with no color indicates no data available from these areas

1. *Sweileh WM, Al-Jabi SW, AbuTaha AS, Zyoud SH, Anayah FMA, Sawalha AF. Bibliometric analysis of worldwide scientific literature in mobile - health: 2006-2016. BMC Med Inform Decis Mak. 2017 May 30;17(1):72.*

Análisis bibliométrico mHealths

Table 6 Countries with a minimum productivity of 50 documents in the field of mobile health

Rank	Country	Frequency	% $N = 5465$
1	United States	1926	35.2
2	United Kingdom	485	8.9
3	Australia	280	5.1
4	Canada	268	4.9
5	South Korea	205	3.8
6	India	183	3.3
7	Germany	173	3.2
8	China	155	2.8
9	Spain	153	2.8
10	France	149	2.7
11	Netherlands	116	2.1
12	Sweden	113	2.1
13	Switzerland	106	1.9
14	Italy	94	1.7
15	South Africa	80	1.5
16	Japan	72	1.3
16	Taiwan	72	1.3
18	New Zealand	65	1.2
19	Turkey	60	1.1
20	Denmark	55	1.0
21	Iran	54	1.0
22	Norway	50	0.9

1. *Sweileh WM, Al-Jabi SW, AbuTaha AS, Zyoud SH, Anayah FMA, Sawalha AF. Bibliometric analysis of worldwide scientific literature in mobile - health: 2006-2016. BMC Med Inform Decis Mak. 2017 May 30;17(1):72.*

Análisis bibliométrico mHealths

Table 7 Institutions and organizations with a minimum productivity of 30 documents in m-Health (2006–2016)

Rank	Institution/Organization	Frequency	% (*N* = 5465)	Country
1	VA Medical Center	85	1.6	USA
23	University of Queensland	31	0.6	Australia
28	Brigham and Women's Hospital	30	0.5	USA

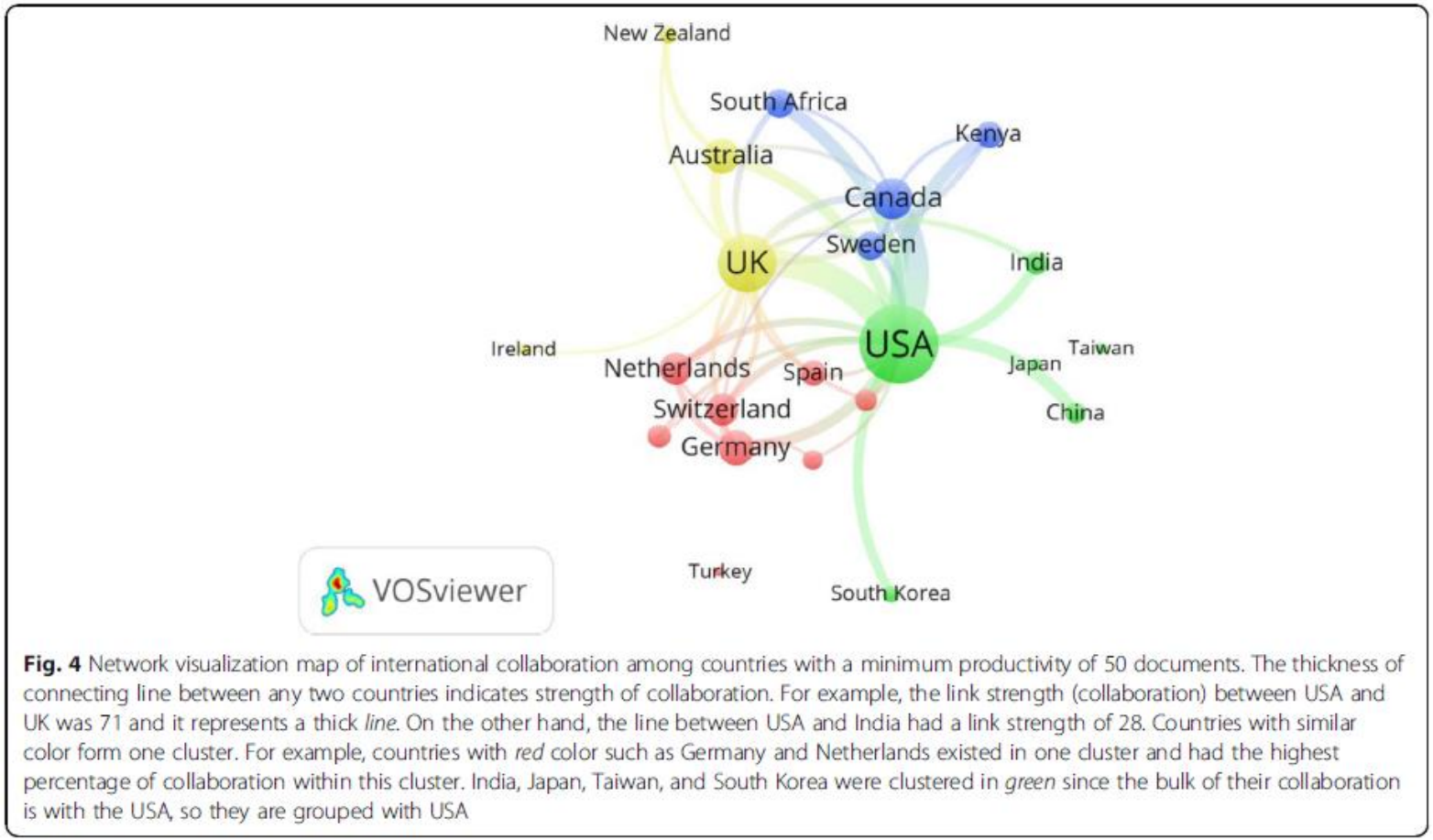


Fig. 4 Network visualization map of international collaboration among countries with a minimum productivity of 50 documents. The thickness of connecting line between any two countries indicates strength of collaboration. For example, the link strength (collaboration) between USA and UK was 71 and it represents a thick *line*. On the other hand, the line between USA and India had a link strength of 28. Countries with similar color form one cluster. For example, countries with *red* color such as Germany and Netherlands existed in one cluster and had the highest percentage of collaboration within this cluster. India, Japan, Taiwan, and South Korea were clustered in *green* since the bulk of their collaboration is with the USA, so they are grouped with USA

1. *Sweileh WM, Al-Jabi SW, AbuTaha AS, Zyoud SH, Anayah FMA, Sawalha AF. Bibliometric analysis of worldwide scientific literature in mobile - health: 2006-2016. BMC Med Inform Decis Mak. 2017 May 30;17(1):72.*

Análisis bibliométrico mHealths

Table 8 Journal names with minimum productivity of 20 publications in m-Health (2006–2016)

Rank	Journal	Frequency	% $N = 5465$
1	*Journal of Medical Internet Research*	193	3.5
2	*Telemedicine and E Health*	129	2.4
22	*Lancet*	20	0.4
22	*Soins Gerontologie*	20	0.4

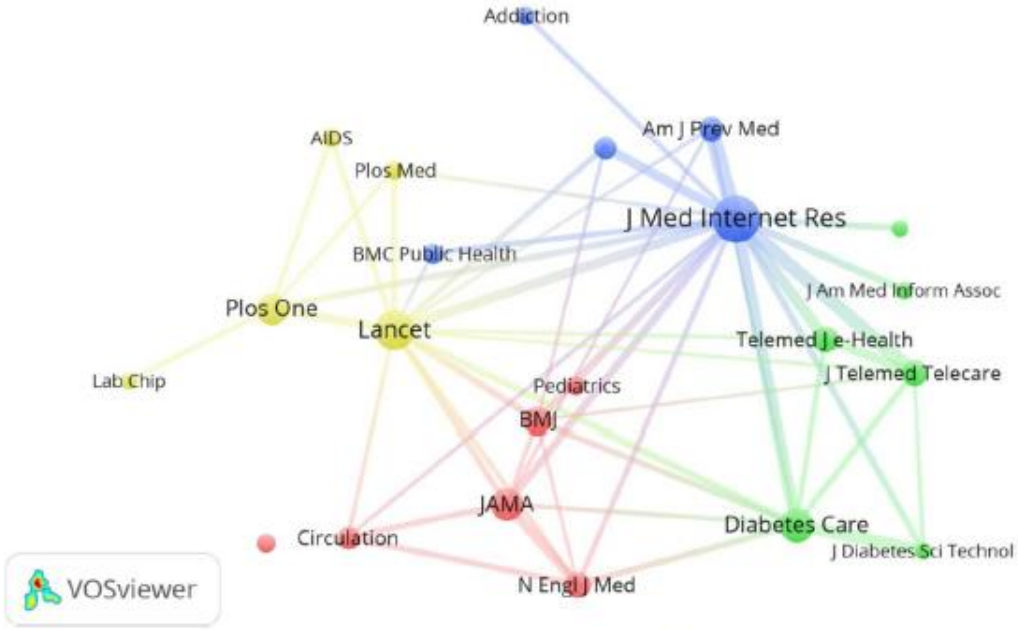


Fig. 5 Network visualization map of journal co-citation analysis for journals which published documents in m-Health with a minimum total of 300 citations. Journal of Medical Internet Research had many connecting lines with various journals indicating that this journal is being co-cited with various journals. Journals in the same cluster with the same color are being commonly co-cited together

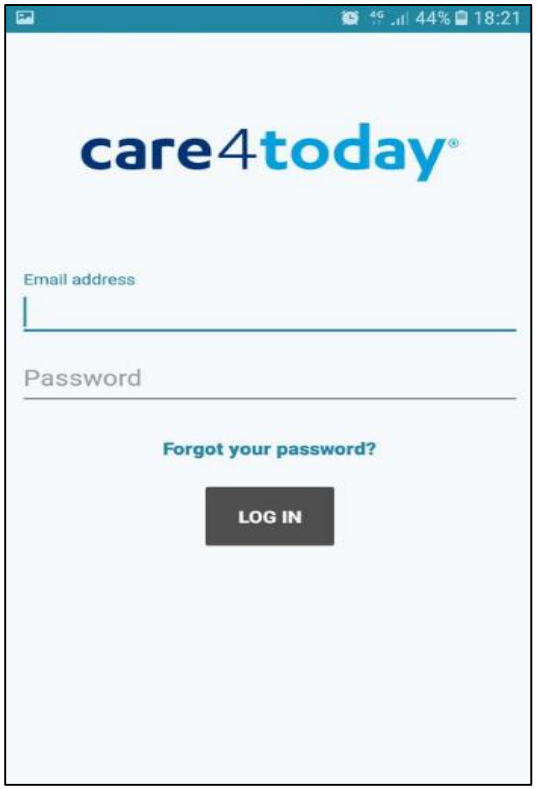
1. *Sweileh WM, Al-Jabi SW, AbuTaha AS, Zyoud SH, Anayah FMA, Sawalha AF. Bibliometric analysis of worldwide scientific literature in mobile - health: 2006-2016. BMC Med Inform Decis Mak. 2017 May 30;17(1):72.*

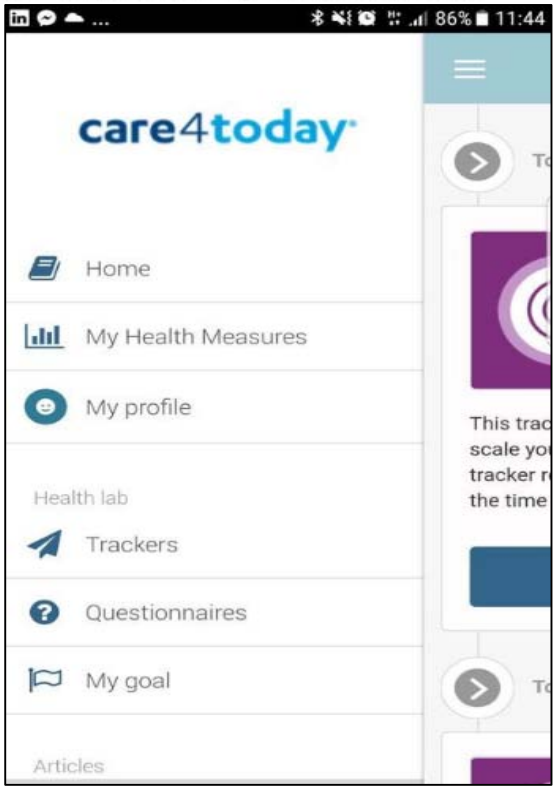
mHealth control paciente: Care4Today

Care4Today® Connect Med Reminder & Health Tracker

Johnson & Johnson Health Medicina

App para smartphones orientada a **controlar el estado de salud general** del paciente





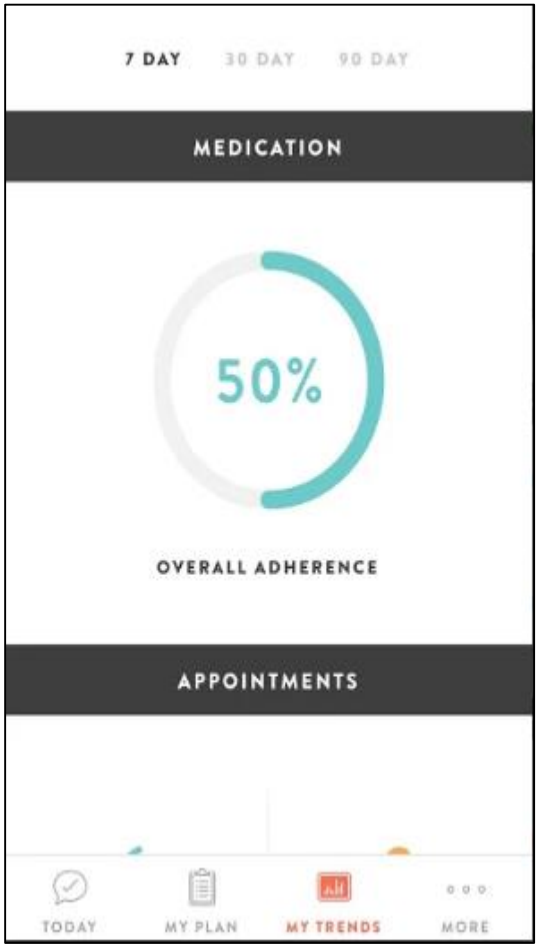
Desarrollada por **Johnson & Johnson:**

- Control de los hábitos y medicación del paciente.
- Seguimiento de la actividad física y registro de los resultados

1. *Johnson & Johnson Health & Wellness Solutions Inc. Care4Today® Connect Med Reminder & Health Tracker. [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=com.jnj.hws.care4today.c4tcstore&referrer=utm_source%3Dc4today%26utm_medium%3Dwebsite%26utm_content%3Dhomepage%26utm_campaign%3DC4Thome*

mHealth control paciente: Care4Today

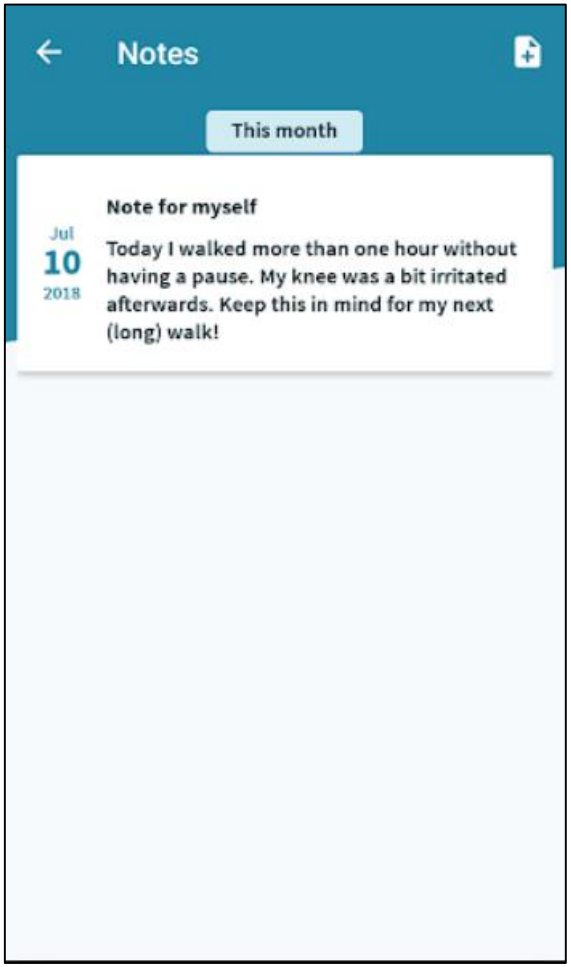
1. Control y recordatorios de medicación



1. *Johnson & Johnson Health & Wellness Solutions Inc. Care4Today® Connect Med Reminder & Health Tracker. [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=com.jnj.hws.care4today.c4tcstore&referrer=utm_source%3Dc4today%26utm_medium%3Dwebsite%26utm_content%3Dhomepage%26utm_campaign%3DC4Thome*

mHealth control paciente: Care4Today

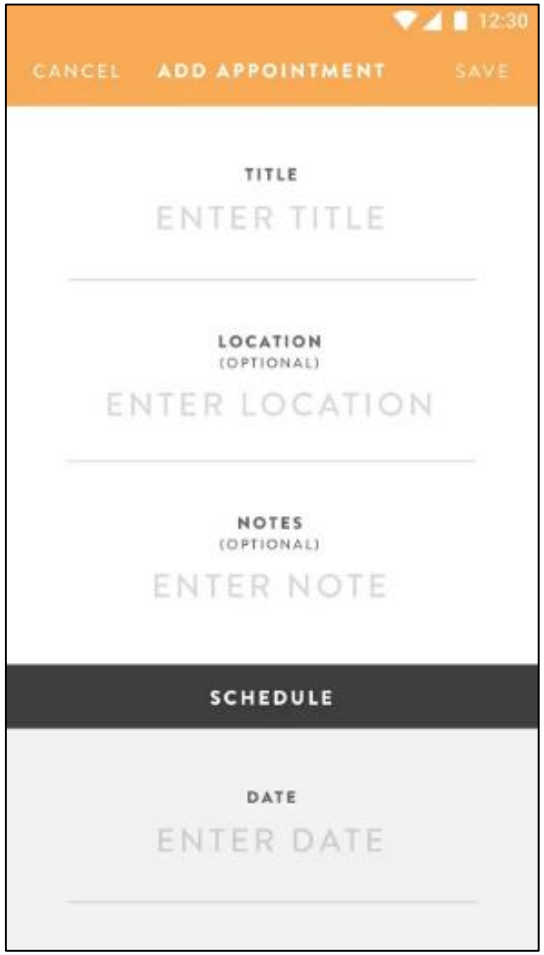
2. Seguimiento de actividad física



1. *Johnson & Johnson Health & Wellness Solutions Inc. Care4Today® Connect Med Reminder & Health Tracker. [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=com.jnj.hws.care4today.c4tcstore&referrer=utm_source%3Dc4today%26utm_medium%3Dwebsite%26utm_content%3Dhomepage%26utm_campaign%3DC4Thome*

mHealth control paciente: Care4Today

3. Registro de citas médicas



1. *Johnson & Johnson Health & Wellness Solutions Inc. Care4Today® Connect Med Reminder & Health Tracker. [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=com.jnj.hws.care4today.c4tcstore&referrer=utm_source%3Dc4today%26utm_medium%3Dwebsite%26utm_content%3Dhomepage%26utm_campaign%3DC4Thome*

mHealth adherencia: RecuerdaMed

RecuerdaMed

Sistema Sanitario Público de Andalucía Salud y bienestar

App para smartphones orientada a **controlar la adherencia del paciente** a los tratamientos

Desarrollada por el **Observatorio para la Seguridad del Paciente de Andalucía:**

- Control exhaustivo de su medicación, para contrastarla, y corregirla si es necesario, con los profesionales sanitarios.

1. *Sistema Sanitario Público de Andalucía. RecuerdaMed [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=es.sdos.medicamentos&hl=es*

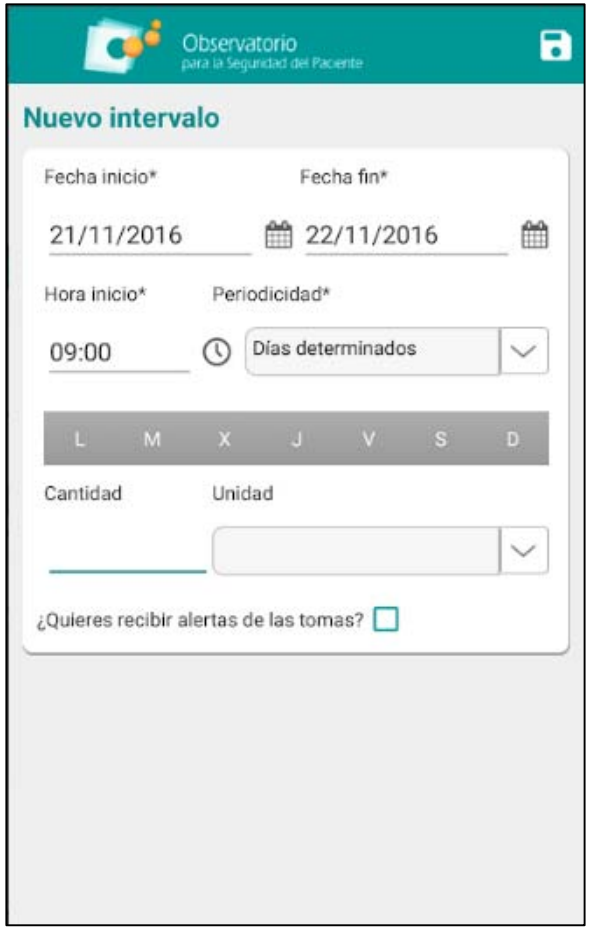
mHealth adherencia: RecuerdaMed

1. Control y registro de medicación

1. *Sistema Sanitario Público de Andalucía. RecuerdaMed [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=es.sdos.medicamentos&hl=es*

mHealth adherencia: RecuerdaMed

2. Recordatorio de posológica



1. *Sistema Sanitario Público de Andalucía. RecuerdaMed [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=es.sdos.medicamentos&hl=es*

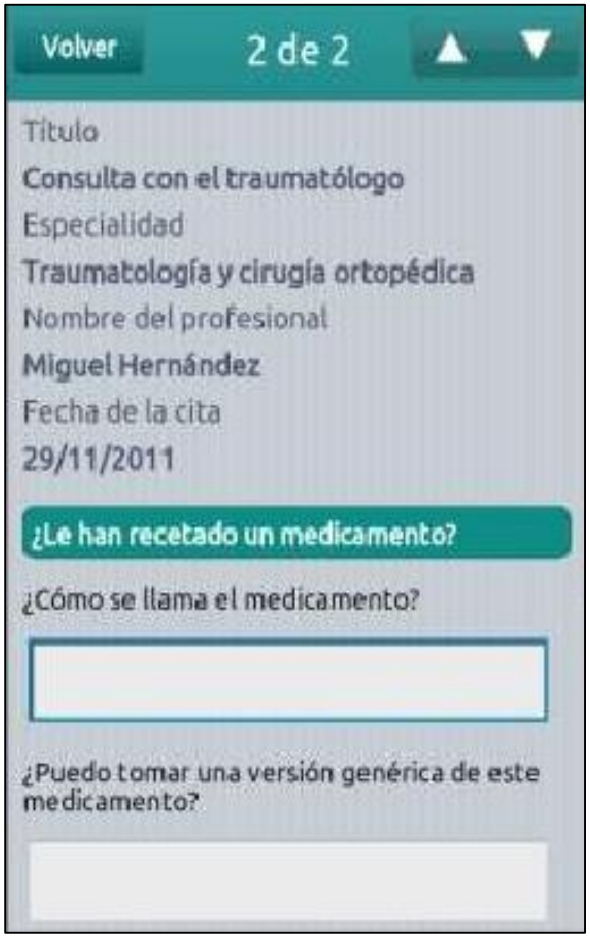
mHealth adherencia: RecuerdaMed

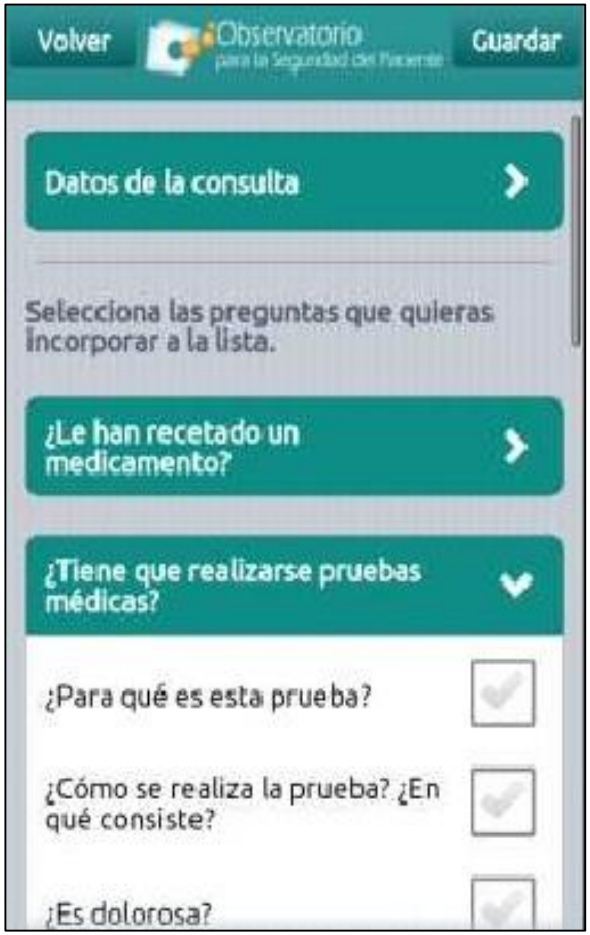
3. Información sobre tratamientos

1. *Sistema Sanitario Público de Andalucía. RecuerdaMed [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=es.sdos.medicamentos&hl=es*

mHealth adherencia: RecuerdaMed

4. Registro de consultas y nuevos tratamientos





1. *Sistema Sanitario Público de Andalucía. RecuerdaMed [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=es.sdos.medicamentos&hl=es*

mHealth adherencia: RecuerdaMed

5. Integración de mHealth con servicios de salud

Experiencia en el **Hospital Puerta del Mar de Cádiz**

Informe para el paciente

Paciente

ID Paciente

Médico

Unidad Hospitalaria
PRUEBA

Próxima visita
--

Próxima recogida de medicación
--

Si tiene instalada en su móvil la app RecuerdaMed puede escanear este código para cargar automáticamente sus medicamentos y programar sus tomas.

FUROSEMIDA GESFUR 20MG/2ML SOLUCION INYECTABLE, 100 AMPOLLAS DE 2 ML SOLUCION
Vía: Intravenenosa lenta

Desayuno			Almuerzo						Merienda			Cena				Al acostarse						
07h	08h	09h	10h	11h	12h	13h	14h	15h	16h	17h	18h	19h	20h	21h	22h	23h	00h	01h	02h	03h	04h	05h	06h
		20 mg								20 mg								20 mg					

Inicio:21/01/2016 | Cada 8 horas - CADA 8H (9-17-1H) | Fin:

Observaciones:

BROMAZEPAN NORMON 1,5MG 500 CAPSULAS DURAS EFG
Vía: Oral

Desayuno			Almuerzo						Merienda			Cena				Al acostarse						
07h	08h	09h	10h	11h	12h	13h	14h	15h	16h	17h	18h	19h	20h	21h	22h	23h	00h	01h	02h	03h	04h	05h	06h
																1.5 mg						

Inicio:24/01/2016 | Cada 24 horas - A LAS 23H | Fin:

Observaciones:

MORFINA CLORHIDRATO 1% 10 AMPOLLAS 1ML SOLUC INYE

1. *Sistema Sanitario Público de Andalucía. RecuerdaMed [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=es.sdos.medicamentos&hl=es*

mHealth adherencia: RecuerdaMed

5. Integración de mHealth con servicios de salud

Experiencia en el **Hospital Puerta del Mar de Cádiz**

- ✓ Lectura de **código QR** y **carga automática de medicación** asociada
- ✓ Información adicional, **recordatorios y control de tomas** desde la app

1. *Sistema Sanitario Público de Andalucía. RecuerdaMed [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=es.sdos.medicamentos&hl=es*

mHealth en prevención: FotoSkin

FotoSkin 17+
Wake App Health SL
Gratis

App para smartphones orientada a mejorar el **diagnóstico precoz del cáncer de piel**

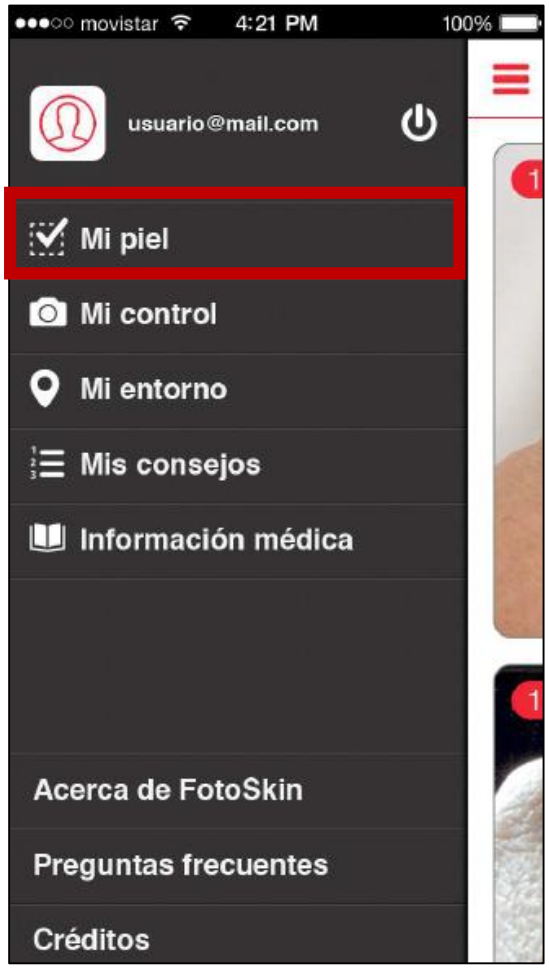
Desarrollada por **dermatólogos españoles**, liderada por **Dr. Vaño, del hospital Ramón y Cajal**

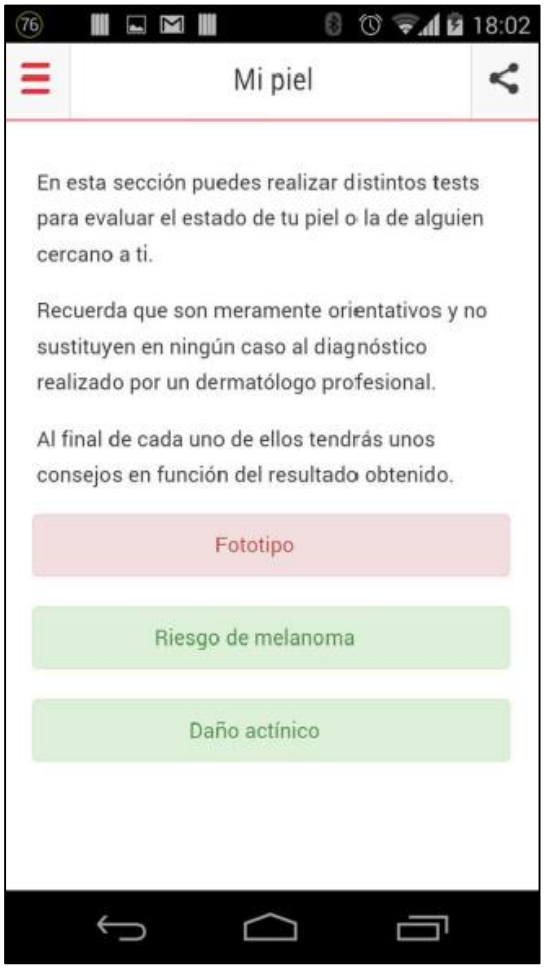
- **Autocontrol fotográfico** por el paciente mejora **diagnóstico precoz** de melanoma y mejora adherencia a revisiones con dermatólogo.

