

‘Evaluating the evidence for Diagnostic Tests’ St Anne’s College



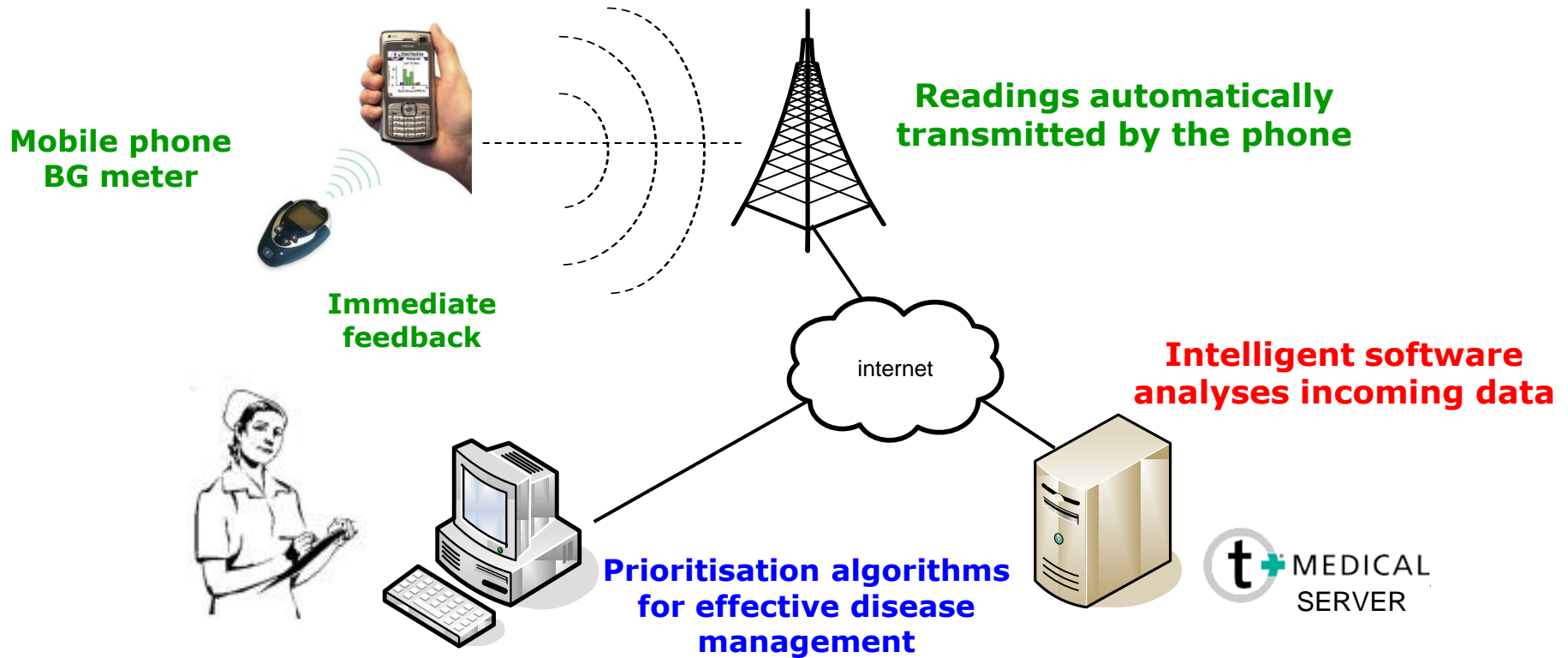
New technologies (Self-monitoring in Chronic Disease Management)



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New technologies for Chronic Disease Management



- 'Diagnostic test' is blood-glucose measurement
- Mobile phone provides platform for electronic patient diary

Electronic patient diary

Last meal

How long is it since you last had a meal?

0-1 hour

1-2 hours

2-4 hours

4-8 hours

More than 8 hours

Back Next

Exercise

How much exercise will you do today?

Skip

Less than usual

About average

More than usual

Back Skip

B.G. Reading

Enter your Blood Glucose Reading (0.0 - 38.0)

