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Extract from first email:

I have done a lot of work on developing mobile phone technology for the self-management of chronic diseases (or long-term conditions) such as diabetes and asthma. We have recently completed a Randomised Controlled Trial with people who have type 1 diabetes. This showed a statistically significant postive outcome (lowering of HbA1c). I wrote a background report on the technology for the Chairman of the NHS Review in Scotland (Prof. David Kerr), as a result of which tele-medicine formed an important part of his report (see www.timesonline.co.uk/printFriendly/0,,1-210-1622754-210,00.html,although the title "Mobile phones to replace doctors in NHS Review"
is not particularly helpful...) I attach a copy of my report to this e-mail ("Telemedicine for Chronic Disease Management") for you to have a look at when you have time. (Below)

In addition, we have begun to commercialise the technology through our spin-off company, e-San Ltd (see www.thinkdiabetes.com). The diabetes mobile phone solution is being used and evaluated in 3 PCT's at the moment and it recently won the 2005 e-health Innovation Award for "Best Device to Empower Patients".

Extract from second email:
As so much of medicine is (quite rightly) evidence-based these days, I thought that you might be interested in seeing the attached (below). It is the abstract which we have had accepted for the meeting in Athens later on this summer of the European Association for the Study of Diabetes. It gives a good summary of the results of our Randomised Controlled Trial of the mobile phone technology for the self-management of type 1 diabetes. The results are also being presented at the American Diabetes Association conference next week, but the abstract for that was much shorter.

Telemedicine for Chronic Disease Management

1. Introduction

In the UK there are 17.5 million people with a long-term condition (mostly diabetes, hypertension, asthma or Chronic Obstructive Pulmonary Disease – COPD). According to the Diabetes in Scotland 2004 report, “Diabetes presents a serious health challenge for Scotland. There are believed to be 160,000 Scots with diabetes and almost certainly many thousands more who are as yet undiagnosed.” Currently average glycaemic control in Scotland is poor (Scottish Study Group, 2001). With Type 2 diabetes being the fastest growing disease in the Western world as a result of poor diet and obesity,
the World Heath Organisation has recently predicted that long-term conditions will be the leading cause of disability by 2020. Already today, around 80% of GP consultations relate to long-term conditions and patients with such conditions or their complications use over 60% of hospital days (Long Term Conditions Action Team Report, NHS Scotland, 2005).

It is generally accepted that there are three levels to the long-term condition “pyramid”, with self-management at the lowest level (level 1, which is applicable to between 70 and 80% of the patients); Disease Management then follows at the next level (level 2 – high-risk patients) and Case Management appears at the top of the pyramid (level 3 – highly complex patients). Telemedicine, as described in this chapter, has a key role to play in both levels 1 and 2, enabling patients to self-manage (level 1) or allowing them to be managed remotely in their homes rather than spending long periods in hospital (level 2).

In the March 2005 special issue of the British Medical Journal on "Managing Chronic Diseases", Wilson, Buck and Ham (2005) write as follows: "*The evidence backing the use of … disease-specific self-management programmes for conditions like diabetes is strong. The challenge … is how to move to a programme that can support the many millions of patients who might benefit*." Self-management programmes are recognized as the best means of improving the health of patients with long-term conditions such as diabetes or asthma but the large-scale introduction of these will require change from current practice. At the moment, for example, patients with diabetes or asthma are encouraged to monitor their blood glucose or peak flow levels and record them on a graph in a patient diary. It is known, however, that paper diaries are poorly kept and highly inaccurate. It is estimated that 50% of patients with asthma should keep a peak flow diary; in practice only 5% do so.

The required change from current practice to sustainable self-management programmes can be facilitated by the introduction of appropriate technology. Adoption of self-management solutions *on a large scale* by people with long-term conditions requires technology that is easy to use, unobtrusive and adapted to their lifestyle. Recent evidence from a Randomised Controlled Trial of telemedicine for people with poorly-controlled diabetes (Farmer *et al*., 2005a and b) points to sustained levels of self-monitoring, improvements in blood glucose levels and attainment of health outcome targets (HbA_{1c} levels), using mobile phone technology and targeted nurse support. The use of this type of telemedicine system with nurse support was shown to offer a cost-effective way to improve outcomes without substantially increasing resources. The telemedicine model proposed in this chapter is based on the same philosophy: **regular self-monitoring with immediate feedback and targeted support from a healthcare professional with full access to patient measurements**. The degree of patient support will vary according to the severity of the condition (level 1 or level 2) but the components of the model are generic.

