Wragge Lawrence Graham &Co

Connected health white paper

Definitions for: Digital Health, eHealth, mHealth, Telecare, Telehealth, Telemedicine & Wellness What do these terms mean?

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ECHAlliance

1 Introduction and Context

1.1 Well before the recent international financial challenges every country in the world faced the inescapable challenge of infinite demand for healthcare services and finite resources, even if their nature and scale varies significantly between industrialised and developing countries. Add to this spiralling costs caused by the invention of new drugs, medical equipment and procedures, higher patient expectations, an ageing population (by 2051, close to 40% of the EU's population will be older than 65) and shortages of health professionals and the scale of the challenge is daunting.

1.2 In 2008, the World Health Organisation (WHO) identified five common shortcomings of healthcare which included:

- fragmented and fragmenting care;
- unsafe care (poor system design that is unable to ensure safety and hygiene standards, along with medication errors and other avoidable adverse effects that are an underestimated cause of death and ill health); and
- misdirected care (neglecting the potential of primary prevention and health promotion to prevent up to 70% of the disease burden and to mitigate adverse effects on health and to make the most of what other sectors can contribute to health).

In 2004, R.J. Blendon and others in a survey involving five countries (US, Canada, UK, Australia and New Zealand) noted that despite the different structural systems, patients in all five countries revealed "consistent dissatisfaction with general health system quality stemming from problems associated with medical errors, inadequate patient – physician communication and insufficient coordination of care". The need to improve quality and deliver integrated care is beyond question.

Some readers in the UK might ask the relevance of these Reports from 2004 and 2008. Anyone reading the Francis Report into the failings of Mid Staffordshire Hospital (NHS Foundation Trust) or the Winterbourne View Hospital Report will immediately understand that the same challenges regrettably are still very relevant today in the UK and we suspect in many EU countries.

1.3 It is important to understand that "Connected Health" (which includes the various related terms such as eHealth, mHealth) is used by different industries and in different sector contexts. The terms are being used in at least three sectors – 1) healthcare 2) social care and 3) the emerging wellness sector. Increasingly these three sectors are overlapping, especially as integrated health and social care gathers momentum. In healthcare systems such as Northern Ireland, which has an integrated Department of Health and Social Care, the opportunities for Connected Health are real and substantial.

1.4 The various Connected Health definitions mean that Connected Health businesses could be equipment or device manufacturers, software developers, clinical or care service providers, support service providers, (e.g. telecommunications & call centres) or any combination of these. What is apparent is that Connected Health to a lesser or greater extent sees the convergence of health, technology (software, IT hardware and digital) media, and telecommunications industries. This raises the question of how the regulation of these industries interact in the context of Connected Health products and services.

1.5 Connected Health involves "disruption" to the developed world healthcare systems (see Clayton Christensen's The Innovator's Prescription where he advocates the need to disrupt the hospital and GP surgery models). Interestingly, this disruption is being led by industries outside healthcare including aerospace (redeploying sensors from aeroplanes), automotive (redeploying sensors from cars), energy (utilising remote monitoring and health services), leisure (wearable devices like the Nike fuel band, the Jawbone App and the Fitbit), technology and telecommunications (including enabling data analytics and health Apps).

1.6 Against this backdrop, the NHS in England currently has to make £20 billion in efficiency savings between 2011-14 in order to meet the expected increased demand for services. At the same time, the White Paper published in July 2010 advocates "freedom, fairness and responsibility by:

(i) putting patients at the heart of everything we do;

(ii) relentless focus on clinical outcomes; and

(iii) empowering healthcare professionals"

to achieve the goal of 'an NHS which achieves results that are amongst the best in the world'.

1.7 In this context Digital Health, eHealth, mHealth, telecare, telehealth and telemedicine are being championed to help deliver more efficient care, achieve significant savings in acute care services and the incidents of chronic disease management, increase quality of services and deliver patient centred care.

