Digital Therapeutics in the NHS: The rise of digital therapies & the evidence that proves they work

Tuesday, 24 April 2018

#DHLCOLLABORATE
#DigitalHealthLondon
Event chair

Dr Mark Davies
GP, Non-Executive Director – BMJ, Chair of Clinical Advisory Board - Your.MD
Definition:

**Digital therapeutics**, a subset of digital health, is a health discipline and treatment option that utilizes a digital and often online health technologies to treat a medical or psychological condition. The treatment relies on behavioural and lifestyle changes usually spurred by a collection of digital impetuses.

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<thead>
<tr>
<th>Time</th>
<th>Item</th>
<th>Speakers</th>
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<tbody>
<tr>
<td>13:20pm</td>
<td>Welcome &amp; Introduction</td>
<td>Dr Mark Davies, GP, Non Exec Director - BMJ, Chair of Clinical Advisory Board - Your.MD</td>
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<tr>
<td>13:30pm</td>
<td>Setting the Scene</td>
<td>Dr Indra Joshi, Clinical Lead, NHS England</td>
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<tr>
<td>13.45pm</td>
<td>‘World class Digital Therapeutics’ and their growing value in the UK</td>
<td>Murray Aitken - Executive Director, IQVIA</td>
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<td>What is a ‘Digital Therapeutic’? And what does a good one look like?</td>
<td>Nelia Padilla - Vice President Digital Health Strategy, IQVIA</td>
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<tr>
<td>14.30pm</td>
<td>Panel: Interrogating the evidence</td>
<td>Neelam Patel - COO, Medcity</td>
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<td>Simon Dixon - Head of Digital Health Strategy, Public Health England</td>
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<td>On the sofa with: Voluntis, myCOPD, Akili, Welldoc, Sleepio</td>
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<td>15.15pm</td>
<td>Coffee Break</td>
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<tr>
<td>15.30pm</td>
<td>Toward a more digitally enabled research world in the NHS and NIHR</td>
<td>Dr Jonathan Sheffield - CEO, NIHR Clinical Research Network (CRN)</td>
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<td>16:00pm</td>
<td>Have Your Say: Rapid fire table top discussion</td>
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<td>16.15pm</td>
<td>Audience Question Time: Shaping a digital therapies toolkit</td>
<td>Chair: Sarah Haywood - CEO, MedCity</td>
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<td>Panel: Dr Indra Joshi - Clinical Lead - NHS England</td>
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<td>Dr Mark Duman – North West Service Champion - Diabetes UK</td>
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<td>Professor Martin Cowie - Professor of Cardiology Royal Brompton and Harefield NHS Foundation Trust</td>
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<td>Dr Mark Kelsey - GP, Clinical Chair, Southampton City CCG,</td>
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<td>Mark Campbell - Acting Programme Director, National Institute for Health and Care Excellence</td>
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<td>Professor Colin Espie Co-Founder and Chief Medical Officer at Big Health</td>
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<td>17.15pm</td>
<td>Closing thoughts &amp; reflections of the afternoon.</td>
<td>Mark Campbell – Acting Programme Director, NICE</td>
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<td>17.30pm</td>
<td>Networking and refreshments</td>
<td>Yinka Makinde – Programme Director, DigitalHealth.London</td>
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<tr>
<td>19.00pm</td>
<td>Event close</td>
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Dr Indra Joshi
Clinical Lead
NHS England
Murray Aitken
Executive Director, IQVIA Institute for Human Data Science
The Growing Value of Digital Health

Digital Therapeutics in the NHS
April 24, 2018

Murray Aitken, Executive Director, IQVIA Institute
IQVIA Institute Research

3rd Report by Institute Related to Digital Health

- October 2013: Patient Apps for Improved Healthcare: From Novelty to Mainstream
- September 2015: Patient Adoption of mHealth: Use, Evidence and Remaining Barriers to Mainstream Acceptance

Contents

- Proliferation of digital health tools
- Innovative uses of sensors
- Delivering value to patients and the health system
- Investments in evidence
- Accelerating use in medicine
Number of consumer health apps has nearly doubled since 2015: 318,500 now available with about 200 new apps added daily to top app stores

