National Assembly for Wales

Health and Social Care Committee

Access to medical technologies in Wales

Evidence from Time for Medicine Limited – MT 18

Submission to The National Assembly for Wales' Health and Social Care Committee inquiry into access to medical technologies in Wales.

Submitted by Time for Medicine, Cardiff Medicentre, Heath Park, Cardiff, CF14 4UJ 18th October 2013

The focus of this submission is the contention that irrespective of the actual and declared commitment by senior politicians, civil servants, clinicians and managers to innovation in the NHS, unless that commitment is shared by managers at all levels in the NHS, start-up and established companies will struggle to overcome deep seated reservations to new practices, and ideological objections to the role of the private sector in the NHS. In addition the speed of NHS response is poor compared to private organisations with decision making centralised, complex and lacking in personal accountability. This markedly increases the financial risk of joint ventures where NHS Wales is a partner.

Both Dr. Paul Williams and the Company would be happy to provide oral evidence if requested in due course.

1. **Background to the Company**
   a. Time for Medicine seeks to make specialist clinical opinion within the NHS available in a more convenient fashion for patients.
   b. The company is a spin out from the University Hospital of Wales in Cardiff (UHW) and was formed in August 2009 by Dr. Paul Williams, Consultant Clinical Immunologist at UHW to develop TeleHealth software for the diagnosis and management of Allergy, as the first of a large number of different conditions, using technology that can be deployed throughout the NHS.
   c. The Company has worked with over 40 leading UK Specialist Doctors (Consultants) to develop a web based platform that can host modules customized by clinical specialty to allow patients to be diagnosed remotely in an NHS setting. The Company's technology uses web and mobile technologies to augment the skills and experience of senior clinical consultants in diagnosing and managing patients' conditions.
   d. A clinician will typically seek relevant clinical information to diagnose a patient's condition through three approaches:
      i. Interrogative (History): Questions that characterise the symptoms and related information
      ii. Physical Examination.
      iii. Investigations: Tests ranging from blood tests to imaging procedures such as X-rays, MRI etc.
   e. The company has:
      i. Worked with the participating Clinical Consultants to map all the above interactions between specialists and patients in outpatient clinics.
      ii. Commenced the digitisation of the above such that patients can be interfaced with in a non-hospital setting.
      iii. Created digital dashboards to present all relevant data to Consultants remotely so that diagnoses can be made, treatment plans formulated and prescriptions created and despatched electronically.
   f. The company has built a web based and cloud hosted platform to handle the interface between patient and consultant. TfM diagnostic platforms can be made available to a Health Board, Trust or Clinical Commissioning Group within the NHS firewall. Currently patients referred by their GP have to wait many weeks to see a specialist, sometimes in a distant major hospital. With TfM's technology the

patient can in a primary care setting (e.g. a GP's surgery, Pharmacy, or a larger facility) go through an online diagnostic session alone or with the assistance of a nurse or administrative assistant. The physical examination can be carried out by the GP and the findings entered to the software. This patient data can be viewed by Consultants in their own offices. Appropriate blood tests and/or other investigations can be requested and results can then be added before being viewed again by consultants. In most cases a specialist diagnosis can then be delivered, without the patient needing to travel to the hospital for an in-person consultation with the specialist consultant. Those patients who do require in-person consultations can then be seen by the appropriate consultant in secondary care with relevant clinical information and test results available, hence streamlining the patient's pathway at the hospital.

g. The Company's technology platform makes more efficient use of an NHS clinical consultant's time, reduces the number of patients needing to be seen in person, streamlines patient pathways, eliminates delays and bottlenecks and reduces the cost of clerical backup by making inputs and outputs electronic.
h. The Company has been supported by the Welsh Government through a range of grants.

2. **Development of the Technology**

Dr. Williams and the Company have made strenuous efforts to ensure that all governance concerns have been properly addressed:

a. The technology and related Intellectual Property was developed in the knowledge and with the full support of Cardiff and Vale University Local Health Board (UHB or predecessor organisation). Proof of principle in relevant areas was the basis for three IP filings in 2005 and 2009 made jointly by UHB and Dr. Williams.
b. Bro Taf Local Research Ethics Committee approval was granted for the initial work in 2004
c. The South East Wales Research Ethics Committee on 27th March 2009 deemed that this work no longer required ethical approval, but was now classed as Clinical Service Development.
d. Dr. Williams secured approval for the methodology of securing patient consent for data collection from the UHW Department of Research and Development on the 28th January 2011.
e. A spin out company from UHB, Time for Medicine Limited (TfM), was formed on August 2nd 2009 and an Assignment of IP and Royalty Agreement was signed by UHB and TfM on January 8th 2010. This Agreement transferred the IP to TfM and articulated a joint commitment to develop this technology in a range of other areas of medicine in addition to allergy. The Agreement also enshrined for UHB a financial interest in the Company through royalties.
f. Formal permission for the handling of patient data was given by the Department of Research and Development of UHB on January 28th 2011. Protocols have been established between TfM and UHB for the secure storage of patient data, operating within the Data Protection Act.