1.8 This White Paper is the first in a series by the European Connected Health Alliance (ECHAlliance www.echalliance.com) and Wragge Lawrence Graham & Co LLP. In this White Paper we pull together the various labels, terms, and descriptions being used to refer to connected health services and products. Future White Papers in 2014 will examine the legal regulatory framework for international Connected Health and the ECHAlliance will be producing a series of summaries for the healthcare systems in countries in the EU.

2 EU Policy Development on eHealth and the EU market

2.1 New technology has been transforming healthcare for decades but since the invention of the computer 'revolutionary' changes transforming quality and cost have long been promised. At the same time the amount spent on healthcare has increased exponentially. eHealth was first promoted in the EU in the 1990's and since 2004 the European Commission has led the coordination of eHealth policy development and deployment by adopting the European eHealth Action Plan.

2.2 In the EU 2004 eHealth Action Plan the "eHealth industry" was forecast to be the third largest industry in the health sector with a value of €11 billion per annum and by 2010 to account for five per cent of the total health budget. In both the old and new Member States, 75 per cent of all expenditure comes from the public sector. The current EU eHealth Action Plan is for 2012 - 20.

2.3 In Europe, healthcare is substantially a public sector industry with around 80 per cent of the cost of the sector comprising human resources. In 2002 this was 17.5 million persons (in the 25 Member States) or 9.3 per cent of the total workforce.

2.4 Another important feature of this market is the development of cross-border services, particularly in the EU. The EU has identified a number of specific services where it wishes to facilitate cross-border services such as e-prescribing and electronic health records.

2.5 On 17 December 2010, the US-EU Memorandum of Understanding (MOU) between the US Department of Health and Human Services and the European Commission was signed covering "cooperation surrounding Health Related Information and Communication Technologies". The MOU seeks to develop eHealth and health IT to promote "individual and community health while fostering innovation and economic growth".

2.6 The ECHAlliance organises on behalf of the EU-US a twice yearly EU-US eHealth Marketplace and Conference (in May in Europe and in October in the US). The MOU provides interoperability standards (technical and semantic) and training strategies to develop the skilled health IT and health professional workforces needed for eHealth. In addition to exchanges for information, there are working groups on a range of projects such as the "Trillium Bridge", a feasibility study to create a Summary Care Record for patients across the Atlantic.

2.7 In early 2014 the European Commission is expected to publish a Green Paper on mHealth for consultation. Originally we understood that it was dealing with Health Apps and possible regulation but will also now cover the benefits of mHealth.

3 An overview of mHealth services

3.1 To illustrate what actual products and/or services may be involved in Connected Health, a helpful example has been produced by Orange for mHealth.

3.2 mHealth involves the combining of products and services from device manufacturers, telecommunications companies and software producers with some healthcare aspect. Orange segments the market into three types of services (a) health professionals, (b) health management and (c) prevention and wellbeing.

3.3 Remote care as a concept is not that new. In the April 1924 edition of the Radio News the headline of the front page of the magazine reads "The Radio Doctor – Maybe!"

Services for health professionals	Health management	Prevention and wellness
Mobile devices for doctors/nurses e.g. scanners	Data Collection Tele assessment Remote monitoring } using a device	Education & Awareness Personal Emergency Alarms Tracking
Mobile access to health information and clinical systems		
B2B		B2C

Source: Orange Telecommunications

3.4 An important distinction above is the sale of services/products to businesses (including NHS organisations) and direct to consumers (potentially patients if they amount to clinical services). The law offers greater legal protection to consumers than businesses.

4 What is Digital Health, eHealth, mHealth, telecare, Telehealth, Telemedicine & Wellness?

4.1 From the invention and development of computers to the creation of the internet, the scope for Connected Health has grown. However, many of the terms used in Connected Health are still very new. It is important to remember any legal regulatory framework will apply to the specific services and/or products which are intended to be provided, not simply any 'label' attached to those services and/or products.