- Apps focused on health conditions and patient care now about for 40% of all apps, up from 27% in 2015
- Increased number of sensors now available bringing new health uses, and consumer satisfaction with apps is increasing
- Use of apps extend across the entire patient journey
- Validation of digital biomarkers and digital therapeutics portend more extensive uses of apps and other digital health tools

Growing confidence in the value patients, providers, payers and overall health system can receive from appropriate use of digital health tools

- Clinical evidence of Digital Health efficacy has grown substantially: 571 studies published with over a quarter released in 2017
- Evaluation/curation platforms can provide guidance to healthcare professionals
- Health-related apps in five therapy areas could reduce total healthcare costs by 1-2% ($7 billion in annual savings in U.S.; GBP170 million in UK)
- Investment in evidence development is high: 860 clinical trials currently underway with 82% of U.S. trials run by patient care organizations

mHealth space is maturing, though still faces some major barriers
Digital Health Tools

- Health System Disease Management Apps
- Consumer Mobile Apps
- Consumer Wearables
- Connected Biometric Sensors
- Smartphone Cameras
- Web-based Interactive Programs
- Text Messaging or Email
- Personal Health Records
- Telemedicine and Virtual Physician Visits
- In-Home Connected Virtual Assistants
- Clinical Trial Patient Information Collection Tools

Source: IQVIA Institute, Sep 2017

HIMSS18 Belgian Delegation
Digital Health in the Patient Journey

Wellness & Prevention
- Exercise & Fitness
- Diet & Nutrition
- Lifestyle & Stress
- Stress Management
- Sleep/Insomnia
- Smoking Cessation
- Alcohol Moderation

Symptom Onset and Seeking Care

Patient Experience Tools
- General Healthcare Information
- Symptom Checking
- Finding a Clinician
- Managing Clinical and Financial Information
- Social Media

Diagnosis

Condition Education & Management
- Self-Monitoring
- Remote Patient Monitoring
- App-Enabled Rehabilitation Program

Condition Monitoring

Treatment

Physician may recommend app-supported disease management programs, connected sensors for remote monitoring, or apps for any use case across the patient journey

Source: IQVIA AppScript Use Categories. IQVIA Institute, Sep 2017

HIMSS18 Belgian Delegation
Number of Published Digital Health Efficacy & Effectiveness Studies

Total: 571 Efficacy Studies Between 2007-2017 (YTD)

Source: AppScript Clinical Evidence, August 14 2017
Notes: Analysis excludes accuracy database studies. Only includes studies with hard outcomes. ‘Observational Study’ includes all trials examining interventional value or impact of an app excluded from the other three categories regardless of design.
Maturity of Digital Health Efficacy Studies by Use Category, 2017

- **Candidates for Adoption**
  - Healthy Eating / Weight Management
  - Asthma
  - Infectious & Parasitic Disease
  - COPD
  - Hearing Loss & Tinnitus
  - CHF
  - Stroke
  - Alzheimer’s Disease
  - Medication Management
  - Alcohol & Substance Abuse
  - Sleep / Insomnia
  - Cancer
  - Smoking Cessation
  - Parkinson’s Disease
  - Hypertension
  - Cardiac Rehab
  - Stress Management
  - Alcohol Moderation
  - PTSD
  - Genitourinary Conditions
  - Diabetes Prevention
  - Arthritis
  - Kidney Disease
  - Pulmonary Rehab

- **Candidates for Inclusion in Clinical Guidelines**
  - Diabetes
  - Depression
  - Anxiety

- **General Lack of Studies**
  - GI Conditions
  - Self-Diagnosis & Symptom Checking
  - Finding an HCP
  - Managing Clinical and Financial Records
  - Medication Discounts
  - Pregnancy
  - Well Newborn
  - ADHD
  - Hyperlipidemia
  - Epilepsy
  - Pneumonia
  - Vision
  - Oral Diseases
  - General HC Info
  - Social Media

- **Potential Disappointments – More Study Required**
  - Exercise
  - Pain Management
  - Dermatological Conditions
  - Schizophrenia / Bipolar
  - Multiple Sclerosis
  - Autism

- **Relative Quantity & Quality of Available Clinical Evidence**
  - No Studies
  - One Observational Study
  - Multiple Observational Studies
  - One RCT Study
  - Multiple RCT Studies
  - One Meta-analysis
  - Multiple Meta-analysis Studies