2. Telemedicine-enabled self-management with targeted support

2.1. Data collection & transmission:

For patients to self-monitor regularly as part of their daily routine, the sensors should be easy to use, unobtrusive and wireless. For patients with diabetes, hypertension and asthma or COPD, glucometers, blood pressure cuffs and peak flow meters with Bluetooth capability are already commercially available today and the range of non-invasive, wireless sensors for healthcare applications is set to grow.

Patients in the early stages of a long-term condition will expect to lead a normal life and so will not want to change their routine or be confined to one specified location for self-monitoring. For such patients, the mobile phone, now that data services have been added to voice and text messaging, is the ideal means of transmitting the data from the wireless sensor or device to a remote server (and to provide real-time feedback). This also ensures equal access to telemedicine for all socio-economic classes ("equality of care") as 90% of the adult population now owns a mobile phone. Data transmission from a mobile phone to a server, via the internet, is a near-instantaneous and secure process, increasingly used by a number of industries. In the telemedicine application, the server will store the patient monitoring data and algorithms for detecting unusual patterns will analyse the incoming measurements with respect to the stored data for that individual (see section 2.4 below).

The frequency of self-monitoring will depend on the patient's long-term condition. For example, patients with type 1 diabetes should measure their blood glucose levels 3 or 4 times a day, whereas hypertensive patients need only check their blood pressure once or twice a week. Patients with respiratory conditions should ideally monitor their peak flows in the morning and evening; in addition, symptom assessment may also help to identify the onset of exarcebations for some patients. In all cases, an electronic patient diary on the phone, requiring the answer to a few simple questions, is likely to help improve the self-management of the condition.

Elderly patients with a more severe condition (for example, COPD or Chronic Heart Failure) are more likely to be confined to their homes. As the digital home becomes more prevalent over time, it will be possible to configure the wireless network within the home to be a “home health hub” which captures the data from the wireless sensors before packaging it for transmission to the remote server.

2.2. Self-management

Self-management of long-term conditions should be based on a “measure-evaluate-act” sequence, closely integrated with patient education. The use of telemedicine to support a self-management programme is described in this section in the context of diabetes and asthma but the model could readily be adapted to deal with other long-term conditions. In the context of people with type 1 diabetes or insulin-treated type 2 diabetes, the sequence would typically run as follows:

Measure – take blood glucose reading;
Evaluate – assess that reading in the context of recent trends in blood glucose measurements, as well as planned food intake and possible exercise;
Act – decide on the most appropriate insulin dose to inject.

For people with asthma, there would be a very similar sequence:

Measure – take peak flow reading;
Evaluate – assess that reading in the context of the peak flow trend, as well as recent use of reliever inhaler and symptom self-assessment;
Act – decide on the most appropriate number of puffs of preventer inhaler, if needed.

It is important to note that, in all cases, the aim will *not* be to provide advice, but instead to empower the patient to make an informed decision at the time that they self-monitor. Typically, the question to be answered might be: “what is the correct action for me to take, given that my blood glucose reading is 11.3 mmol/l or my peak flow value is 450 l/min?”

For patients who require insulin injections (type 1 diabetes or insulin-treated type 2 diabetes), the main aim of self-management is to take sufficient insulin to keep blood glucose levels down, whilst avoiding hypoglycaemia. For asthma patients, the main aim of self-management is the appropriate use of inhalers to deal with worsening symptoms, especially the use of steroids to cope with exacerbations as they begin to develop. Patients will usually have been given an action plan by their GP or asthma nurse, but again the proper application of this plan depends on the correct evaluation of the latest peak flow reading and/or current symptoms.

If adherence to the self-management programme is to be sustained over the long term, the measure-evaluate-act sequence needs to be completed as rapidly as possible and to be fully integrated into the patient’s lifestyle. In addition, the feedback must be provided as soon as the blood glucose or peak flow measurement has been completed and needs to be *personalised*, enabling the person with the long-term condition to take the “optimal” action *for him or her*.