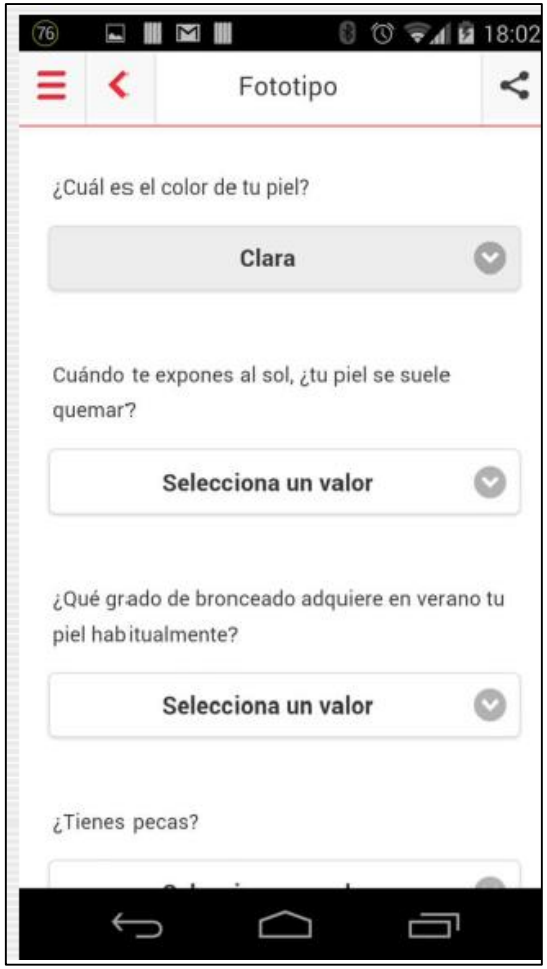
1. *Wake App Health SL. Fotoskin. [citado 5 de febrero de 2019]. Disponible en: https://itunes.apple.com/es/app/fotoskin/id828889220#?platform=iphone*

mHealth en prevención: FotoSkin

1. Evaluación del tipo y del estado de la piel



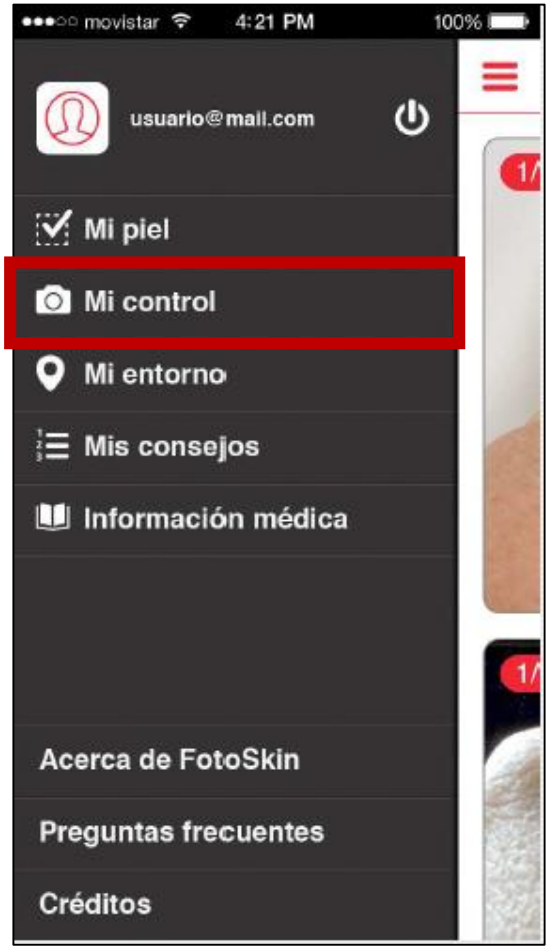


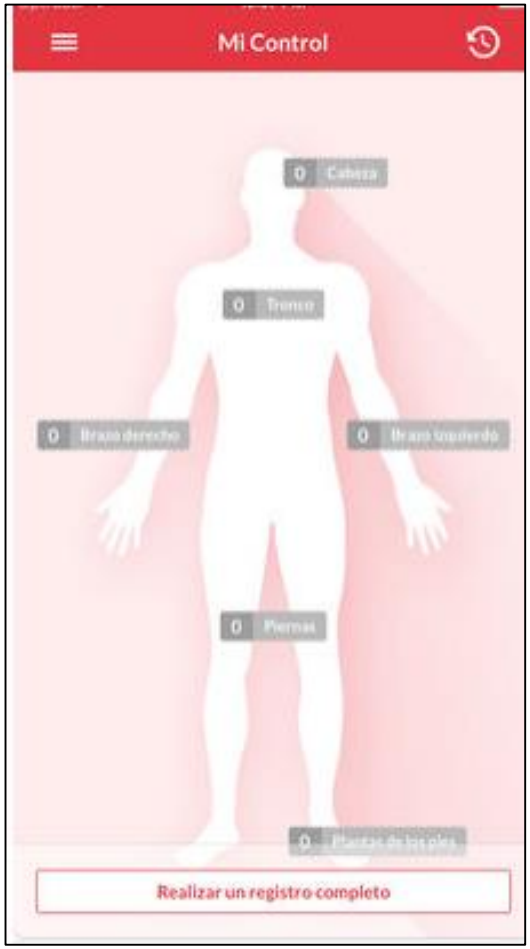


1. *Wake App Health SL. Fotoskin. [citado 5 de febrero de 2019]. Disponible en: https://itunes.apple.com/es/app/fotoskin/id828889220#?platform=iphone*

mHealth en prevención: FotoSkin

2. Auto control

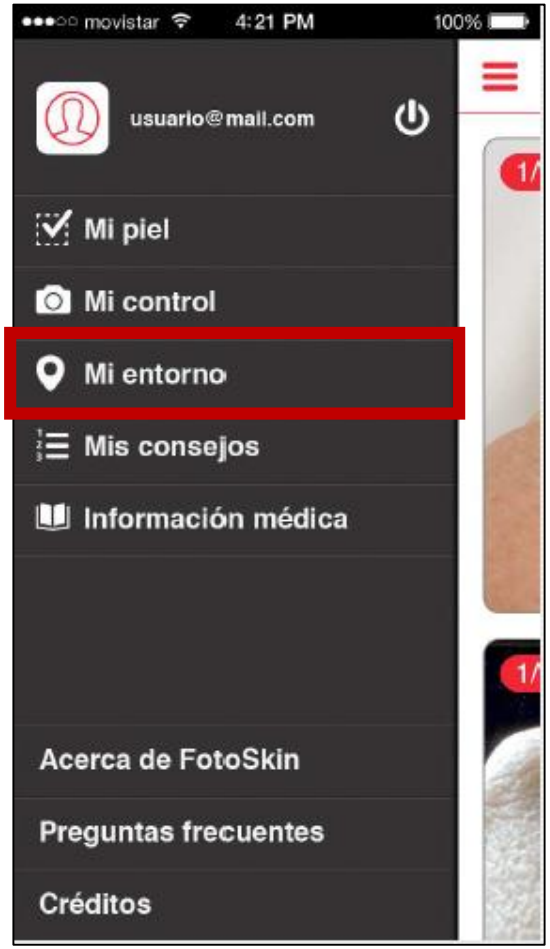


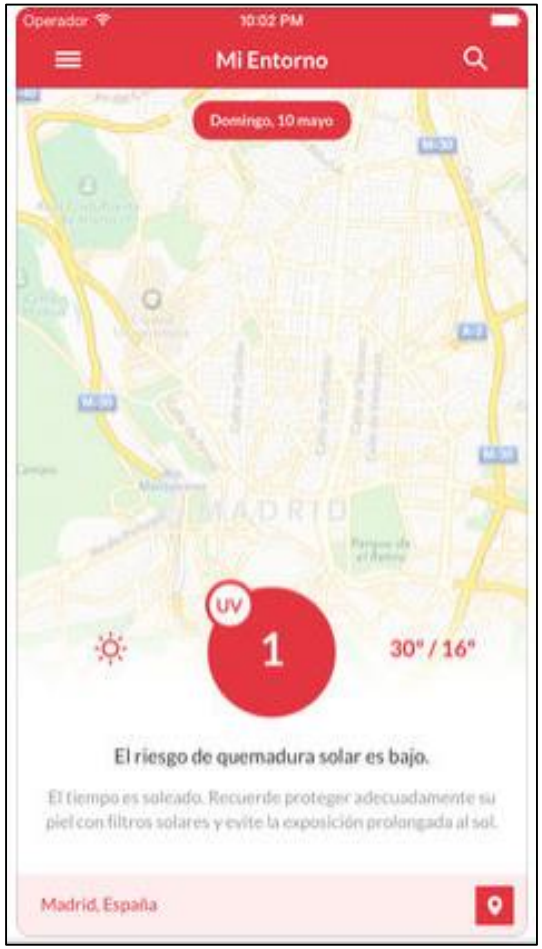


1. *Wake App Health SL. Fotoskin. [citado 5 de febrero de 2019]. Disponible en: https://itunes.apple.com/es/app/fotoskin/id828889220#?platform=iphone*

mHealth en prevención: FotoSkin

3. Entorno

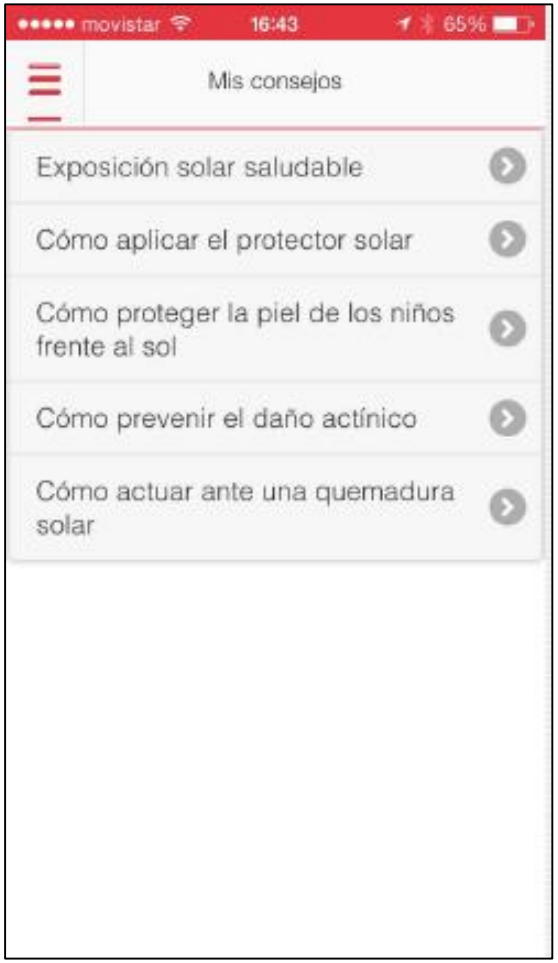


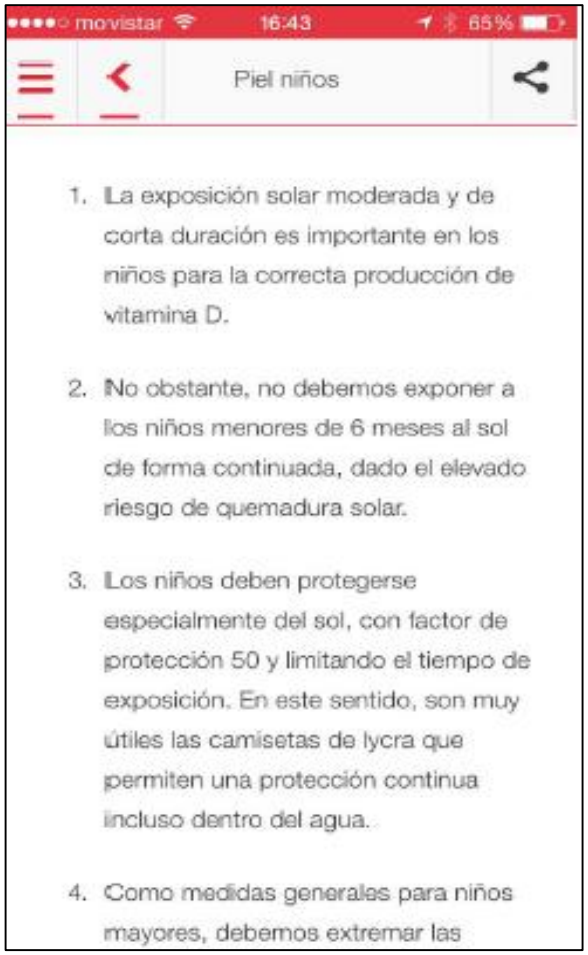


1. *Wake App Health SL. Fotoskin. [citado 5 de febrero de 2019]. Disponible en: https://itunes.apple.com/es/app/fotoskin/id828889220#?platform=iphone*

mHealth en prevención: FotoSkin

4. Consejos





1. *Wake App Health SL. Fotoskin. [citado 5 de febrero de 2019]. Disponible en: https://itunes.apple.com/es/app/fotoskin/id828889220#?platform=iphone*

mHealth en prevención: FotoSkin

4. Información médica

1. *Wake App Health SL. Fotoskin. [citado 5 de febrero de 2019]. Disponible en: https://itunes.apple.com/es/app/fotoskin/id828889220#?platform=iphone*

mHealth en prevención: FotoSkin

ELSEVIER DOYMA

ACTAS
Dermo-Sifiliográficas

Full English text available at
www.actasdermo.org

✓ App con publicación científica

CARTA CIENTÍFICO-CLÍNICA

Autocontrol fotográfico mediante *smartphones* para mejorar el diagnóstico precoz del melanoma

Skin Self-examination Using Smartphone Photography to Improve the Early Diagnosis of Melanoma

Sr. Director:

La autoexploración cutánea por parte del paciente ha demostrado ser una medida muy útil en la prevención secundaria del melanoma[1–4]. Diferentes estudios avalan que las campañas de concienciación y de autocontrol cutáneo permiten diagnosticar melanomas más finos y, por tanto, de mejor pronóstico[5]. El autocontrol puede optimizarse mediante la realización de fotografías de forma protocolizada[6]. Este registro fotográfico facilita por un lado la identificación de lesiones nuevas y, por el otro, permite apreciar cambios significativos en nevos preexistentes. Como ventaja adicional, los sistemas de autocontrol fotográfico mejoran el cumplimiento y la precisión del paciente en sus autocontroles[2]. Otras medidas que han demostrado ser útiles en el autocontrol fotográfico son la comparación de las fotografías con esquemas corporales[7] y la visualización de ejemplos de lesiones benignas y malignas[2].

Actualmente el autocontrol fotográfico por parte del paciente para mejorar la prevención secundaria del melanoma no es una práctica habitual[8], a pesar de ser una medida que ha demostrado ser efectiva[1–4]. Entre las razones que pueden influir están: la falta de conocimiento acerca de la importancia del seguimiento fotográfico, la incomodidad de realizar fotografías con una cámara fotográfica cuyas imágenes han de ser luego descargadas y almacenadas en el ordenador y la falta de cumplimiento del autocontrol por olvido.

Con estas premisas, presentamos una solución tecnológica para fomentar el autocontrol por parte del paciente: el desarrollo de una aplicación para *smartphones* (FotoSkin®) que permite al paciente realizar periódicamente y de forma protocolizada fotografías de su piel (mapeo corporal), que luego pudiera llevar a la consulta y mostrar al dermatólogo para que este conozca de forma más precisa la evolución de sus lunares u otro tipo de lesiones cutáneas (fig. 1). La aplicación incluye además otras 3 secciones que contribuyen

Figura 1 Diseño general de la aplicación para *smartphones* «FotoSkin® ».

a mejorar el conocimiento del paciente acerca del cáncer de piel, su concienciación y, por tanto, su cumplimiento con los controles y visitas al dermatólogo: 1) una sección informativa en la que se muestra al paciente las diferencias entre lesiones benignas y lesiones sospechosas o malignas, 2) una sección de algoritmos para ver el fototipo, riesgo de melanoma y nivel de daño actínico, y 3) una parte dinámica con el entorno que indica el índice de radiación ultravioleta y emite unos consejos prácticos de fotoprotección y exposición solar saludable.

1. *Vañó-Galván S, Paoli J, Ríos-Buceta L, Jaén P. Skin self-examination using smartphone photography to improve the early diagnosis of melanoma. Actas Dermosifiliogr. 2015 Jan-Feb;106(1):75-7.*

mHealth en prevención: FotoSkin

ACTAS Dermo-Sifiliográficas

Teledermatología diferida: análisis de validez en una serie de 2.000 observaciones

Store-and-Forward Teledermatology: Assessment of Validity in a Series of 2000 Observations

S. Vañó-Galván[a], Á. Hidalgo[b], I. Aguayo-Leiva[a], M. Gil-Mosquera[c], L. Ríos-Buceta[a], M.N. Plana[d], J. Zamora[d], A. Martorell-Calatayud[e], P. Jaén[a]

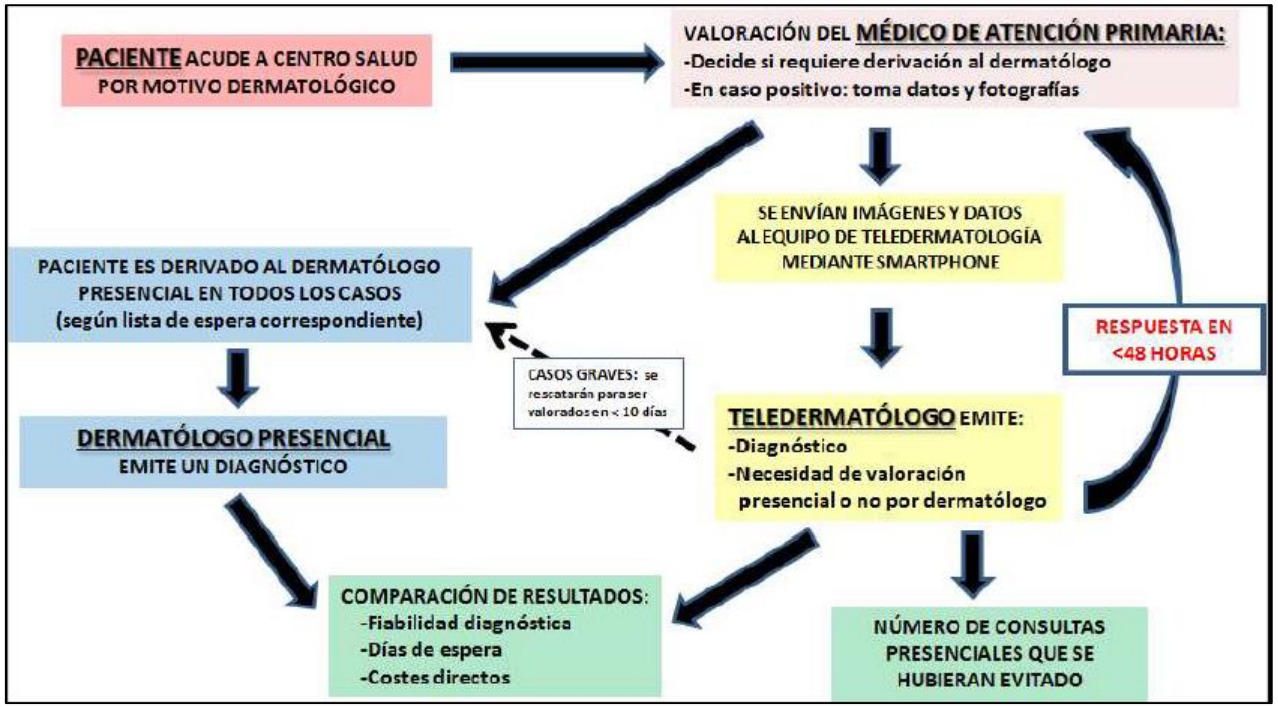
[a] Servicio de Dermatología, Hospital Ramón y Cajal, Universidad de Alcalá, Madrid, España
[b] Profesor Titular de Fundamentos del Análisis Económico, Universidad de Castilla-La Mancha, Toledo, España
[c] Medicina de Familia, Hospital Ramón y Cajal, Madrid, España
[d] Unidad de Bioestadística Clínica. Hospital Universitario Ramón y Cajal. CIBER en Epidemiología y Salud Pública (CIBERESP): Instituto de Investigación Sanitaria (IRYCIS). Madrid, España
[e] Servicio de Dermatología, Hospital de Requena, Valencia, España

Objetivo: evaluar el impacto de la teledermatología mediante smartphones en el sistema de derivación de pacientes desde Atención Primaria a Atención Especializada[1].

1. *Vañó-Galván S, Hidalgo A, Aguayo-Leiva I, Gil-Mosquera M, Ríos-Buceta L, Plana MN, Zamora J, Martorell-Calatayud A, Jaén P. [Store-and-forward teledermatology: assessment of validity in a series of 2000 observations]. Actas Dermosifiliogr. 2011 May;102(4):277-83.*

mHealth en prevención: FotoSkin

- **58 días de media de lista de espera** en Madrid (2015) para derivación de Atención Primaria a consulta de Dermatología.



Análisis de **101 pacientes** con cualquier patología cutánea que el **Médico de Atención Primaria** decidiera **derivar a Dermatología**. **Comparación** de **diagnóstico** presencial y a distancia y de **tiempo de espera** hasta consulta[1]**.**

1. *Vañó-Galván S, Hidalgo A, Aguayo-Leiva I, Gil-Mosquera M, Ríos-Buceta L, Plana MN, Zamora J, Martorell-Calatayud A, Jaén P. [Store-and-forward teledermatology: assessment of validity in a series of 2000 observations]. Actas Dermosifiliogr. 2011 May;102(4):277-83.*

mHealth en prevención: FotoSkin

Resultados:

1. De los 101 pacientes, se hubiera **evitado derivación en 30 (30%).**
2. De las 71 derivaciones, se rescataron **10 pacientes como preferentes.**
3. De los 10 preferentes: **4 casos de cáncer de piel**
4. En total: **93 aciertos y 8 fallos diagnósticos** (todos los fallos fueron derivados a consulta presencial).
5. **Reducción tiempo de espera** en pacientes preferentes (5,2 frente a 42 días).
6. Media de tiempo requerido por MAP para envío de datos: 58 segundos.
7. No se pudo realizar un diagnóstico por mala calidad de fotografías en 4 pacientes (4%).

Conclusión: la teledermatología mediante smartphones es un método ágil y útil para mejorar la derivación de pacientes desde AP a especializada

1. *Vañó-Galván S, Hidalgo A, Aguayo-Leiva I, Gil-Mosquera M, Ríos-Buceta L, Plana MN, Zamora J, Martorell-Calatayud A, Jaén P. [Store-and-forward teledermatology: assessment of validity in a series of 2000 observations]. Actas Dermosifiliogr. 2011 May;102(4):277-83.*

mHealth transplante cardiaco: mHeart

Plataforma **mHeart**, página web y aplicación móvil para llevar a cabo un **seguimiento del paciente con trasplante cardiaco**

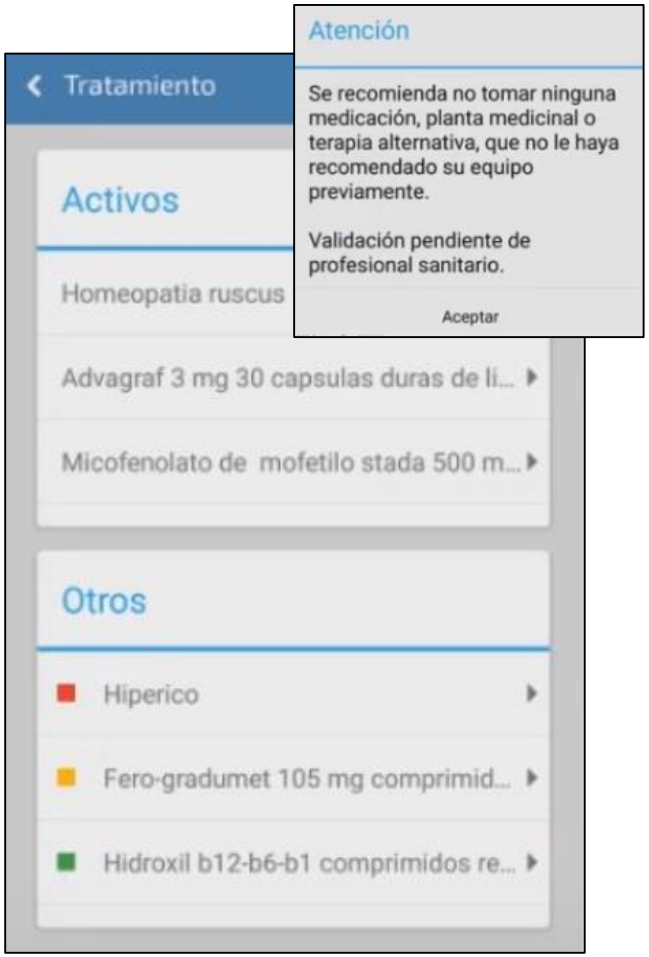
Desarrollada por el **Servicio de Farmacia** y **Unidad de Trasplante Cardiaco** del **Hospital de La Santa Creu I Sant Pau de Barcelona:**

- **Seguimiento y control** del paciente con trasplante cardiaco
- Seguimiento de **medicación, interacciones, adherencias, administración errónea, conservación** inadecuada de medicación **y características personales.**

1. *61 Congreso Nacional Sociedad Española de Farmacia Hospitalaria. Experiencias con apps -trasplante cardiaco. (Ponencia oral) Gomis Pastos, Mar. Gijón 7 de octubre de 2016. [citado 5 de febrero de 2019]. Disponible en: http://61congreso.sefh.es/video-ponencia.php?idrcrs=62*

mHealth transplante cardiaco: mHeart

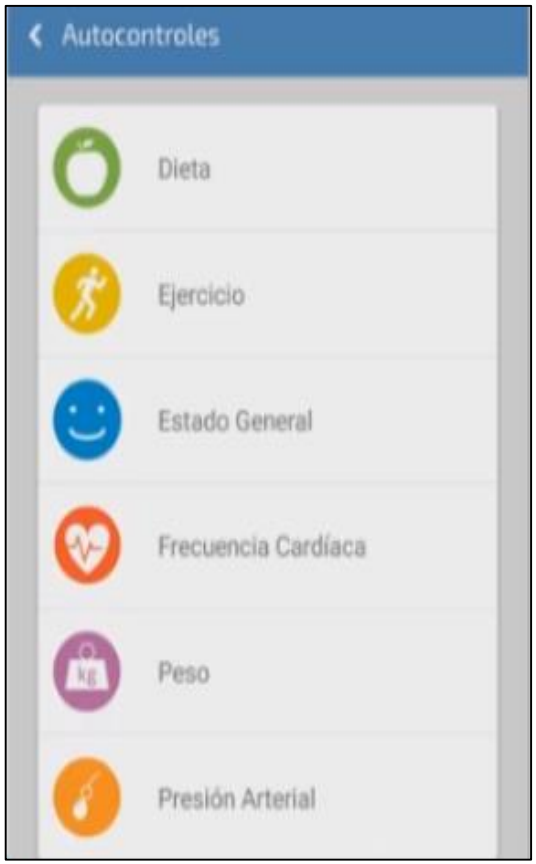
1. Seguimiento medicación y recordatorios

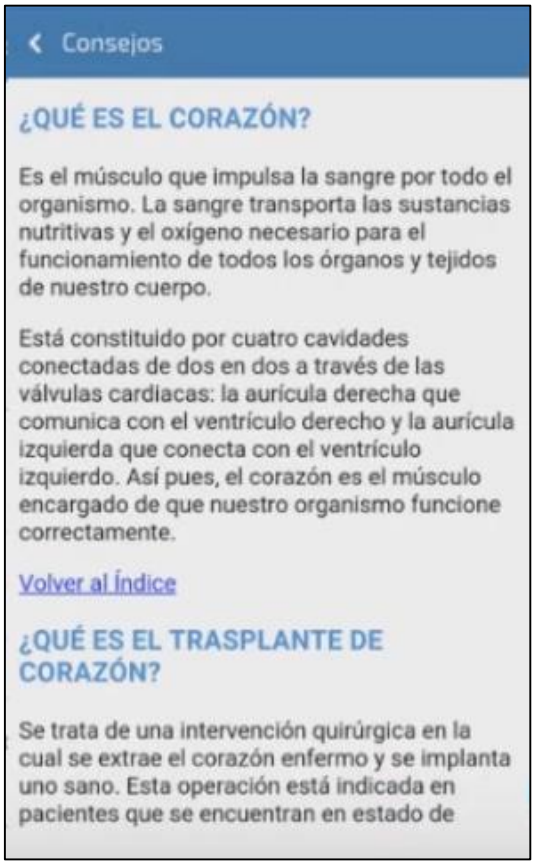


1. *61 Congreso Nacional Sociedad Española de Farmacia Hospitalaria. Experiencias con apps -trasplante cardiaco. (Ponencia oral) Gomis Pastos, Mar. Gijón 7 de octubre de 2016. [citado 5 de febrero de 2019]. Disponible en: http://61congreso.sefh.es/video-ponencia.php?idrcrs=62*

mHealth transplante cardiaco: mHeart

2. Registro de actividad, parámetros de salud y consejos





1. *61 Congreso Nacional Sociedad Española de Farmacia Hospitalaria. Experiencias con apps -trasplante cardiaco. (Ponencia oral) Gomis Pastos, Mar. Gijón 7 de octubre de 2016. [citado 5 de febrero de 2019]. Disponible en: http://61congreso.sefh.es/video-ponencia.php?idrcrs=62*