**Sources:** IQVIA AppScript Clinical Evidence Database, Aug 2017

**Notes:** Only includes studies that evaluated the interventional value of a digital health solution (mobile or web app, connected device, or other mobile intervention such as texting) on patient outcomes such as activity levels, lab results, or healthcare resource utilization. Average of study results for the highest quality evidence available (i.e., meta-analysis > RCT > Observational)
Clinically-validated apps also have economic value to the NHS

Key Assumptions

- **Use of 5 Curated Apps** used in 5 underlying studies suggesting acute care utilization benefits

- **Delivery** to each target patient for the given use case (but not necessarily used by patient)

- **No “Spill Over” Benefits** to other conditions (i.e., no reduced healthcare utilization for stroke based on improved blood sugar control in diabetics)

Source: IQVIA AppScript Essentials Value Model, Aug 2017 (data on file)
Clinicians’ requirements for prescribing apps

Fraction of AppScript Essentials that meet requirements

<table>
<thead>
<tr>
<th>Patient Usability</th>
<th>Accuracy, Efficacy and Safety</th>
<th>Data Privacy/Security Assurances</th>
<th>Mitigation of Malpractice Risk</th>
<th>Acceptable Financial Incentives</th>
<th>Acceptable Clinician Workflow &amp; Usability</th>
<th>Clinician Adoption To-Date</th>
</tr>
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<tbody>
<tr>
<td>Wellness &amp; Prevention</td>
<td>Little</td>
<td>Little</td>
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<td>Condition Management</td>
<td>Little</td>
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Emerging Accelerators of Adoption

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<td>None</td>
<td>Few</td>
<td>A Significant Number</td>
<td>Most</td>
<td>All</td>
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Source: American Medical Association, Digital Health Study, Sep 2016; IQVIA Institute Analysis, Sep 2017
The UK has made progress in creating an environment where clinically validated digital health apps can begin to succeed.
However, the UK is not yet a leader in Digital Health

Global VC Investment in Digital Health 2017(1)

- UK: 3%
- Other: 97%

Global Digital Health Efficacy Study Publications 2007- Present(2)

- UK: 8%
- Other: 92%

Source:
(1) Marc Sluijs. DIGITALHEALTH.NETWORK. 2017.
(2) AppScript Clinical Evidence Database
Opportunity in Real World Research: What if it was easier to do *Digital Therapeutics* studies in the UK?

1. **Simplified Study Application & Setup**
2. **Pre-Contracted “Digital Therapeutics Research Network”**
3. **App Prescribing Platform & 3rd Party Research Apps**
   - that enables patients to donate their data
4. **Bench of Qualified Independent Research Teams**
   - to produce high quality research publications
5. **Ability to Immediately Transition to Use in Routine Care**
Clinical Evidence Standards: Embracing the *Digital Therapeutics “Goldilocks Principle”*

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<tr>
<th></th>
<th>Too Informal <strong>Bad Data</strong></th>
<th>Just Right <strong>Effectiveness Evidence</strong></th>
<th>Too Formal <strong>Efficacy Evidence</strong></th>
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<tbody>
<tr>
<td><strong>Examples</strong></td>
<td>• Marketing case studies</td>
<td>• Pragmatic RCTs conducted in patients and sites similar to likely use</td>
<td>• Certain Traditional RCTs that leverage patients and sites that are not similar to likely use</td>
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<tr>
<td><strong>Requirements</strong></td>
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<tr>
<td>Affordable</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
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<tr>
<td>Good Science: Stands up to Independent Review</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Reproducible in Real World</td>
<td>?</td>
<td>✓</td>
<td>?</td>
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<tr>
<td>Outcome</td>
<td>• Too much data</td>
<td>• Sufficient evidence</td>
<td>• Not enough evidence</td>
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<tr>
<td></td>
<td>• Data may not be predictive of value</td>
<td>• Evidence is reliably predictive of value</td>
<td>• Evidence may not be predictive of value</td>
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The Growing Value of Digital Health

Digital Therapeutics in the NHS
April 24, 2018

Murray Aitken, Executive Director, IQVIA Institute
Nelia Padilla
Vice President, Global Services Global Lead, Digital Health at IQVIA
What is a Digital Therapeutic?

And What Does a Good One Look Like?

