Health apps: regulation and quality control

Wednesday 19 November 2014, Academy of Medical Sciences
Regulating Health Apps in the EU & US

Julian Hitchcock
AMS-RAE Joint Meeting on Health Apps: Regulation & Quality Control
19 November 2014
Legal stuff - Disclaimer

The information in this presentation is not exhaustive and is provided for information and education purposes only. While every endeavour is made to ensure that the information is correct at the time of publication, the legal position may change as a result of matters including new legislative developments, new case law, local implementation variations or other developments. The information does not take into account the specifics of any person's position and may be wholly inappropriate for your particular circumstances. The information is not intended to be legal advice, cannot be relied on as legal advice and should not be a substitute for legal advice.
Regulation in the US
US Approach

• Device = “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.” [s201(h) Food, Drug & Cosmetic Act (“FDCA”)]

• General rule: if “intended use” of an article (including software) is for medical purpose, then it will be regulated as a device.

• Captures accessories to regulated medical devices, or apps that transform a mobile platform into a regulated medical device.

• But “regulated by enforcement discretion” if “intended use” is general health/wellness (e.g. an exercise cycle) for the able-bodied, then it will not be regulated as a device.

• Classification according to risk.
US Approach

- **Class 1**
  - Lowest risk
  - Usually (but not always) marketed without pre-market review.

- **Class 2**
  - Intermediate risk
  - Manufacturer must file premarket ("510(k)") notification, demonstrating that the article is “substantially equivalent” to an existing Class 2 device.

- **Class 3**
  - Highest risk
  - Usually requires submission of premarket approval ("PMA") application: complex and expensive.
  - Default class!
US Approach

- FDA Guidance – 2013
- Unclear where discretion would be exercised.
- Why regulate apps that merely automate simple and well-understood clinical applications/algorithms to perform basic clinical analyses?
  - E.g. Apgar scoring app: 5 variables each ranging from 0-2!
- Rigid application of the accessory rule
- E.g. blood pressure cuff app: outside MDDS.
The US App Developers’ Problem

- Lack of clarity as to:
  - whether an app is regulated as a device; and
  - what requirements apply if it is so regulated.
- Especially unclear for apps where patient-specific data is entered:
  - Draft Guidance states that some apps that analyse patient-specific data would be regulated, but
  - Gives no guidance on classification
  - The Class 3 default!!
  - Apgar or pain scale apps in Class 3!!
    - Pre-market approval
    - Petition for down-classification
- Prohibitive to many innovative app developers
Other developments

- Congress might take the competence away from FDA...
  - Proposed Software Act
    - "Health s/w", "Clinical s/w" &... "Medical s/w" (= FDA rump)
  - Proposed PROTECT Act
    - Would also deprive FDA of its role re clinical & health s/w
- The line between unregulated wellness and regulated disease claims needs to be cleared up
- Clarification of accessory rule in mHealth necessary
- Clarification of software modules regulation necessary
- Clarification of regulatory pathway
- Transitional regime?
- Not much action on “pharmaceutical apps’ so far – what will happen there?
- Enforcement policy?
Regulation in the EU
No specific app regulations

- Relevant laws, regulations and codes include:
  - Contract & Sale of Goods
  - Confidentiality
  - Negligence
  - *Product Liability Directive 85/374*
  - *General Product Safety Directive 2001/95*
  - *Information Society Technical Standards Directive 98/34*
  - *Electronic Commerce Directive 2000/31*
  - *Privacy & Electronic Communications Directive 2002/58*
  - *Misleading & Comparative Advertising Directive 2006/114*
  - *Bribery Act 2010*
  - *ABHI Code*
Key regulations ... in flux!!

- Active Implantable Medical Devices Directive 90/385
- Medical Devices Directive 93/42
- IVD Devices Directive 98/79
- Data Protection Directive 95/46
- Medical Devices Regulation 2019?
- IVD Regulation 2019?
- General Data Protection Regulation 2019?
Directive 93/42 on medical devices

- “Medical device”: “Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
  - diagnosis, prevention, monitoring, treatment or alleviation/compensation of disease or handicap
  - investigation, replacement or modification of the anatomy or of a physiological process
  - control of conception (art. 1.2a MDD)…”
- General purpose software used in healthcare setting is not medical device (recital 6 Directive 2007/47)
- Accessories to devices are regulated as devices in their own right
Why being a “device” matters

• “Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive when duly supplied and properly installed, maintained and used in accordance with their intended purposes.”

  Art. 2 Medical Devices Directive

  & Art. 2 Active Implantable Medical Devices Directive

• Risk classification
Software becomes a “medical device”...

- Embedded Software
- Stand Alone Software

Must be intended by manufacturer to be used...
Stand alone software

- **Software itself is a medical device, if the intended use is to specifically fulfill one or more medical purposes mentioned in the definition of a medical device.**

- **Software for general purposes is not a medical device, even if it is used in connection with healthcare.**

Stand alone software will be qualified as an IVD or IVD accessory if it satisfies the definition of an IVD or of an accessory to an IVD as set out in Directive 98/79/EC.