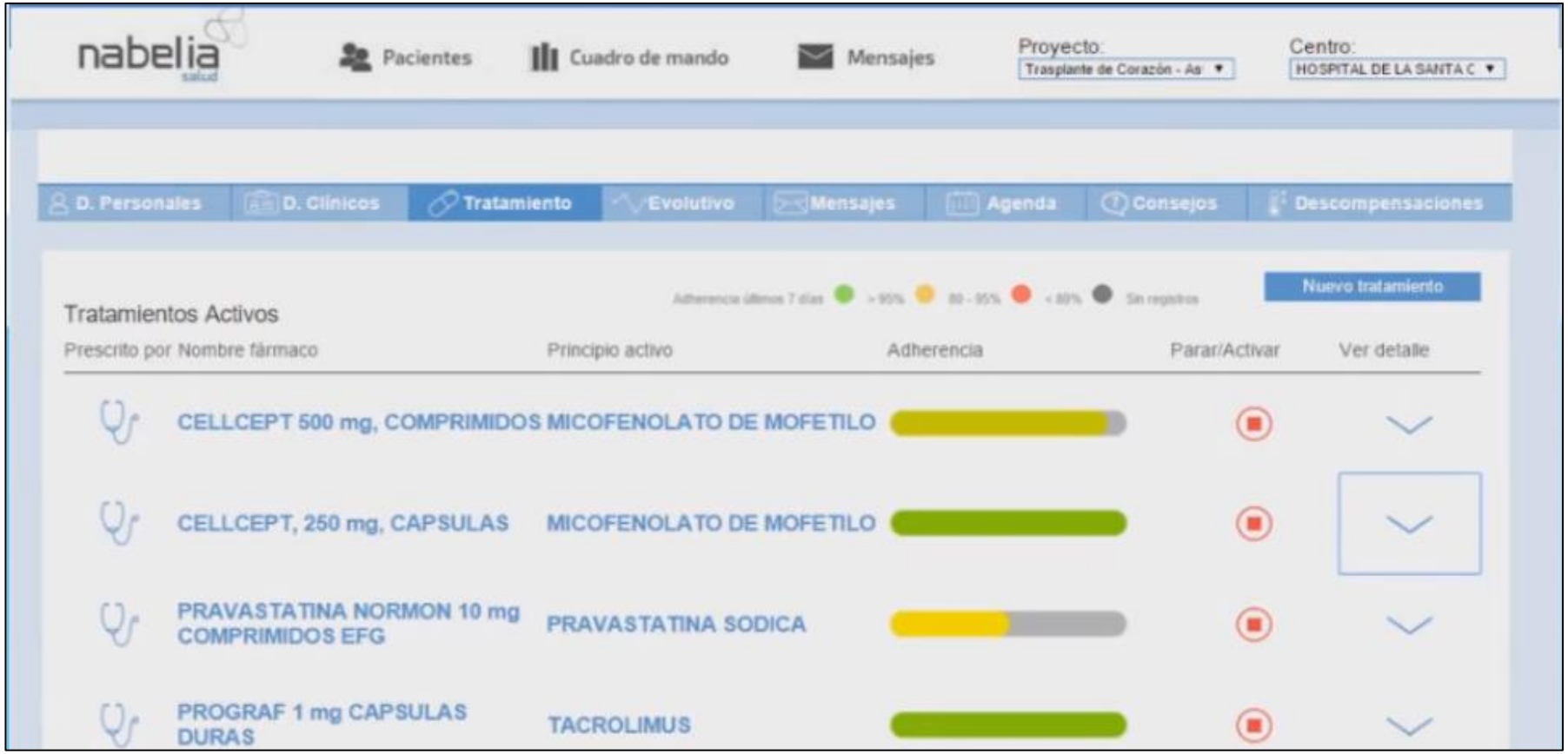
mHealth transplante cardiaco: mHeart

3. Sistema mensajería bidireccional hospital-paciente

1. *61 Congreso Nacional Sociedad Española de Farmacia Hospitalaria. Experiencias con apps -trasplante cardiaco. (Ponencia oral) Gomis Pastos, Mar. Gijón 7 de octubre de 2016. [citado 5 de febrero de 2019]. Disponible en: http://61congreso.sefh.es/video-ponencia.php?idrcrs=62*

mHealth transplante cardiaco: mHeart

4. Control de adherencia por el clínico



1. 61 Congreso Nacional Sociedad Española de Farmacia Hospitalaria. Experiencias con apps -trasplante cardiaco. (Ponencia oral) Gomis Pastos, Mar. Gijón 7 de octubre de 2016. [citado 5 de febrero de 2019]. Disponible en: http://61congreso.sefh.es/video-ponencia.php?idrcrs=62

mHealth transplante cardiaco: mHeart

5. Seguimiento constantes del paciente; modificación tratamiento

1. 61 Congreso Nacional Sociedad Española de Farmacia Hospitalaria. Experiencias con apps -trasplante cardiaco. (Ponencia oral) Gomis Pastos, Mar. Gijón 7 de octubre de 2016. [citado 5 de febrero de 2019]. Disponible en: http://61congreso.sefh.es/video-ponencia.php?idrcrs=62

mHealth transplante cardiaco: mHeart

Impact of mHealth in Heart Transplant Management (mHeart) NCT02554578

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Detailed Description:

Non-adherence to immunosuppressive medications generally ranges from 20-40% and is associated with acute rejection episodes and graft loss. Many solid organ transplant centres have incorporated transplant pharmacists into the multidisciplinary transplant clinical team focused on improving outcomes and safety associated with drug therapy.

Mobile technology has undergone rapid advances in the past several years and the use of mHealth in pharmaceutical care is changing pharmacy practice. Several published reports have identified general mobile applications suited for improve adherence. But evidence supporting supporting the benefits in clinical practice is limited.

This study expects to analyse the potential of mHealth to improve medication adherence and heart transplant patient management in real clinical clinical practice.

The investigators asses a new multidisciplinary follow-up programme in heart transplant recipients supported by mobile health (mHealth) with the with the aim to improve medication adherence, prevent drug related problems and improve patient clinical outcomes

Study Design

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	158 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Effectiveness Improving Medication Adherence in Heart Transplant Management
Study Start Date :	October 2015
Estimated Primary Completion Date :	December 2016

1. *Impact of mHealth in Heart Transplant Management (mHeart) NCT02554578.(Internet).ClinicalTrial.gov [citado 5 de febrero de 2019]. Disponible en: https://clinicaltrials.gov/ct2/show/study/NCT02554578*

mHealth transplante cardiaco: mHeart

Impact of mHealth in Heart Transplant Management (mHeart) NCT02554578

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Arms and Interventions

Arm	Intervention/treatment
Experimental: Pharmaceutical care programme supported by mHealth	Other: Multidisciplinary follow-up programme supported by mHealth The follow-up programme integrates an online health platform (app and web) to monitor patients remotely, into the multidisciplinary team workflow, in order to improve heart transplant management. Patients will use the mobile application designed to help them to manage their health issues and facilitate communication with the transplant team. Data recorded manually by the patient using the mHealth application include pharmacotherapeutic information (medication adherence, barriers to adherence, side effects, interactions, etc.), clinical symptoms and other relevant clinical information (blood pressure, cardiac frequency, exercise, glucose level, diet, mood, etc.). mHealth will be used by the transplant team as a complementary way of deliver patient care. Analysis of the data collected by the multidisciplinary team may help to prioritise and provide personalized pharmacotherapeutic and medical interventions to patients and their families. Other Name: Heart transplantation management by a multidisciplinary team and supported by mobile health (mHealth)
No Intervention: Routine healthcare by the transplant team	

1. *Impact of mHealth in Heart Transplant Management (mHeart) NCT02554578.(Internet).ClinicalTrial.gov [citado 5 de febrero de 2019]. Disponible en: https://clinicaltrials.gov/ct2/show/study/NCT02554578*

mHealth transplante cardiaco: mHeart

Rev Esp Cardiol. 2018;71(Supl 1):118

REVISTA ESPAÑOLA DE CARDIOLOGIA

5009-4 - NUEVAS ESTRATEGIAS PARA EL SEGUIMIENTO DE PACIENTES TRASPLANTADOS CARDIACOS: PROYECTO MHEART

Mar Gomis-Pastor, Sonia Mirabet, M. Antonia Mangues, Anna Feliu, Andreu Ferrero-Gregori, Elisabeth Gálvez, Sandra Ros, Laura López, Vicens Brossa y Eulalia Roig, del Hospital de la Santa Creu i Sant Pau, Barcelona.

Objetivo

El proyecto mHeart es un programa asistencial de atención farmacoterapéutica al **paciente trasplantado cardiaco (TxC)** con el soporte de las nuevas tecnologías. El objetivo principal es **mejorar la adherencia al tratamiento debido al elevado impacto de esta en la supervivencia postrasplante.**

1. *Congreso De Las Enfermedades Cardiovasculares, Sociedad Española Cardiología. Nuevas estrategias para el seguimiento de pacientes trasplantados cardiacos: proyecto mHeart. (Ponencia oral) Gomis Pastos, Mar. Sevilla, 25 de octubre de 2018. [citado 5 de febrero de 2019]. Disponible en: http://www.revespcardiol.org/controladores/congresos-herramientas.php?idCongreso=76&idSesion=4329&idComunicacion=51170*

mHealth transplante cardiaco: mHeart

Método

Estudio llevado a cabo en un hospital universitario terciario. Se llevó a cabo una selección de estrategias que combinadas pudieran **mejorar la ruta asistencial actual:**

1. **Asistencia integral;**
2. **Nuevas tecnologías sanitarias;**
3. **Intervenciones efectivas y sostenibles (EMI).**

Fases del proyecto:

1. Estudio DIPP-mHeart. Desarrollo e implementación de una h**erramienta mHealth para el seguimiento del paciente crónico polimedicado adaptado al paciente TxC**. 2014-2016.
2. **Estudio Val-mHeart. Validación de mHeart** como dispositivo médico. Pilotaje de 2 meses, 32 pacientes TxC, 2016.
3. **Ensayo clínico mHeart** (Clinicaltrials.gov NCT02554578). Medir el impacto del programa en rechazo, QoL y otras variables. 2 años, 136 pacientes TxC. Finalizó 31/01/2018.

1. *Congreso De Las Enfermedades Cardiovasculares, Sociedad Española Cardiología. Nuevas estrategias para el seguimiento de pacientes trasplantados cardiacos: proyecto mHeart. (Ponencia oral) Gomis Pastos, Mar. Sevilla, 25 de octubre de 2018. [citado 5 de febrero de 2019]. Disponible en: http://www.revespcardiol.org/controladores/congresos-herramientas.php?idCongreso=76&idSesion=4329&idComunicacion=51170*

mHealth transplante cardiaco: mHeart

Resultados

El estudio DIPP-mHeart dio lugar a la **plataforma mHeart, página web y aplicación móvil** para llevar a cabo un tratamiento integral de paciente con comorbilidades y polimedicado (figura). Una encuesta a profesionales y pacientes nos permitió conocer **potenciales limitaciones** que debían ser resueltas:

1. Calidad y seguridad;
2. Integración;
3. Implementación, extensibilidad y coste;
4. Protección de datos confidenciales;
5. Inversión de tiempo de profesionales.

La plataforma se encuentra integrada en el entorno sanitario monitorizada por 1 enfermera, 1 farmacéutica y 1 psicóloga. **El estudio piloto Val-mHeart, confirmó que mediante la plataforma mHeart se podían identificar pacientes no adherentes y mejorar > 25% la adherencia al tratamiento** (test Hayness-Sacket y Morisky-Green) en pacientes polimedicados TxC. Además de obtener una elevada satisfacción en los pacientes, el 100% de los cuales recomendarían su uso a otro paciente. **El ensayo clínico mHeart se encuentra en fase de análisis.**

1. *Congreso De Las Enfermedades Cardiovasculares, Sociedad Española Cardiología. Nuevas estrategias para el seguimiento de pacientes trasplantados cardiacos: proyecto mHeart. (Ponencia oral) Gomis Pastos, Mar. Sevilla, 25 de octubre de 2018. [citado 5 de febrero de 2019]. Disponible en: http://www.revespcardiol.org/controladores/congresos-herramientas.php?idCongreso=76&idSesion=4329&idComunicacion=51170*

mHealth seguimiento paciente: Listeo+

Listeo+

Sistema Sanitario Público de Andalucía Salud y bienestar

PEGI 3

App para smartphones orientada a hacer **seguimiento prequirúrgica del paciente**

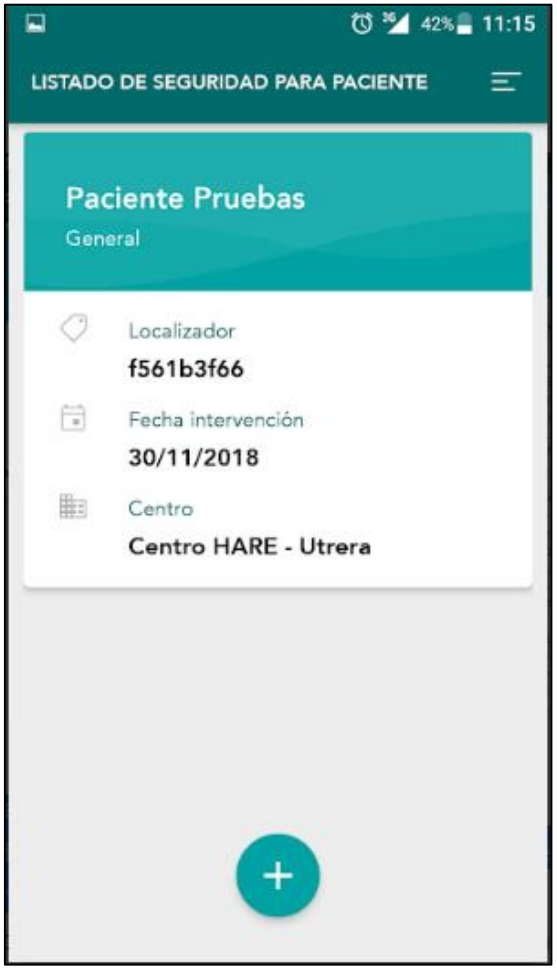
Desarrollada por el **Observatorio para la Seguridad del Paciente de Andalucía:**

- Listados de **verificación de la seguridad prequirúrgica** al paciente personalizados, con los que chequear todos los **aspectos importantes antes** de someterse a una **intervención quirúrgica.**

1. *Sistema Sanitario Público de Andalucía. Listeo+ [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=es.sdos.comprueba*

mHealth seguimiento paciente: Listeo+

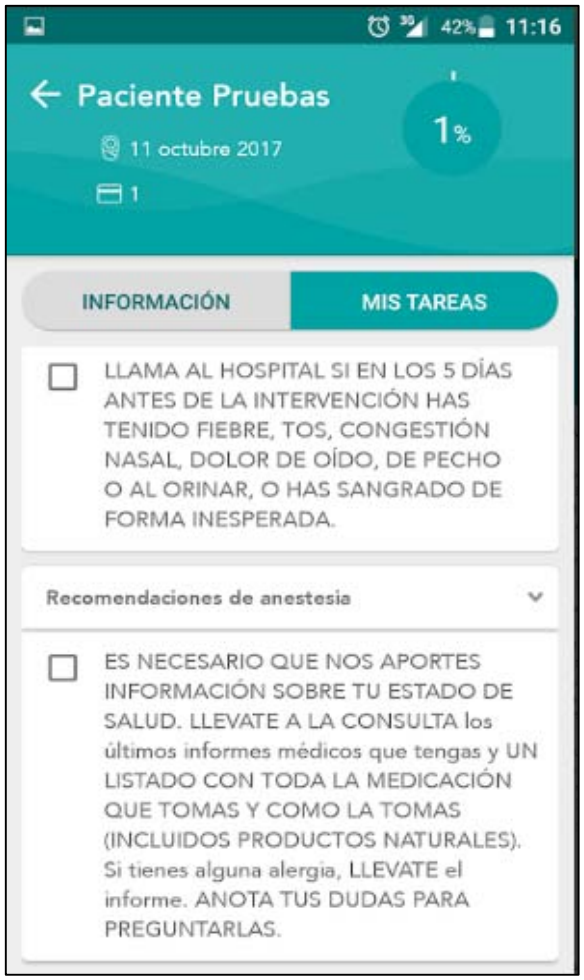
1. Integración de mHealth con servicios de salud



1. *Sistema Sanitario Público de Andalucía. Listeo+ [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=es.sdos.comprueba*

mHealth seguimiento paciente: Listeo+

2. Recordatorios y alarmas de acciones a realizar antes operación



1. *Sistema Sanitario Público de Andalucía. Listeo+ [citado 5 de febrero de 2019]. Disponible en: https://play.google.com/store/apps/details?id=es.sdos.comprueba*

mHealth seguimiento paciente: Listeo+

Listeo+

"The app will allow health professionals to **monitor in real-time patients' preparation and critical preoperative recommendations fulfillment.**"
"We expect **a reduction in avoidable preoperative cancellations** due to a lack of or a poor patient preparation[1]."

Effect of a Mobile App on Preoperative Patient Preparation for Major Ambulatory Surgery: Protocol for a Randomized Controlled Trial

Manuel Herrera-Usagre[1,2], PhD (Sociology), MSc; Vicente Santana[1], BNursing, MSc; Ramon Burgos-Pol[3], MPH, BPharm; Juan Pedro Oliva[4], BNursing, Med DM; Eliazar Sabater[3], MD; Maria Rita-Acosta[5], BNursing, Med DM; Miguel Angel Casado[3], PharmD, PhD; Susana Cruces[4], BNursing; Manuel Pacheco[1], BE; Carlos Solorzano Perez[4], BE

[1]Andalusian Agency for Healthcare Quality, Sevilla, Spain
[2]Department of Sociology, Pablo de Olavide University, Sevilla, Spain
[3]Pharmacoeconomics & Outcomes Research Iberia, Paseo de Joaquín Rodrigo 4-I, 28224, Pozuelo de Alarcón, Madrid, Spain
[4]Hospital de Alta Resolución de Utrera, APS Bajo Guadalquivir, Utrera, Sevilla, Spain
[5]Hospital de Alta Resolución Sierra Norte, APS Bajo Guadalquivir, Constantina, Sevilla, Spain

JMIR Publications
The Leading eHealth Publisher

1. *Herrera-Usagre M, Santana V, Burgos-Pol R, Oliva JP, Sabater E, Rita-Acosta M, Casado MA, Cruces S, Pacheco M, Solorzano Perez C Effect of a Mobile App on Preoperative Patient Preparation for Major Ambulatory Surgery: Protocol for a Randomized Controlled Trial JMIR Res Protoc 2019;8(1):e10938*

Guías para evaluación de mHealth

thebmj

Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist

Smisha Agarwal,[1,2,3] Amnesty E LeFevre,[1,2] Jaime Lee,[1,2] Kelly L'Engle,[4,5] Garrett Mehl,[6] Chaitali Sinha,[7] Alain Labrique[1,2] for the WHO mHealth Technical Evidence Review Group

[1] Johns Hopkins Bloomberg School of Public Health, Department of International Health, Baltimore, MD 21205, USA [2]Johns Hopkins University, Global mHealth Initiative, Baltimore [3]Gillings School of Global Public Health, University of North Carolina, Chapel Hill, NC, USA [4]Family Health International 360, Durham, NC, USA [5]School of Nursing and Health Professions, University of San Francisco, San Francisco, CA, USA [6]World Health Organization, Department of Reproductive Health and Research, Geneva, Switzerland [7] International Development Research Centre, Ottawa, Canada

Se han publicado guías para comunicar intervenciones sanitarias basadas en tecnologías móviles en salud: grupo mHealth Technical Evidence Review Group de la World Health Organization[1]

World Health Organization

1. *Agarwal S , LeFevre AE, Lee J, L'Engle K, Mehl G, Sinha C et al. Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist. BMJ. 2016;352:i1174*

Guías para evaluación de mHealth

Table 1 | mHealth evidence reporting and assessment (mERA) guidelines, including mHealth essential criteria

Criteria	Item no	Notes	Page no where item is reported
Infrastructure (population level)	1	Clearly presents the availability of infrastructure to support technology operations in the study location. This refers to physical infrastructure such as electricity, access to power, connectivity etc. in the local context. Reporting X% network coverage rate in the country is insufficient if the study is not being conducted at the country level	
Technologyplatform	2	Describes and provides justification for the technology architecture. This includes a description of software and hardware and details of any modifications made to publicly available software	
Interoperability/ Health information systems (HIS) context	3	Describes how mHealth intervention can integrate into existing health information systems. Refers to whether the potential of technical and structural integration into existing HIS or programme has been described irrespective of whether such integration has been achieved by the existing system	
Intervention delivery	4	The delivery of the mHealth intervention is clearly described. This should include frequency of mobile communication, mode of delivery of intervention (that is, SMS, face to face, interactive voice response), timing and duration over which delivery occurred	
Intervention content	5	Details of the content of the intervention are described. Source and any modifications of the intervention content is described	
Usability/content testing	6	Describe formative research and/or content and/or usability testing with target group(s) clearly identified, as appropriate	
User feedback	7	Describes user feedback about the intervention or user satisfaction with the intervention. User feedback could include user opinions about content or user interface, their perceptions about usability, access, connectivity, etc	
Access of individual participants	8	Mentions barriers or facilitators to the adoption of the intervention among study participants. Relates to individual-level structural, economic and social barriers or facilitators to access such as affordability, and other factors that may limit a user's ability to adopt the intervention	
Cost assessment	9	Presents basic costs assessment of the mHealth intervention from varying perspectives. This criterion broadly refers to the reporting of some cost considerations for the mHealth intervention in lieu of a full economic analysis. If a formal economic evaluation has been undertaken, it should be mentioned with appropriate references. Separate reporting criterion are available to guide economic reporting	
Adoption inputs/ programme entry	10	Describes how people are informed about the programme including training, if relevant. Includes description of promotional activities and/or training required to implement the mHealth solution among the user population of interest	
Limitations for delivery at scale	11	Clearly presents mHealth solution limitations for delivery at scale	
Contextual adaptability	12	Describes the adaptation, or not, of the solution to a different language, different population or context. Any tailoring or modification of the intervention that resulted from pilot testing/usability assessment is described	
Replicability	13	Detailed intervention to support replicability. Clearly presents the source code/screenshots/ flowcharts of the algorithms or examples of messages to support replicability of the mHealth solution in another setting	
Data security	14	Describes the data security procedures/ confidentiality protocols	
Compliance with national guidelines or regulatory statutes	15	Mechanism used to assure that content or other guidance/information provided by the intervention is in alignment with existing national/regulatory guidelines and is described	
Fidelity of the intervention	16	Was the intervention delivered as planned? Describe the strategies employed to assess the fidelity of the intervention. This may include assessment of participant engagement, use of backend data to track message delivery and other technological challenges in the delivery of the intervention	

1. *Agarwal S , LeFevre AE, Lee J, L'Engle K, Mehl G, Sinha C et al. Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist. BMJ. 2016;352:i1174*

mHealth en adherencia: ALICE app

A Spanish Pillbox App for Elderly Patients Taking Multiple Medications: Randomized Controlled Trial

José Joaquín Mira[1,2,3], MSc, PhD; Isabel Navarro[2], BA; Federico Botella[4], PhD; Fernando Borrás[5], PhD; Roberto Nuño-Solinís[6], MSc; Domingo Orozco[7], MD, PhD; Fuencisla Iglesias-Alonso[8], MD; Pastora Pérez-Pérez[9], PhD; Susana Lorenzo[10], MD, MPH, PhD; Nuria Toro[6], BA

[1]Sant Joan-Alicante Health District, Consellería Sanidad, Alicante, Spain
[2]Health Psychology Department, Miguel Hernández University, Elche, Spain
[3]Research Network on Health Services in Chronic Diseases (REDISSEC), Madrid, Spain
[4]Center of Operations Research University Institute, Miguel Hernández University, Elche, Spain
[5]Statistics, Mathematics and Informatics Department, Miguel Hernández University, Elche, Spain
[6]Basque Institute for Healthcare Innovation (O+berri), Barakaldo, Spain
[7]Department of Family Medicine, Faculty of Medicine, Miguel Hernández University, Alicante, Spain
[8]Castilla La Mancha Health Service (SESCAM), Toledo, Spain
[9]Andalusian Patient Safety Observatory, Andalusian Agency for Health Care Quality, Seville, Spain
[10]Hospital Universitario Fundación Alcorcón, Madrid, Spain

Objetivo

"The objective of this study was to design, implement, and evaluate a **medication self-management app (called ALICE) for elderly patients taking multiple medications with the intention of improving adherence and safe medication use.**"

1. *Mira JJ, Navarro I, Botella F, Borrás F, Nuño-Solinís R, Orozco D, Iglesias-Alonso F, Pérez-Pérez P, Lorenzo S, Toro N A Spanish Pillbox App for Elderly Patients Taking Multiple Medications: Randomized Controlled Trial J Med Internet Res 2014;16(4):e99*

mHealth en adherencia: ALICE app

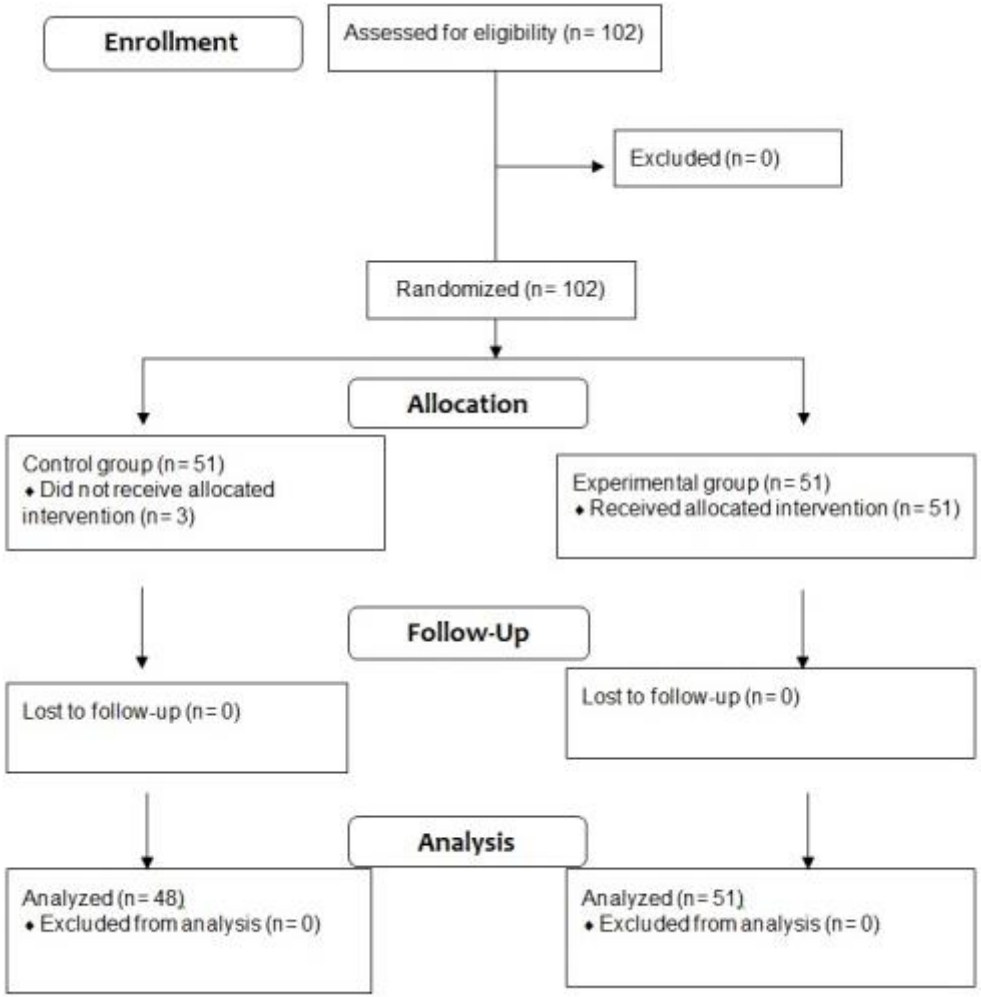
Métodos y diseño del estudio

A single-blind randomized controlled trial was conducted with a control and an experimental group (N=99) in Spain in 2013. The characteristics of ALICE were specified based on the suggestions of 3 nominal groups with a total of 23 patients and a focus group with 7 professionals. ALICE was designed for Android and iOS to allow for the personalization of prescriptions and medical advice, showing images of each of the medications (the packaging and the medication itself) together with alerts and multiple reminders for each alert. **The randomly assigned patients in the control group received oral and written information on the safe use of their medications and the patients in the experimental group used ALICE for 3 months.** Pre and post measures included rate of missed doses and medication errors reported by patients, scores from the 4-item Morisky Medication Adherence Scale (MMAS-4), level of independence, self-perceived health status, and biochemical test results**. In the experimental group, data were collected on their previous experience with information and communication technologies, their rating of ALICE, and their perception of the level of independence they had achieved.** The intergroup intervention effects were calculated by univariate linear models and ANOVA, with the pre to post intervention differences as the dependent variables.

1. *Mira JJ, Navarro I, Botella F, Borrás F, Nuño-Solinís R, Orozco D, Iglesias-Alonso F, Pérez-Pérez P, Lorenzo S, Toro N A Spanish Pillbox App for Elderly Patients Taking Multiple Medications: Randomized Controlled Trial J Med Internet Res 2014;16(4):e99*

mHealth en adherencia: ALICE app

Métodos y diseño del estudio



1. *Mira JJ, Navarro I, Botella F, Borrás F, Nuño-Solinís R, Orozco D, Iglesias-Alonso F, Pérez-Pérez P, Lorenzo S, Toro N A Spanish Pillbox App for Elderly Patients Taking Multiple Medications: Randomized Controlled Trial J Med Internet Res 2014;16(4):e99*

mHealth en adherencia: ALICE app

Población del estudio

Demographic characteristics	Control n=48	Experimental n=51	*P* [a]
Age (years), mean (SD)	72.9 (6)	70.9 (8)	.16
Sex, n (%)			
Women	23 (48)	21 (41)	.50
Men	25 (52)	30 (59)	
Civil status, n (%)			
Single	1 (2)	1 (2)	.10
Married	39 (81)	32 (63)	
Widowed	8 (17)	14 (27)	
Divorced	0 (0)	4 (8)	
Living arrangements, n (%)			
Alone	9 (19)	12 (23)	.56
With partner/relative	39 (81)	39 (76)	
Who organized their medication, n (%)			
Patient himself/herself	41 (85)	47 (92)	.29
Partner/relative/caregiver	7 (15)	4 (8)	
Self-perceived health status, n (%)			
Poor	5 (10)	2 (4)	.64
Fair	14 (29)	17 (33)	
Good	26 (54)	28 (55)	
Excellent	3 (6)	4 (8)	

[a]Based on the Pearson chi-square test or the Student *t* test for independent samples.

[b]Patients could have more than 1 disorder.

[c]Percentage calculated over the total number of patients with diabetes.

[d]Percentage calculated over the total of men in the sample.