Nelia Padilla
Global Digital Health Lead
Consulting Services
IQVIA
Healthcare is undergoing a digital revolution

UK’s NHS Aims to Build a Library of Reliable Mobile Health Apps

A new sort of health app can do the job of drugs

ASCO 2016: Study Finds Use of Mobile Web App Associated With Improved Outcomes in Lung Cancer

Digital Health: OncoPower May Revolutionize Cancer Treatment Outcomes
Yet, because something qualifies as a digital health, it does not mean it is a digital therapeutic – so what is a digital therapeutic?

If you trust Wikipedia, it’s:
“a subset of digital health, is a health discipline and treatment option that utilizes a digital and often online health technologies to treat a medical or psychological condition.”

OR

If you trust the CEO’s of self-labeled digital therapeutics firms, it’s:
A combination of software / technology used by patients that treats / impacts disease

Sources:
Digital Therapeutics in the NHS Summit
Importantly, *Digital Therapeutics* (DTx) represent a new way for the NHS to address improved clinical outcomes for its patients.

In an ideal world, outcomes matter more than the product used.

Types of Products for NHS Patients

- **Drugs**
- **Devices**
- **Digital Therapeutics**

**Clinical Outcomes**

- Increase lifespan
- Improve quality of life
- Cure disease
What does a good digital therapeutic look like?

Digital Therapeutics (DTx) Maturity Criteria

1. Intended Use
2. Demonstrated Efficacy
3. Regulatory Clearance
4. Incorporation into Standard of Care
5. Demonstrated Cost-Effectiveness
The maturity of a DTx can be evaluated against these criteria

1. **Intended Use**
   - Informs Treatment
   - Treats Non-Serious Condition
   - Treats Serious Condition
   - Treats Critical Condition

2. **Demonstrated Efficacy**
   - No Studies
   - Lit Review
   - Pilot / Case Study
   - Obs Study
   - RCT or Other Well-Controlled Study
   - RCT + Real-World Evidence

3. **Regulatory Clearance**
   - Clearance Req’d, Not obtained
   - Clearance Not Required
   - Regulatory Clearance or CE Mark
   - Cleared Effectiveness Claims

4. **Incorporation into Standard of Care**
   - No Incorporation/Acceptance
   - Recommendation for some digital assistance
   - Recommendation for specific digital product type

5. **Demonstrated Cost-Effectiveness**
   - No Studies
   - Potential “Read Across” from Clinicals
   - Non-published Models
   - Peer Reviewed Models
   - Real World Cost of Care Study

Digital Therapeutics in the NHS Summit
(1) Derived from IMDRF. “Software as a Medical Device”: Possible Framework for Risk Categorization and Corresponding Considerations
Study Design: Cluster-randomized clinical trial comparing A1C levels for patients using BlueStar intervention vs. patients in control group

Decrease in A1C Levels Over 12 Months for BlueStar vs. Control

Study Design: Randomized clinical trial with 190 patients comparing improvement in A1C levels for patients on Insulia intervention vs. placebo

Decrease in A1C after 4 Months with Insulia

Percent of Patients Achieving 7% A1C Target

Source: A. Daoudi, et al., A Smartphone for adjustment of basal insulin dose and for coaching: benefits in terms of glycaemic control for type 2 diabetes patients. Poster presentation, EASD 2013
AKL-T01

Study Design: Multi-center, randomised, double-blind, active-controlled study in 348 children diagnosed with ADHD

Study Design: Randomized, placebo-controlled trial measuring sleep efficiency of 164 adults across 3 arms: cognitive behavioral therapy, imagery relief therapy (IRT: placebo), treatment as usual (TAU).

**Sleepio vs. Placebo and TAU**

- % Achieving healthy patterns, Sleep efficiency >80%
  - Sleepio: 76%
  - Placebo: 29%
  - Treatment as usual: 18%
  - In-person CBT-I (benchmark data): 70-75%

Study Design: Two-arm parallel single-blind, randomized controlled trial with 90 patients comparing 6 minute walk test distance pre and post intervention with MyCOPD vs. face to face intervention

The adjusted mean difference for the 6MWT between groups demonstrated non-inferiority of the MyCOPD intervention.

