

THE DANGERS OF E-HEALTH

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Abstract: In 2005 there were 51 unique definitions of e-Health in use, and a wide range of themes covered, suggesting a lack of clarity on the subject. It is an exciting area with much potential. There is a proliferation of activity, including huge funding invested by the European Commission. Given the large financial investment, we should ensure that the return is an effective e-Health intervention, and a resultant improvement in patient safety. But can e-Health actually do harm? All doctors are aware of the potential for harm, for example in telemedicine there are numerous reports of adverse events. There is little work in the scientific literature on the dangers of e-Health. The evidence base for e-Health is strikingly narrow, and there are few high quality studies demonstrating that patient safety benefits. Most studies do not have a structured system of reporting adverse outcomes. This leads to some ambiguity as to whether clinicians should advocate for e-Health on behalf of their patients. Other sectors have already embraced evaluations. We need a phased system of evaluation, with clear and transparent processes for reporting outcomes. High quality studies should be conducted and the results published so that all stakeholders can make an informed decision.

1 WHAT IS e-HEALTH?

Many people could give their interpretation of what e-Health means, but is there a standard definition? In 2001, Eysenbach noted that everyone was talking about it, but 'few people have come up with a clear definition' (Eysenbach, 2001). An excellent systematic review of the area in 2005 highlighted that there were 51 unique definitions in use (Oh, 2005). There were a wide range of themes covered, but 'no clear consensus about the meaning of the term'.

Some feel that the term should remain in the business sector, and question its place in the academic environment (Eysenbach, 2001). It certainly appears to have been founded in the intersection between academia, healthcare and business. There is no doubt that each group has different aims and objectives for e-Health. These may not give the same results.

Although e-Health has morphed over the last ten to fifteen years, it is now becoming reasonably clear what it entails. The European Commission (EC) Information Society has provided the following definition: 'e-Health means Information and Communication Technologies [ICT] tools and services for health'. The academic area of Health

Informatics is also concerned with information and communication, but technology to a lesser extent. E-Health also covers the practical application of the academic side of Health Informatics.

Patients are to the fore in e-Health, and the Commission also notes that 'widespread implementation of eHealth will enable more "patient-friendly" healthcare services to be developed.' It is clear that existing clinical practice needs to continue its shift toward the patient-centrism, and e-Health seems to be a potent way of doing this.

The result of all this activity is that e-Health is now an exciting area with much potential. It is useful to examine some current projects to further contextualise the discussion.

2 CURRENT ACTIVITY IN e-HEALTH

The European Commission is to the fore in advocating for more work in e-Health. They have already spent 500 million euro on it since the early nineties, and note that [t]his has placed Europe in a leading position in the use of regional health networks, electronic health records in primary care

and deployment of health cards.’ There is no doubt that funding also drives further activity in private industry.

The Seventh Research Framework Programme aims to invest more than 50 billion euro in the period 2007-2013, with prioritisation of e-Health. This financial injection can give a high impact to e-Health and such large scale funding should definitely have a visible effect. But there is inherent risk in such an outlay. For example, Coiera has noted that when countries invest in major information and communication technology systems for healthcare, it is actually visible in the GDP (Gross Domestic Product) (Coiera, 2010)

epSOS is an example of how e-Health can have a measurable pan-european effect. Many European member states are currently involved in design and implementation of electronic health records. epSOS ‘aims at building and evaluating a service infrastructure demonstrating cross-border interoperability between electronic health records in Europe’. Similarly the CALLIOPE project ‘creates an open forum to support the implementation of interoperable eHealth infrastructures and services across Europe’. Interoperability has reached the forefront of the effort, as it has become clear that many individual autonomous efforts have greater potential if run in parallel.

Worldwide, there is a growing emphasis on e-Health, particularly in the United States as a result of the Obama stimulus plan. The HITECH legislation awards financial incentives for successful efforts. Sensibly, they must show ‘meaningful use’. Even before this there have been successful e-Health implementations – for example by Kaiser Permanente and the Veteran’s Association. These efforts increasingly allow patients to access their health information, and lead other countries by example. One of the meaningful use requirements is that population and public health must be improved. It seems logical that this will be achieved by using technology, but is there a demonstrable benefit?