1. *Mira JJ, Navarro I, Botella F, Borrás F, Nuño-Solinís R, Orozco D, Iglesias-Alonso F, Pérez-Pérez P, Lorenzo S, Toro N A Spanish Pillbox App for Elderly Patients Taking Multiple Medications: Randomized Controlled Trial J Med Internet Res 2014;16(4):e99*

mHealth en adherencia: ALICE app

Población del estudio

Demographic characteristics	Control n=48	Experimental n=51	p [a]
Disorders [b]			
Diabetes	46 (96)	43 (84)	.06
Insulin-dependent patients[c]	9 (20)	15 (36)	.09
Depression/anxiety	5 (10)	4 (8)	.66
Hypercholesterolemia	24 (50)	28 (55)	.62
Benign prostatic hyperplasia[d]	3 (75)	7 (14)	.22
High blood pressure	40 (83)	38 (74)	.28
Other cardiovascular diseases	22 (46)	21 (41)	.64
Arthrosis	11 (23)	9 (18)	.51
Renal failure	8 (89)	6 (12)	.48
Chronic obstructive pulmonary disease	10 (21)	9 (18)	.69
Digestive disorders	11 (23)	4 (8)	.04
Number of drugs prescribed, mean (SD)	7.9 (3)	7.6 (3)	.55
Number of doctors involved, mean (SD)	2.3 (1)	2.3 (2)	.99

[a]Based on the Pearson chi-square test or the Student *t* test for independent samples.

[b]Patients could have more than 1 disorder.

[c]Percentage calculated over the total number of patients with diabetes.

[d]Percentage calculated over the total of men in the sample.

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mHealth en adherencia: ALICE app

Resultados

Data were obtained from **99 patients (48 and 51 in the control and experimental groups, respectively).** Patients in the experimental group obtained better MMAS-4 scores (*P*<.001) and reported fewer missed doses of medication (*P*=.02). ALICE only helped to significantly reduce medication errors in patients with an initially higher rate of errors (*P*<.001). **Patients with no experience with information and communication technologies reported better adherence (*P*<.001), fewer missed doses (*P*<.001), and fewer medication errors (*P*=.02).** The mean satisfaction score for ALICE was 8.5 out of 10. In all, 45 of 51 patients (88%) felt

Conclusiones

The ALICE app improves adherence, helps reduce rates of forgetting and of medication errors, and increases perceived independence in managing medication. Elderly patients with no previous experience with information and communication technologies are capable of effectively using an app designed to help them take their medicine more safely.

1. *Mira JJ, Navarro I, Botella F, Borrás F, Nuño-Solinís R, Orozco D, Iglesias-Alonso F, Pérez-Pérez P, Lorenzo S, Toro N A Spanish Pillbox App for Elderly Patients Taking Multiple Medications: Randomized Controlled Trial J Med Internet Res 2014;16(4):e99*

mHealth en enfermedades crónicas: estudio ValCronic

Telemedicine in Primary Care for Patients With Chronic Conditions: The ValCrònic Quasi-Experimental Study

Domingo Orozco-Beltran[1,2*], MD, PhD; Manuel Sánchez-Molla[3*], MD, PhD; Julio Jesus Sanchez[4*], Ing; José Joaquin Mira[5,6*], MSc, PhD; ValCrònic Research Group[7*]

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[2] San Juan de Alicante Hospital, San Juan Health District, San Juan de Alicante, Spain
[3] Elche Health Department, Hospital General de Elche, Elche, Spain
[4] Ingeniería y Proyectos e-Health, Telefónica Spain, Madrid, Spain
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[7] Ministry of Health of Valencia, Valencia, Spain,

Objetivo

The objective of our study was to evaluate **the impact of telemonitoring** on patients with long-term conditions at high risk for rehospitalization or an emergency department visit, **in terms of target disease control (diabetes, hypertension, heart failure, and chronic obstructive pulmonary disease).**

1. *Orozco-Beltran D, Sánchez-Molla M, Sanchez JJ, Mira JJ, ValCrònic Research Group Telemedicine in Primary Care for Patients With Chronic Conditions: The ValCrònic Quasi-Experimental Study J Med Internet Res 2017;19(12):e400*

mHealth en enfermedades crónicas: estudio ValCronic

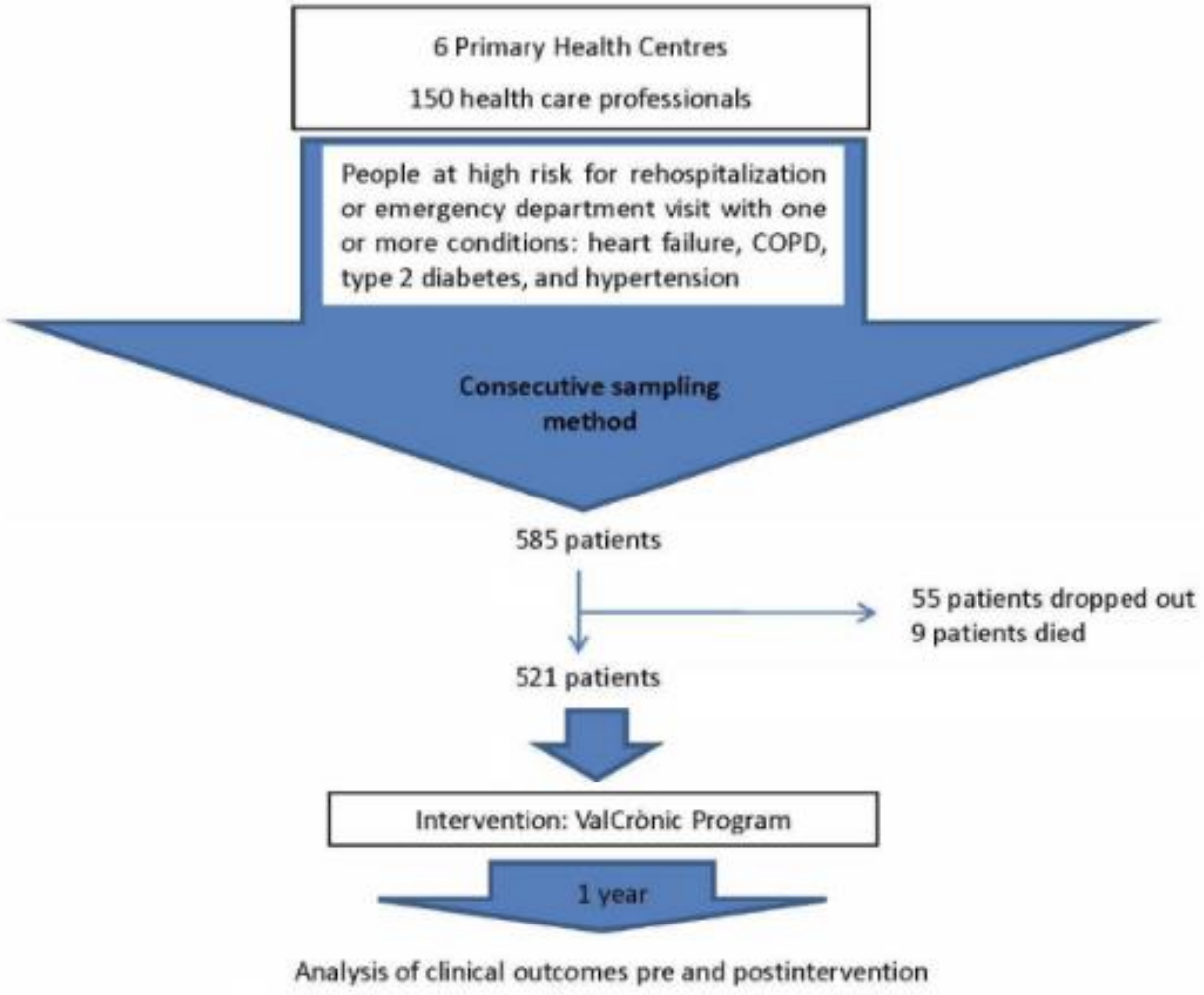
Métodos y diseño del estudio

We conducted a quasi-experimental study with a before-and-after analysis to assess the **effectiveness of the ValCrònic program after 1 year of primary care monitoring.** The study included high-risk patients with 1 or more of the following conditions: **diabetes, high blood pressure, heart failure, and chronic obstructive pulmonary disease.** We assessed risk according to the Community Assessment Risk Screen. Participants used an electronic device (tablet) to self-report relevant health information, which was then automatically entered into their eHealth record for consultation

1. *Orozco-Beltran D, Sánchez-Molla M, Sanchez JJ, Mira JJ, ValCrònic Research Group Telemedicine in Primary Care for Patients With Chronic Conditions: The ValCrònic Quasi-Experimental Study J Med Internet Res 2017;19(12):e400*

mHealth en enfermedades crónicas: estudio ValCronic

➢ Métodos y diseño del estudio



1. *Orozco-Beltran D, Sánchez-Molla M, Sanchez JJ, Mira JJ, ValCrònic Research Group Telemedicine in Primary Care for Patients With Chronic Conditions: The ValCrònic Quasi-Experimental Study J Med Internet Res 2017;19(12):e400*

mHealth en enfermedades crónicas: estudio ValCronic

Población de estudio

Participant characteristics (n=521).

Characteristics	Data
Sex, n (%)	
Female	203 (38.9)
Male	318 (61.1)
Age (years), mean (SD), 95% CI	70.4 (10.3), 68.9-71.9
Hospital admissions during the year, n (%)	
0	374 (71.7)
≥1	147 (28.3)
No. of drugs prescribed, mean (SD), 95% CI	8.25 (4.0), 7.65-8.85
Disease type[a], n	
Heart failure	182
COPD[b]	178
Diabetes	333
Arterial hypertension	396
No. of conditions, n	
1	9
2	347
3	141
4	24

[a]Participants could have more than 1 disease.

[b]COPD: chronic obstructive pulmonary disease.

1. *Orozco-Beltran D, Sánchez-Molla M, Sanchez JJ, Mira JJ, ValCrònic Research Group Telemedicine in Primary Care for Patients With Chronic Conditions: The ValCrònic Quasi-Experimental Study J Med Internet Res 2017;19(12):e400*

mHealth en enfermedades crónicas: estudio ValCronic

Resultados

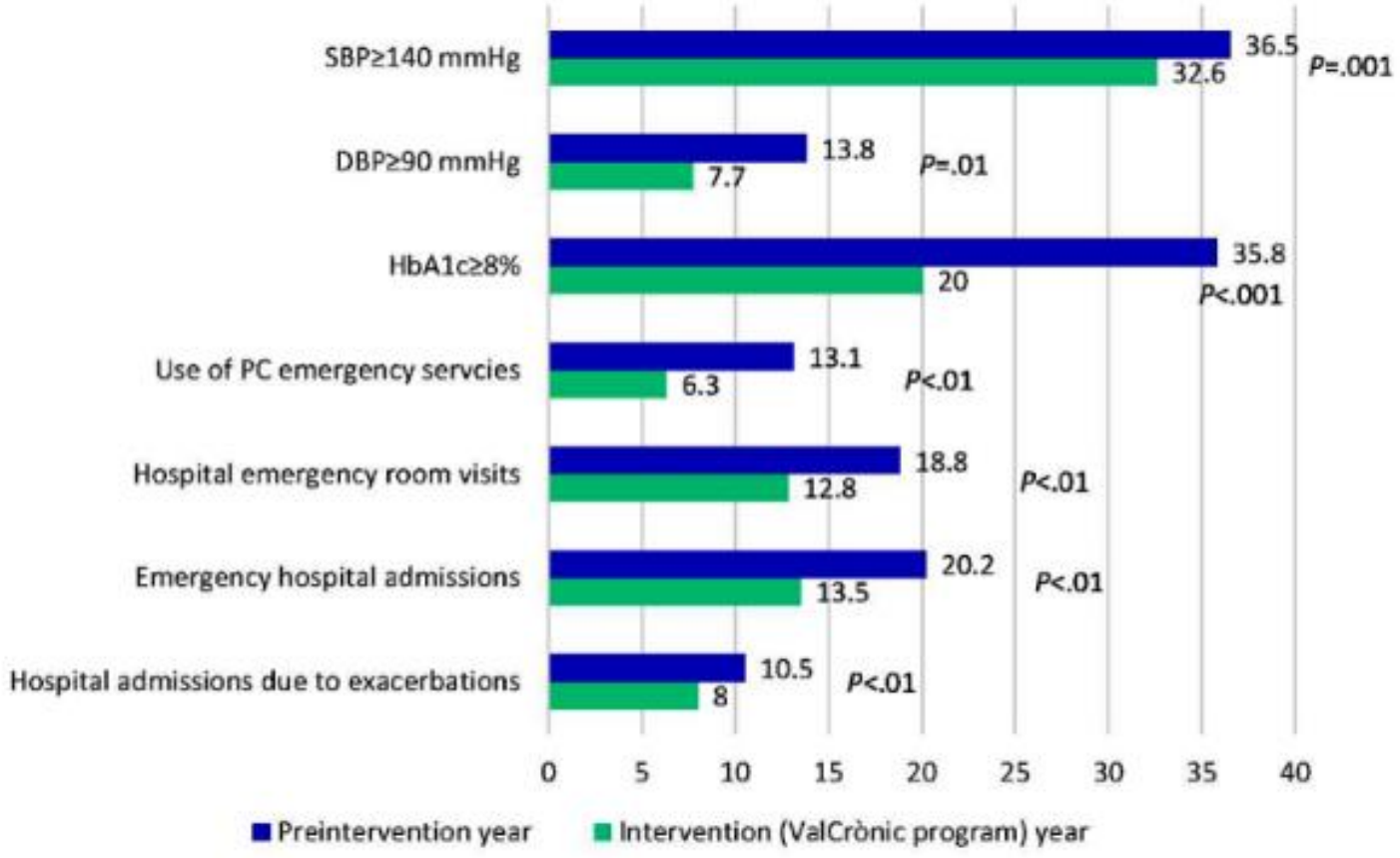
The total sample size was **521 patients**. Compared with the preintervention year, **there were significant reductions in weight** (82.3 kg before vs 80.1 kg after; *P*=.001) **and in the proportion of people with high systolic** (≥140 mmHg; 190, 36.5% vs 170, 32.6%; *P*=.001) **and diastolic** (≥90 mmHg; 72, 13.8% vs 40, 7.7%; *P*=.01) blood pressures, and hemoglobin A_{1c} ≥8% (186, 35.7% vs 104, 20.0%; *P*=.001). There was also a **decrease in the proportion of participants who used emergency services in primary care** (68, 13.1% vs 33, 6.3%; *P*<.001) **and in hospital** (98, 18.8% vs 67, 12.8%; *P*<.001). Likewise, fewer participants required hospital admission due to an emergency (105, 20.2% vs 71, 13.6%; *P*<.001) or disease exacerbation (55, 10.5% vs 42, 8.1%; *P*<.001).

1. *Orozco-Beltran D, Sánchez-Molla M, Sanchez JJ, Mira JJ, ValCrònic Research Group Telemedicine in Primary Care for Patients With Chronic Conditions: The ValCrònic Quasi-Experimental Study J Med Internet Res 2017;19(12):e400*

mHealth en enfermedades crónicas: estudio ValCronic

Resultados

Comparison between preintervention year and intervention (ValCrònic program) year regarding study outcomes: proportion of patients with poor blood pressure and hemoglobin A_{1c} (HbA_{1c}) control; and proportion of patients who visited primary care- (PC) or hospital-based emergency services due to an exacerbation or were hospitalized. DBP: diastolic blood pressure; SBP: systolic blood pressure



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mHealth en enfermedades crónicas: estudio ValCronic

Resultados

Outcomes	Time point, n (%)		ARR[a] (95% CI)	RRR[b] (95% CI)	NNT[c] (95% CI)
	Preintervention year	ValCrònic year			
Systolic blood pressure ≥140 mmHg	190 (36.5)	170 (32.6)	3.9 (0-10)	10.7 (0-25)	26 (10-52)
Diastolic blood pressure ≥90 mmHg	72 (13.8)	40 (7.7)	6.1 (2-10)	44.2 (20-62)	16 (9.9-40.3)
Hemoglobin A_{1c}≥8%	186 (35.7)	104 (20.0)	15.8 (10-21)	44.1 (31-55)	6 (4.7-9.6)
Use of primary care emergency services due to exacerbation of ValCrònic conditions	68 (13.1)	33 (6.3)	6.8 (3-10)	51.9 (29-68)	15 (9.5-30.8)
Visit to hospital emergency due to exacerbation of ValCrònic conditions	98 (18.8)	67 (12.8)	6.1 (2-11)	32.2 (9-49)	16 (9.5-62.9)
Emergency hospital admission(s)	105 (20.2)	71 (13.6)	6.7 (2-11)	33.2 (11-49)	15 (8.9-48.1)
Hospital admission(s) due to exacerbation of ValCrònic conditions	55 (10.5)	42 (8.1)	2.5 (0-8)	23.8 (9-37)	40 (20-58)

[a]ARR: absolute risk reduction.

[b]RRR: relative risk reduction.

[c]NNT: number needed to treat to prevent a harmful outcome.

Conclusiones

The ValCrònic telemonitoring program in patients at high risk for rehospitalization or an emergency department visit appears to be **useful to improve target disease control and to reduce the use of resources.**

1. *Orozco-Beltran D, Sánchez-Molla M, Sanchez JJ, Mira JJ, ValCrònic Research Group Telemedicine in Primary Care for Patients With Chronic Conditions: The ValCrònic Quasi-Experimental Study J Med Internet Res 2017;19(12):e400*

mHealth en control de la depresión: Smiling is Fun

An Internet-Based Intervention for Depression in Primary Care in Spain: A Randomized Controlled Trial

Jesús Montero-Marín[1,2,3], PhD; Ricardo Araya[4], MD, PhD; María C Pérez-Yus[2,3,5], PhD; Fermín Mayoral[2,6], MD, PhD; Margalida Gili[2,7], MD, PhD; Cristina Botella[8,9], PhD; Rosa Baños[9,10], PhD; Adoración Castro[2,7], PhD; Pablo Romero-Sanchiz[6], PhD; Yolanda López-Del-Hoyo[2,3,11], PhD; Raquel Nogueira-Arjona[12], PhD; Margarita Vives[2,7], MD, PhD; Antoni Riera[8], PhD; Javier García-Campayo[2,3,13], MD, PhD

[1]Faculty of Health Sciences and Sports, University of Zaragoza, Zaragoza, Spain
[2]Primary Care Prevention and Health Promotion Research Network, RedIAPP, ISCIII, Madrid, Spain
[3]Aragon Institute for Health Research (IIS Aragon), Zaragoza, Spain
[4]London School of Hygiene and Tropical Medicine, London, United Kingdom
[5]Aragon Health Sciences Institute, Zaragoza, Spain
[6]Mental Health Clinical Management Unit, Institute of Biomedical Research of Malaga (IBIMA), Regional Universitary Hospital Carlos Haya, University of Malaga, Málaga, Spain
[7]University of Balearic Islands, Palma de Mallorca, Spain
[8]Universitat Jaume I, Castellón de la Plana, Spain
[9]Ciber Fisiopatología Obesidad y Nutrición (CB06/03) Instituto Salud Carlos III, Madrid, Spain
[10]University of Valencia, Valencia, Spain
[11]University of Zaragoza, Zaragoza, Spain
[12]University of Malaga, Málaga, Spain
[13]University Hospital Miguel Servet, Zaragoza, Spain

Objetivo

Our aim was to **compare the effectiveness of a low-intensity therapist-guided (LITG) Internet-based program and a completely self-guided (CSG) Internet-based program with improved treatment as usual (iTAU)** care for depression

1. *Montero-Marín J, Araya R, Pérez-Yus MC, Mayoral F, Gili M, Botella C, Baños R, Castro A, Romero-Sanchiz P, López-Del-Hoyo Y, Nogueira-Arjona R, Vives M, Riera A, García-Campayo J An Internet-Based Intervention for Depression in Primary Care in Spain: A Randomized Controlled Trial J Med Internet Res 2016;18(8):e231*

mHealth en control de la depresión: Smiling is Fun

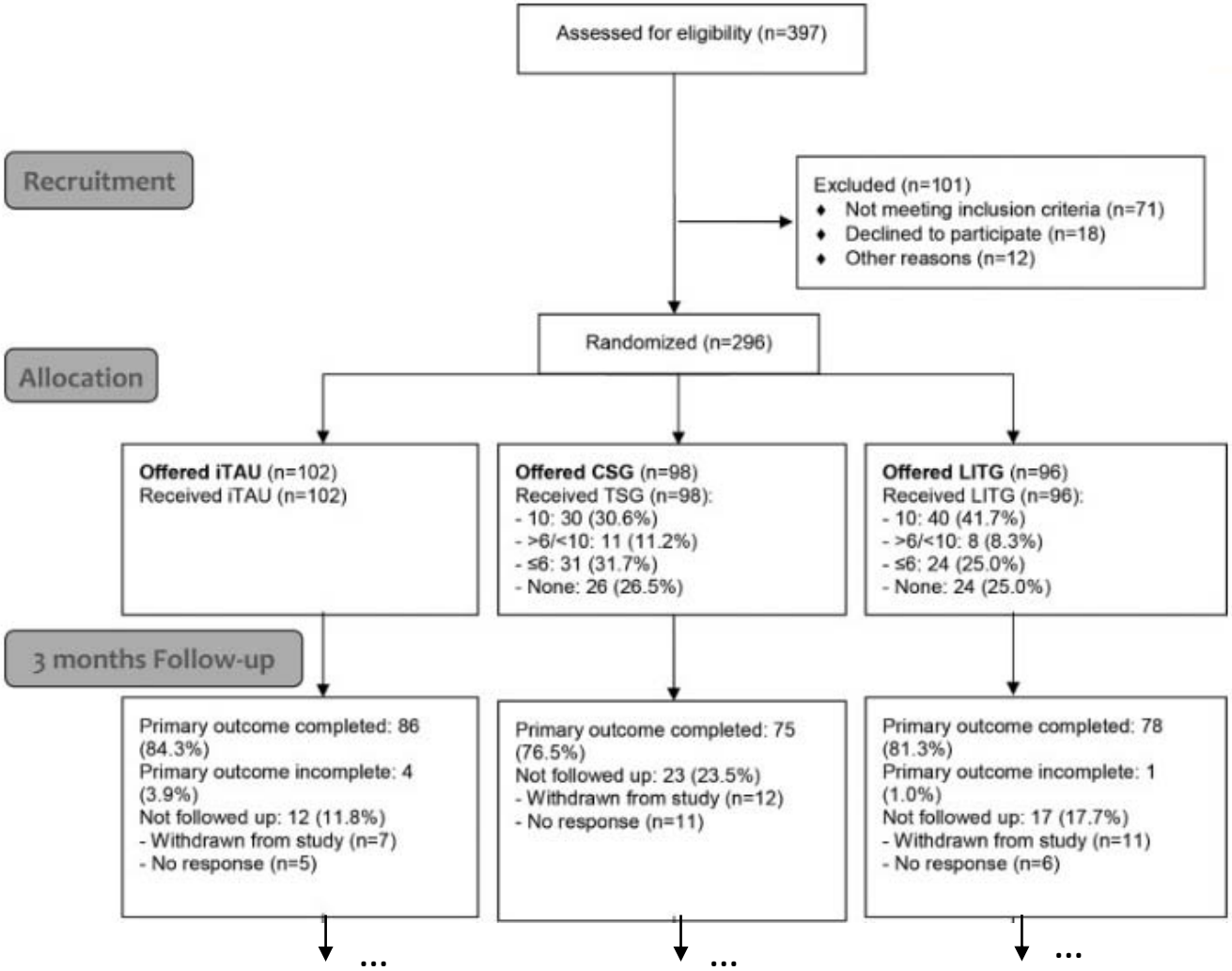
➢ Métodos y diseño del estudio

Multicenter, three-arm, parallel, RCT design, carried out between November 2012 and January 2014, **with a follow-up of 15 months.** In total, **296 adults from primary care settings in four Spanish regions, with mild or moderate major depression, were randomized to LITG (n=96), CSG (n=98), or iTAU (n=102).** Research completers at follow-up were 63.5%. **The intervention was Smiling is Fun, an Internet program based on cognitive behavioral therapy.** All patients received iTAU by their general practitioners. Moreover, LITG received Smiling is Fun and the possibility of psychotherapeutic support on request by email, whereas CSG received only Smiling is Fun. The main outcome was the Beck Depression Inventory-II at 3 months from baseline. Mixed-effects multilevel analysis for repeated measures were undertaken.

1. *Montero-Marín J, Araya R, Pérez-Yus MC, Mayoral F, Gili M, Botella C, Baños R, Castro A, Romero-Sanchiz P, López-Del-Hoyo Y, Nogueira-Arjona R, Vives M, Riera A, García-Campayo J An Internet-Based Intervention for Depression in Primary Care in Spain: A Randomized Controlled Trial J Med Internet Res 2016;18(8):e231*

mHealth en control de la depresión: Smiling is Fun

➢ Métodos y diseño del estudio



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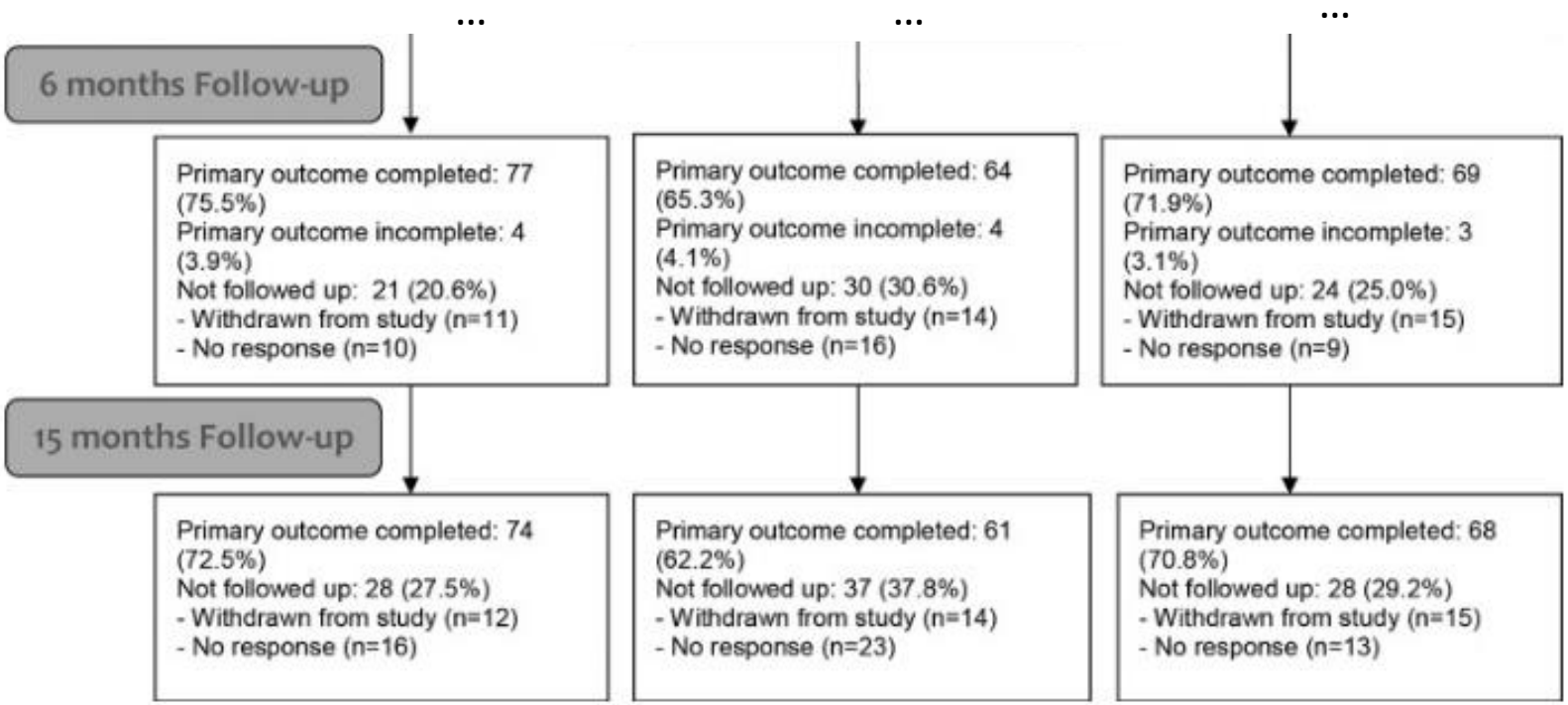
mHealth en control de la depresión: Smiling is Fun

Métodos y diseño del estudio



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mHealth en control de la depresión: Smiling is Fun

Población de estudio

Characteristics at baseline	iTAU, n=102	CSG, n=98	LITG, n=96
Sociodemographics			
Age, mean (SD)	43.04 (9.66)	42.57 (11.94)	43.19 (9.30)
Sex female, n (%)	76 (74.5)	72 (73.5)	76 (79.2)
Living with family, n (%)	92 (90.2)	90 (91.8)	82 (85.4)
University education, n (%)	30 (29.4)	29 (29.6)	32 (33.3)
Employed, n (%)	54 (52.9)	51 (52.0)	52 (54.2)
Income, n (%)			
<1 national minimum wage	27 (26.5)	34 (34.7)	22 (22.9)
1-2 national minimum wage	42 (41.2)	33 (33.7)	40 (41.7)
≥3 national minimum wage	33 (32.4)	31 (31.6)	34 (35.4)
On medication, n (%)	91 (89.2)	84 (85.7)	88 (91.7)
Number of GP visits, median (Q_1-Q_3)	5 (2-8)	5 (3-10)	5 (3-8)
Clinical measures			
Depression severity			
BDI-II, mean (SD); median (Min to Max)	22.18 (5.25); 23 (14-28)	22.33 (4.85); 23 (14-28)	22.36 (4.91); 23 (14-28)
Perceived health			
EuroQol VAS, mean (SD); median (Min to Max)	57.04 (15.77); 57 (20-90)	55.45 (19.23); 50 (10-100)	56.04 (18.34); 60 (0-100)
Physical Health SF-12, mean (SD); median (Min to Max)	48.87 (11.26); 49.47 (23.52-66.60)	48.52 (11.61); 49.87 (16.76-65.59)	48.60 (11.16); 50.99 (26.12-66.43)
Mental Health SF-12, mean (SD); median (Min to Max)	28.71 (10.43); 26.68 (10.51-55.69)	28.03 (9.33); 26.16 (5.53-56.02)	28.60 (8.91); 26.83 (14.09-56.09)

1. *Montero-Marín J, Araya R, Pérez-Yus MC, Mayoral F, Gili M, Botella C, Baños R, Castro A, Romero-Sanchiz P, López-Del-Hoyo Y, Nogueira-Arjona R, Vives M, Riera A, García-Campayo J An Internet-Based Intervention for Depression in Primary Care in Spain: A Randomized Controlled Trial J Med Internet Res 2016;18(8):e231*

mHealth en control de la depresión: Smiling is Fun

Resultados

	iTAU (a) mean (SD)	CSG (b) mean (SD)	LITG (c) mean (SD)	g (a-b)	P (a-b)	B (95% CI) (a-b)	g (a-c)	P (a-c)	B (95% CI) (a-c)	g (b-c)	P (b-c)	B (95% CI) (b-c)
BDI-II	n=67	n=57	n=64									
Time 0	21.76 (5.39)	22.59 (4.78)	21.73 (4.83)									
Time 1	17.91 (11.06)	16.59 (10.60)	17.08 (10.24)	0.12	.444	-1.15 (-4.08 to 1.79)	0.08	.634	-0.71 (-3.61 to 2.20)	-0.05	.764	0.44 (-2.45 to 3.34)
Adjusted					.359	-1.35 (-4.23 to 1.54)		.613	-0.74 (-3.60 to 2.12)		.674	0.61 (-2.23 to 3.45)
Time 2	18.12 (12.15)	14.27 (10.00)	13.56 (11.56)	0.34	.007	-4.22 (-7.28 to -1.16)	0.38	.005	-4.34 (-7.36 to -1.33)	0.07	.938	-0.12 (-3.14 to 2.90)
Adjusted					.003	-4.55 (-7.56 to -1.55)		.004	-4.31 (-7.27 to -1.35)		.862	0.26 (-2.70 to 3.22)
Time 3	16.72 (10.97)	11.53 (10.72)	11.39 (10.96)	0.48	.001	-5.10 (-8.20 to -1.99)	0.48	.003	-4.62 (-7.66 to -1.58)	0.01	.758	0.48 (-2.57 to 3.54)
Adjusted					<.001	-5.47 (-8.51 to -2.42)		.002	-4.62 (-7.61 to -1.63)		.574	0.86 (-2.14 to 3.85)

[a]*g*: Hedge's g as an effect size measure; B: regression coefficients; adjusted: adjusted analysis controlling baseline, sex, and age; a-b: iTAU vs CSG comparison; a-c: iTAU vs LITG comparison; b-c: CSG vs LITG comparison.