“... it is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Stand alone software for general purposes when used in a healthcare setting is not a medical device.”

Recital 6, Directive 2007/47EC
App as medical device

- Check decision trees in MEDDEV 2.1/6 to determine if app is in scope of “medical device”

Regulatory continuum towards medical device regulation

Wellness
- search
- transfer
- move
- store
- display
- count

Medical:
- Diagnostic
- Therapeutic

- trend
- alter
- highlight

- amplify
- analysis
- interpret
- alarms
- calculates
- controls
- converts
- detects
- diagnose
- measures
- monitors
MHRA Guidance 2014

Guidance on medical device stand-alone software (including apps)

The following guidance is for healthcare and medical software developers who are unsure of the regulatory requirements for CE marking stand-alone software as a medical device.

**Introduction**

Many manufacturers, software developer, academics, clinicians and organisations are using software for both healthcare and social care needs.

This guidance explains how this technology is regulated. It covers stand-alone software (also known as software as a medical device) but not software that is part of an existing medical device because this seen to be part of the device, eg software that controls a CT scanner.

**Key points and existing guidance**

**Stand-alone software**

Software which has a medical purpose which at the time of it being placed onto the market is not incorporated into a medical device.

**Intended purpose**

Regulation of medical devices is limited by the intended purpose as defined by the manufacturer. This will include claims given in promotional materials for the device, eg brochures and webpages.

**Medical purpose**

Software that has a medical purpose could be a medical device. A medical device is defined in the medical device Directive (MDD) as:

“software... intended by the manufacturer to be used for human beings for the purpose of:
Apps & Data Protection

• “Personal data”
  - “data which relate to a living individual who can be identified (a) from those data, or (b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller”.

• “Sensitive personal data”
  - class of personal data containing information as to (e.g.) “racial or ethnic origin of the data subject” and “physical or mental health or condition”.

• Conditions
  - Data subject must explicitly consent to the processing of his personal data (or much harder alternatives).

• Export of personal data... “adequate level of protection”.

Personal data?

Collecting and processing data may give rise to personal data processing and related obligations.

- Criterion: information is related to data subject that are identified or identifiable, whether directly or indirectly

- related to: “data relates to an individual if it refers to the identity, characteristics or behaviour of an individual or if such information is used to determine or influence the way in which that person is treated or evaluated” (WP136)
Personal data?

- Identifiable: “to determine whether a person is identifiable account should be taken of all the means likely reasonably to be used either by the controller or by any other person to identify the said person.” (WP136)

- Not identifiable if [clinical trial example]: “serial numbers attributed randomly to each clinical case, in order to ensure coherence and to avoid confusion with information on different patients. The names of patients stay exclusively in possession of the respective doctors bound by medical secrecy.” (WP 136)
Processing of personal health data

• Health data is special category of data - processing prohibited UNLESS

• Consent: “...any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed”. Special data? Explicit consent required (see article 29 WP Opinion 15/2011).

• Consent obtained in clinical context valid? Consent to treatment = consent to processing data?
General Data Protection Regulation?

GDPR Proposal released on 25 January 2012

- Informed consent and burden of proof it was obtained
- Privacy by design – software & devices have to be designed and built as to enable GDPR and data subject’s rights by default
- EU delegated acts to specify technical standards related to GDPR requirements
- High fines (up to 2% annual WW turnover)
- Privacy officers mandatory for large companies
- Privacy impact assessment mandatory for each act of processing
GDPR – important definitions

- Article 4 (10) “genetic data”
  “all data, of whatever type, concerning the characteristics of an individual which are inherited or acquired during early prenatal development”

- Article 4 (12) “data concerning health”
  “any information which relates to the physical or mental health of an individual, or to the provision of health services to the individual”

Clarification is needed around ‘genetic data’ and ‘data concerning health’ to ensure that these definitions are only intended to apply to personal data that falls within these categories, rather than all related data.
Genetic data
- "Special category" requiring permission or art. 83 exemption

Biometric data
- "Specific risk group" for purpose of impact assessment

Data concerning health
- "Special category" requiring permission, art. 81 or art. 83 exemption
- "Specific risk group" for purpose of impact assessment
GDPR – processing of personal data

Processing of genetic data or data concerning health (article 9)

- only with consent; OR
- processing of data concerning health is necessary for health purposes and subject to conditions and safeguards (Article 81); OR
- processing is necessary for historical, statistical or scientific research purposes subject to conditions and safeguards (Article 83)
- controller has burden of proving that the data subject has given the consent to the processing operation
- consent is not a valid legal ground for the processing of personal data, where there is a clear imbalance between the data subject and the controller (likely: HCP / patient relation)
GDPR - anonymisation

• Anonymous data falls outside of the scope of the Regulation. However, the act of removing identifiers to ensure that data are no longer personal – anonymisation – could fall within the definition of processing (Article 4).