The latest generation of mobile phones, which can be programmed using languages such as Java, makes it possible for the personalised feedback to be delivered to the patient in real time. The patient-specific model and analytical software required to provide the feedback for the evaluation process will be stored both locally on the phone and remotely on the server. The model, in its simplest form, could be a set of target values, agreed with the patient’s clinician, for example the “hyperglycaemia threshold” below which a patient with diabetes would aim to keep his or her blood glucose levels and which could be gradually reduced as self-management improved. A more complex model, for an asthma patient for

example, could track the variability of peak flow values and self-adapt to take into account seasonal variations in air quality and/or pollen count.

For level 2 patients confined to their homes, a set-top box linked to the TV is an alternative means of delivering the same personalised healthcare information for self-management and self-care. Either the mobile phone or the set-top box could also be configured to receive additional information where appropriate, for example local weather alerts for patients with respiratory conditions such as asthma or COPD.

The patient should also have the option of accessing their own data via their own web page (Coulter, 2004), if they so wish, but the telemedicine model will not rely on this. In the long term, the database containing the patients' self-monitoring data will be integrated with the Electronic Patient Record (EPR) database in ways that are discussed in section 3 below.

2.3. Targeted support

One of the key benefits of the telemedicine model described in this chapter will be the immediate access by the healthcare team to the patient's self-monitoring data, whenever it is required. Any intervention by healthcare professionals, remotely or during a surgery/clinic appointment, is greatly enhanced if they are able to discuss the patients' clinical measurements with them.

The telemedicine model proposed here will also enable a greater range of healthcare professionals to be involved in the management of the patient with a long-term condition: from consultants in secondary care to the pharmacist dispensing a repeat prescription for metformin or a steroid inhaler, as well as the patient's GP and Practice Nurse.

All of these will be able to access the patient data at any time via a secure web page, after appropriate user authentication (McNeil, 2005). The longer-term vision, however, is for part of the targeted support to be delivered by trained clinical staff in a Chronic Disease Management (CDM) call centre (similar to NHS24 but with nursing staff specifically trained in the management of long-term conditions, for example Asthma Nurses or Diabetes Specialist Nurses). Models for remote management of patients, developed in the US by Evercare and Kaiser Permanente, have recently been tested in English Primary Care Trusts (see http://www.natpact.nhs.uk/cms/358.php). A call centre focusing specifically on long-term conditions (diabetes, heart failure and coronary heart disease) is being set up in East London ("Team Health", a joint initiative between the Department of Health and Pfizer – see http://www.natpact.nhs.uk/cms/328.php#HPCTPfizer). The main advantage of the telemedicine CDM call centre model proposed here with respect to these models is that the "on-line carers" in the proposed model will have access to *all* of the patient's self-monitoring data, including the most recent readings which may be giving cause for concern, to help them decide on the most appropriate intervention. It is possible that the whole of the Scottish population with long-term conditions could be supported from one telemedicine CDM centre.

The level of support offered to the patients by the remote carers will depend on how far along the path to good self-management they have progressed. In a small-scale test of this telemedicine model with poorly-controlled diabetes patients (Farmer et al, 2005b), each patient received 1.5 phone calls per month from the Diabetes Nurse, with each call lasting, on average, just over 7 minutes. The allocation of 10 minutes per month for each patient for the clinical data review over the phone was sufficient to support this initially poorly-managed cohort and led to a four-fold increase in the number of well-controlled patients in nine months.

The frequency of interaction with level 2 patients will obviously need to be higher, as these patients require a greater degree of support. For these patients, who are mostly confined to their homes, the

richness and value of the interaction with the remote carer will be greatly increased if it takes place over a video link ("virtual visiting"). The technology to provide this service could be supplied through a video set-top box, connected to the patient's TV. A pilot study of such technology in a GP Practice in Cheshire reduced the use of hospital beds by over 40% amongst vulnerable old people (Audit Commission Report, 2002). There is evidence that remote video technology in the home health care setting is effective, well received by patients, capable of maintaining quality of care and has the potential for cost savings (Johnston *et al*., 2000).