3. **Major Challenges faced in Developing and Deploying the Technology**

a. During the period 2004 to 2006, following the filing of the first patent jointly by UHB and Dr. Williams, the proposal to develop the core technology supporting the initiative within the NHS received the full backing of the NHS Trust Deputy Chief Executive, Medical Director and Finance Director. Unfortunately it proved impossible to develop these innovative approaches in practice due to the inability of enthusiastic Consultants working alone to coordinate support from multiple middle managers. Faced with an absence of progress to introduction of this innovation within the NHS, in late 2006 Dr. Williams proposed forming a spin out company.
b. In 2007 senior Trust management proposed supporting this spin out initiative and Heads of Agreement were signed between UHB and Dr. Williams to support the company financially as equal partners. However, again, there was no managerial follow through leading to a complete failure to make progress... In August 2009 Time for Medicine was formed, but the UHB Executive Board decided in October 2009 not to follow through with the financial commitment (contrary to what was agreed in 2007). The Assignment Agreement between UHB and the Company was signed in January 2010 giving UHB a financial interest in the Company's success without any investment.
c. In January 2011 the UHB Department of Research and Development approved the format of a patient consent paragraph to be inserted in all patient appointment letters in a number of clinical specialties to

facilitate the collection of anonymised patient data to support the development of the technology. In late 2011 it became apparent that this was not happening and subsequent investigation revealed that a number of non-clinical middle managers had decided that they did not approve of the agreed procedure. The Company sought the intervention of the UHB Medical Director who rectified the situation and reinstated the procedure approved by the UHB Department of Research and Development.

d. In October 2012 the Company in collaboration with the Clinicians of the Cardiff Integrated Sexual Health (ISH) Clinic were successful in gaining a Technology Strategy Board SMART Grant to develop and pilot asymptomatic screening and triage software for the Cardiff ISH Clinic. The award of the grant was to support a pilot programme:

> *"To investigate, as a reference site, the introduction of decision support software into the Cardiff Integrated Sexual Health (ISH) clinic in order to enable identification of low risk, asymptomatic patients so that more complex cases can be directed to senior ISH clinicians in order to meet care targets for patients seeking diagnosis and care for suspected Sexually Transmitted Infections (STIs)."*

The goal of the project is to streamline patient pathways by matching each patient's needs with the appropriate level of care and ensure that the clinic is successful in achieving compliance with British Association of Sexual Health and HIV Key Performance Indicators. In particular the requirement that 98% of people are offered an appointment, or walk-in, within 48 hours of contacting an STI provider, a target the Clinic has not been able to achieve. As part of the work plan for the project it was agreed that a Healthcare Support Worker would be required to support eight additional clinics of 3 hours duration. The Company proposed paying for this Healthcare Support Worker time, but the process needed sanctioning through the signing of a Service Level Agreement by the appropriate specialty Board. However, a number of managers, including the Board Secretary of UHB who currently heads up the Innovation function at UHB, declined to sign the document as they were unhappy about some clauses in the 2010 Agreement, which had already been authorised by the Board of UHB. This unwelcome intervention put the project on hold for four months, and caused embarrassment for the Company, NHS Wales and the Welsh Government with the Technology Strategy Board, a distinguished source of research funding in the UK, and has required the intervention of the UHB Chief Executive and Medical Director to resolve the impasse.

4. **Conclusions and Recommendations**

a. If the Welsh Government wishes major innovation in NHS Wales, then its wishes need to be conveyed to and enforced at all levels of management within Welsh Health Boards.

b. Within each Health Board there should be a clear innovation champion with specific and credible experience in innovation transfer or adoption, with a commitment to third party engagement free of ideological encumbrance, whose responsibilities should include the resolution of all problems concerned with collaboration with medical technology companies.

c. Engagement with new medical technologies – especially disruptive innovations - may require a new standardised form of agreement. This must be supported by high-level agreement (eg at or 1 step below Health Board level) but must not become delayed by bureaucracy. Decision making must be immediate and focussed.

d. For such an agreement, there needs to be created a 'Promissory note' system, signed by the Medical Director or equivalent, stipulating that the company bearing it should be allowed to pass without managerial hindrance, with relevant reasonable requests approved immediately. Any query relating to their proposed activity should be referred immediately and directly by any manager to the Innovation champion, who will have to respond within a week or arrange a meeting to resolve such queries within 2 weeks.

e. The Innovation champion should meet regularly with collaborating companies at a frequency that is appropriate to the innovations concerned. The innovation champions should have a recognised open

line of communication to the Welsh Government's Director of Innovation in Healthcare whose brief should include the rapid diffusion of all beneficial innovations throughout the NHS in Wales.

Clive Minihan
Director
029 2075 7744