1. *Montero-Marín J, Araya R, Pérez-Yus MC, Mayoral F, Gili M, Botella C, Baños R, Castro A, Romero-Sanchiz P, López-Del-Hoyo Y, Nogueira-Arjona R, Vives M, Riera A, García-Campayo J An Internet-Based Intervention for Depression in Primary Care in Spain: A Randomized Controlled Trial J Med Internet Res 2016;18(8):e231*

mHealth en control de la depresión: Smiling is Fun

Resultados

There was no benefit for either CSG [(B coefficient=-1.15; P=.444)] or LITG [(B=-0.71; P=.634)] compared to iTAU, at 3 months. **There were differences at 6 months [iTAU vs CSG (B=-4.22; P=.007); iTAU vs LITG (B=-4.34; P=.005)] and 15 months [iTAU vs CSG (B=-5.10; P=.001); iTAU vs LITG (B=-4.62; P=.002)].** There were no differences between CSG and LITG at any time. Adjusted and intention-to-treat models confirmed these findings.

Conclusiones

An **Internet-based intervention for depression combined with iTAU conferred a benefit over iTAU alone in the Spanish** primary health care system

1. *Montero-Marín J, Araya R, Pérez-Yus MC, Mayoral F, Gili M, Botella C, Baños R, Castro A, Romero-Sanchiz P, López-Del-Hoyo Y, Nogueira-Arjona R, Vives M, Riera A, García-Campayo J An Internet-Based Intervention for Depression in Primary Care in Spain: A Randomized Controlled Trial J Med Internet Res 2016;18(8):e231*

mHealth en control cardiovascular: Telestroke

Development, Implementation, and Evaluation of a Telemedicine Service for the Treatment of Acute Stroke Patients: TeleStroke

Carlos Parra[1*], BEc; Francisco Jódar-Sánchez[1*], MSc; M. Dolores Jiménez-Hernández[2*], MD; Eduardo Vigil[3*], BMed; Alfredo Palomino-García[2*], BMed; Francisco Moniche-Álvarez[2*], BMed; Francisco Javier De la Torre-Laviana[2*], BMed; Patricia Bonachela[4*], BEng; Francisco José Fernández[5*], BEng; Aurelio Cayuela-Domínguez[6*], MD; Sandra Leal[4*], BEng

[1]Virgen del Rocío University Hospital, Technological Innovation Group, Seville, Spain
[2]Virgen del Rocío University Hospital, Neurological Department, Seville, Spain
[3]Virgen del Rocío University Hospital, Clinical Documentation Service, Seville, Spain
[4]Virgen del Rocío University Hospital, Research, Development and Innovation Department, Seville, Spain
[5]Everis, Research and Technological Development Group, Seville, Spain
[6]Seville District, Seville, Spain

Objetivo

Development, implementation, and evaluation of a **care service for the treatment of acute stroke** patients based on **telemedicine (TeleStroke) at Virgen del Rocío University Hospital.**

1. *Parra C, Jódar-Sánchez F, Jiménez-Hernández MD, Vigil E, Palomino-García A,Moniche-Álvarez F, De la Torre-Laviana FJ, Bonachela P, Fernández FJ,Cayuela-Domínguez A, Leal S. Development, Implementation, and Evaluation of aTelemedicine Service for the Treatment of Acute Stroke Patients: TeleStroke. Interact J Med Res. 2012 Nov 15;1(2):e15.*

mHealth en control cardiovascular: Telestroke

Método y diseño del estudio

The evaluation phase, conducted from October 2008 to January 2011, involved patients who **presented acute stroke symptoms confirmed by the emergency physician; they were examined using TeleStroke in two hospitals**, at a distance of 16 and 110 kilometers from Virgen del Rocío University Hospital. We **analyzed the number of interconsultation sheets, the percentage of patients treated with fibrinolysis, and the number of times they were treated.** To evaluate medical professionals' **acceptance of the TeleStroke system, we developed a web-based questionnaire** using a Technology Acceptance Model.

1. *Parra C, Jódar-Sánchez F, Jiménez-Hernández MD, Vigil E, Palomino-García A,Moniche-Álvarez F, De la Torre-Laviana FJ, Bonachela P, Fernández FJ,Cayuela-Domínguez A, Leal S. Development, Implementation, and Evaluation of aTelemedicine Service for the Treatment of Acute Stroke Patients: TeleStroke. Interact J Med Res. 2012 Nov 15;1(2):e15.*

mHealth en control cardiovascular: Telestroke

Método y diseño del estudio

The evaluation phase, conducted from October 2008 to January 2011, involved patients who **presented acute stroke symptoms confirmed by the emergency physician; they were examined using TeleStroke in two hospitals**, at a distance of 16 and 110 kilometers from Virgen del Rocío University Hospital. We **analyzed the number of interconsultation sheets, the percentage of patients treated with fibrinolysis, and the number of times they were treated.** To evaluate medical professionals' **acceptance of the TeleStroke system, we developed a web-based questionnaire** using a Technology Acceptance Model.

1. *Parra C, Jódar-Sánchez F, Jiménez-Hernández MD, Vigil E, Palomino-García A,Moniche-Álvarez F, De la Torre-Laviana FJ, Bonachela P, Fernández FJ,Cayuela-Domínguez A, Leal S. Development, Implementation, and Evaluation of aTelemedicine Service for the Treatment of Acute Stroke Patients: TeleStroke. Interact J Med Res. 2012 Nov 15;1(2):e15.*

mHealth en control cardiovascular: Telestroke

- **Población del estudio (n=28)**

		No Fibrinolysis	Fibrinolysis
Age	40 – 49	2 (22.2)	3 (15.8)
	50 – 59	2 (22.2)	1 (5.0)
	60 – 69	1 (11.1)	4 (21.0)
	70 – 80	4 (44.4)	11 (58.2)
Sex	Females	3 (33.3)	10 (52.6)
	Males	6 (66.7)	9 (47.4)
Origin[a]	Own decision	3 (33.3)	6 (35.3)
	Health center	3 (33.3)	4 (23.5)
	Emergency department	0 (0)	1 (5.9)
	MICU[b]	3 (33.3)	7 (35.3)
Displacement of the patient	Own vehicle	4 (44.4)	7 (36.8)
	Ambulance	5 (55.6)	12 (63.2)

[a] There are values missing for these variables.

[b] MICU: Mobile Intensive-Care Unit.

1. *Parra C, Jódar-Sánchez F, Jiménez-Hernández MD, Vigil E, Palomino-García A,Moniche-Álvarez F, De la Torre-Laviana FJ, Bonachela P, Fernández FJ,Cayuela-Domínguez A, Leal S. Development, Implementation, and Evaluation of aTelemedicine Service for the Treatment of Acute Stroke Patients: TeleStroke. Interact J Med Res. 2012 Nov 15;1(2):e15.*

mHealth en control cardiovascular: Telestroke

Resultados

A total of 28 patients were evaluated through the interconsultation sheet. Out of 28 patients, **19 (68%) received fibrinolytic treatment. The most common reasons for not treating with fibrinolysis included: clinical criteria in six out of nine patients (66%) and beyond the time window in three out of nine patients (33%).** The mean "onset-to-hospital" time was 69 minutes, the mean time from admission to CT image was 33 minutes, the mean "door-to-needle" time was 82 minutes, and the mean "onset-to-needle" time was 150 minutes. **Out of 61 medical professionals, 34 (56%) completed a questionnaire to evaluate the acceptability of the TeleStroke system. The mean values for each item were over 6.50, indicating that respondents positively evaluated each item.**

1. *Parra C, Jódar-Sánchez F, Jiménez-Hernández MD, Vigil E, Palomino-García A,Moniche-Álvarez F, De la Torre-Laviana FJ, Bonachela P, Fernández FJ,Cayuela-Domínguez A, Leal S. Development, Implementation, and Evaluation of aTelemedicine Service for the Treatment of Acute Stroke Patients: TeleStroke. Interact J Med Res. 2012 Nov 15;1(2):e15.*

mHealth en control cardiovascular: Telestroke

Resultados

Items		Min-Max	Mean ± SD
Perceived usefulness			
	TS could enhance my effectiveness of job	1-10	7.35 ± 2.06
	TS would allow greater control over DTP[a]	1-10	7.68 ± 1.98
	TS could support critical aspects in DTP	3-10	8.18 ± 1.80
	If I use TS[b], I will increase my chances to develop my career	1-10	7.06 ± 2.36
	Using TS would make my job easier	1-10	6.62 ± 2.62
	Using TS would improve my job performance	1-10	7.32 ± 2.03
	Using TS would help me to accomplish DTP more quickly	1-10	6.97 ± 2.89
	TS could improve the quality of DTP that I deliver	3-10	7.82 ± 1.87
	Overall, TS could be useful to improve DTP	1-10	8.06 ± 1.98

...

1. *Parra C, Jódar-Sánchez F, Jiménez-Hernández MD, Vigil E, Palomino-García A,Moniche-Álvarez F, De la Torre-Laviana FJ, Bonachela P, Fernández FJ,Cayuela-Domínguez A, Leal S. Development, Implementation, and Evaluation of aTelemedicine Service for the Treatment of Acute Stroke Patients: TeleStroke. Interact J Med Res. 2012 Nov 15;1(2):e15.*

mHealth en control cardiovascular: Telestroke

Resultados

...

Perceived ease of use			
	Learning to use TS would be easy for me	4-10	7.56 ± 1.71
	My interaction with TS would be clear and understandable	3-10	7.09 ± 1.91
	I think that DTP made through TS would be clear	3-10	7.82 ± 1.80
	It would be easy for me to become skillful at using TS	4-10	7.21 ± 1.74
	Overall, I believe that TS will be easy to use	2-10	6.65 ± 2.14
Subjective norm			
	Colleagues whose opinions I value think I should use TS	3-10	7.91 ± 1.91
	My superiors think that I should use TS	8-10	9.47 ± 0.75
	Other health professionals whose opinions I value think I should use TS	3-10	7.91 ± 1.90
	The management of the hospital supports me to use TS	2-10	9.03 ± 1.66
	Overall, I believe that the hospital supports the use of TS	5-10	8.94 ± 1.32

...

1. *Parra C, Jódar-Sánchez F, Jiménez-Hernández MD, Vigil E, Palomino-García A,Moniche-Álvarez F, De la Torre-Laviana FJ, Bonachela P, Fernández FJ,Cayuela-Domínguez A, Leal S. Development, Implementation, and Evaluation of aTelemedicine Service for the Treatment of Acute Stroke Patients: TeleStroke. Interact J Med Res. 2012 Nov 15;1(2):e15.*

mHealth en control cardiovascular: Telestroke

Resultados

...

Facilitating conditions			
	A specific person will be available to solve problems regarding to TS	1-10	6.65 ± 2.00
	I will have the resources necessary to use TS	3-10	7.94 ± 1.84
	I will receive training to use TS	2-10	7.12 ± 2.21
	TS will be compatible with other systems I use	4-10	8.18 ± 1.58
	The hospital has the infrastructure necessary to I use TS	4-10	7.91 ± 1.83
Intention to use			
	I intend to use TS as it is available in the hospital	4-10	9.03 ± 1.55
	I intend to use TS for DTP as often as needed	4-10	8.97 ± 1.42
	Whenever possible, I intend to use TS	3-10	8.82 ± 1.73

Conclusiones

The implementation of **TeleStroke has made it possible for patients in the acute phase of stroke to receive effective treatment, something that was previously impossible because of the time required** to transfer them to referral hospitals.

1. *Parra C, Jódar-Sánchez F, Jiménez-Hernández MD, Vigil E, Palomino-García A,Moniche-Álvarez F, De la Torre-Laviana FJ, Bonachela P, Fernández FJ,Cayuela-Domínguez A, Leal S. Development, Implementation, and Evaluation of aTelemedicine Service for the Treatment of Acute Stroke Patients: TeleStroke. Interact J Med Res. 2012 Nov 15;1(2):e15.*

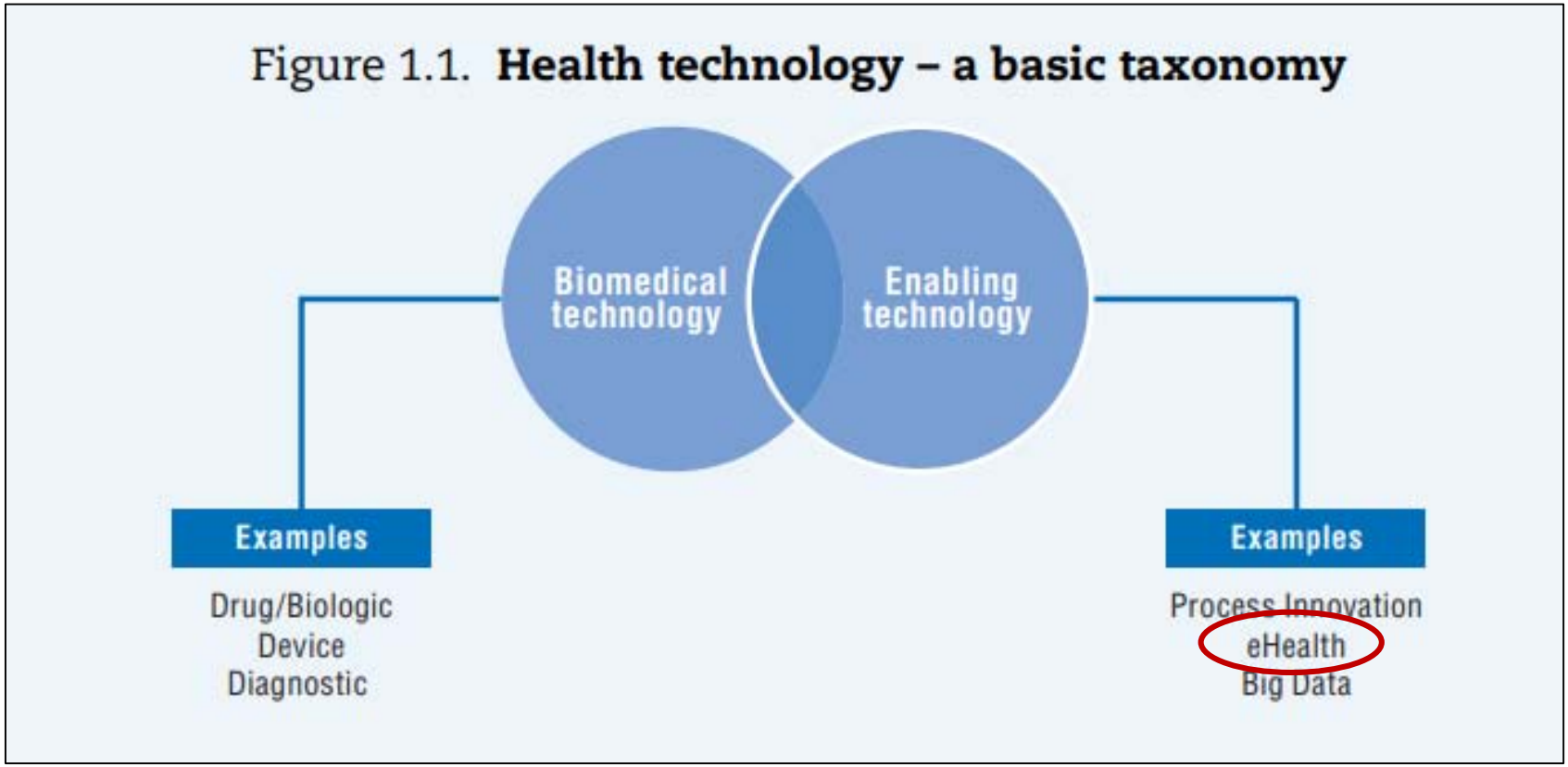
Generación de evidencia con mHealth

Real World Data y Real World Evidence

[porib]
pharmacoeconomics & outcomes research iberia

Ampliación del concepto de Tecnología Sanitaria

"**Health technology and innovation is defined as the application of knowledge to solve practical clinical and health problems.** Such a definition includes biomedical technology – such as medicines, medical devices and diagnostics (Dx) – as well as enabling technology such as **mobile health (mHealth)** and Big Data.[1]"



1. *OECD (2017), New Health Technologies: Managing Access, Value and Sustainability, OECD Publishing, Paris. [citado 5 de febrero de 2019]. Disponible en: http://g8fip1kplyr33r3krz5b97d1.wpengine.netdna-cdn.com/wp-content/uploads/2017/01/OECD-on-new-drugs-and-pricing.pdf*

Sin datos no hay evidencia: Real World Data

"**Real World Data (RWD)** refers to human health-relevant data that is not collected in randomized controlled clinical trials (RCTs).[1]"

"**Real world evidence (RWE)** is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD.[2]"

Real World Data

Real World Evidence

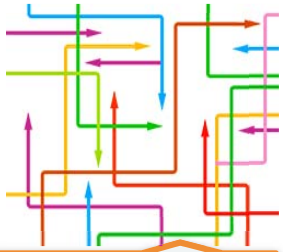
1. *European Comission. Real World Data facts sheet [Internet]. Luxemburgo: Publications Office of the European Union, 2018. [citado 5 de febrero de 2019]. Disponible en: https://ec.europa.eu/research/health/pdf/factsheets/real_world_data_factsheet.pdf*
2. *U.S. Food & Drug Administration (FDA). Science & Research, Real World Evidence. [Internet] Silver Springs, FDA Center for Drug Evaluation and Research (CDER). [citado 5 de febrero de 2019]. Disponible en: https://www.fda.gov/scienceresearch/specialtopics/realworldevidence/default.htm*

Sin datos no hay evidencia: Real World Data

"**RWD** is health-related data derived from a **diverse human population** in **real life settings**[1]"

Historias Clínicas

Encuestas de salud



Datos administrativos

Registro de pacientes

Biobancos

Estudios observacionales

Seguros médicos

Salud móvil (mHealth)

1. *European Comission. Real World Data facts sheet [Internet]. Luxemburgo: Publications Office of the European Union, 2018. [citado 5 de febrero de 2019]. Disponible en: https://ec.europa.eu/research/health/pdf/factsheets/real_world_data_factsheet.pdf*

Fuentes de datos en Real World Evidence

Fuentes de datos primarias

Son aquellas diseñadas con el fin de investigar o evaluar a una población de pacientes

- Estudios observacionales prospectivos
- Registros de pacientes

Fuentes de datos secundarias

No están diseñadas con el fin de investigación sino de gestión, pero contienen información útil para analizar

- Historia clínica electrónica
- Bases de datos de administraciones / gestión
- eHealth-mHealth: aplicaciones móviles en salud y weareables

1. *OECD (2017), New Health Technologies: Managing Access, Value and Sustainability, OECD Publishing, Paris. [citado 5 de febrero de 2019]. Disponible en: http://g8fip1kplyr33r3krz5b97d1.wpengine.netdna-cdn.com/wp-content/uploads/2017/01/OECD-on-new-drugs-and-pricing.pdf*

Aplicaciones Real World Evidence

"**RWE cannot be expected to fill information gaps** in situations where original pre-market evidence assessed a product's efficacy with a **high-level of uncertainty**[1]"

"**RWE can be useful** for assessing the **clinical effectiveness of a product in real situations** with patients with different profiles[1]."

Real World Evidence

- EPA
- Recogida rutinaria de información

→ Resultados en salud y costes

- ✓ Cambios de posología
- ✓ Focalizar mejor el tratamiento (ej. pacientes con comorbilidades)
- ✓ Revisión coste-efectividad

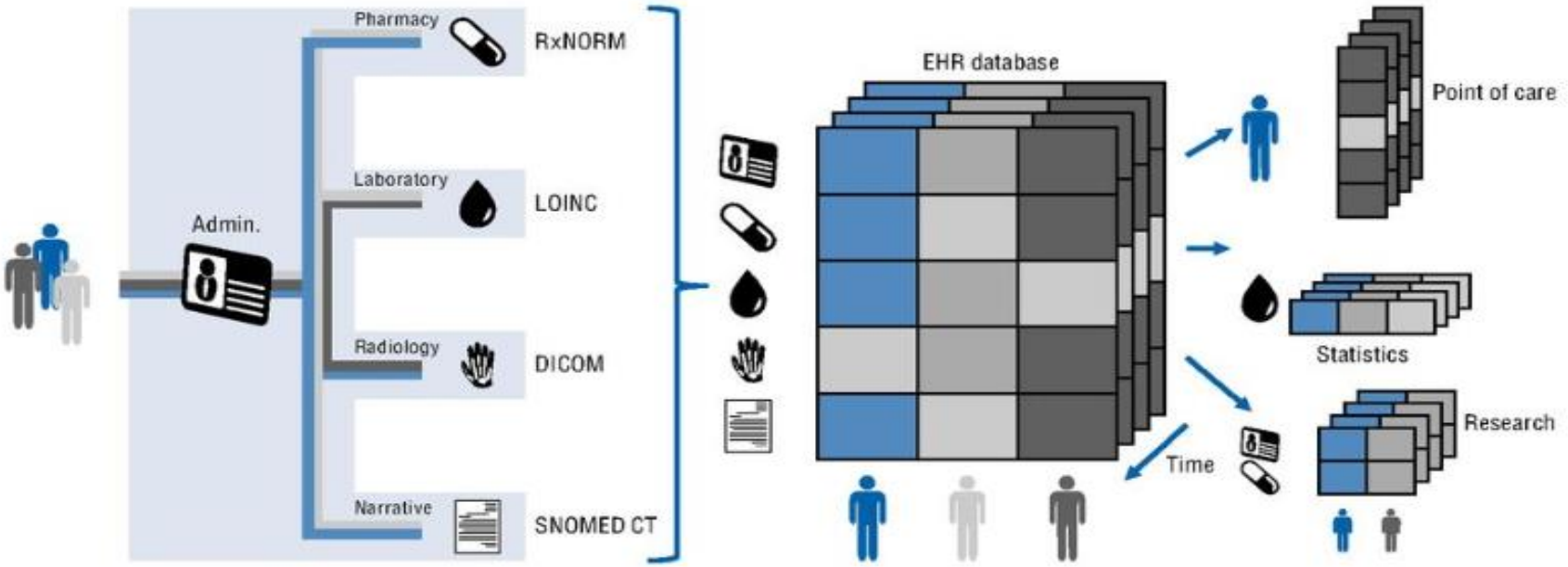


1. *OECD (2017), New Health Technologies: Managing Access, Value and Sustainability, OECD Publishing, Paris. [citado 5 de febrero de 2019]. Disponible en: http://g8fip1kplyr33r3krz5b97d1.wpengine.netdna-cdn.com/wp-content/uploads/2017/01/OECD-on-new-drugs-and-pricing.pdf*

Aplicaciones Real World Evidence

La información **RWE que se genera a traves de la mHealth** puede ser utilizada para realizar un **mejor control del paciente,** para realizar registros de **información y estudiar patrones,** y para **generar evidencia en un entorno real y no controlado.**

Figure 6.4. **Multiple uses of data within clinical electronic health record systems**



1. *OECD (2017), New Health Technologies: Managing Access, Value and Sustainability, OECD Publishing, Paris. [citado 5 de febrero de 2019]. Disponible en: http://g8fip1kplyr33r3krz5b97d1.wpengine.netdna-cdn.com/wp-content/uploads/2017/01/OECD-on-new-drugs-and-pricing.pdf*

Barreras de implantación mHealth

Integración e interoperabilidad de sistemas

Privacidad, confidencialidad y seguridad

Grado de aceptación

[porib]
pharmacoeconomics & outcomes research iberia

Interoperabilidad de los sistemas

HIMSS
transforming health through IT™

Capacidad de los sistemas de información, dispositivos y aplicaciones para **conectarse de forma coordinada** y dentro de las limitaciones de las organizaciones sanitarias para tener **acceso, intercambiar y utilizar cooperativamente los datos entre *stakeholders*** con el objetivo de **optimizar la salud de las personas y los colectivos**[1]

En el ámbito sanitario, la interoperabilidad promueve la **optimización de la salud** al proporcionar un **acceso** perfecto a la información correcta y necesaria para **abordar de manera más integral la salud de las personas y las poblaciones**[1]**.**

1. *Healthcare Information and Management Systems Society (HIMSS). What is Interoperability? [Internet] Chicago, HIMSS [citado 5 de febrero de 2019]. Disponible en: https://www.himss.org/library/interoperability-standards/what-is-interoperability*

Interoperabilidad de los sistemas

Ventajas de la interoperabilidad en eHealth[1]

Profesionales sanitarios

- Mejorar calidad y seguridad mediante coordinación
- Información actualizada sobre el estado del paciente y pautas clínicas basadas en la evidencia para respaldar los procedimientos de toma de decisiones

Pacientes

Seguridad mejorada de los tratamientos recibidos, entrega de atención en el punto de necesidad, atención integrada que incluye calidad y tratamiento seguro en el extranjero, por ejemplo. En una situación de emergencia en otro Estado miembro de la UE.

Usuarios

Costes de implementación e integración significativamente más bajos. Por ejemplo, una imagen de resonancia magnética de un hospital puede ser intercambiada y utilizada por varios profesionales y estructuras sin la necesidad de repetir las pruebas

Compañías

Expandir un mercado único digital para la asistencia sanitaria, abriendo la competencia y reduciendo los costes para los desarrolladores. En este sentido, la cooperación es vital: una colaboración completa y amplia permite compartir costes y reduce las reinversiones futuras para actualizar los sistemas.

1. *European Comission. Interoperability & standardisation: connecting eHealth servicesty? Luxemburgo: Publications Office of the European Union 2014. [citado 5 de febrero de 2019]. Disponible en : https://ec.europa.eu/digital-single-market/en/interoperability-standardisation-connecting-ehealth-services*

Interoperabilidad. Experiencia Listeo+

Effect of a Mobile App on Preoperative Patient Preparation for Major Ambulatory Surgery: Protocol for a Randomized Controlled Trial

Manuel Herrera-Usagre[1,2], PhD (Sociology), MSc; Vicente Santana[1], BNursing, MSc; Ramon Burgos-Pol[3], MPH, BPharm; Juan Pedro Oliva[4], BNursing, Med DM; Eliazar Sabater[3], MD; Maria Rita-Acosta[5], BNursing, Med DM; Miguel Angel Casado[3], PharmD, PhD; Susana Cruces[4], BNursing; Manuel Pacheco[1], BE; Carlos Solorzano Perez[4], BE

[1]Andalusian Agency for Healthcare Quality, Sevilla, Spain
[2]Department of Sociology, Pablo de Olavide University, Sevilla, Spain
[3]Pharmacoeconomics & Outcomes Research Iberia, Paseo de Joaquín Rodrigo 4-I, 28224, Pozuelo de Alarcón, Madrid, Spain
[4]Hospital de Alta Resolución de Utrera, APS Bajo Guadalquivir, Utrera, Sevilla, Spain
[5]Hospital de Alta Resolución Sierra Norte, APS Bajo Guadalquivir, Constantina, Sevilla, Spain

JMIR Publications
The Leading eHealth Publisher

Codiseño del sistema y del piloto

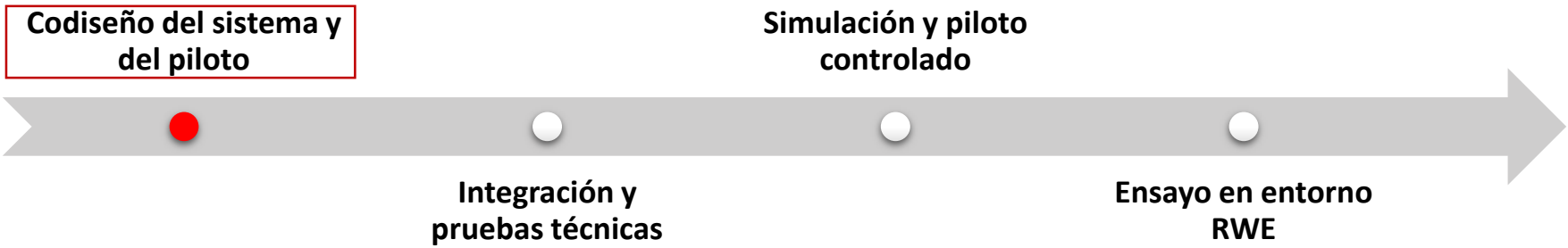
Integración y pruebas técnicas

Simulación y piloto controlado

Ensayo en entorno RWE

1. *Herrera-Usagre M, Santana V, Burgos-Pol R, Oliva JP, Sabater E, Rita-Acosta M, Casado MA, Cruces S, Pacheco M, Solorzano Perez C. Effect of a Mobile App on Preoperative Patient Preparation for Major Ambulatory Surgery: Protocol for a Randomized Controlled Trial*

Interoperabilidad. Experiencia Listeo+

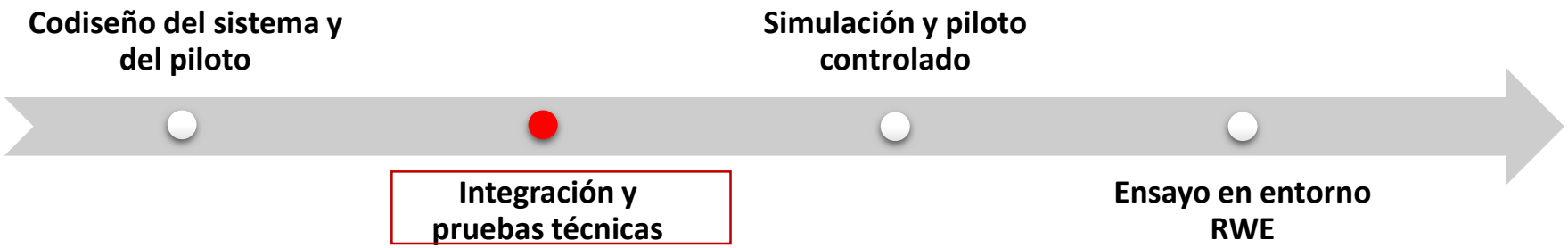


Diseño de la intervención

- Se realizará un proceso iterativo para desarrollar el prototipo, con varios ciclos de diseño en el que participen profesionales de salud, empleando maquetas o prototipos.
- Se utilizarán cuestionarios de usabilidad validados para conocer las preferencias, expectativas, barreras y facilitadores (en pacientes y profesionales). Los resultados de cada iteración servirán para generar una nueva maqueta o prototipo de la aplicación móvil.