• Not clear about how ‘personal data’ relates to the different types of data used in research and data collection for meeting regulatory obligations (registry, PMCF studies) – anonymised data; key-coded or pseudonymised data; and identifiable data

• Clarity in the scope is essential so that those sharing and using patient data in research and to meet regulatory obligations are fully aware of their responsibilities, but do not implement beyond the requirements that are necessary in law
GDPR – profiling

Profiling (Article 20)

Limits to "profiling", a technique used to analyse or predict a person's performance at work, economic situation, location, health, preferences, reliability or behaviour based on the automated processing of his/her personal data.
GDPR – right to erasure

• The right to withdraw consent and right to erasure (Article 17 GDPR)

Difficult to implement if data is stored in archived backups

• Real risk that statistical analyses will be “depowered” as a result of such changes as result of exercise of rights (particularly in the case of orphan diseases or conditions with difficult inclusion and exclusion criteria, such as paediatric), thereby calling into question existing registrations (let alone future developments).

(Result:- clinical trials and clinical investigations will be conducted outside Europe to avoid any such risk.)
Medical Devices Regulation (MDR)

- **Medical Device**: “any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific direct or indirect medical purposes of... diagnosis, prevention, monitoring, prediction, treatment or alleviation of disease.”

- **Accessory**: “an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the device(s) to be used in accordance with its/their intended purpose(s); or to specifically assist the medical functionality of the medical device(s) in view of its/their intended purpose(s)”

- Medical Devices and Accessories are referred to as “devices”.

MDR: “Information Society Services”

- Includes devices and accessories that are offered to natural or legal persons in the EU by means of services that is “normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services”.
  - “At a distance” means that the service is provided without the parties being simultaneously present.

- Devices used in medical examinations or treatment at a doctor's surgery using electronic equipment where the patient is physically present are not deemed to be used in an “information society service” but will be caught by other provisions of the MDR.
IVD Regulation

- **IVD** includes “apparatus, equipment, *software or system*, whether used alone *or in combination*, intended by the manufacturer to be used *in vitro* *for the examination of specimens*... solely or principally for the purpose of providing information:
  - concerning a physiological or pathological state;
  - concerning a congenital abnormality physical or mental impairments;
  - concerning the predisposition to a medical condition or a disease;
  - to determine the safety and compatibility with potential recipients;
  - to predict treatment response or reactions;
  - to define or monitor therapeutic measures.”
IVD Regulation

- Digitisation of the information for later analysis *in silico*...?
- Bioinformatics: later analysis is inherent. Invariably, such systems are used "*in combination*" with primary devices for acquisition: mere sequencing.
- Sequencing *per se* merely: it endeavours to confirm sequences of nucleotide bases. It’s an assay, not a test.
- Interpretation is what happens downstream, at a time when the specimen itself may have been discarded.
- **Intention**: if the manufacturer of the acquisition apparatus intends it to be used "*in combination*" with the bioinformatic system, then does that other system become an "accessory to an in vitro medical device" and, therefore, susceptible to the Regulation?
IVD Regulation

- **“Accessory”** to an IVD: “an article which..., is intended by its manufacturer to be used together with one or several particular IVDs to specifically enable or assist the IVD to be used in accordance with its/their intended purpose(s).”

- **“Device for self testing”**: “any device intended by the manufacturer to be used by lay persons, including testing services offered to lay persons by means of information society services.”

- **“Companion diagnostic”**: “a device specifically intended and essential for the selection of patients with a previously diagnosed condition or predisposition as suitable and unsuitable for a specific therapy with a medical product or a range of medicinal products.”

- **“Device for genetic testing”**: “an IVD the purpose of which is to identify a genetic characteristic of a person which is inherited or acquired during prenatal development.”
IVD Regulation

• Art 1(6): “Direct to consumer advertising of devices classed as prescription only by this Regulation shall be illegal.... The following devices may only be supplied on a medical prescription.... Devices for genetic testing; companion diagnostics.”

• Potential obstacle to apps that are accessories to bioinformatic systems.
Art 4a (genetic information, counselling & informed consent)

- A device may only be used for the purpose of a genetic test if the indication is given by persons admitted to the medical profession under the applicable national legislation after a personal consultation.

- A device may be used for purposes of a genetic test only in a way that the rights, safety and well-being of the subjects are protected and that the clinical data generated in the course of the genetic testing are going to be reliable and robust.

- Information. Before using a device for the purpose of a genetic test the person mentioned in paragraph 1 shall provide the person concerned with appropriate information on the nature, the significance and the implications of the genetic test.
Art 4a (genetic information, counselling & informed consent)

• **Genetic counselling.** Appropriate genetic counselling is mandatory before using a device for the purpose of predictive and prenatal testing and after a genetic condition has been diagnosed. It shall include medical, ethical, social, psychological and legal aspects and has to be addressed by physicians or another person qualified under national law in genetic counselling. The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of his or her family.

• **Consent.** A device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The consent has to be given explicitly and in writing. It can be revoked at any time in writing or orally.
GDPR/MDR/IVD Regulations
Will they happen?

2 April 2014: European Parliament:

- “Adopts as its position at first reading the text adopted on 22 October 2013”
- “Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;”

- New Commission
- Responsibility passes from DG SANCO to DG ENTERPRISE
- New Rapporteur for MDR.
- Same Rapporteur for IVD Reg.
- IVD Reg: constitutional?
Changing context

- Portability
- Cloud computing
- Big data
- Bioinformatics
Thank you for your attention!