Once patients are regularly using the telemedicine solution and demonstrating improved self-management of their condition, it will be possible to decrease the frequency of calls from the remote carers. The choice of which patients to call will be facilitated by *prioritization algorithms* running on the CDM server. The objective of these algorithms will be to ensure that the time available to the Diabetes or Asthma Nurse is devoted to the patients with the greatest need for advice or intervention at that particular time. Typically, the carers will want to investigate those patients who are showing a marked reduction in the frequency of self-monitoring, or an increase in the occurrence of hypo- or hyperglycaemia (diabetes patients) or whose peak flows are regularly below their personalised target values (asthma patients).

For those patients who have their condition reasonably well controlled, the review of the clinical measurements and/or symptom data will take place at the regular 6-monthly visit to the Diabetes or Asthma Clinic in their local surgery. At that visit, the Diabetes Specialist Nurse, Asthma Nurse or GP will access the telemedicine server in exactly the same way as any of the remote carers. The result of the monitoring data review could be a slight adjustment of the patient-specific model held on the server, for example a lowering of the hyperglycaemia threshold or an adjustment to the recommended use of preventer inhaler in the self-care plan for asthma management. The updates to the model, made in consultation with the patient, will be made on the relevant web page and the model stored on the patient's phone or set-top box will automatically be updated by an over-the-air software download initiated by the server.

2.4. Alerts (either patient-initiated or automated)

Most of the time, the self-monitoring data for a long-term condition is normal; the majority of the readings by far will be within the "envelope of normality" of the patient-specific model. Whenever abnormal readings occur, there will be two possibilities: either, the patient is sufficiently concerned to call the CDM centre or the surgery – indeed, he or she may be prompted to do so by the agreed self-care plan stored on the phone or set-top box – or analytical software on the server will automatically generate "alerts".

The *alerting algorithms* will be an extension of the prioritization algorithms and will be used to highlight *significant* deviations from expected data. The emphasis will be on detecting changes which are of greater magnitude or occurring much more rapidly than desirable. An indication of the loss of control for a diabetes patient could be provided by the detection of outliers (individual unexpected data points) or unusual patterns (combinations of data points whose structure and frequency are unexpected) in the time-series of blood glucose measurements. With asthma or other respiratory conditions, the remote carer should be alerted when a patient fails to take appropriate action as an exacerbation develops beyond its initial stages.

The response to an alert will be an extension of the targeted support communication scheme. The carer processing the alert will again access all the relevant data in the Web-based patient archive in order to decide on the most appropriate intervention (for example, call the patient or initiate an emergency visit). The aim will be to detect worsening conditions as early as possible, allowing home-based care rather than extra visits to the surgery or hospitalisation, whenever feasible.

2.5. Extending the model to vital sign monitoring

The telemedicine-enabled model of Chronic Disease Management for level 2 patients could be extended to other groups of patients who would enjoy a higher quality of life if they were at home rather than in a hospital ward. Hospital resources could also be targeted more efficiently if some patients were to be monitored at home as part of an appropriate tele-care strategy, based on vital sign monitoring. For such patients, the non-invasive monitoring of parameters such as the electrocardiogram (ECG), blood pressure, oxygen saturation, respiration and temperature would provide an indication of the patient's health status.

An important issue with vital sign monitoring is whether the monitoring should be regular but intermittent, or continuous. The first alternative is more likely to be acceptable to patients but it will rely on their co-operation on a daily basis and important events may be missed. Continuous monitoring will only be possible if it can be done unobtrusively however, in which case the problem of sensor or electrode drop-out is an important issue. Recent developments in ambulatory monitoring with wearable technology suggest that it is becoming feasible to monitor individuals reliably over extended periods of time (Bonato, 2003). With a hybrid strategy based on an initial period of continuous monitoring when the patient first returns home, the switch to intermittent monitoring could occur when the vital sign data indicated that the patient was sufficiently stable for this to happen. Beyond that, alerts would be generated as described in section 2.4 above, except that the alerting algorithms would process multiple parameters rather than the single-parameter data stream usually associated with a long-term condition.