The panelists skew towards maturity, particularly on efficacy

1. **Intended Use**
   - Sleepio: myCOPD
   - akili: insulia
   - BlueStar
   - Treats:
     - Sleepio: Treatment Non-Serious Condition
     - akili: Insulia Serious Condition
     - BlueStar: Critical Condition

2. **Demonstrated Efficacy**
   - No Studies
   - Lit Review
   - Pilot / Case Study
   - Obs Study
   - RCT or Other Well-Controlled Study
   - RCT + RWE

3. **Regulatory Clearance**
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   - No Studies
   - Potential "Read Across" from Clinicals
   - Non-published Models
   - Peer Reviewed Models
   - Real World Cost of Care Study

* Akili’s product, EVO has been submitted to the FDA for regulatory clearance

(1) Derived from IMDRF. “Software as a Medical Device”: Possible Framework for Risk Categorization and Corresponding Considerations
Please welcome today’s panelists

Anand Iyer, Chief Strategy Officer

Vincent Hennemand, VP of Strategy, Corporate, & BD

Sophie Bostock, UK Innovation Lead, Big Health

Simon Bourne, CEO, My mHealth (Developer of MyCOPD)

Pierre Leurent, CEO, Voluntis (Developer of INSULIA)
Panel: Interrogating the evidence
Panel

- Pierre Leurent, CEO, Voluntis
- Simon Bourne, CEO, My mHealth
- Sophie Bostock, UK Innovation Lead, Big Health
- Vincent Hennemand, VP of Strategy, Corporate, & BD, Akili
- Anand Iyer, Chief Strategy Officer at WellDoc, Inc.

Chaired by:
Neelam Patel, COO, MedCity
Simon Dixon, Head of Digital Strategy, Public Health England
Dr Jonathan Sheffield, OBE
CEO of the National Institute for Health Research, Clinical Research Network
Towards a more digitally enabled Research world in the NHS and NIHR

Dr Jonathan Sheffield, Chief Executive Officer
NIHR Clinical Research Network
Demonstration by:
Mick Mullane, Digital Innovation Lead, National Institute for Health Research (NIHR)
Meeting the growing health and care needs of the nation

The demand for health and social care will continue to grow as the population ages, co-morbidities become more common, and the trend to personalised medicine continues. In response, NIHR needs to develop life-changing treatments faster in an environment of rising expectations amongst the public and increasing pressures on health and social care. This requires us to:

• Deliberate a more personalised experience for the public to take part in research at every step of the journey,
• Attract, support and grow the best health and care researchers,
• Ensure that NIHR funded research improves the quality of health and care for patients and the public,
• Work with our customers (Life Sciences industry and charities) to maximise impact and benefit for all,
• Provide world-class research facilities.

The issue is made more urgent due to uncertainties surrounding how industry and other funders will react to Brexit, creating new opportunities for the UK’s role in Life Sciences. The NIHR needs to deliver these changes quickly so that we meet the growing healthcare needs of the nation.

Digital has transformed other industries, but has had a limited impact on research across health and social care. So we needed to work out how digital can help solve these challenges...
We engaged with over 200 stakeholders to help us understand what Digital meant for the NIHR and to build real momentum for a transformational digital strategy.

We ran focus groups, interviews & online surveys to gather stakeholders’ views about the changes they would like to see & how digital can help. Involving patients & the public at every step of the journey to ensure a strategy is designed which meets their needs. Stakeholders are excited about the impact digital could have on how we do research and want to continue working with us to make it happen.

**Engaging with stakeholders across the health & care system**

**Involving stakeholders from across the country**

*92 engaged during the process

*Life Sciences Industry includes pharma, medtech, biotech, diagnostic, contract research organisations etc.
Stakeholder feedback

From the PATIENTS & THE PUBLIC

“Awareness (of research) in the general public is very low and there is no understanding that you have a choice”

“I am committed to research but I had questions and uncertainties about the study and there was no one to ask. So I decided not to bother”

“If you gave me some great content, slides and videos, I would talk about research at the Women’s Institute”

“If you want to reach us younger people, you need to use social [media]”

“Didn’t receive feedback during the trial therefore it was de-motivating and the burden became more significant…”

“Research can be a lonely and frightening experience for patients”

From the RESEARCH COMMUNITY

“My heart sinks when I need to go back through the application process, confused with the offer of more help I don’t know what different parts of the NIHR could do for me. I just see it as more forms to fill in”