1. *Herrera-Usagre M, Santana V, Burgos-Pol R, Oliva JP, Sabater E, Rita-Acosta M, Casado MA, Cruces S, Pacheco M, Solorzano Perez C. Effect of a Mobile App on Preoperative Patient Preparation for Major Ambulatory Surgery: Protocol for a Randomized Controlled Trial*

Interoperabilidad. Experiencia Listeo+



Integración y pruebas técnicas

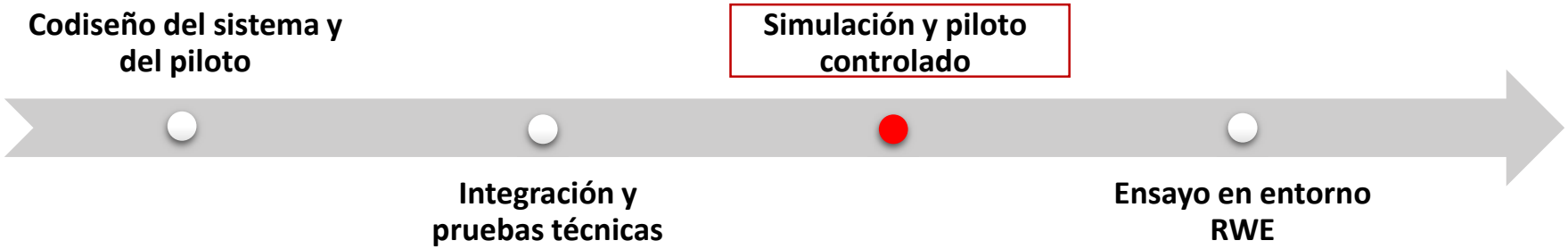
- El sistema será integrado en la HCE y testado. Se evaluará cada componente del sistema

Id	Prueba	Si	No	Acciones de mejora
1	La app se encuentra en los markets de IOS y Android			
2	La app se descarga correctamente en el dispositivo			
3	La app arranca correctamente con la pantalla de inicio			
4	…			
n	La app muestra correctamente la notificación push de “Fecha de intervención”			

- Se realizará posteriormente un pilotaje técnico (“prueba de salón”) con el objeto de disponer de un prototipo funcional de la app Listeo+.

1. *Herrera-Usagre M, Santana V, Burgos-Pol R, Oliva JP, Sabater E, Rita-Acosta M, Casado MA, Cruces S, Pacheco M, Solorzano Perez C. Effect of a Mobile App on Preoperative Patient Preparation for Major Ambulatory Surgery: Protocol for a Randomized Controlled Trial*

Interoperabilidad. Experiencia Listeo+

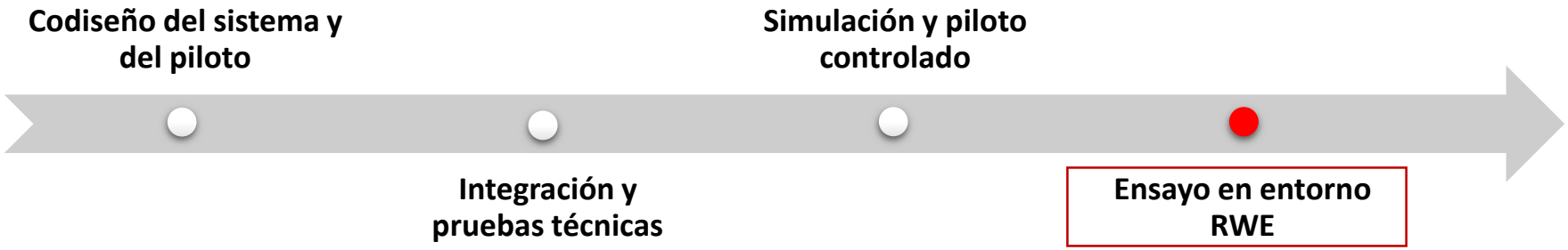


Simulación y piloto controlado

- Se realizará un pilotaje en entorno simulado: 5 pacientes ya intervenidos con anterioridad
- Se dispondrá de un mes antes del inicio de la fase de reclutamiento de paciente como fase de pilotaje, con el objeto de ajustar el funcionamiento de la app. Habrá una persona en la organización dedicada a ayudar a los pacientes, resolviendo dudas y problemas técnicos

1. *Herrera-Usagre M, Santana V, Burgos-Pol R, Oliva JP, Sabater E, Rita-Acosta M, Casado MA, Cruces S, Pacheco M, Solorzano Perez C. Effect of a Mobile App on Preoperative Patient Preparation for Major Ambulatory Surgery: Protocol for a Randomized Controlled Trial*

Interoperabilidad. Experiencia Listeo+



Ensayo en entorno real (RWE)

- Se inicia con la fase de reclutamiento de pacientes hasta el fin del proyecto.

1. *Herrera-Usagre M, Santana V, Burgos-Pol R, Oliva JP, Sabater E, Rita-Acosta M, Casado MA, Cruces S, Pacheco M, Solorzano Perez C. Effect of a Mobile App on Preoperative Patient Preparation for Major Ambulatory Surgery: Protocol for a Randomized Controlled Trial*

Privacidad, confidencialidad y seguridad

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Página Principal → Últimas noticias de salud → Noticia

HealthDay

Las aplicaciones para la atención de la salud ofrecen poca protección de la privacidad, según un estudio

Muchas no tienen políticas y podrían compartir los datos con terceros, señalan unos investigadores

Traducido del inglés: jueves, 10 de marzo, 2016

MIÉRCOLES, 9 de marzo de 2016 (HealthDay News) -- Si usted confía en su smartphone para compartir información médica con su médico, quizá esté poniendo en riesgo la privacidad de sus expedientes de salud, advierte un nuevo estudio.

La nueva investigación encuentra que las políticas de privacidad de los programas (o "aplicaciones") de salud diseñados para los smartphones que comparten información médica altamente sensible entre pacientes y médicos tienen carencias, y con frecuencia ni siquiera existen.

1. *HealthDay. Las aplicaciones para la atención de la salud ofrecen poca protección de la privacidad, según un estudiol. [Internet] MedlinePlus, 10de Marzo 2016 [citado 5 de febrero de 2019]. Disponible en: http://salud.wikiplus.org/medlineplus/spanish/news/fullstory_157724.html*

Privacidad, confidencialidad y seguridad

EL PAÍS

Materia

PRIVACIDAD EN INTERNET ›

¿Dónde acaban los datos privados que recogen las 'apps' de salud?

Casi todas las aplicaciones analizadas en un estudio compartían datos personales con terceros

JAVIER SALAS

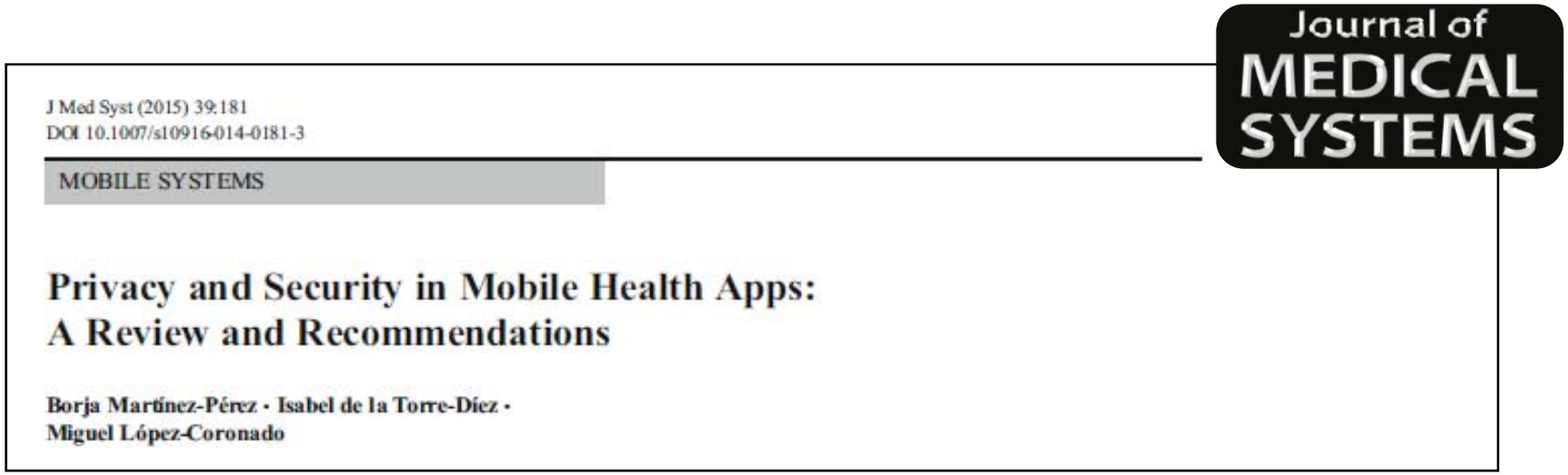
8 MAR 2016 - 19:01 CET

Las aplicaciones de móviles, tabletas y relojes inteligentes nos pueden ayudar a mantenernos en forma, a perder peso, a vigilar la diabetes, e incluso apoyarnos en el seguimiento de un cáncer y hasta monitorizando la salud mental. No es difícil imaginar el carácter privado y sensible de los datos que se vuelcan —o que se recogen sin preguntar— en estos programas. Sin embargo, lo más habitual es que el usuario viva en la inopia: ni sabe lo que comparte ni el desarrollador de la aplicación le informa de nada.

Hay 500 millones de usuarios de 'apps' médicas en el mundo y el desconocimiento sobre el flujo de datos privados es notable

1. *Javier Salas. ¿Dónde acaban los datos privados que recogen las 'apps' de salud? [Internet] El País, 8 de Marzo 2016 [citado 5 de febrero de 2019]. Disponible en: https://elpais.com/elpais/2016/03/07/ciencia/1457369646_082762.html*

Privacidad, confidencialidad y seguridad



J Med Syst (2015) 39:181
DOI 10.1007/s10916-014-0181-3

MOBILE SYSTEMS

Privacy and Security in Mobile Health Apps: A Review and Recommendations

Borja Martínez-Pérez · Isabel de la Torre-Díez · Miguel López-Coronado

Journal of MEDICAL SYSTEMS

"La privacidad de la Información Médica es un **derecho individual** para controlar la **adquisición, utilización y publicación de los datos individuales** de salud identificables del usuario.[2]"

"Obligación de aquellos que reciben la Información Médica de los usuarios a **respetar la privacidad de aquellos a los que los datos refieren.**[2]"

1. *Martínez-Pérez B, de la Torre-Díez I, López-Coronado M. Privacy and security in mobile health apps: a review and recommendations. J Med Syst. 2015 Jan;39(1):181.*
2. *National Committee on vital and health statistic. Home page [Internet) Hyattsville, CDC/National Center for Health Statistics[citado 5 de febrero de 2019]. Disponible en: https://ncvhs.hhs.gov/*

Privacidad, confidencialidad y seguridad

Table 1 Laws requisites regarding privacy and security in mHealth applications

Cover data	The data which must be covered are that information that can be used to identify a person. It includes ID numbers, physical, physiological, mental, economic, genetic, social, medical, cultural factors regarding the past, present or future of the patient.
Information requirements	Before providing their Personal Health Information (PHI), users must be informed about the identity of the person/entity that will use the PHI, the purposes of the collecting, the entity's privacy practices, whether the provision is compulsory or voluntary, the rights they have to access/modify the data and a contact method for more information or complaints. This information must be given directly to a parent or legal tutor in case of children under 13.
Consent requirements	The user/patient's consent to the data collecting must be obtained by the entity, when this collecting cannot be justified by a statutory ground. The entity is enhanced to obtain this consent written. In the case of children under 13, they cannot consent their data collection, being their parents or legal tutors the ones to do so.
Data retention	Generally, PHI should be kept only the necessary time for the purpose which was collected and must be erased once the purpose is reached. Entities must also include a clear data retention policy as part of their security procedures.
Security	The entities are required to implement and maintain appropriate technical, administrative, physical and organizational security measures to protect PHI form accidental or unlawful loss and unauthorized access or disclosure. Since health data is very sensitive, the security must be higher.
Breach notification obligations	In case of a personal data breach, the entities must notify it to the competent authority as well as the user whose data has been compromised without unreasonable delay, especially when the breach may have adversely affected to the user. In cases of massive breaches, the media should be also notified.
Data transfers	Entities need the users' consent to transfer their personal data to another entity or a third party, even when this transfer is necessary to complete one of the purposes of the data collecting, unless the transfer is allowed by law.

1. *Martínez-Pérez B, de la Torre-Díez I, López-Coronado M. Privacy and security in mobile health apps: a review and recommendations. J Med Syst. 2015 Jan;39(1):181.*

Privacidad, confidencialidad y seguridad

➢ ¿Cuál es la situación actual?

"Los profesionales sanitarios y los pacientes están **adoptando la tecnología móvil más rápido que la capacidad de los proveedores** de proteger la **seguridad y la privacidad**[1]."

"La utilización de la tecnología móvil para **recoger información clínica en el contexto hospitalario alcanza hasta un 45%** (desde un 30 en 2014) y un **93% de los médicos utilizan su Smartphone personal para acceder a registros de salud electrónicos**, aunque **solo el 38% bajo una política** de utilización de tecnología móvil **formal**[1]."

1. *Healthcare Information and Management Systems Society (HIMSS). 2018 HIMSS Cybersecurity Survey. [Internet) Chicago, HIMSS [citado 5 de febrero de 2019]. Disponible en: https://www.himss.org/2018-himss-cybersecurity-survey*

Privacidad, confidencialidad y seguridad

La confidencialidad, privacidad y seguridad de datos forma parte del proceso de evaluación de mHealth por Tic Salut y CalidadApps:

Cómo crear una aplicación móvil segura, accesible, usable e interoperable[1].

Cuando se realiza el procesamiento de los datos de un sujeto, deben garantizarse los siguientes aspectos clave:

- **Consentimiento claro y explícito:** se necesita un consentimiento explícito para tratar datos personales. El formulario de consentimiento no puede ser ambiguo y tiene que usar un lenguaje sencillo y comprensible. Es necesario, por ejemplo, añadir un check para consentir cada uno de los tratamientos que se realizarán de los datos y no sirve incluir un «Acepto los términos y las condiciones de uso» genérico. Los consentimientos previos al reglamento que no cumplan este punto deben volverse a solicitar. En el caso de menores de 16 años, el consentimiento lo tiene que proporcionar un tutor legal -esta edad se reduce hasta los 13 años en algunos estados-.
- **Derecho de acceso:** el sujeto tendrá acceso a todos sus datos en un formato amigable y comprensible, junto con la información adicional detallada en el artículo 15 del RGPD (como los fines del procesamiento).
- **Derecho de rectificación:** el sujeto podrá modificar todos los datos de su perfil, incluidos los que se han obtenido a través de otras fuentes.
- **Derecho al olvido**: se garantizará que se eliminan físicamente todos los datos de una persona si esta así lo pide, y cesará su transmisión a terceros sin demora injustificada. Este derecho se aplicará siempre que no comprometa otros como la libertad de expresión.

1. *TIC Salut Social. Guia bàsica de recomanacions pel desenvolupament d'apps de salut I atenció social. [Internet] Barcelona, Generalitat de Catalunya 2013-2019 [citado 5 de febrero de 2019]. Disponible en https://ticsalutsocial.cat/wp-content/uploads/2018/12/20181213_guia-apps_v01_cast.pdf*

Privacidad, confidencialidad y seguridad

Confidencialidad y privacidad

Las recomendaciones de este bloque tratan de abordar las garantías exigibles a la app de salud en materia de protección de datos, habida cuenta del carácter especialmente protegido de la información sobre salud, así como los mecanismos de seguridad que implementa una app para garantizar la privacidad y confidencialidad de la información.

Privacidad y protección de datos

Recomendación 21. Antes de su descarga e instalación, la app de salud informa sobre qué datos del usuario se recogen y para qué fin, sobre las políticas de acceso y tratamiento de datos y acerca de posibles acuerdos comerciales con terceros.

Recomendación 22. La app de salud describe de forma clara y comprensible los términos y condiciones sobre la información registrada de carácter personal.

Recomendación 23. El funcionamiento de la app de salud preserva la privacidad de la información registrada, recoge consentimientos expresos del usuario y advierte de los riesgos derivados del uso de aplicaciones móviles de salud en red.

Recomendación 24. Si la app de salud recoge o intercambia información de salud o cualquier otro dato especialmente sensible de sus usuarios, garantiza las medidas de seguridad correspondientes.

Recomendación 25. La app de salud informa a los usuarios cuando tiene acceso a otros recursos del dispositivo, cuentas del usuario o perfiles en redes sociales.

Recomendación 26. La app de salud garantiza en todo momento el derecho de acceso a la información registrada y la actualización ante cambios de su política de privacidad.

Recomendación 27. La app de salud dispone de medidas para proteger a los menores de acuerdo con la legislación vigente.

1. *Agencia de Calidad Sanitaria de Andalucía. Recomendaciones, confidencialidad y privacidad. [Internet] Sevilla, Agencia de Calidad Sanitaria de Andalucía, Consejería de Salud de Andalucia [citado 5 de febrero de 2019]. Disponible en: http://www.calidadappsalud.com/confidencialidad-privacidad/*

Grado de aceptación de las mHealth

JHQR

Visión ciudadana sobre la prescripción de aplicaciones móviles de salud y el uso de tecnologías de la información y la comunicación en el entorno sanitario en Andalucía

B. Sotillos-González, B. Buiza-Camacho, M. Herrera-Usagre*, Á. Escobar-Ubreva, M.C. Fernández-Bermejo, V. Santana-López y J. Ferrero-Álvarez-Rementería

Agencia de Calidad Sanitaria de Andalucía, Sevilla, España

Material y métodos: Estudio transversal descriptivo encuadrado en el «Barómetro andaluz sobre aplicaciones móviles de salud», basado en encuestas telefónicas a la ciudadanía mayor de edad residente en Andalucía (2016). Muestreo aleatorizado polietápico combinado, afijación proporcional por provincia, tamaño de hábitat, género y grupo de edad. Tamaño muestral: n = 1.069 individuos. Análisis de distribución de frecuencias, tablas de contingencia y test 2 con SPSS.

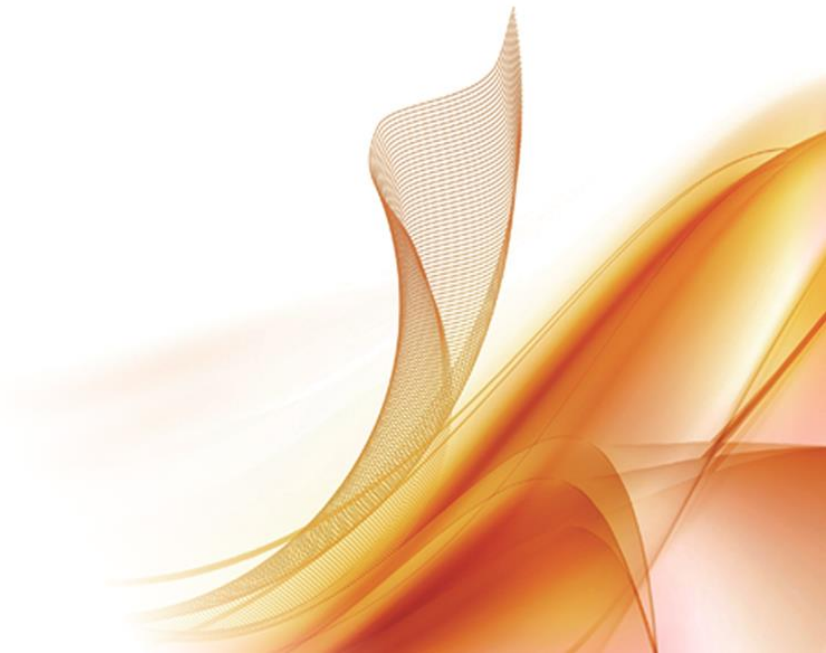
Resultados: Únicamente el 7,6% de la ciudadanía, sobre todo aquella con estudios superiores, se ha comunicado con algún profesional sanitario a través de canales de las tecnologías de la información y la comunicación (TIC). A un 55% de quienes nunca se han comunicado de esta manera les gustaría hacerlo. Solo el 1,3% de la ciudadanía ha recibido recomendaciones sobre aplicaciones móviles de salud por algún profesional sanitario. Del resto, el 73,8% estarían dispuestos a ello. Los colectivos con mayor predisposición para ambas cuestiones son las personas menores de 44 años, estudiantes o con estudios secundarios o superiores finalizados, las personas laboralmente activas, con un estado de salud bueno o muy bueno y sin ninguna enfermedad crónica diagnosticada. No se hallaron diferencias significativas en ninguna de las variables por sexo, tamaño de hábitat o por convivir con personas con discapacidad.

Conclusiones: La utilización de las TIC en la relación profesional-paciente y la recomendación de aplicaciones móviles de salud tienen todavía escasa presencia, pero hay una alta predisposición ciudadana a ellas. Los resultados obtenidos son congruentes con estudios anteriores sobre la influencia de los factores sociodemográficos en el uso y predisposición al uso de las TIC y de las aplicaciones móviles de salud recomendadas.

1. *B. Sotillos-González, B. Buiza-Camacho, M. Herrera-Usagre, Á. Escobar-Ubreva, M.C. Fernández-Bermejo, V. Santana-López, J. Ferrero-Álvarez-Rementería, Visión ciudadana sobre la prescripción de aplicaciones móviles de salud y el uso de tecnologías de la información y la comunicación en el entorno sanitario en Andalucía, Journal of Healthcare Quality Research 2018, Volume 33, Issue 4, 225-233,*

mHealth y Evaluación Económica

Publicaciones e interés de la evaluación económica en mHealth



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Evaluación Económica de mHealth

- **¿Se puede demostrar que las apps en salud son efectivas, eficientes y que pueden mejorar el funcionamiento del sistema sanitario?**
  - Las mHealth como otra tecnología sanitaria
- **¿Se está generando evidencia científica de calidad en el campo de las mHealth?**
  - Variabilidad y falta de homogeneidad en la calidad de las publicaciones.

Las **mHealth** se han considerado generalmente como **herramientas eficientes que producen ahorros**. A pesar de ello, hay **poca evidencia** al respecto[1,2,3]

1. *Kallander K, et al. Mobile health (mHealth) approaches and lessons for increased performance and retention of community health workers in low- and middle-income countries: a review. J Med Internet Res. 2013;15(1):e17.*
2. *Free C, et al. The effectiveness of mobile-health technologies to improve health care service delivery processes: a systematic review and metaanalysis. PLoS Med. 2013;10(1):e1001363.*
3. *Free C, et al. The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review. PLoS Med. 2013;10(1):e1001362.*

Evaluación Económica de mHealth

Telemedicine and e-Health

Original Research

Cost-Utility and Cost-Effectiveness Studies of Telemedicine, Electronic, and Mobile Health Systems in the Literature: A Systematic Review

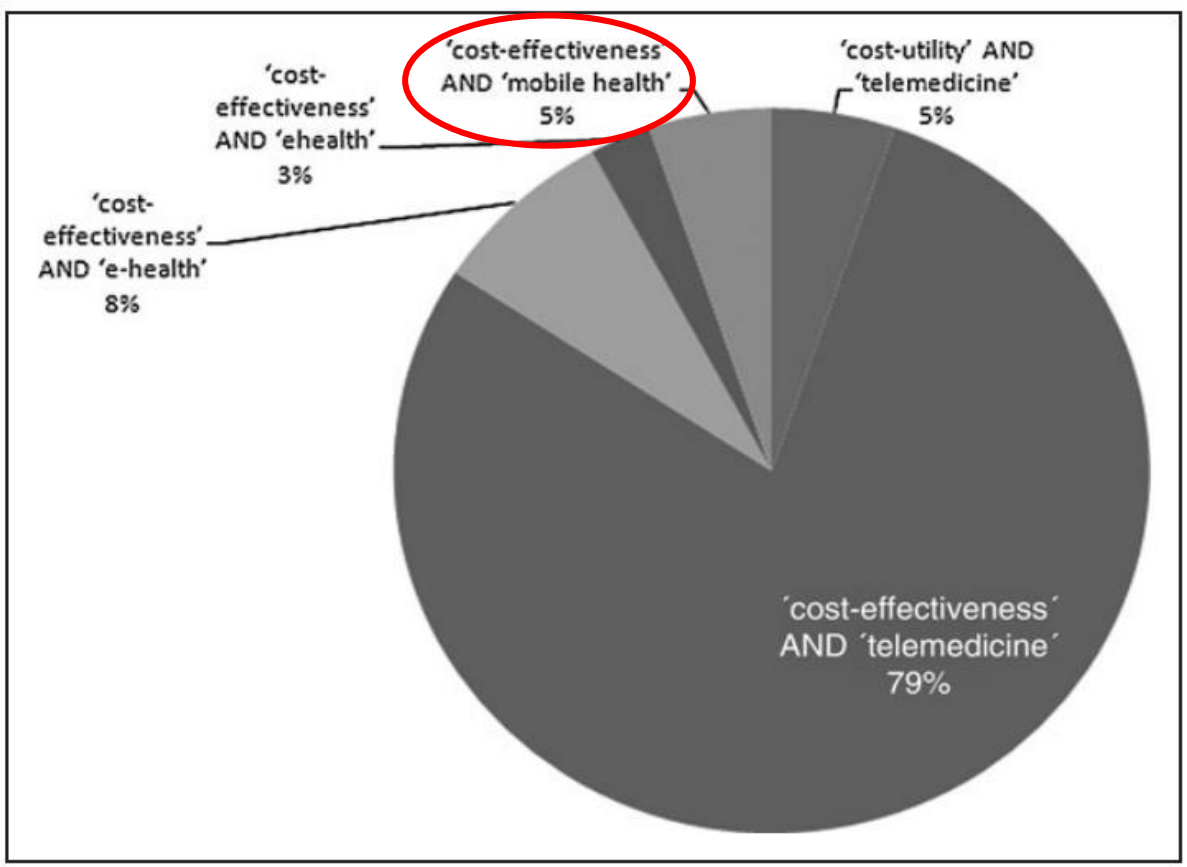
Isabel de la Torre-Díez, PhD,[1] Miguel López-Coronado, PhD,[1] Cesar Vaca, MS,[2,3] Jesús Sáez Aguado, PhD,[2,3] and Carlos de Castro, PhD

Departments of [1] Signal Theory and Communications, and Telematics Engineering, [2] Informatics, and [3] Statistics, University of Valladolid, Valladolid, Spain. [4] Department of Informatics and Numeric Analysis, University of Cordoba, Cordoba, Spain.

"**Conclusions:** There are few cost-utility and cost-effectiveness studies for e-health and m-health systems in the literature. Some cost-effectiveness studies demonstrate that telemedicine can reduce the costs, but not all. Among the main limitations of the economic evaluations of telemedicine systems are the lack of randomized control trials, small sample sizes, and the absence of quality data and appropriate measures.[1]"

1. *de la Torre-Díez I, López-Coronado M, Vaca C, Aguado JS, de Castro C. Cost-utility and cost-effectiveness studies of telemedicine, electronic, and mobile health systems in the literature: a systematic review. Telemed J E Health. 2015 Feb;21(2):81-5. doi: 10.1089/tmj.2014.0053. Epub 2014 Dec 4.*

Evaluación Económica de mHealth



"Future work will evaluate the cost-utility and cost-effectiveness of an m-health application for managing and educating patients with cardiopathies. Different scenarios will be proposed to analyze the cost-effectiveness and cost-utility of this application[1]."

"There may not be many studies about the cost-utility and cost-effectiveness of e-health, m-health, and telemedicine systems because there are confidential studies carried out by private companies and different public health systems, which are not directly accessible to the public[1]."

1. *de la Torre-Díez I, López-Coronado M, Vaca C, Aguado JS, de Castro C. Cost-utility and cost-effectiveness studies of telemedicine, electronic, and mobile health systems in the literature: a systematic review. Telemed J E Health. 2015 Feb;21(2):81-5. doi: 10.1089/tmj.2014.0053. Epub 2014 Dec 4.*

Evaluación Económica de mHealth

PLOS ONE
A peer-reviewed, open access journal

RESEARCH ARTICLE

What is the economic evidence for mHealth? A systematic review of economic evaluations of mHealth solutions

Sarah J. Iribarren[1]*, Kenrick Cato[2,3], Louise Falzon[4], Patricia W. Stone[2,5]

[1] University of Washington, Department of Biobehavioral Nursing and Health Informatics, School of Nursing, Seattle, Washington, United States of America, [2] Columbia University, School of Nursing, New York, New York, United States of America, [3] Office of Nursing Research, EBP and Innovation, New York-Presbyterian Hospital, New York, New York, United States of America, [4] Center for Behavioral Cardiovascular Health, Department of Medicine, Columbia University Medical Center, New York-Presbyterian Hospital, New York, New York, United States of America, [5] Columbia University, School of Nursing, Center for Health Policy, New York, New York, United States of America

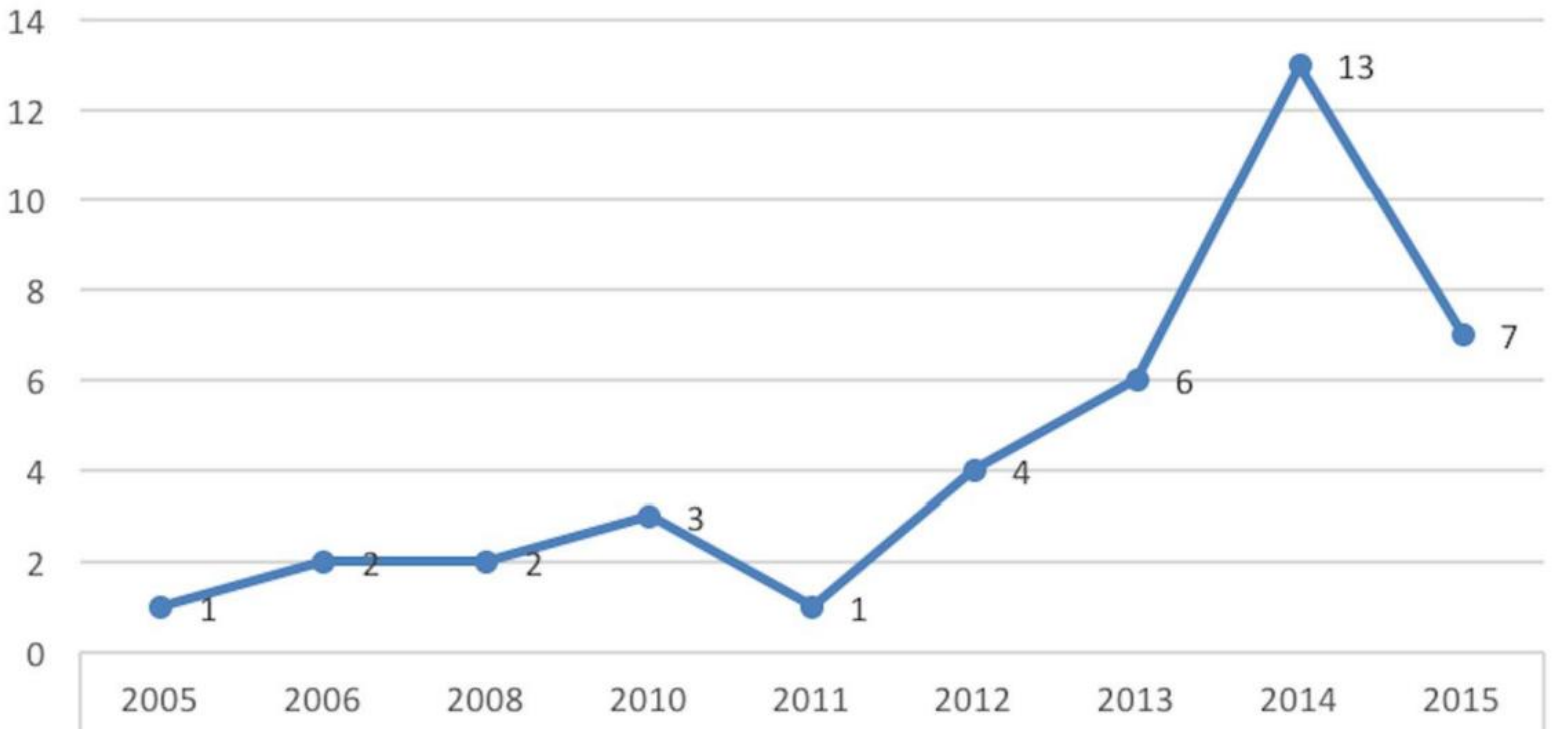
"Methods: Seven electronic bibliographic databases, grey literature, and relevant references were searched. Eligibility criteria included original articles, comparison of costs and consequences of interventions health and economic outcomes and published in English[1]."