3. Integration of Chronic Disease Management within e-health infra-structure

Access to the EPR database for Scotland will be through a secure firewall and will require appropriate user authentication (likely to be two-factor authentication). The telemedicine database containing the patient self-monitoring data (both clinical measurements and symptom diaries, where appropriate) will reside on a separate server. In the medium term (3 to 5 years), a service-based infra-structure will need to be developed to allow the EPR database to be *federated* with other databases, such as the telemedicine database.

The main challenges for such an informatics infra-structure are inter-operability and security (Simpson *et al.*, 2005). Security is also to be understood in the sense that the owner of the data will determine exactly under which circumstances the data may be accessed. This will require issues such as denial of access and appropriate transactional support across organisational boundaries to be addressed.

The aggregation of healthcare data through federation of databases will also bring with it the benefits of data mining; for example, previously unknown correlations between different parameters held in separate databases could be uncovered. It will be possible, for example, to investigate the effect of regional and/or seasonal variations in air quality on asthma control or the impact of different diets or insulin regimens on diabetes management. In the longer term (5 to 10 years), the integration of multiple, disparate data sources will help to deliver cost-effective, high-quality care and treatment for other diseases also. For example, cancer specialists will be able to access from one computer terminal the electronic patient record (with DNA profile), CT scans, histopathology slides and daily symptom data (during chemotherapy) for any of their patients, so that they may optimize the care and treatment of these patients at all stages from diagnosis to follow-up after chemotherapy.

4. Conclusion

The telemedicine model as described in section 2 is feasible with today's technology; indeed, some of its components have already been tested in pilot projects and clinical trials. It could be used to enable

personalised self-management programmes, with targeted support, for thousands of Scottish patients with long-term conditions within three years.

The main argument for healthcare IT (computerized health records) is that the electronic patient record should be available at any time to any healthcare professional involved in the care of the patient, whether it be the consultant or ward sister in hospital or the Practice Nurse and GP in the local surgery. The case for healthcare ICT, as articulated here, is firstly that it will provide considerable added value to the EPR by providing accurate, time-stamped clinical measurement data for the healthcare professional. Secondly, the communications technology will not only solve the problem of transferring the measurements *from* the patient with the long-term condition to the database but it will also enable the immediate feedback of relevant information *to* the patient, because of the two-way communication.

There is very good agreement between the contents of this chapter and key sections from the Long Term Conditions Action Team Report (2005), in particular the latter's recommendation that tailored advice and self-management resources should be provided to individuals. The authors of the Report also state that "effective long-term condition management should be based on generic approaches to managing specific conditions, rather than condition specific approaches, i.e. the basic principles of long-term condition management should be the same, irrespective of the specific condition." This fits in exactly with the underlying philosophy of the telemedicine model outlined here.

There is also a statement in the Action Team Report that "effective prevention and management of chronic conditions requires an evolution of health care, away from a model that is focused on acute symptoms towards a co-ordinated, comprehensive system of ongoing care. This includes continuing to move away from episodic to continuous support in Primary Care for people with long-term conditions." The aim of the telemedicine model is to empower individuals to take responsibility for the management of their condition, in the knowledge that their local community pharmacist, or Practice Nurse, or GP, will be able to review their data and contact them should they get into difficulty. It is unrealistic, however, to expect these healthcare practitioners to provide all of the required support, especially out of hours, and so this chapter proposes the setting-up of a CDM call centre staffed by healthcare professionals with full access to the patient measurements and symptom data. This could be seen as an extension of the CDM nursing team operating in one of the Community Health Partnerships in Scotland.

Although the focus in Scotland has tended to be on elderly level 2 patients (see, for example, Oates and Tracey, 2005), this report has considered both level 1 and level 2 patients. This is deliberate: firstly, level 1 patients represent 70-80% of the population with long-term conditions (the Diabetes in Scotland 2004 report estimates that one in three Scottish people over the age of *thirty* has a long-term condition); and secondly, if the telemedicine model outlined here is to be *sustainable* on a long-term basis, it has to be introduced with patients at a relatively early stage of disease progression (for example, newly-diagnosed type 2 diabetes patients who have to be educated about diet and exercise and who need to monitor their weight and blood pressure). The development of personalised, self-management skills in level 1 patients in 2005 will significantly reduce the numbers of level 2 and level 3 patients in Scotland in 2025.

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