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NHS Health Apps
– evaluating safety of health apps

Dr Maureen Baker CBE DM FRCGP
Chair of Council RCGP

Inderjit Singh
Head of Enterprise Architecture
NHS England
Declaration of Interests (MB)

• Strategic Safety Adviser to HSCIC
• Previously Clinical Director of Patient Safety HSCIC (NHS CFH)
• Led development of NHS ISB safety standards (ISB 029 and 060)
• Led development of safety assurance methodology on NHS Choices Apps Library
HSCIC Safety Team

• Clinical Safety Officers (registered clinicians trained in principles of safety and risk as applied to Health IT

• Safety Engineers (background in safety critical industries – aerospace, defence, rail)
Apps for the public – what the users said?

Citizen

“Where do I find health apps that can help me”

“Are these apps safe?”

“Don’t need another app store”

“Supplemented but not just based on patient ratings”

Clinicians

“Would like somewhere to be able to signpost “

App Developers

“How can people find my app easier”

“I want rigour in the review process”

“Don’t just want any app included”

“Don’t want an overly cumbersome process”

“Not valuable if not safe”
Health Apps Library

Safe and trusted apps to help you manage your health

Welcome to the Health Apps Library

- Discover apps to help you manage your health
- Reviewed by the NHS to ensure they are clinically safe
- Rated by you and the health care community

Latest apps

- MyDirectives
  - Decision aids
  - Not yet rated
  - Free

- The Immunisation App
  - Drugs
  - Not yet rated
  - Free

- Headache Diary
  - Manage your health
  - 3 stars
  - Paid

- Mindlogr
  - Manage your health
  - 5 stars
  - Free

- FibroMapp
  - Body parts
  - 3 stars
  - Paid

- Whizz-Kidz mobile
  - Service information
  - 3 stars
  - Free
App Submission process

Step 1. Submit –
Developer submits an app

Step 2. Initial triage
Apps Team review the supplied information to check what the app does

Critical step in the safety process - An initial triage checklist is completed on each App and its function. Does it pose any harm to patient safety?

If Yes to Step 2 – Safety Assurance is required. Evidence of compliance with the Safety Standard – ISB0129

Step 3. Clinical Review
Safety Engineer and Clinicians review the app where required.

Step 4. Yes or No
The app is approved and published or rejected due to not meeting our criteria

Step 5. On-going Review
The app listing is reviewed on a regular basis and if a user flags concern to us
App Triage - Is the App a Medical Device?

The review process has been structured in a way to determine an App's function, type of service it delivers.

First and foremost – Section 1 of HSCIC triage process aims to establish whether or not an App is eligible to be a medical device.

Where ISB0129 does NOT apply as the App is a Medical Device.

Example questions from the triage checklist in order to determine if the App falls under the requirements of a Medical Device.

• CE marked?

• functions include control or monitoring of a Medical device?

• response time is time critical to patient care?

Note: Answering yes to one or more of the above suggests the App may be a medical device (or a part of). Seek MHRA advice www.mhra.gov.uk
App Triage – Categorisation of App Function?

Triage Section 2 - Establishing the categorisation of the software / function e.g.:

- Informational application?
- Calculation and / or monitoring application?
- Transactional application, to support booking appointments or repeat medication?
- Decision Support application?

Look to clarify if an App falls under requirements of ISB0129 Clinical Risk Management: Its Application in the Manufacture of Health IT.
App Triage – Applicable to ISB0129? Yes

When safety assurance is required under ISB0129.

Example question from the triage checklist.

- provides Clinical decision support based on user input for treating or diagnosing a specific disease or disorder
- integrates with other Health IT systems
- is a transactional system (e.g. supporting appointment booking)

E.g. Apps providing, access to the patients GP Health IT system, medication dosage calculators, prescribing.
App Triage – Applicable to ISB0129? No

When safety assurance is NOT required under ISB0129.

Example questions from triage checklist.

- if the App is NOT integrating with other Health IT systems
- solely automates general office functions to assist in payments and billing etc
- performs calculations / monitoring of general health and wellbeing with no Clinical support
- provides information from a reputable organisation

E.g. Healthy life style apps that presents information to the user, or user records and monitors own diet, weight.
What is required under ISB0129

Manufacturer’s evidence of ‘Clinical Risk Management’

- Risk Analysis
- Risk Evaluation
- Risk Control
- Delivery, Monitoring and Modification

Note: Clinical Risk Management runs throughout lifecycle
Apps Figures

Total Apps Submissions 246

- Approved: 174
- Invalid submission: 34
- Outstanding: 38

Approved Apps Safety assessments (174)

- ISB 0129 Not applicable: 150
- ISB 0129 Compliant: 24
Where next?