3 THE EVIDENCE BASE IN e-HEALTH

Clinicians have been trained to keep a sharp focus on evidence based medicine. This involves staying up to date with a vast quantity of regularly published medical trials, guidelines and warnings. This indoctrination is effective and leads to the common question ‘What is the evidence?’ The

pharmaceutical industry is now very familiar with this approach, and is involved in promoting and conducting many drug research trials. It is widely accepted that no drug can reach the market without going through a systematic and careful evaluation of product effectiveness, and equally the side effect profile being examined in detail. This latter process is one that continues many years after a product is released.

The idea of having evidence for e-Health should not now come as a surprise. Although there is a certain excitement for a clinician to see impressive new technology, the same process of validation is now being applied as has happened in pharmaceuticals. One example is Health Technology Assessment, which may examine the economic benefit of an intervention that is being introduced on a national basis. The cases of faecal occult blood testing, or the vaccine for cervical carcinoma highlight this process. So have e-Health developers stepped up to the plate?

A search on the MEDLINE database (where most clinicians go to access up-to-date trial data) for ‘ehealth or e-Health’ shows that there have been only 28 human clinical trials published in the last 10 years. With such paucity of evidence, why are we spending so much on the area? Perhaps a wider search is justified.

4 CASE STUDY: e-HEALTH INTERVENTIONS FOR OLDER PEOPLE

Our research group presented findings recently which suggested that there is actually a proliferation of research in the area of e-Health, but it can be difficult to access (O’Hanlon, 2010). Using a detailed and heterogeneous strategy, we searched for e-Health interventions which were developed specifically for older people, or tailored to services for older people. In fact we were able to find 3,158 studies which were in some way concerned with e-Health interventions. From this trove, we then searched in more detail to see which trials had shown concrete benefit for older people, again in the last ten years. The final result was only 57 trials meeting these criteria.

Our study concluded that the number of good quality trials showing beneficial effects specifically for older people is small. We suggested that more research was needed in this area before large scale adoption of these interventions.

These findings were hugely disappointing. Most doctors have seen examples of technology improving patient care; or more probably improvements in their own life due to technology. The internet has such huge potential that it almost seems disingenuous to suggest that the evidence base for e-Health is not what we might expect. Rather, it seems logical that e-Health should be a huge boon for healthcare.

With our patients being thrust towards the centre of the e-Health strategy, what role should clinicians take? Should we encourage patients to embrace e-Health as much as they can, or should we act as a shield against it? The fact that there is a dearth of evidence suggests two conclusions: first, research should be a core element of any funding strategy; and second that as things stand we cannot wholeheartedly embrace e-Health interventions without some caution. Our patients deserve the best – but they need to be sure that it is safe.

5 PATIENT SAFETY

Reason's 'Swiss Cheese Theory' suggests that adverse clinical events can occur, even with several layers of protection. Clinical medicine is an area fraught with safety issues and potential harms for patients. Approximately one in ten patients sustains an adverse event while in hospital. It has been reported that 15% of these events lead to impairment or disability lasting more than 6 months. In one study, adverse events led to a mean increase in length of stay of 8 days. There is considerable weight behind any argument that all healthcare interventions need to be risk-proof.

Despite this, many e-Health interventions do not have a robust safety analysis performed before they are introduced. Perhaps there is a prevailing opinion that e-Health cannot cause harm. Coiera has been watching recent ICT developments in many countries and has noted that we have not yet had 'the first health information technology plane crash' (Coiera, 2010). This could be due to high safety standards, good planning, or possibly good luck. There have been numerous minor incidents in many countries such as unnecessary radiation doses being administered, health records being hacked into, and electronic records simply having the wrong information. But given how widespread ICT is becoming in healthcare, there is huge potential for a very significant adverse event, with catastrophic impact for patients. The patient safety agenda must

penetrate into e-Health development, just as it now has entered other areas of medicine.