Health

4.2 WHO defines health as 'a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity'.

4.3 The terms Digital Health, eHealth, mHealth, telecare, telehealth and telemedicine do not have either a commonly accepted or industry-wide meaning. Also there are no legal definitions in UK law or EU law. The terms include the provision of health and care services by way of hardware and/or software devices, remote monitoring devices, devices that assist independent living, remote communications by healthcare professionals and mobile and IT solutions that are designed to improve an individual's healthcare or monitor it. Increasingly they involve educating and empowering people to manage their health (wellness) and long-term conditions. Additional benefits for health systems are greater efficiency and improvements in quality. The terms are flexible and often used inter-changeably. The services also involve Business to Business (B2B) and Business to Consumers (B2C) models and contracts.

Digital Health

4.4 Paul Sonnier (Popper and Company) has defined Digital Health in his LinkedIn Digital Health Group as follows:

"Digital health is the convergence of the digital revolution with health, writ large. In addition to medicine and healthcare, digital health encompasses consumer-focussed sports, fitness and wellness solutions, which can be considered preventive medicine.

As enumerated by Dr Eric Topal in his book "The Creative Destruction of Medicine: how the Digital Revolution Will Create Better Health Care" there are eight super-convergence elements comprising Digital Health:

1 Wireless, Sensors and Devices

2 Genomics (A, C, G, T = digital)

3 Social Networking

4 Mobile Connectivity and Bandwidth

5 Imaging

6 Health Information Systems

7 The Internet

8 Computing Power and the Data Universe".

See the Digital Health Group on LinkedIn for wider comments and debate on the definition (http://www.linkedin.com/groups/Digital-Health-Definition-2181454.S.206358708).

An alternative definition from the recently formed Digital Health Institute in Scotland is:

"Digital Health is an upcoming discipline that involves the use of information and communication technologies to help address the health problems and challenges we all face. Digital Health, in the form of mobile technology, social media and sensor technology already helps us to reduce inefficiencies in healthcare delivery, improve access, reduce costs, increase quality, and make medicine more personalized and precise. These digital capabilities, now more than ever, need to be focused on changing how we use and interact with technology, to empower people to be equal partners in the design and delivery of their own Health & Care services."
(http://dhi-scotland.com/how-dhi-works/)

eHealth

4.5 WHO has adopted the following broad definitions of eHealth:

"eHealth is the use of information and communication technologies (ICT) for health" (Global Observatory for eHealth – a WHO initiative); and

"the overarching term for the range of tools based on information and communication technologies used to assist and enhance the prevention, diagnosis, treatment, monitoring and management of health and lifestyle".

Geysenbach (Journal of Medical Internet Research 2001:3(2):E20) has said "eHealth characterises a technical development, but also a state of mind, a way of thinking, an attitude and commitment for networked, global thinking, to improve healthcare locally, regionally, and worldwide by using information and communication technology".

mHealth

4.6 WHO has not adopted a definition for mHealth. The 2010 mHealth Summit of the Foundation for the National Institutes of Health defined mHealth as:

"the delivery of healthcare services via mobile communication devices".

The US Department of Health and Human Services defines mHealth on its website as "the use of mobile and wireless devices to improve health outcomes, healthcare services and health research".

Some commentators emphasise mobile devices and technologies to make it clear it is not simply about the mobile phone (voice services).

Telecare & Telehealth

4.7 The NHS's Whole System Demonstrator: An Overview of Telecare and Telehealth defined telecare as using:

"a combination of alarms, sensors and other equipment to help people live independently".

Accordingly, telecare involves services to people in their own homes which might alert changes to them or call centres. Care homes and Housing Associations in the UK have been using these types of services for many years and examples include personal alarms, fall detectors, temperature, gas and carbon monoxide detectors. These services are social care, not strictly regulated healthcare/medical services.

The Whole System Demonstrator defined telehealth as using:

"equipment to monitor people's health in their own home".