Move from informational only apps to a set of transformational apps aligned to key health priorities

- Online Care Planning for Dementia integrated with GP system
- Online Test Results and Care Planning
- Online Care Planning for Long Term Conditions integrated with GP system
- GP appointment Booking/repeat meds
- Supporting Older People and Carers
- Supporting Young People with Sexual and Mental Health
- Online Redbook for new parents
- Internet Radio App
- Supporting Older People and Carers
Next steps – “kitemark”

• The NIB Framework introduces the concept of a “kitemark”

• Need to consider different dimensions – safety, evidence base etc

• Build upon existing thinking - clinical safety review and also existing regulatory frameworks i.e. medical devices directive

• Need to identify different areas of consideration and key stakeholder groups
Evaluating the cost-effectiveness of healthcare apps

Bernice Dillon
Medical Technologies Evaluation Programme
Outline

- About NICE
- How NICE considers value
- Medical Technologies Evaluation Programme (MTEP)—how it works
What NICE does

NICE's role is to improve outcomes for people using the NHS and other public health and social care services. We do this by:

• **Producing** evidence based guidance and advice for health, public health and social care practitioners.

• **Developing** quality standards and performance metrics for those providing and commissioning health, public health and social care services.

• **Providing** a range of informational services for commissioners, practitioners and managers across the spectrum of health and social care.
NICE guidance and information programmes
NICE’s medtech activities

• Easy access
  – Single access point - MTEP
  – Single route of publication: NICE Pathways

• Guidance
  – Interventional Procedures (regulatory)
  – Medical Technologies
  – Diagnostics
  – Technology Appraisals

• Evidence generation
  – Scientific Advice Programme
  – Research facilitation after guidance research recommendations

• Medtech Information Briefings

• Support for implementation
What do decision makers need to know about new technologies?

- Incremental benefit for patients
- Impact on health system resources
- Fit with health system priorities

Product value
NICE’s assessment of value

• Standard clinical evidence and health economic techniques
  – Clinical evidence – systematic reviewing and meta-analysis, linked evidence approaches etc
  – Health economics – modelling, sensitivity analysis etc

• World class academic assessment groups and external assessment centres

• Regular review of technical methods with stakeholders

• Further development of technical methods (e.g. MRC funded activities)
Medtech evaluation encompasses NICE’s core principles

- Based on the best evidence available
- Expert input
- Patient and carer involvement
- Independent advisory committees
- Genuine consultation
- Regular review
- Open and transparent process
# Medical Technologies Evaluation Programme (MTEP) bespoke design (1)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Programme design and operational features</th>
</tr>
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<tbody>
<tr>
<td>The relatively sparse evidence base for medical technologies by comparison with, for example, pharmaceuticals</td>
<td>All forms of evidence (published and unpublished and with no design or quality threshold) are considered. Further evidence generation facilitated by NICE for promising technologies with guidance recommendations for further research</td>
</tr>
<tr>
<td>Medical technologies evolve at a rapid pace</td>
<td>Short timelines. 10 weeks from notification to selection, 38 weeks from selection to guidance development</td>
</tr>
<tr>
<td>Medical technology products are usually promoted to the NHS with specific claimed benefits when used in place of or addition to standard care</td>
<td>The sponsor’s case for adoption drives the initial assessment and, if selected, evaluation of the product to simulate NHS decision-making. Clear and explicit value propositions are required from the sponsor before a decision is taken to evaluate</td>
</tr>
<tr>
<td>Medtech products are often claimed to be resource-releasing and more convenient.</td>
<td>System benefits are given equal prominence to patient benefits and sustainability benefits are identified and actively considered.</td>
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### Medical Technologies Evaluation Programme (MTEP)

**bespoke design (2)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Programme design and operational features</th>
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<tbody>
<tr>
<td>The medical technology industry is large and diverse with a high rate of output of innovative products</td>
<td>Innovators (usually a commercial sponsor, i.e. Manufacturer or distributor) notify their products directly to NICE so that as wide a range of products as possible can be considered.</td>
</tr>
<tr>
<td>Improving the efficiency of health services is a top policy priority</td>
<td>Medical Technologies Guidance specifically examine products which are plausibly resource releasing and the primary economic methodology used is cost-consequences analysis which gives an estimate of the saving per patient if the case for adoption is supported by the evidence.</td>
</tr>
<tr>
<td>Innovative products may be slowly and/or unevenly adopted</td>
<td>Products which are novel but not new can be notified and may be evaluated if there is evidence that they have plausible claimed benefits and are not being routinely adopted.</td>
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<tr>
<td>Technical considerations (safety, compatibility, procurement, maintenance, calibration, training, upgrades) can significant influence clinical utility</td>
<td>Access to world-leading technical expertise to commission bespoke studies to answer specific questions which are relevant to the assessment clinical or cost utility.</td>
</tr>
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MTEP overview – selection and routing

**Engagement**
- General process
- Product specific considerations

**Notification**
- Sponsor makes notification via NICE website
- MTEP team assesses eligibility of product to be notified
- MTEP prepares Briefing Note