"Searches identified 5902 results, of which 318 were examined at full text, and 39 were included in this review[1]."

1. *Iribarren SJ, Cato K, Falzon L, Stone PW (2017) What is the economic evidence for mHealth? A systematic review of economic evaluations of mHealth solutions. PLoS ONE 12(2): e0170581. doi:10.1371/journal.pone.0170581*

Evaluación Económica de mHealth

Fig. Count of economic evaluation article by year.



"Findings highlight a growing body of economic evidence for mHealth interventions. The identified economic evaluations varied by disease or condition focus, economic outcome measurements, perspectives, and were distributed unevenly geographically, limiting formal meta-analysis.[1]"

1. *Iribarren SJ, Cato K, Falzon L, Stone PW (2017) What is the economic evidence for mHealth? A systematic review of economic evaluations of mHealth solutions. PLoS ONE 12(2): e0170581. doi:10.1371/journal.pone.0170581*

Evaluación Económica de mHealth

Study characteristics summary of economic evaluations with reported positive costing outcomes

	n = 39 No(%)	Positive costing outcome within category No(%)
Country		
US	9(23.1)	7(77.8)
UK	6(15.4)	4(66.7)
African Countries (Malawi, Kenya, Uganda, Cameroon)	5(12.8)	5(100)
Other European countries (Sweden, Spain, Switzerland)	4(10.3)	4(100)
Other Countries (Canada, New Zealand, Korea, Mexico)	4(10.3)	1(25)
China	3(7.65)	2(66.7)
Australia	3(7.69)	3(100)
Thailand	2(5.13)	1(50.0)
Malaysia	2(5.13)	1(50.0)
Multi-country study (South Africa, Mexico, Guatemala)	1(2.56)	1(100)
Country by income level		
Upper income country (UIC)	25(64.10)	19(76.0)
Upper-middle-income economies (UMIC)	9(23.08)	5(55.6)
Lower-middle-income (LMIC)	2(5.13)	2(100)
Low income (LIC)	3(7.69)	3(100)
mHealth as primary intervention or component in other interventions		
Primary intervention	35(89.7)	26(74.3)
Component of intervention	4(10.3)	3(75.0)
mHealth type		
Behavior change communication	27(69.2)	20(74.1)
Data collection	7(18.0)	4(57.1)
Service delivery	5(12.8)	5(100)

1. *Iribarren SJ, Cato K, Falzon L, Stone PW (2017) What is the economic evidence for mHealth? A systematic review of economic evaluations of mHealth solutions. PLoS ONE 12(2): e0170581. doi:10.1371/journal.pone.0170581*

Evaluación Económica de mHealth

Study characteristics summary of economic evaluations with reported positive costing outcomes

	n = 39 No(%)	Positive costing outcome within category No(%)
Intervention focus		
Outpatient clinic attendance	7(17.95)	6 (85.7)
Cardiovascular diseases (e.g., Heart failure, hypertension)	5(12.8)	4(80.0)
Diabetes	4(10.3)	3(75.0)
Pulmonary (e.g., asthma, COPD, smoking)	3(7.69)	2 (66.7)
Screening, surveillance (e.g., cancer)	3(7.69)	2 (66.7)
HIV/AIDS	2(5.13)	1 (50.0)
Risk assessment/reduction	2(5.13)	1(50.0)
Obesity	2(5.13)	1(50.0)
Tuberculosis	2(5.13)	1(50.0)
Maternal/child care	2(5.13)	1(50.0)
Mosquito born (Dengue, malaria)	2(5.13)	1(50.0)
Decision support	2(5.13)	2(100)
Physical Activity	1(2.56)	1(100)
Post-surgical f/u	1(2.56)	1(100)
Vaccinations	1(2.56)	1(100)
mHealth related function		
SMS (e.g., reminder, information, support)	22(56.41)	17(77.3)
Mobile application (App)	9(23.1)	5(55.6)
Multiple (e.g., app and SMS, SMS and IVR/wireless devices)	1(2.56)	1(100)
PDA, palm pilot	1(2.56)	1(100)
Sensors (fall, heart, ingestible), digital devices (smoke detector connected to phone)	3(7.69)	3(100)
SMS survey or data collection	3(7.69)	2(66.7)

1. *Iribarren SJ, Cato K, Falzon L, Stone PW (2017) What is the economic evidence for mHealth? A systematic review of economic evaluations of mHealth solutions. PLoS ONE 12(2): e0170581. doi:10.1371/journal.pone.0170581*

Evaluación Económica de mHealth

Conclusions

"In **29 studies (74.3%),** researchers reported that the mHealth **intervention was cost-effective, economically beneficial, or cost saving at base case."**

"A number of the studies were rated as reporting high quality evidence and findings suggest **high rates of reporting positive costing outcomes using mHealth interventions compared with usual care or other comparators."**

"Further research is needed in low and low-middle income countries to understand the impact of mHealth components that contribute most to positive outcomes. The growing number of planned economic evaluations, along with improved reporting and further targeted synthesis of economic evaluations, will help guide policymakers and funders."

1. *Iribarren SJ, Cato K, Falzon L, Stone PW (2017) What is the economic evidence for mHealth? A systematic review of economic evaluations of mHealth solutions. PLoS ONE 12(2): e0170581. doi:10.1371/journal.pone.0170581*

Interés de evaluación Económica de mHealth

METHODOLOGY Open Access

CrossMark

Defining a staged-based process for economic and financial evaluations of mHealth programs

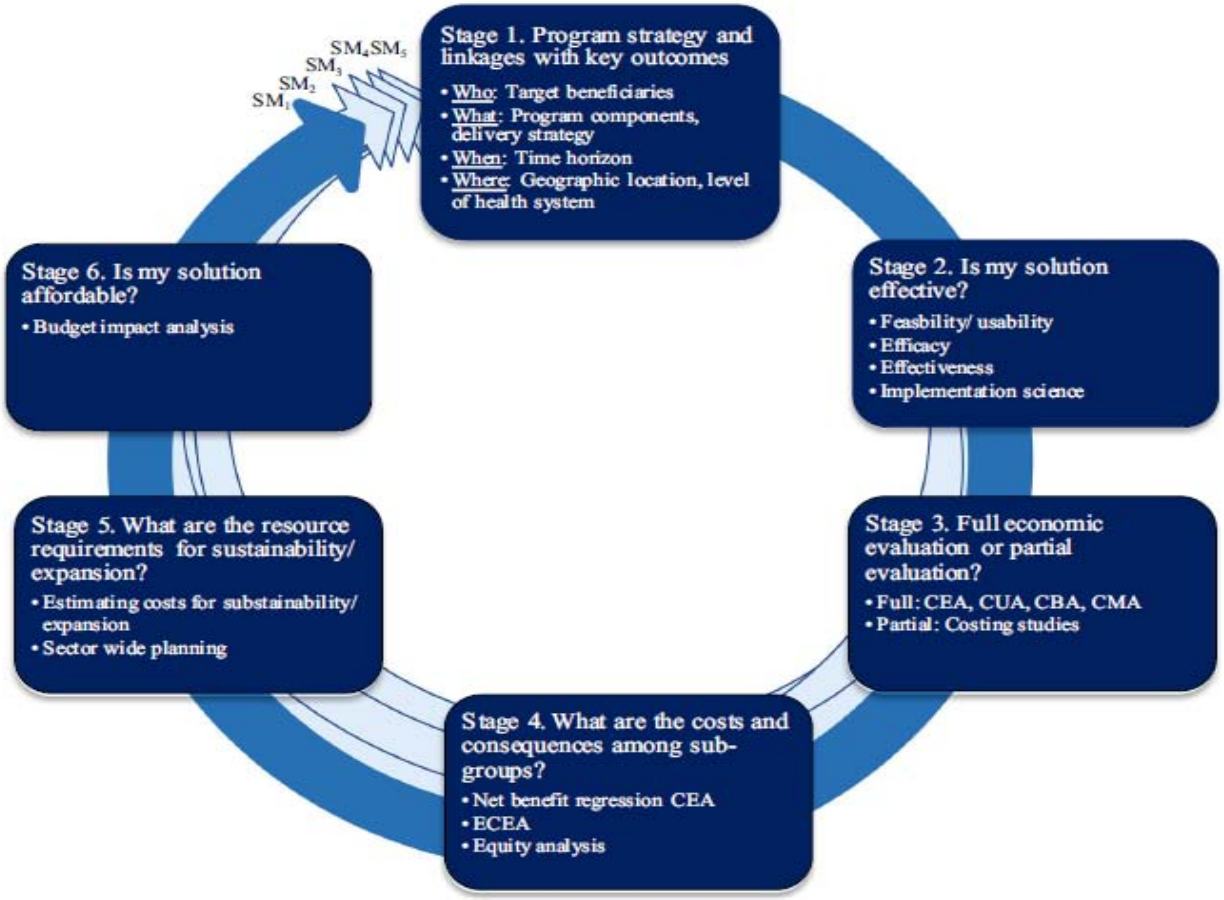
Amnesty E. LeFevre[1,2*], Samuel D. Shillcutt[1], Sean Broomhead[3], Alain B. Labrique[1,2] and Tom Jones[3]

Es necesario **generar evidencia** para catalizar la **progression de intervenciones basadas en mHealth** durante las **distitnas fases de madurez** (SM) de este tipo de tecnología (pre-prototipo, prototipo, pilotaje y fase de escala)[1].

1. *LeFevre AE, Shillcutt SD, Broomhead S, Labrique AB, Jones T. Defining a staged-based process for economic and financial evaluations of mHealth programs. Cost Eff Resour Alloc. 2017 Apr 17;15:5..*

Interés de evaluación Económica de mHealth

- **Proceso por fases óptimo** para integrar las evaluaciones económicas y financieras en intervenciones mHealth[1]



1. *LeFevre AE, Shillcutt SD, Broomhead S, Labrique AB, Jones T. Defining a staged-based process for economic and financial evaluations of mHealth programs. Cost Eff Resour Alloc. 2017 Apr 17;15:5..*

Interés de evaluación Económica de mHealth

- En el proceso de **escalar un iniciativa mHealth**, será necesario cuestionarse sobre la **eficiencia** de la intervención: **relación entre los resultados en salud obtenidos y los costes**[1]

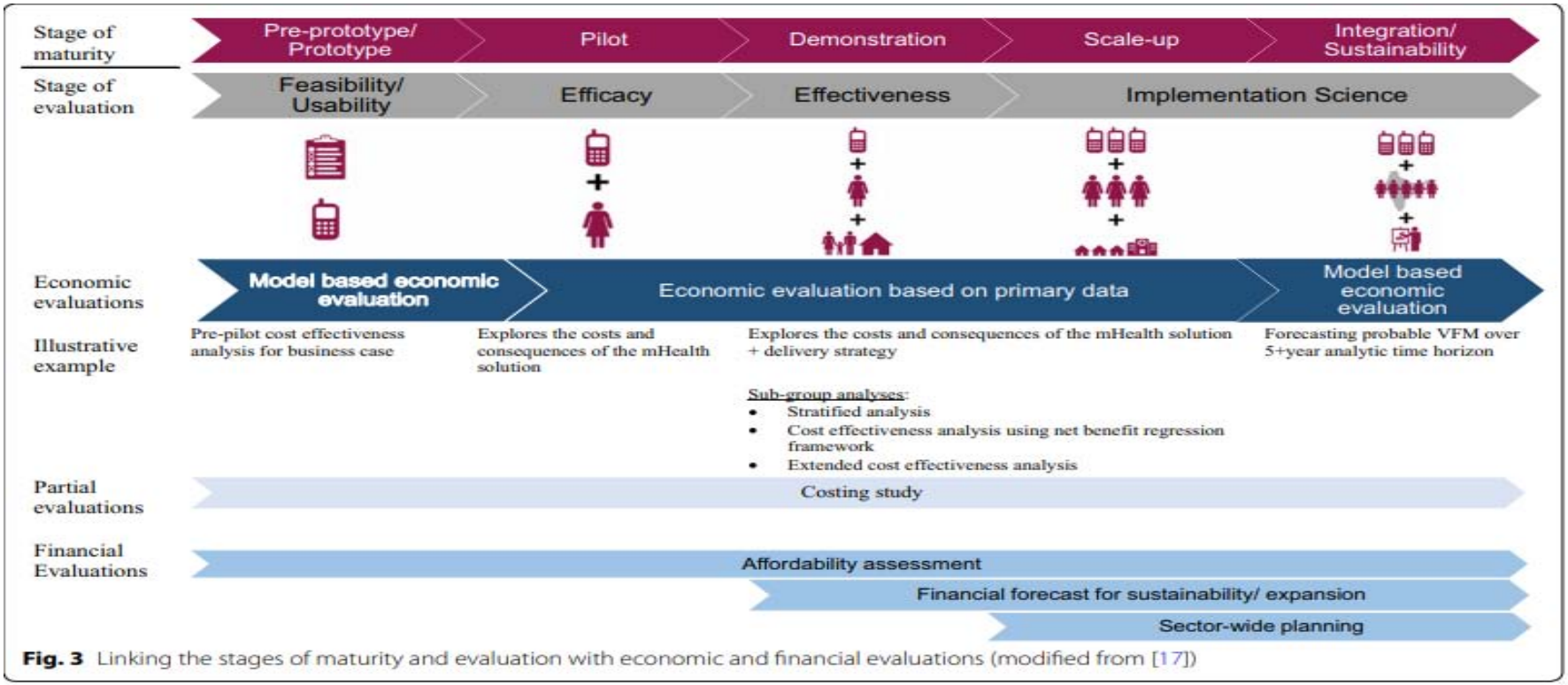


Fig. 3 Linking the stages of maturity and evaluation with economic and financial evaluations (modified from [17])

1. *LeFevre AE, Shillcutt SD, Broomhead S, Labrique AB, Jones T. Defining a staged-based process for economic and financial evaluations of mHealth programs. Cost Eff Resour Alloc. 2017 Apr 17;15:5..*

NICE: estándar evidencia para mHealth

NICE National Institute for Health and Care Excellence

Evidence standards framework for digital health technologies

As digital health technologies develop at an increasing pace, we've worked with partners to develop standards that ensure new technologies are clinically effective and offer economic value.

The aim of these standards is to make it easier for innovators and commissioners to understand what good levels of evidence for digital healthcare technologies look like, while meeting the needs of the health and care system, patients, and users.

We've created these standards as part of a working group led by NHS England. The group also includes:

- Public Health England
- MedCity
- DigitalHealth.London.

NICE National Institute for Health and Care Excellence

NHS England

Public Health England

MEDCITY CAMBRIDGE | LONDON | OXFORD

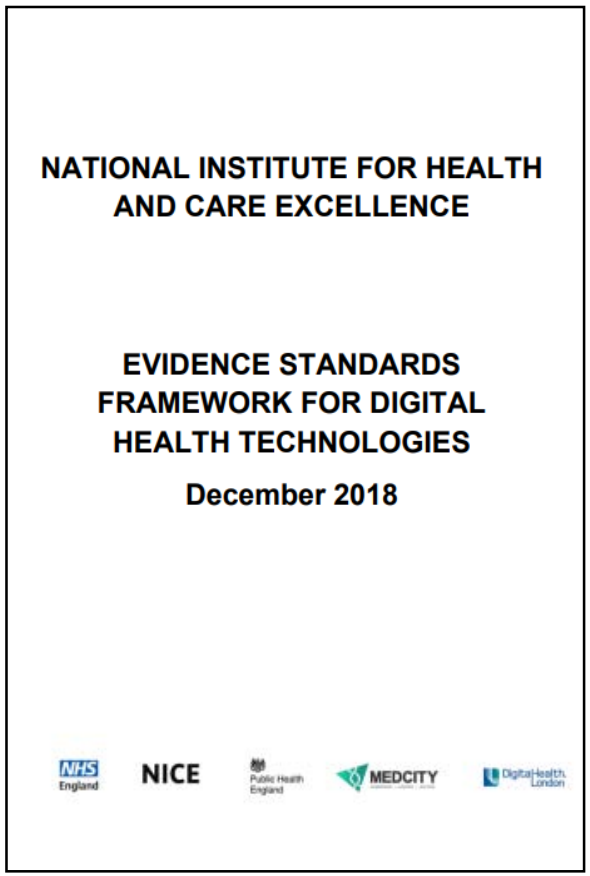
DigitalHealth.London

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

Evidence standards framework for digital health technologies

NICE accredited
www.nice.org.uk/accreditation


NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

EVIDENCE STANDARDS FRAMEWORK FOR DIGITAL HEALTH TECHNOLOGIES

December 2018

NHS England · NICE · Public Health England · MEDCITY · Digital Health London

The aim of the standards

Provide advice to digital health innovators:

- about how the NHS makes decisions
- about the standards of evidence they will be expected to produce for different types of digital technologies.

Help NHS commissioners:

- to make more informed and consistent decisions by providing a framework for the levels of evidence they should expect to see presented to them.

Improve the approach to developing and commissioning digital health technologies:

- by making it more dynamic and value driven, with a focus on offering real value to patients.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

Evidence standards framework for digital health technologies

NICE accredited
www.nice.org.uk/accreditation

The standards

Download the evidence standards framework for digital technologies (PDF)

The evidence standards framework is made up of 2 sections:

1. Evidence for effectiveness for intended use.
2. Evidence for economic impact.

Both parts of the framework have a proportional approach to defining evidence standards. This recognises:

- the sparsity of available evidence in the field of digital healthcare
- the challenges of developing traditional clinical trials for digital health technologies
- the significant opportunities offered by digital health technologies to collect real world data to inform effectiveness judgements.

This work directly supports the relevant principles of the Department of Health and Social Care code of conduct for data-driven health and care technology. We welcome comment and feedback on the standards framework - find out how to do this in the 'tell us what you think' section below.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

2. Evidence for economic impact standards.

NICE accredited
www.nice.org.uk/accreditation

The economic impact standards aim to promote a consistent and streamlined pathway for economic assessment of DHTs. Using the standards will help developers and others to understand the information needed for an economic analysis and potentially increase the capacity for economic analysis across the wider innovation landscape. A better understanding of economic impact should result in more accurate business cases and increasing confidence in investing in DHTs. The standards support the relevant principles in the code of conduct for data-driven health and care technology.

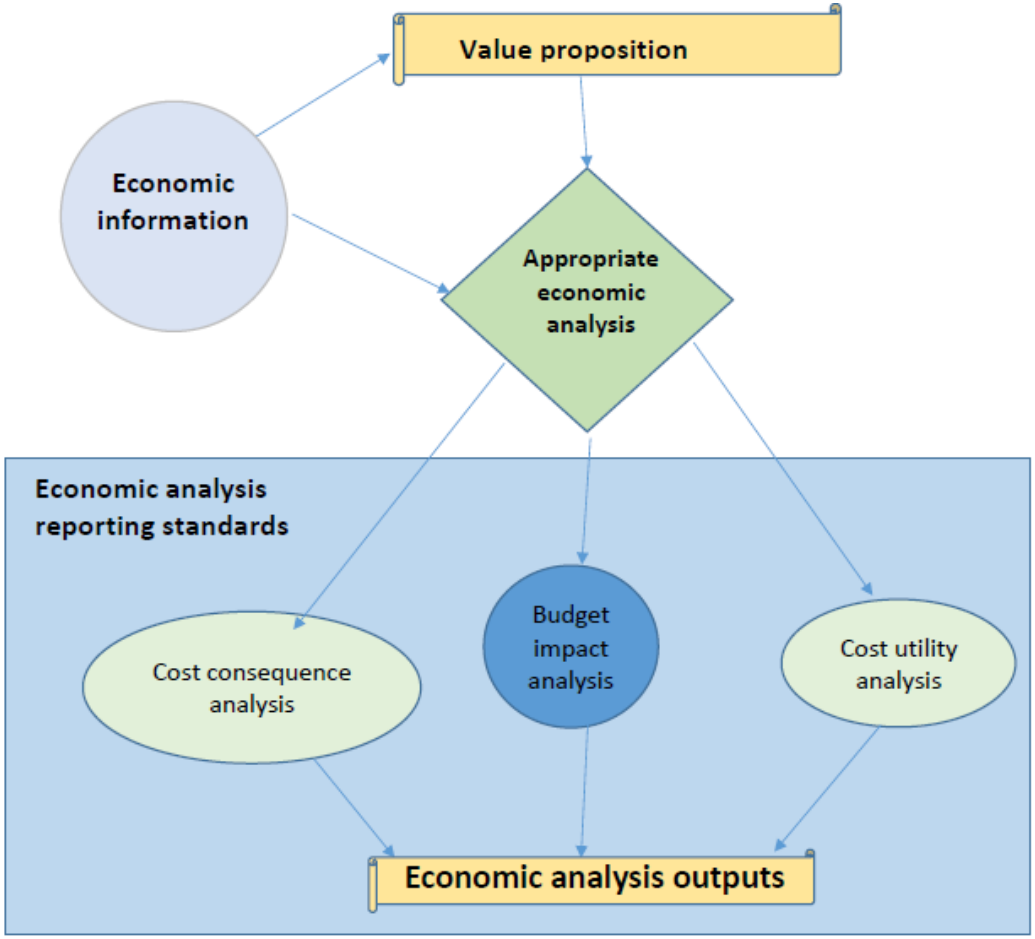
The evidence for economic impact standards are separated into 3 components:

- key economic information (table 7)
- appropriate economic analysis (table 8)
- economic analysis reporting standards (table 9).

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

NICE: estándar evidencia para mHealth

2. Evidence for economic impact standards.



1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

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The economic impact standards aim to promote a consistent and streamlined pathway for economic assessment of DHTs. Using the standards will help developers and others to understand the information needed for an economic analysis and potentially increase the capacity for economic analysis across the wider innovation landscape. A better understanding of economic impact should result in more accurate business cases and increasing confidence in investing in DHTs. The standards support the relevant principles in the code of conduct for data-driven health and care technology.

The evidence for economic impact standards are separated into 3 components:

- key economic information (table 7)
- appropriate economic analysis (table 8)
- economic analysis reporting standards (table 9).

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

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Table 7 Evidence for economic impact standards: key economic information

Key economic information	Component	Standard
User population size.	N/A.	Describe the user population, its size, the expected uptake and the sources for each of these. Note any subgroups with different expected uptake rates and how these may change over time. Demonstrate that the user population size is: • calculated using appropriate and current national or local sources for the target population (for example, accurate epidemiological data of prevalence and incidence of the relevant health problem), or expert estimates if this is not available • calculated using uptake rates from pilot data or other usage data from the developer • validated as a fair representation of what is expected (including any variations by subgroup and over time) by showing approval and support from relevant professionals in the UK health and social care system. Note that NICE's resource impact assessment manuals describe an approach to calculating population size.
Care pathways.	Existing pathway.	Describe the steps in the current care pathway for the relevant population and setting. Use national clinical guidelines, national guidance or academic literature and consultation with healthcare professionals and patients to map out the existing care pathway. If there is no existing care pathway, the impact of adopting the technology should be clearly specified using an approach which can be used as a basis for an economic model. In some cases there may be multiple existing care pathways, each of which should be fully described. Show that the existing care pathway: • is mapped in a comprehensive, detailed and stepwise approach (for example, using a flow chart). • is validated as an accurate representation of current care (that is, it is the most commonly used active intervention) by relevant professionals in the UK health and social care system.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

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Table 7 Evidence for economic impact standards: key economic information

	Proposed pathway.	Describe the steps in the proposed new care pathway or pathways incorporating the DHT intervention for the relevant population and setting. Detail any infrastructure and service-level changes needed to existing pathways and associated systems to implement, operate and maintain the new pathway. Describe any influential contextual issues that may act as barriers or enablers to implementation.
Parameters for the economic model.	Intervention parameters (health and other outcomes from intended use).	Describe the health and other outcomes associated with using the DHT and in current practice. When possible, quantify the uncertainty associated with parameters (for example, with confidence intervals or probability distribution). The best quality evidence available for the impact of the interventions should be used. Sources for health and other outcomes should be as described in the relevant tier of the evidence for effectiveness standards. Evidence syntheses may be needed when there is more than 1 relevant data sources. More robust estimates will be needed for higher financial-risk interventions.
	Cost parameters.	Show that the cost parameters are informed by costs relevant to a health and social care decision-maker. Suitable sources include NHS reference costs or national tariffs. All costs associated with the interventions should be considered.
	Resource use parameters.	Show that the resource use parameters are based on study, pilot or real-world usage data, or on information obtained from relevant clinical or social care professionals or other appropriate sources. Show that the resource use parameters for the existing care pathway are validated as an accurate and comprehensive itemisation of resources currently used (including any variations by subgroup and over time) by evidencing approval and support from relevant professionals in the UK health and social care system. Show that the resource use parameters for the new care pathway are validated as an accurate and comprehensive itemisation of resources necessary and expected to be used in the new care pathway (including any variations by subgroup and over time) by evidencing approval and support from relevant professionals in the UK health and social care system.
	Utilities (when a cost-utility analysis is appropriate).	Show that utility data are measured using an appropriate standard measure, such as the EQ-5D. A rationale for the choice of measure should be provided. Show that the data has been collected in an appropriate way.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

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Table 8 Evidence for economic impact standards: appropriate economic analysis

Financial risk (from a payer perspective, over a specified time period)	Economic analysis standard	Outputs
Low risk	Budget impact analysis.	Estimated yearly budget impact for years 1 to 5, sensitivity analysis results.
	Cost-consequence analysis.	Estimated costs and benefits.
High risk	Budget impact analysis.	Estimated yearly budget impact for years 1 to 5, sensitivity analysis results.
	For DHTs with health outcomes funded by the NHS and Personal Social Services, a cost-utility analysis should be done using NICE's guide to the methods of technology appraisal as a reference case.	Estimated incremental cost-effectiveness ratio, sensitivity analysis results.
	For DHTs funded by the public sector with health and non-health outcomes, or for DHTs that focus on social care, a cost-utility analysis should be done. If this is not possible, a cost-consequence analysis may be acceptable. The analysis should be done using developing NICE guidelines: the manual as a reference case.	Estimated incremental cost-effectiveness ratio, (cost-utility analysis) or estimated costs and benefits (cost-consequence analysis).

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

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Table 9 Evidence for economic impact standards: economic analysis reporting

Component	Standards
Economic perspective	Describe and justify and provide rationale for the perspective used. This should be that of the decision-maker or payer (for example from a UK health and social care system perspective or societal perspective if local authority or public health decision-maker).
Time horizon	Describe and justify the time horizon used. This should be long enough to capture all costs and to account for all health outcomes.
Discounting	Describe and justify whether discounting was used. Discounting can be applied to costs and savings that occur after the initial year using standard UK Treasury recommendations.
Sensitivity analyses	Describe and justify the sensitivity analyses used. Present the results of the sensitivity analyses clearly depicting the main parameters and assumptions that have the largest effect.
Equity analysis	If there are good clinical data to show that the effects differ by demographic factors, include subgroup analyses to show the relevant economic impact.
Descriptions of any additional analytical methods	Describe any analytical methods involved in the economic analysis such as methods for synthesising data from different sources, extrapolating, validating or adjusting data and approaches to using skewed, missing, censored, heterogeneous or uncertain data.
Critique of the economic analysis	Present the strengths and weaknesses of the economic analysis and its generalisability to the local context.

1. *National Institute for Health and Care Excellence (NICE) Evidence standards framework for digital health technologies. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

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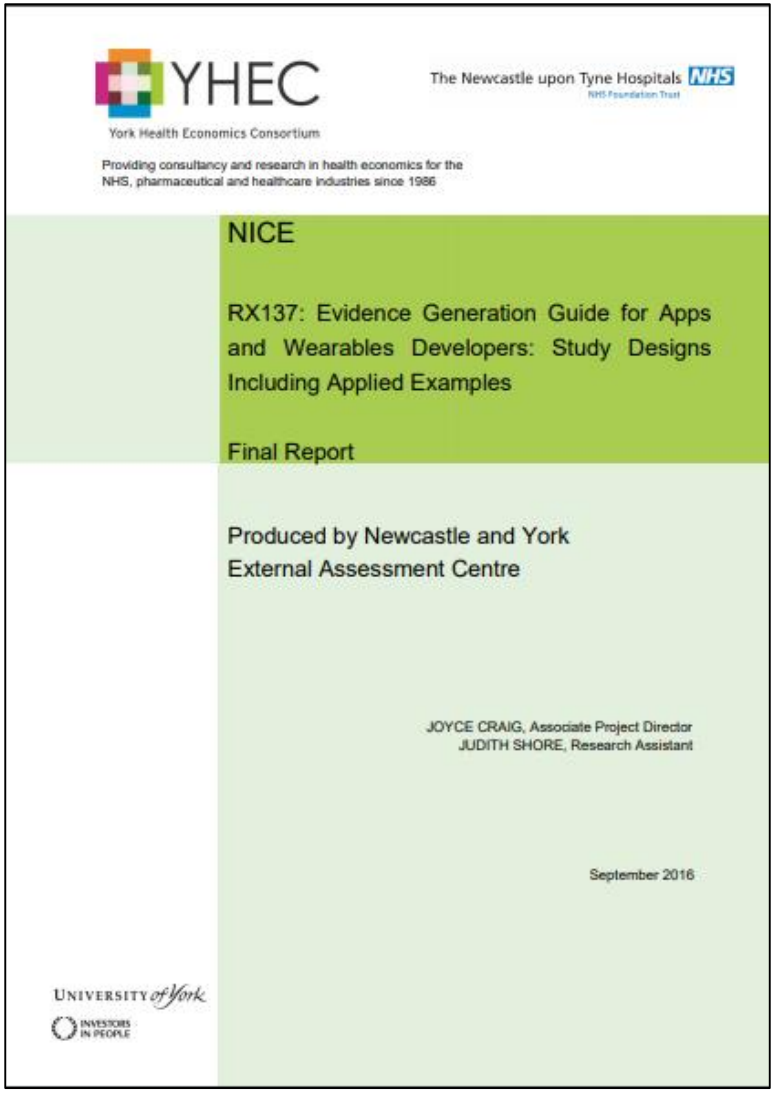

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AIM AND STRUCTURE OF DOCUMENT

"This document **does not prescribe methodologies for specific research questions to address each concern, but is rather part of a larger effort to develop a systematic approach to determining which study designs are best able to address given research questions**. Its aim is to provide information for app and wearable developers and users of evidence, including commissioners, evaluators and the public, to understand the relative strengths and limitations of various research designs and how their use may affect study results and interpretation."