In contrast to telecare services, telehealth services covers the remote monitoring of physiological data such as blood sugars, blood pressure, heart rate, stress levels or lung function by such devices as pulse oximeters, spirometers and glucometers. Some commentators have interpreted this definition as being limited to the capture and transmission of this health data to a healthcare professional (for subsequent diagnosis or consultations (remotely or otherwise) with a patient).

Telemedicine

4.8 WHO has adopted the following broad definition of telemedicine:

> "The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities".

The distinction between telehealth and telemedicine is that a telemedicine service is the provision of a regulated healthcare service (so where a doctor/patient relationship exists and is regulated by health laws in the applicable country) but where the health professional and patient are not in the same location.

Wellness

4.9 There are a number of academic papers investigating a definition of wellness including a whole chapter in the British Columbia Atlas of Wellness tracing its origin back to post-1945 and the end of the Second World War. The Atlas of Wellness proposes six dimensions of wellness (physical, emotional, intellectual, spiritual, occupational and environmental). The US National Wellness Institute states "Wellness is an active process through which people become aware of, and make choices towards, a more successful existence" and it refers to six dimensions of wellness.

In recent years wellness has developed a consumer driven dimension with people using devices (such as the Nike Fuelband, the Jawbone Up and Fitbit) and Apps to empower themselves to self-manage and take responsibility for their health.

Remote Healthcare

4.10 While we were finalising this White Paper we discovered the Institute of Remote Healthcare (IRHC) which was established as long ago as 2008 by the Energy and Maritime industry! It uses the term "Remote Healthcare" to cover telemedicine, virtual territory hospitals, clinical support, near patient diagnosis, fitness to work controls, public health and emergency response planning. It aims to be "the recognised professional association for Remote Healthcare Practitioners". It promotes improved standards in healthcare of those who work in remote places associated with environmental hazards.

The IRHC has used the basic form of telemedicine ("a doctor on one end of a telephone line gives advice to a nurse/medic at a remote location") for more than 40 years! It is undertaking important work on services, equipment and supplies standards as well as training for Remote Healthcare Practitioners (see www.irhc.org.uk)

Connected Health

4.11 The ECHAlliance promotes the term "Connected Health" as the umbrella description covering digital health, eHealth, mHealth, telecare, telehealth and telemedicine. In the US "Connected Health" has emerged with the three aims of improving access, efficiency and quality of healthcare. Arguably "eHealth" and "mHealth" labels indicate how slow healthcare is in adapting to these new technologies and communication tools because in the financial services sector no one today talks about "eBanking" just banking. In financial services the enabling technology and communication tools have just become a part of the services provided. Healthcare needs to catch up.

5 Why are these definitions important?

5.1 It is unsurprising that there are no definitive definitions for Digital Health, eHealth, mHealth, telecare, telehealth, telemedicine and wellness when there is no global health market driven by global technical standards (both equipment and data), legal regulation and global health and care providers.

5.2 A European Commission Report as long ago as 2008 stated “as long as the eHealth market is characterised by a lack of regulation and legal certainty, barriers to the progress of eHealth will persist”.

5.3 The various definitions which have emerged are clearly helpful for everyone involved in health and care (especially those selling telecommunications, devices, media and digital products and services) to understand the range of services and enabling technology being developed. Connected Health services are being promoted internationally by telecommunications, media and technology businesses and again, unsurprisingly, they use the terms in different ways which best suit their perspectives and business opportunities. The problem with this is the scope for confusion and misunderstanding, for example, telehealth being used interchangeably with telemedicine.

5.4 The emerging definition of Digital Health, particularly the Digital Health Institute in Scotland, explicitly champions the benefits of reducing inefficiencies, increasing access, reducing costs, increasing quality but at the same time empowering people to manage their healthcare. It is clear that “Technology is not the solution, it is the enabler. The solution is the patient. The patient is an apprentice and technology the support structure.”
Dr. John Moore, Alelion.