**Selection and routing**
- MTAC selects for guidance development
- MTAC routes to most appropriate programme

In informal+supportive

MTEP Process Guide 10 wks
## Eligibility and selection criteria

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<tr>
<th>Eligibility</th>
<th>Selection</th>
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<tbody>
<tr>
<td>Timing</td>
<td>Patient benefit</td>
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<td>New or novel</td>
<td>System benefit</td>
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<td>Suitable for evaluation</td>
<td>Disease impact</td>
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<td>Cost considerations</td>
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<td></td>
<td>Sustainability</td>
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Ineligible or not-selected topics are returned to the sponsor with a summary of the Committee’s considerations.
Some common pitfalls and potential solutions

<table>
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<tr>
<th>Common problem</th>
<th>Solution</th>
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<tr>
<td>Evidence doesn’t match the claim</td>
<td>Be clear about best possible application of product before commissioning study</td>
</tr>
<tr>
<td>Lack of clarity about the product’s position in care pathway</td>
<td>Talk to UK-based clinicians about how they might use the product and how it would change treatment</td>
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<tr>
<td>Unrealistic view of potential savings</td>
<td>Understand current treatment and availability – don’t assume a more expensive comparator is widely used</td>
</tr>
<tr>
<td>Not enough evidence to support the case for adoption</td>
<td>Share all possible sources of data with NICE – post-market, audit, unpublished</td>
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MTEP overview - MTG development

Scope

- Stakeholder comment on draft scope
- NICE issues final scope/ decision problem to sponsor

Guidance development

- Sponsor submission
- Critique by EAC
- Draft guidance meeting
- Consultation
- Final guidance meeting

Dissemination and implementation

NICE implementation tools

MTEP Process Guide 38 weeks
MTG development: scope defines decision problem

<table>
<thead>
<tr>
<th>Population</th>
<th>Adult patients undergoing PICC insertion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Sherlock 3CG Tip Confirmation System</td>
</tr>
</tbody>
</table>
| Comparators              | • PICC insertion followed by chest X-ray to confirm tip placement  
                            • Fluoroscopy to guide PICC insertion and confirm tip placement |
| Outcomes (see scope for full details) | • Accuracy of catheter tip placement  
• Incidence of catheter malposition  
• Need for catheter re-positioning  
• Impact of malposition-related complications  
• Reduced staff time  
• Requirement for confirmatory chest X-ray  
• Requirement for fluoroscopy to correctly place the PICC tip  
• Time taken to insert PICC  
• PICC failure/re-insertion rates |
| Subgroups                | None specified                           |
MTG development: evidence considerations

- MTEP methodology requires manufacturers to submit evidence, including an economic model
  - Published/unpublished/no design or quality threshold

- The evidence should demonstrate:
  - Equivalent or superior clinical performance compared to current standard clinical care – the comparator
  - NHS cost savings (which may occur anywhere in the care pathway)

- The evidence may be based on:
  - Systematic review of the clinical and economic evidence with appropriate meta-analyses
  - De novo cost analysis (where needed)
  - Clinical and technical expert advice

- The submitted evidence is reviewed by an independent external assessment centre
MTG development: cost consequences methodology

- Expectation technology is therapeutically near equivalent to comparator
- Costs and resource consequences of the technology as well as relevant clinical benefits
- Not required: valuation of patient health status or treatment preferences
MTG recommendations

• Usually:
  - Case supported (wholly, partly or not)
  - Consider using in <case for adoption> <research>
  - Resource consequences

NICE medical technology guidance addresses specific technologies notified to NICE by manufacturers. The ‘case for adoption’ is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This ‘case’ is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.
Development of further evidence

- MTEP has a research workstream as an integral part of programme
- Designed to facilitate research to address gaps in evidence which led to research recommendations in MTG or DG
- Flexible approach to research products but must be able to be completed within ~ two years
- Subject to findings and evaluation – updated guidance
- 8 active topics
Thanks for listening
www.nice.org.uk/mt

Notify a technology:
medtech@nice.org.uk
Harnessing the power and knowledge of patients and the public to enable more effective selfcare and use of mhealth
In a July-October 2014 PatientView/Health 2.0 global survey of over 1,000 patients with long-term conditions, and their carers, respondents were asked to comment on the following question:

“Do any of the following PREVENT YOU from downloading some health apps, or using them regularly?”

41% of respondent patients state: "The sheer number of health apps makes choosing them confusing" —This is the primary reason why people do not use health apps

Source: Survey of 1,020 patients with long-term conditions (and their carers) …
“What do patients and carers WANT from health apps?”
conducted by PatientView in collaboration with Health 2.0, July-October 2014, with the input of relevant healthcare stakeholders (policy-makers, suppliers of apps and mobile services, and healthcare professionals).

Launched at Health 2.0 November 2014
The importance of user perspectives

- Approximately 20 new health apps are created every week.
- Over 100,000 health apps are available today.
- Of the 100,000-plus, only 1% are likely to be tested for safety and efficacy.
- The remainder are largely health-and-wellness apps that regulators anticipate should not prove harmful to consumers.
- The FDA has already acknowledged that it will only be regulating a very small subset of health apps … so, some other type of consumer guidance is needed.
myhealthapps (MHA) is all about providing support to consumers, so that they are able to make informed choices in their selection of health apps …
User guides on health apps should address many problems

1. **Enhancing quality of life in a way not provided through traditional healthcare**
Mobile technology allows consumers greater access to facilities that can support health and wellness. Consumers previously seeking such support outside the traditional healthcare system had to work hard to find it. Health apps seem a natural, obvious tool to satisfy these consumers’ growing demands for extra support.