6 POTENTIAL DANGERS OF e-HEALTH

Because it is currently low priority on the e-Health agenda, consideration has not been adequately given to what may occur if e-Health harms patients. All doctors are aware that telemedicine can be harmful – video imaging may not have suitable resolution; using distance communication tools may encourage doctors not to attend in person, even when nearby; and when patients are left at home with self-monitoring tools they may not continue to use them as regularly as they should (just like medications). Despite this a search for 'telemedicine dangers' produces just 8 results on MEDLINE. There is little written to comment critically on e-Health interventions, and few studies report systematically on adverse outcomes.

Interaction between humans and computers has been well studied, and it is clear that the introduction of computers to clinical practice leads to a sometimes dramatic sociotechnical change. A simple but common example of placing a computer in the general practitioner (GP) consulting room has had the result of altering the doctor-patient dynamic. It has been argued that computers must be recognised as a key part of the consultation. (Purves, 1996) Margalit concurs, adding that the computer is now a 'party in the visit'. (Margalit, 2006) It is interesting to note that a recent study comparing computer use in 2001 and 2008, GPs now show greater reluctance to use computers. (Noordman, 2010) Having a computer in the room negatively impacts on body posture of the GP, and the amount of information given by the GP to the patient.

These striking findings may seem to have relatively little effect overall, but subtle changes in communication between doctors and patients can lead to a dramatic reduction in the amount of useful dialogue. It is easy for patients to think that a doctor who focuses on a computer cares little for the core reason they came to consult them. Doctor's visits are already too brief, and Noordman's study also showed that when using the computer they were actually shorter than when it was not used.

With these seemingly minor examples in mind, it is useful to consider what one of the core reasons d'être of e-Health is: to improve patient care. In fact, tools such as clinical decision support systems

(CDSS) were introduced in an attempt to reduce human error. We should be more structured in how we assess these tools from now onwards to ensure that they do not reduce one risk while simultaneously augmenting another one.

7 A FRAMEWORK FOR EVIDENCE

It is unsurprising that evaluation of e-Health has previously been highlighted as a necessity. But why has it not been instituted in a transparent, user-friendly way? Nguyen suggested that the US Food and Drug Administration (FDA) system of classification should be adopted to e-Health. Phase I determines safety and effect. Phase II is a clinical trial which establishes efficacy. Phase III confirms effectiveness in a larger group, possibly comparing to another intervention, and looks at adverse effects. Phase IV consists of post-marketing surveillance studies.

This simple schema could be adopted as the standard for evaluation of e-Health interventions. It may not fit all study types, but it would promote transparency, confidence and awareness of e-Health's benefits and risks.

8 CONCLUSIONS

It is foolish to imagine that poor outcomes cannot occur due to e-Health. All technology has potential to harm, or to alter existing dynamics so that existing layers of protection do not work effectively. It is time to recognise the dangers of e-Health and to work proactively to limit this danger and ensure a safer future for all users of health services.

REFERENCES

- Coiera E. World of Health IT conference. March 2010.
- Eysenbach G. What is e-health? *J Med Internet Res.* 2001 Apr-Jun;3(2):E20.
- Margalit RS, Roter D, Dunevant MA, Larson S, Reis S. Electronic medical record use and physician-patient communication: an observational study of Israeli primary care encounters. *Patient Educ. Couns.* 61 (1) (2006), pp. 134–141.
- Noordman J, Verhaak P, van Beljouw I, van Dulmen S.Noordman. Consulting room computers and their effect on GP-patient communication: comparing two periods of computer use. *Fam Pract.* 2010 Jul 26. [Epub ahead of print]
- Nguyen HQ, Cuenco D, Wolpin S, Benditt J, Carrieri-Kohlman V. Methodological considerations in evaluating eHealth interventions. *Can J Nurs Res.* 2007 Mar;39(1):116-34.
- Oh H, Rizo C, Enkin M, Jadad A. What is eHealth?: a systematic review of published definitions. *World Hosp Health Serv.* 2005;41(1):32-40.
- O'Hanlon S. European Union Geriatric Medicine Specialists conference. October 1st 2010
- Purves IN. Facing future challenges in general practice: a clinical method with computer support. *Fam. Pract.* 13 (6) (1996), pp. 536–543.