1. *York Health Economics Consortium (YHEC), The Newcastle upon Tyne Hospitals, National Institute for Health and Care Excellence (NICE). Evidence Generation Guide for Apps and Wearables Developers: Study Designs Including Applied Examples [Internet] London, YHEC 2016 [citado 5 de febrero de 2019]. Disponible en: https://www.yhec.co.uk/yhec-content/uploads/2017/03/YHEC-Study-Designs-28.03.17.pdf*

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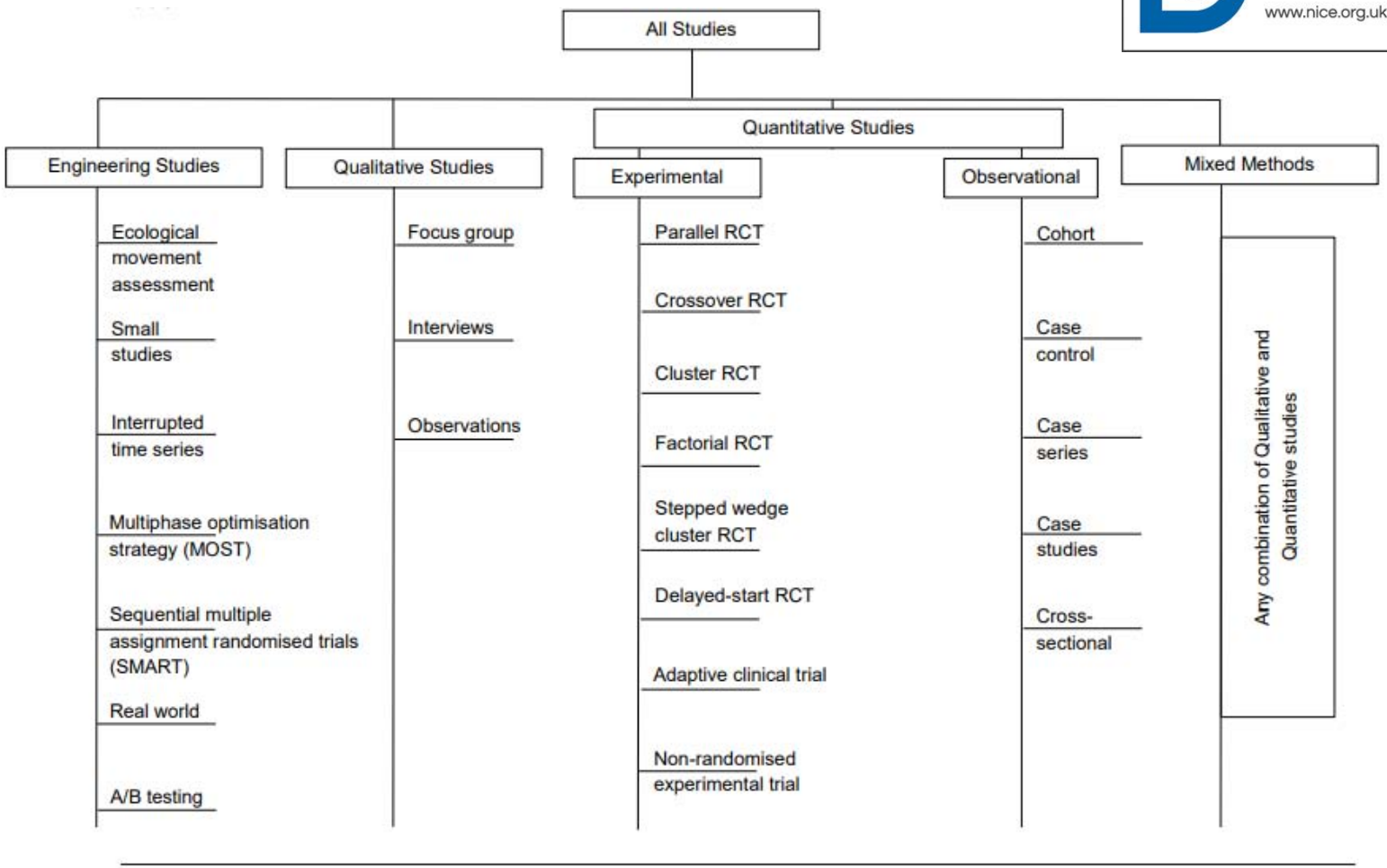
- **Tipos de estudios para generar evidencia en mHealth.**



1. *York Health Economics Consortium (YHEC), The Newcastle upon Tyne Hospitals, National Institute for Health and Care Excellence (NICE). Evidence Generation Guide for Apps and Wearables Developers: Study Designs Including Applied Examples [Internet] London, YHEC 2016 [citado 5 de febrero de 2019]. Disponible en: https://www.yhec.co.uk/yhec-content/uploads/2017/03/YHEC-Study-Designs-28.03.17.pdf*

NICE: MedTech Innovations Briefings

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Medtech innovation briefings

Medtech innovation briefings (MIBs) are NICE advice. They are designed to support NHS and social care commissioners and staff who are considering using new medical devices and other medical or diagnostic technologies.

The briefings will help avoid the need for organisations to produce similar information locally, saving staff time and resources.

The information provided includes a description of the technology, how it's used and its potential role in the treatment pathway.

A MIB also includes a review of relevant published evidence and the likely costs of using the technologies. They are designed to be fast, flexible and responsive to the need for information on innovative technologies.

MIBs are commissioned by NHS England and produced in support of the NHS 5-Year Forward View, specifically as one of a number of steps which will accelerate innovation in new treatments and diagnostics.

MIBs may be authored by one of four external assessment centres (EACs). They are:

- CEDAR external assessment centre
- KiTEC external assessment centre
- Newcastle upon Tyne Hospitals NHS Foundation Trust external assessment centre
- York Health Economics Consortium external assessment centre.

For feedback or requests for more information email: mibs@nice.org.uk.

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More information

Find out how we select topics and prepare the briefings:

Process and methods for medtech innovation briefings PDF 500 KB

More detailed information on MIBs:

Frequently asked questions PDF 500 KB

1. *National Institute for Health and Care Excellence (NICE). Medtech innovation briefings. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

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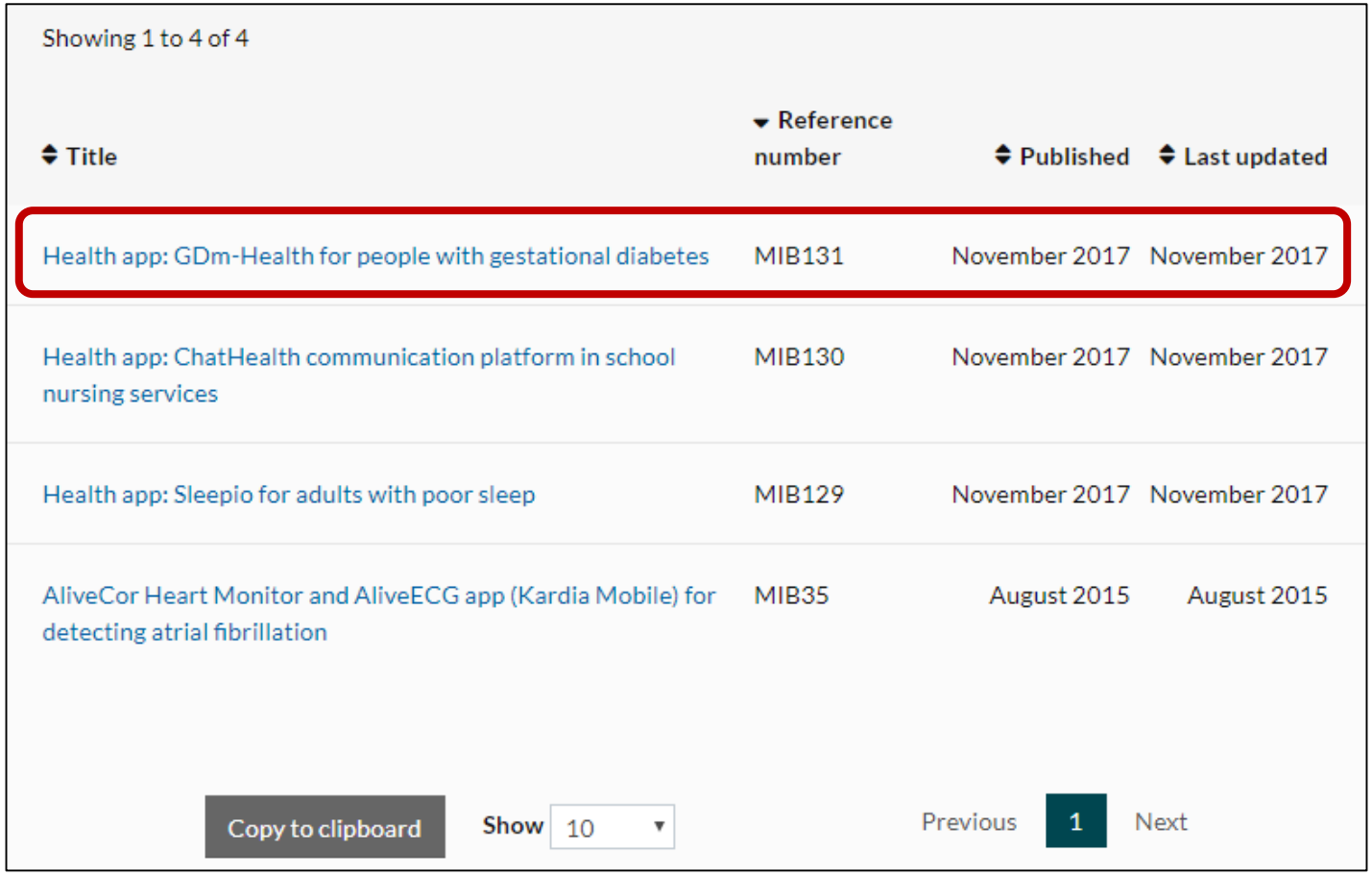

Showing 1 to 4 of 4

Title	Reference number	Published	Last updated
Health app: GDm-Health for people with gestational diabetes	MIB131	November 2017	November 2017
Health app: ChatHealth communication platform in school nursing services	MIB130	November 2017	November 2017
Health app: Sleepio for adults with poor sleep	MIB129	November 2017	November 2017
AliveCor Heart Monitor and AliveECG app (Kardia Mobile) for detecting atrial fibrillation	MIB35	August 2015	August 2015

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1. *National Institute for Health and Care Excellence (NICE). Medtech innovation briefings. [Internet] London, NICE 2018 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies*

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Health app: GDm-Health for people with gestational diabetes

Medtech innovation briefing [MIB131] Published date: November 2017

Overview

Summary

The technology

Evidence on effectiveness

Costs and resource use

Usage and user experience

Specialist commentators comments

Specialist commentators

Development of this briefing

About this app

- GDm-Health is a health application designed for people with gestational diabetes to allow for remote monitoring of blood glucose levels and communication with healthcare professionals.
- The mobile app downloads data from the user's blood glucose meter and sends it to a secure website, which is monitored by healthcare professionals. The website allows midwives to send SMS text messages to patients and record notes on the website for other healthcare staff.
- GDm-Health is free to download and use. Its use may result in efficiency savings from reducing face-to-face clinic appointments.

Evidence summary

- **Clinical effectiveness:** GDm-Health has the potential to have a positive impact for people with gestational diabetes. There is some evidence that the app is a reliable method to communicate blood glucose levels and improves patient satisfaction with their care. However, there is currently no evidence comparing GDm-Health with standard care and so the impact on clinical outcomes is uncertain.
- **Cost and resource impact:** Cost savings may arise from reducing the need for face-to-face appointments but the overall resource impact has not been quantified and is uncertain because of the limited information available. A report by 1 NHS trust suggests cost and resource savings, and other trusts using GDm-Health report more efficient use of staff time.
- **User benefits:** GDm-Health is currently available in 4 NHS trusts. Users report benefits including fewer appointments and greater control over their own care.

1. *National Institute for Health and Care Excellence (NICE). Medtech innovation briefings, Health app: GDm-Health for people with gestational diabetes[Internet] London, NICE 2017 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/advice/mib131*

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Development of this briefing

Table 1 Technology components

Component (first UK launch, version number)	Regulatory status	Cost
GDm-Health iOS/Android app (for patient users). (Not yet available across NHS, used in research since 2012 and as pilot in Oxford since 2014, v4.15).	The developer has stated that GDm-Health does not meet the current eligibility criteria for CE marking as a medical device or for regulation by the Care Quality Commission.	Free to download for patients. Patients must have a compatible device and internet connection.
GDm-Health secure website (for healthcare professionals, v4.15).	As above.	Cost incurring to NHS trusts (licensing and phone provision costs).

1. *National Institute for Health and Care Excellence (NICE). Medtech innovation briefings, Health app: GDm-Health for people with gestational diabetes[Internet] London, NICE 2017 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/advice/mib131*

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- Specialist commentators
- Development of this briefing

Table 2 Summary of evidence

Mackillop et al. (2014)	
Study size, design and location	Cohort study, n=57. Hospital-based maternity diabetes clinic, UK. Pilot for Mackillop et al. (2016).
Intervention and comparator(s)	Intervention: GDm-Health Comparator: none
Key outcomes	In the service development phase, mean weeks of usage was 12.9. 16,534 blood glucose readings were submitted. The overall percentage of blood glucose readings with additional information was 98.3% labelled as a meal, and 15.7% with free text comments. A total of 466 text messages were sent to patients from the website, resulting in 26 medication adjustments.
Strengths and limitations	Beta testing was done in 7 patients and additional functionality was added to the system before testing in a larger patient group. There was high usage and excellent compliance with the system. However, the study used a small sample size, and there was a risk of bias in the sample because patients could choose to use the app. There was also no comparator group. The work was funded by the National Institute of Health Research Biomedical Research Centre Programme.

1. *National Institute for Health and Care Excellence (NICE). Medtech innovation briefings, Health app: GDm-Health for people with gestational diabetes[Internet] London, NICE 2017 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/advice/mib131*

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Table 2 Summary of evidence

Hirst et al. (2015)	
Study size, design and location	User satisfaction survey, n=52. Maternity diabetes clinic, UK.
Intervention and comparator(s)	Intervention: GDm-Health Comparator: none
Key outcomes	Patients reported a high degree of satisfaction with GDm-Health, particularly if they lived far from the hospital or had other commitments. Patients were highly satisfied with system reliability: any problems uploading data were because of poor local network connections rather than with GDm-Health.
Strengths and limitations	This was a validated questionnaire with high completion rates. However, there was a small sample size, possible risk bias in the sample because patients could choose to use the app, and it used only 1 tool to measure satisfaction. It was also non-comparative. The work was funded by the National Institute of Health Research Biomedical Research Centre Programme.

1. *National Institute for Health and Care Excellence (NICE). Medtech innovation briefings, Health app: GDm-Health for people with gestational diabetes[Internet] London, NICE 2017 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/advice/mib131*

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Hirst et al. (2016)	
Study size, design and location	Cohort study, n=49. Maternity diabetes clinic, UK.
Intervention and comparator(s)	Intervention: GDm-Health Comparator: none
Key outcomes	Proportion of births that were large for gestational age, accuracy of blood glucose readings and ability to identify readings with respect to meals were facilitated by GDm-Health. Compared with normal-for-gestational-age babies, large-for-gestational-age babies had higher mean and 2-hour postprandial readings. The odds of delivering a large-for-gestational-age baby increased around 5 times for every 1 standard deviation increase in mean blood glucose and mean postprandial blood glucose (but not fasting blood glucose).
Strengths and limitations	This was not a full publication (letter), had only a small sample size, it was non-comparative, and outcomes did not focus on the effectiveness of GDm-Health. There was also possible risk bias in the sample because patients could choose to use the app. The work was funded by the National Institute of Health Research Biomedical Research Centre Programme.

1. *National Institute for Health and Care Excellence (NICE). Medtech innovation briefings, Health app: GDm-Health for people with gestational diabetes[Internet] London, NICE 2017 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/advice/mib131*

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Technology costs

The GDm-Health app is free to download. It can only be used with a mobile internet connection, which may incur additional costs to the user.

Bluetooth- or NFC-compatible blood glucose monitors and mobile devices can be supplied to patients if needed. However, such monitors may be standard care in some NHS trusts, and many patients will be able to use their own mobile device.

Comparator costs

People with gestational diabetes attend an outpatient clinic every 2 weeks during their third trimester, providing written details of blood glucose measurements in person or by email.

The NICE guideline on diabetes in pregnancy has a supplementary costing statement, which outlines the standard care per-patient costs for monitoring pregnant people with type 2 and gestational diabetes. According to the costing statement, the total cost for monitoring is £386.48 per patient.

1. *National Institute for Health and Care Excellence (NICE). Medtech innovation briefings, Health app: GDm-Health for people with gestational diabetes[Internet] London, NICE 2017 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/advice/mib131*

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Table 3 Estimated technology costs

Component	Cost	Details
Compatible mobile device	£10 to £130.	We expect that 95% or more of users will use their own device. The hospital may provide the additional devices if needed
Phone contract	£5 to £10 per month.	
Hosting for the secure website	Around £2,000 per year for 7 web-based applications (individual clinic systems) £1,143 per year for the current 4 clinics	The website is currently hosted by the Oxford University Hospitals NHS Foundation Trust virtual server facility, which incurs all costs
Security certificate.	£300 every 3 years	
App and website maintenance	Around £41,340 per year	0.5 WTE band 7 scientist (795 hours per year at £52 per hour) Based on an hourly cost of £52 for band 7 community-based scientific staff (PSSRU, 2016)

1. *National Institute for Health and Care Excellence (NICE). Medtech innovation briefings, Health app: GDm-Health for people with gestational diabetes[Internet] London, NICE 2017 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/advice/mib131*

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Potential resource impact

GDm-Health is intended to reduce the frequency of face-to-face appointments, not replace them altogether. Most standard care costs will still be incurred with the use of GDm-Health, but users may need fewer appointments than people having standard care.

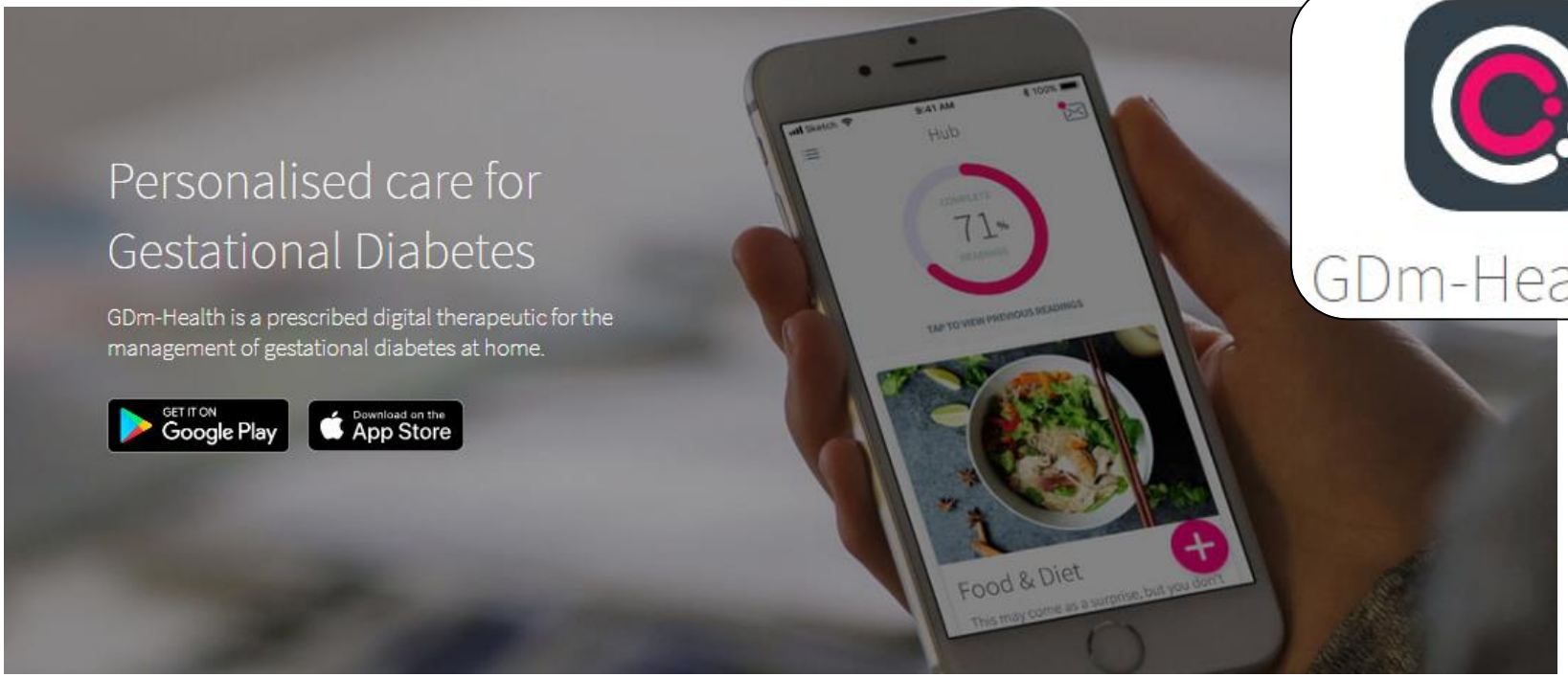
Adopting GDm-Health may need changes to local protocols for managing gestational diabetes. These could include introducing protocols for responding to users, remote monitoring, communication between users and other members of the healthcare team, training and data storage, and management and security. Implementing and managing GDm-Health may need additional staff, such as project management. As a result, the roles of the lead midwife or diabetic specialist nurse may need to change to reflect less face-to-face contact with patients, but more contact through SMS text messages.

Using GDm-Health standardises the way patients record their measurements. Midwives can respond in real time instead of potentially having to wait for data by email. This could lead to shorter face-to-face appointments for users, and therefore less resource use.

There are 4 NHS trusts using the system, at an approximate cost to the Oxford University Hospitals NHS Foundation Trust of £42,583 per year. Based on the costs of standard care, using GDm-Health could save approximately £230 per patient by reducing the need for additional appointments.

1. *National Institute for Health and Care Excellence (NICE). Medtech innovation briefings, Health app: GDm-Health for people with gestational diabetes[Internet] London, NICE 2017 [citado 5 de febrero de 2019]. Disponible en: https://www.nice.org.uk/advice/mib131*

GDm-Health app



NHS

Invented in the NHS

Invented in the NHS for the NHS, as a direct response to a clinical need. Designed by clinicians to be faster than pen and paper.

NHS

NHS Approved

Listed on NHS Digital Apps Libra NICE approval expected imminently.

Reduces Clinic Visit

Self-management, combined remote monitoring, gives pati greater control of their gestati diabetes and reduces the nur of clinic visits.

Increases Accuracy & Speed

Improves the efficiency of the workflow by streamlining the process of communication between midwives and patients.

Secure

Patient data is securely stored on the cloud as a completely isolated instance with HSCN connectivity and rigorous data security and privacy.

Supports Governance

Electronic capture of data enables detailed auditing of care and outcomes while supporting clinical governance.

1. *Sensyne Health. Personalised care for Gestational Diabetes; GDm-Health app. [Internet] OxfordSensyne Health plc. 2018 [citado 5 de febrero de 2019]. Disponible en:https://www.sensynehealth.com/gdm*

GDm-Health app

GDm-Health™

1. Sensyne Health. Personalised care for Gestational Diabetes; GDm-Health app. [Internet] OxfordSensyne Health plc. 2018 [citado 5 de febrero de 2019]. Disponible en:https://www.sensynehealth.com/gdm

Proceso de madurez estrategia mHealth

1. **Validez**
   - ✓ Distintivo/Acreditación

TIC Salut

AppSaludable

2. **Fiabilidad y eficacia**
   - ✓ Verificación de las pruebas de pilotaje con pacientes reales: Testeo de modelos reales

3. **¿Eficiencia para el sistema?**
   - ✓ Evaluación económica….¿pero cómo?

NICE accredited
www.nice.org.uk/accreditation

a) **No evidencia sobre efectividad:** Análisis de costes
b) **Evidencia sobre efectividad**: Análisis coste-efectividad (ACE), coste-utilidad (ACU), minimización de costes…

Proceso de madurez estrategia mHealth

¿Cuáles son las barreras potenciales más importantes en este proceso?

✓ Fiabilidad y eficacia

Testeo de modelos reales

Necesidad de garantizar :

- **Variables de eficacia homogéneas** respecto a potencial comparador
- Pruebas de **pilotaje** en pacientes reales para validar la intervención
- **Muestra** suficiente de pacientes

✓ ¿Eficiencia para el sistema?

Evaluación económica

Necesidad de garantizar :

- Datos de **eficacia/efectividad**. Si los resultados de evaluación económica son parciales (análisis de costes), la utilidad para la toma de decisiones es escasa
- Los inputs en variables de eficacia deben ser suficientemente **robustas** para poder generar resultados de coste-efectividad creíbles.

Proceso de madurez estrategia mHealth

➢ Posibles soluciones: como rellenar el gap de la falta de información sobre eficacia y eficiencia

✓ Fiabilidad y eficacia

Testeo de modelos reales

Valor esperado con información perfecta:

- Valoración de la Influencia de la incertidumbre en los inputs en el valor del resultado final.

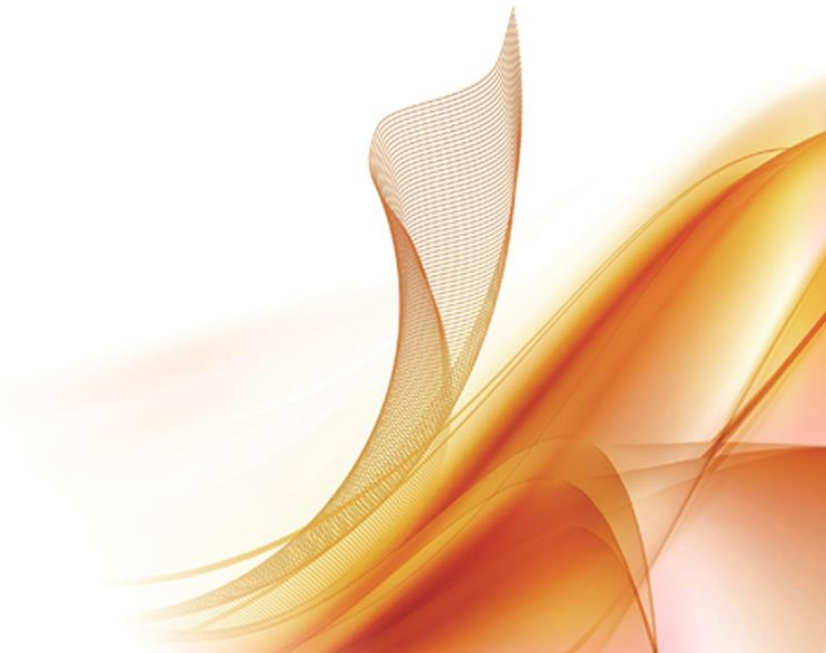
✓ ¿Eficiencia para el sistema?

Evaluación económica

- Proyección del impacto de la implementación de la iniciativa de mHealth en el sistema.
- Modelización mediante modelos de Markov.

Reflexiones finales

El valor de las mHealths



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ISPOR 2018 top 10 HEOR trends: m-Health

Learning how to make better use of mHealth-based data is crucial to sound evaluation of real-world evidence.

From Fitbits to apps like MyFitnessPal, to blood glucose monitors that attach to a smart phone and send readings directly to the patient's health record, to national programs of telehealth and other countrywide telemedicine initiatives, optimism continues to rise about the potential of mHealth (mobile health) to improve patient care in a cost-effective manner. As with most emerging technologies, however, evaluation and refinement can help ensure that mHealth achieves this potential.

The widespread availability of mHealth has begun to generate enormous amounts of real-world data that can be used for the evaluation of mHealth and of more traditional healthcare. These data can be rich and unique, but can also present some challenges. They tend to be less systematic than other data sources, may or may not be easily integrated with other healthcare data for analytic purposes, and can easily be influenced by selective patient use of mHealth, meaning that results may not be generalizable to all patients. Learning how to make better use of real-world data is crucial to sound evaluation in this area.

For all these reasons, ISPOR and the International Society for Pharmacoepidemiology 6 mHEALTH FITBITS, HEALTH APPS, AND THE RISE OF REAL-WORLD DATA established a special joint task force on Real-World Evidence in Healthcare Decision Making Initiative to improve standards and practice for the conduct and reporting of real-world data studies.13,14 As with drugs and other healthcare products and services, evidence about the effectiveness, safety, and cost-effectiveness of mHealth is likely to be desired by clinicians, patients, and payers as they consider adoption and reimbursement of these new technologies. As a result, evaluation of mHealth is a rapidly growing focal point for those involved in health economics and outcomes research.

1. *ISPOR. 2018 Top 10 HEOR Trends. (internet.). [citado 5 de febrero de 2019]. Disponible en https://www.ispor.org/docs/default-source/publications/top10trends.pdf?sfvrsn=e6052ae7_2..*

Reflexiones

- **No existe una normativa clara sobre el marco legal** de las aplicaciones mHealth.
- mHealth son útiles para **optimizar recursos, garantizar resultados en salud y cubrir necesidades asistenciales de los pacientes.**
- mHealth surge como una alternativa de aplicación en el entorno sanitario, siendo una realidad que puede aportar **beneficios para el paciente, el profesional sanitario y el pagador.**
- mHealth tiene un gran potencial de desarrollo. Sin embargo, es necesario **garantizar la calidad y la seguridad** de esta tecnología.
- Aunque su utilización hoy en día es todavía escasa, existe una **alta predisposición a su uso por parte de los pacientes.**

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Muchas gracias por su atención