2. **Helping overwhelmed healthcare providers**
Providers, for their part, are trying to find ways of alleviating their increasing workload. Ideally, they would like to recommend easy-to-access mechanisms of helping consumers self care (in order to make their own job more manageable).
How are the health apps featured on MHA selected?
Two factors dictate whether a health app is featured on MHA

1. The health app has been nominated as a favourite by patient groups, or disability groups, carers’ groups, family groups, consumer groups (or by empowered consumers)

2. The app developer is transparent about the nature of the app
1. Patient groups and empowered consumers identify favourite apps to MHA in a number of ways

Over time, MHA tries to obtain more than one nomination/review from different patient/consumer groups for each health app.

Negative comment is included if provided.

The levels of usage of the app among the members of the patient group nominating the app is obtained (when available).
Myfitnesspal - 13 nominations/reviews on myhealthapps

*for example*

**Reviewer:** Patient group specialising in learning disorders, USA.

**Review:** “Users are able to keep track of their caloric intake, as well as exercise. In addition, the exercise is included in the amount of caloric intake, so that people can see a direct correlation between exercise and caloric intake.”

**Source:** PatientView survey, July-August 2012.

**Usage:** Between 6-10%.

Glooko - 4 nominations/reviews on myhealthapps

*for example*

**Reviewer:** Person living with diabetes, UK.

**Review:** “I use Glooko infrequently, but it easily tracks blood-glucose readings, and offers useful trend analysis.”

**Source:** PatientView survey, August 2014.

**Usage:** Between 6-10%.

mySugr Companion - 6 nominations/reviews on myhealthapps

*for example*

**Reviewer:** Talley Henning Brown, Juvenile Diabetes Research Foundation (JDRF), USA

**Review:** “In addition to the numbers—blood-glucose levels, bolus amounts, carb counts—you can also make a record of the fine details, like the placement of an infusion set or sensor on any given day, changes in how you’re feeling, and photos of meals. Instead of being a chore, Companion makes management into a game. Every action you take, which you then log in the app, awards points. Reach 50 points in a day, and you tame the diabetes monster. (Literally—the app’s mascot is an animated green character that accompanies the user along the way to every T1D goal.) Another effect of mySugr’s management-as-game approach: it may help take the stress off. The team at mySugr designed Companion with the goal of not only motivating users toward their personal best in T1D management but also steering them away from the sense of discouragement that can come with an out-of-range number.”

**Source:** [http://jdrf.org/blog/2013/raising-the-game/](http://jdrf.org/blog/2013/raising-the-game/)

**Usage:** Not specified

**Weblink of reviewer:** [http://jdrf.org/](http://jdrf.org/)
2. The app developer is transparent about the nature of the app

Background checks carried out include the following:

• Pricing (plus hidden pricing; prices of upgrades).

• The contact details, and the geographic location, of the app developer. These must be readily available in the public domain.

• Information on the funder/s of the app (not necessarily always the same as the app developer). This, too, must be available in the public domain.

• Information on any medical advisers involved in the making of the app (again, these might not always be the same as the developer). This must be available in the public domain.
Further information (if available) is provided by PatientView/MHA on:

- **Countries** in which the app can be used.
- The **languages** in which the app is published.
- The **platform/s** upon which the app is available (Apple, Android, Windows, Blackberry, browser, etc).
- The **functions** of the health app: networking; reminders; support for symptoms/disabilities; self-monitoring; tracking; information, etc.
- Whether the health app has **regulatory approval** such as CE marking, FDA approval, or is featured on the NHS Health Apps Library.

Second criteria for adoption onto MHA:
“The app developer is transparent about the nature of the app”
Available on:

- [ ]

(click to download)

Supported languages:

- Dutch
- English
- French
- German
- Italian
- Polish
- Spanish
- Swedish

Cost:

Free; Pro version $19.99
€17.99; £13.99

Diabetes logbook that awards points for meaningful entries.

myhealthapps.net rating

[ ]

Read more

Find out how hearts are won

Approved by

[ ]

Read more

Languages

Dutch / English / French / German / Italian / Polish / Spanish / Swedish

Countries of use

Any in which the user is familiar with one of these languages

Cost

Free; Pro version $19.99 €17.99; £13.99

Developer

mySugr GmbH
(Based in Austria)
http://mysugr.com/

Funder

As technical developer

Medical Adviser

Lutz Heinemann, Co-founder of the Profile Institute for Metabolic Research GmbH in Neuss, Germany. Partnership with Santé Diabète (an NGO servicing in Western Africa - mainly supported by IDF and others) and JDRF (NGO focused on type 1 diabetes)

Features

- Reminders
- Support to deal with symptoms/disabilities
- Self-monitoring
- Trackers
- Information