“We don’t know where to start or who they should talk to within the NHS. Knowing what research is going on is mainly the result of who you know”

“Approval occurs at local level. It would be much better to do this at national level”

“We can’t see the whole research portfolio… you either get a twig or the whole forest”

About DATA

“Difficulties in accessing routine data... Difficulties in gaining approvals... challenges facing recruitment... are all key obstacles to research”

“You trust your data in the NHS. If you take part in an NHS branded study then you know your data isn’t going anywhere”

“Seamless systems and quick turnaround times would make UK the most attractive place to do research”

“We need new digital skills if we want to do research in new ways”

“Information governance departments get nervous about data. Patients don’t have massive hang-ups and we block it”

Evidence

Conclusions

• Patients & the Public are rarely thanked for taking part, making them feel disengaged
• Low awareness of the different opportunities that exist to get involved in research
• Information required to make an informed decision is not readily available

• Researchers processes are complex, fragmented and time consuming
• Navigating the health & social care system is difficult for the research community
• Establishing local agreements is a time consuming & labour intensive process

• Gaining access to data is challenging, time consuming and costly
• Patients are happy and want to share their data
• The skills and tools to handle data etc. are lacking across the health research system
Develop and implement five strategic digital services

Five strategic digital services to help deliver better outcomes for patients & the public across UK health and social care through research.

• A platform to debate and shape research
• Digital experience for patients and the public
• An end to end digital research service
• A platform to attract, develop and retain research professionals
• Data donor: giving patients control over the data and us access to new sources

All underpinned by consent and data security.
The end-to-end digital research service
Digital research experience for patients and the public

Ayesha was watching music videos on YouTube with her flatmates.

She came across a video from one of her favourite artists talking about their mental health experience.

She clicked through to the NIHR’s Get Involved site and learnt about the value of health research.

She used the ‘My Research’ service to join a mental health study.

She was delighted to find how easy it was to take part.

...she could book appointments on the go...  
...send measurements from the comfort of her home saving several trips to hospital...  
...claim expenses simply and quickly online...

She received regular updates about how the study was progressing...and a thank you telling her about the results when the study ended. She also received updates about future topics and studies she could join.
Data Donor

Frank took part in a sponsored run to raise money for his favourite charity.

He received a thank you email saying he could also support the charity by getting involved in research.

**JOINING DATA DONOR**

**MANY WAYS TO GET INVOLVED**

**HOW DATA DONOR DONATION HELPS RESEARCH**

**CHOOSE WHAT DATA TO SHARE**

**THANK YOU FOR SUPPORTING RESEARCH**

**SOMETIME LATER...**

Diana sees that the data Frank is willing to share makes him a good match for her study.

Frank receives a request to use his data in Diana’s study... he accepts.

Diana is notified that she can use the data and Frank is notified that he has joined the study.

Sometime later... Frank learns about the impact the study had on better care and was thanked for donating his data to Diana’s study.
‘We’ve Got Your Back’ Study
How the different pieces can fit together

1. Simplified Study Setup

2. Digital Therapeutics Research Network

3. DEMO
   - App Prescribing Platform & Research Apps

4. Qualified Independent Research Teams

5. Immediately Transition to Routine Care
Have Your Say

Table-top discussions

15 mins
Question Time: Shaping a digital therapies toolkit
Panel

- Dr Indra Joshi, Clinical Lead, NHS England
- Professor Martin Cowie, Professor of Cardiology & Honorary Consultant Cardiologist, Royal Brompton & Harefield NHS Foundation Trust
- Mark Duman, North West Service Champion, Diabetes UK
- Mark Campbell, Acting Programme Director, NICE
- Dr Mark Kelsey, GP, Clinical Chair, Southampton City CCG
- Professor Colin Espie, Co-founder and Chief Medical Officer, Big Health

Chaired by:
Stage: Sarah Haywood, CEO, MedCity
Floor: Dr Mark Davies, GP, Non Exec Director, BMJ, Chair Clinical Advisory Board, Your.MD
Closing thoughts

Mark Campbell
Acting Programme Director – Devices and Diagnostics
National Institute for Health and Care Excellence
Yinka Makinde
Programme Director –
DigitalHealth.London
Thank you