5.5 In our legal opinion, a more important distinction with these definitions is whether the products and/or services involved are regulated by telecommunication and technology laws and/or health laws. To answer these legal issues comprehensively you need clear legal definitions which do not exist either in the UK or on a pan European (EU) basis. We doubt that the definitions which have emerged to date have considered the legal implications of the definitions. This distinction is more important as by the very nature of some of these services they will cross national boundaries and regulatory systems. This distinction is critical for healthcare providers, regulators and Connected Health businesses to understand the legal compliance obligations and where any lack of regulation needs to be addressed in order to safeguard the public and patients. Our next White Paper will outline in more detail these legal regulatory issues.

Conclusion

The ECHAlliance believes that Connected Health is an integral part of:

- Developing citizen centric health and social care services not just “patient” services;
- Empowering citizens to take responsibility for and manage their wellbeing, health and long-term conditions; and
- Improving the quality and efficiency of health and social care services.

Wragge Lawrence Graham & Co believe that in order for Connected Health services to help achieve these objectives, clarity of definitions and legal regulation is required.

Bleddyn Rees

Wragge Lawrence Graham & Co LLP June 2014

About Wragge Lawrence Graham & Co LLP

Wragge Lawrence Graham & Co is one of only a small number of firms which combine genuine healthcare expertise with the expertise of a leading commercial firm. Other UK firms have experience of the NHS and/or the private healthcare sector but we have extensive experience of both. To this we bring international healthcare experience from four continents and advising eight Departments of Health giving us unique knowledge in the emerging global health market.

Connected Health is a sweet spot covering our health, life science, technology and telecommunication sectors. We are at the forefront of the development of Connected Health and the head of our Healthcare Team, Bleddyn Rees, is a Non Executive Director of the ECHAlliance.

As a leading advisor to the NHS, the Healthcare team has substantial knowledge of its legal and operational structure. This is illustrated by our client base where we have advised over 200 NHS bodies including the UK Department of Health, 73 Foundation & Acute Trusts, 70 Primary Care Trusts and 80 Clinical Commissioning Groups. Our experience of providing full-service advice to FTSE 100 clients and our first-class regulatory and technical expertise means that we are also ideally placed to advise private sector clients operating in the health sector.

About the European Connected Health Alliance (ECHAlliance)

The ECHAlliance is a not for profit organisation designed to support and promote the wider adoption of healthcare and wellbeing (including sports and fitness) products, services, applications and innovation. In bringing together commercial, academic and healthcare stakeholders, ECHAlliance facilitates focused leadership for the development of ‘Connected and MHealth’ markets and practices across Europe and beyond. The scope includes the economic development of the full range of eHealth, EHR, TeleCare, TeleHealth, Telemonitoring and mHealth sectors.

ECHAlliance provides a unique partnership of organisations, companies and government bodies and will assist in the creation of “business” opportunities for our members.

Notice

This paper contains information of general interest about legal issues, but does not give legal advice. You should always seek appropriate legal advice from a suitably qualified lawyer who is properly briefed on your issues and circumstances before taking, or refraining from taking, any action.

Contacts:

Wragge Lawrence Graham & Co

Bleddyn Rees
Partner: Connected Health and International Healthcare

Tel: +44 (0)207 664 0321
Mobile: +44 (0)7831 493765
bleddyn.rees@wragge-law.com

Robert Breedon
Partner: Healthcare Commissioning and Integrated Care

Tel: +44(0)207 074 7817
Mobile: +44(0)7894 253120
robert.breedon@wragge-law.com

John Cooper
Partner: Healthcare Regulatory

Tel: +44 (0)870 730 2878
Mobile: +44 (0)7921 795137
john.cooper@wragge-law.com

David Hamlett
Partner: Health Care Contracts and Integrated Care

Tel: +44 (0)870 733 0633
Mobile: +44 (0)7721 780226
david.hamlett@wragge-law.com

ECHAlliance

Brian O'Connor
Chairman
brian@echalliance.com

or

Lorraine Acheson
Outreach Manager
lorraine@echalliance.com

www.wragge-law.com **www.echalliance.com**