Summary

Diabetes logbook that awards points for meaningful entries, with the aim of ‘taming the diabetes monster’ by overcoming challenges. Easy logging with tags and notes. Multiple photographs (for instance, of food) can be added to each entry, and made more relevant by linking to a location (for instance, a restaurant). Data analysis includes graphs. Received FDA approval as a medical device in January 2013, and the developer has declared the app CE marked. mySugr Junior is a free companion logbook app by the same developer, intended for children with diabetes.
The final step before uploading a new health app on MHA is to allocate a heart rating

All the apps on this site have won recommendations from patients. Our heart ratings give you an easy way to compare between the apps chosen for this site. The ratings are based on what patients tell us are most important about an app. This is how each rating adds up to a maximum of 5 hearts:

<table>
<thead>
<tr>
<th>Rating</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helps you control your condition / keep you healthy</td>
<td>💌 Hearts</td>
</tr>
<tr>
<td>Is trustworthy</td>
<td>💌 Gray Heart</td>
</tr>
<tr>
<td>Is easy for you to use</td>
<td>💌 Heart</td>
</tr>
<tr>
<td>Allows you to network with people like you / who understand you</td>
<td>💌 Gray Heart</td>
</tr>
<tr>
<td>Can be used regularly</td>
<td>💌 Heart</td>
</tr>
</tbody>
</table>
How the MHA heart-rating system was derived

Following the 2012 publication of the print-version prototype of myhealthapps, called *The European Directory of Health Apps*, PatientView analysed all the reviews for the 200 apps featured in the publication. Five factors that patients say they want from health apps were identified—and went on to become the MHA five-heart rating. MHA held a number of cross-stakeholder meetings in 2012, discussing the five factors, and also conducted a survey of patients and the public to obtain weightings of importance for each of the five factors.
How the MHA heart-rating system was derived

The process by which the heart-rating system was derived is described in a White Paper (What Do People Want from Health Apps?) published in October 2013, and released at the 2013 European Health Forum Gastein, by invitation of the European Commission’s DG CONNECT.

http://alexwyke.files.wordpress.com/2013/10/health-app-white-paper-to-go.pdf
Today on myhealthapps

Launched November 14th 2013
• 404 health apps listed
• 676 reviewers
• 50 languages
• 176 medical/health/wellbeing specialties featured
• 8,000 returning visitors (75% increase since February 2014)
• average page views = 3.85
• average time spent on site = 3.22 mins

Moving in the right direction, and improving, with presence on …
• Twitter (one year)
• Facebook (one month)

https://twitter.com/my_health_apps
https://www.facebook.com/myhealthapps
myhealthapps is ALL ABOUT effective partnering

- Networks (Mobile World Capital, ECHA, KTN)
- 120,000 patient groups
- Pharma, medtech & mobile industries
- Public health policy (EU, national & international)
- 400 app developers
- Health research & academia
- Regulators (EU, NHS, FDA etc)
- HCPs & providers
Partners may advise or be actively involved in projects

Our ongoing partnership relationships

Commercial organisations
● GSK
● Janssen
● Novo Nordisk
● Telefonica

Non commercial organisations
● Digital Health and Care Alliance
● European Health Forum Gastein
● NHS England (Health Apps Library)
● European Connected Health Alliance
● Health 2.0
● Mobile World Capital
● TicBiomed
● TechUK

Project work with
● European Commission
● Greek presidency of the EU
● Health 2.0
● Sycamore House Medical Centre, Birmingham
● TicBiomed
● UK government’s Knowledge Transfer Network

In discussions with
● World Health Organization
● Mobile Manufacturers Forum
Examples of innovative co-creation with other stakeholders

Conducted with the UK government’s Knowledge Transfer Network:

Cross-stakeholder meeting to define the challenges faced in mhealth (October 2013, held at the King’s Fund, London)

Examples of innovative co-creation with other stakeholders

Survey on the value of services in the home to support independent living and care for people with long-lasting illnesses/conditions

Commissioned by the Greek Presidency and the European Commission

Interim results of the April 2014 Pilot Study

Presented by Dee O’Sullivan, Director, myhealthapps.net, PatientView (administrators of the study)


Examples of innovative co-creation with other stakeholders

October 2014: Launch of the first-ever toolkit that aims to help patients and the public understand and use health apps

http://www.blastphotography.co.uk/patientview.html

Also with the support of NHS England, and with encouragement from the European Commission
An innovatory two-stage process for developing health apps that meet the needs of patients and the public:

**Stage 1**
A July-October 2014 global survey of over 1,000 patients with long-term conditions (and their carers) has allowed myhealthapps.net and Health2.0 to identify unmet patient/carer needs in the health-app arena. Results to be published in November 2014

**Stage 2**
A free collaborative workshop by MHA will connect patient and carer groups, health policy-makers, healthcare professionals, telecoms and mobile experts, and pharma and medical-device experts with health-app developers.

12th November 2014, London
Examples of innovative co-creation with other stakeholders

Ongoing, as of October 2014:
Measuring the impact of health apps on patients with Sycamore House Medical Centre, Birmingham
Examples of innovative co-creation with other stakeholders

Ongoing, as of October 2014:
Measuring the impact of health apps on patients
with Sycamore House Medical Centre, Birmingham
Contact myhealthapps.net

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