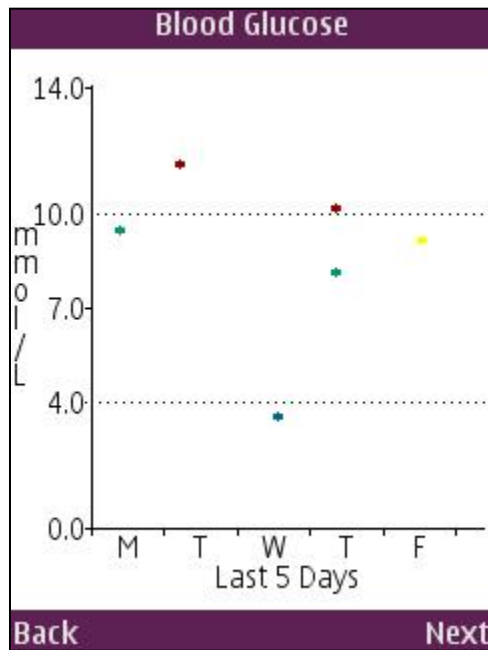
mmol/L

Press BT for Bluetooth link

Back BT Skip

Electronic patient diary

Personalised feedback screens



Summary of clinical studies and trials

- Asthma 3 published clinical studies, 1 completed with Asthma UK
- COPD 1 trial at Bristol Royal Infirmary published in *Respiratory Medicine*
- Type 1 diabetes 1 Randomised Controlled Trial published in *Diabetes Care*
1 study on-going in Oxford
- Type 2 diabetes 3 published clinical studies (inc. two in *Informatics in Primary Care*)
1 study on-going in Oxfordshire GP Practices
- Hypertension 1 trial presented at *European Stroke Conference*
1 study on-going in Oxfordshire GP Practices
- Cystic fibrosis 1 published clinical trial (data submitted to NICE)
- Cancer 1 study published in *Annals of Oncology*
1 study just completed at Churchill Hospital
- Health Economics **Whole-System Demonstrator with Department of Health**




Diabetes Care




Thorax



Oxford Diabetes Type 1 clinical trial



**Division of Public Health and Primary Care
University of Oxford**




**The Oxford Centre
for Diabetes, Endocrinology and Metabolism**

Principal Investigators:


- Prof. L. Tarassenko
- Prof. A. Neil
- Prof A. Farmer

- 9-month *Randomised Controlled Trial* with patients from Young Adult Clinic
- Inclusion criteria:
 - Type 1 diabetes, aged between 18 and 30
 - Twice daily or basal bolus insulin therapy
 - Poor glycaemic control (HbA_{1C} between 8 and 11%)
- Aim to detect a difference of 0.7% in HbA_{1C} based on baseline mean value of 9%

Oxford Diabetes Type 1 clinical trial



**Division of Public Health and Primary Care
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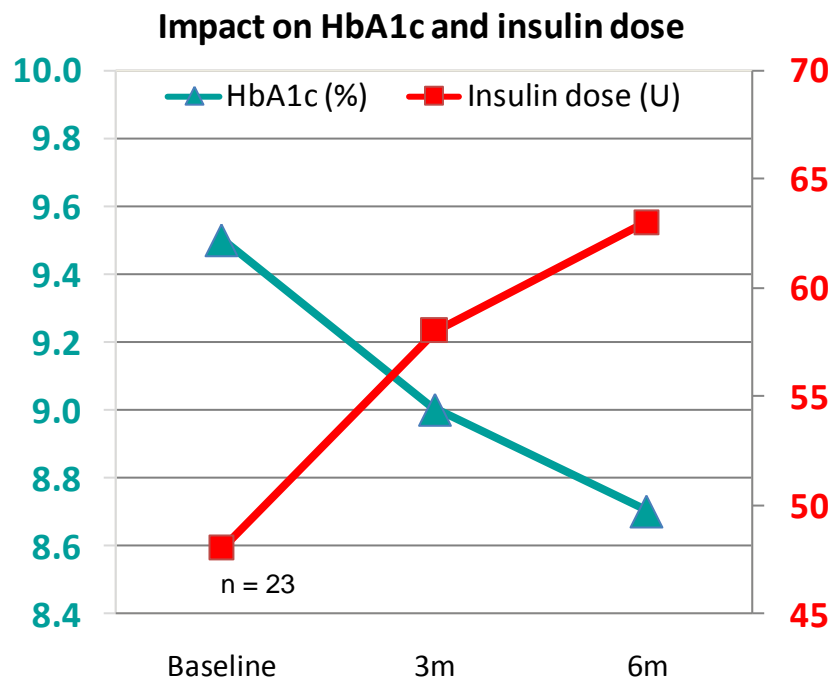
Principal Investigators:

- Prof. L. Tarassenko
- Prof. A. Neil
- Prof A. Farmer

- 9-month *Randomised Controlled Trial* with patients from Young Adult Clinic
- Control group: mobile phone + Bluetooth BG meter + electronic patient diary
- Intervention group: mobile phone + Bluetooth BG meter + electronic patient diary + feedback screens + telehealth nurse support

Insulin optimisation in Type 2 diabetes (2008-9)

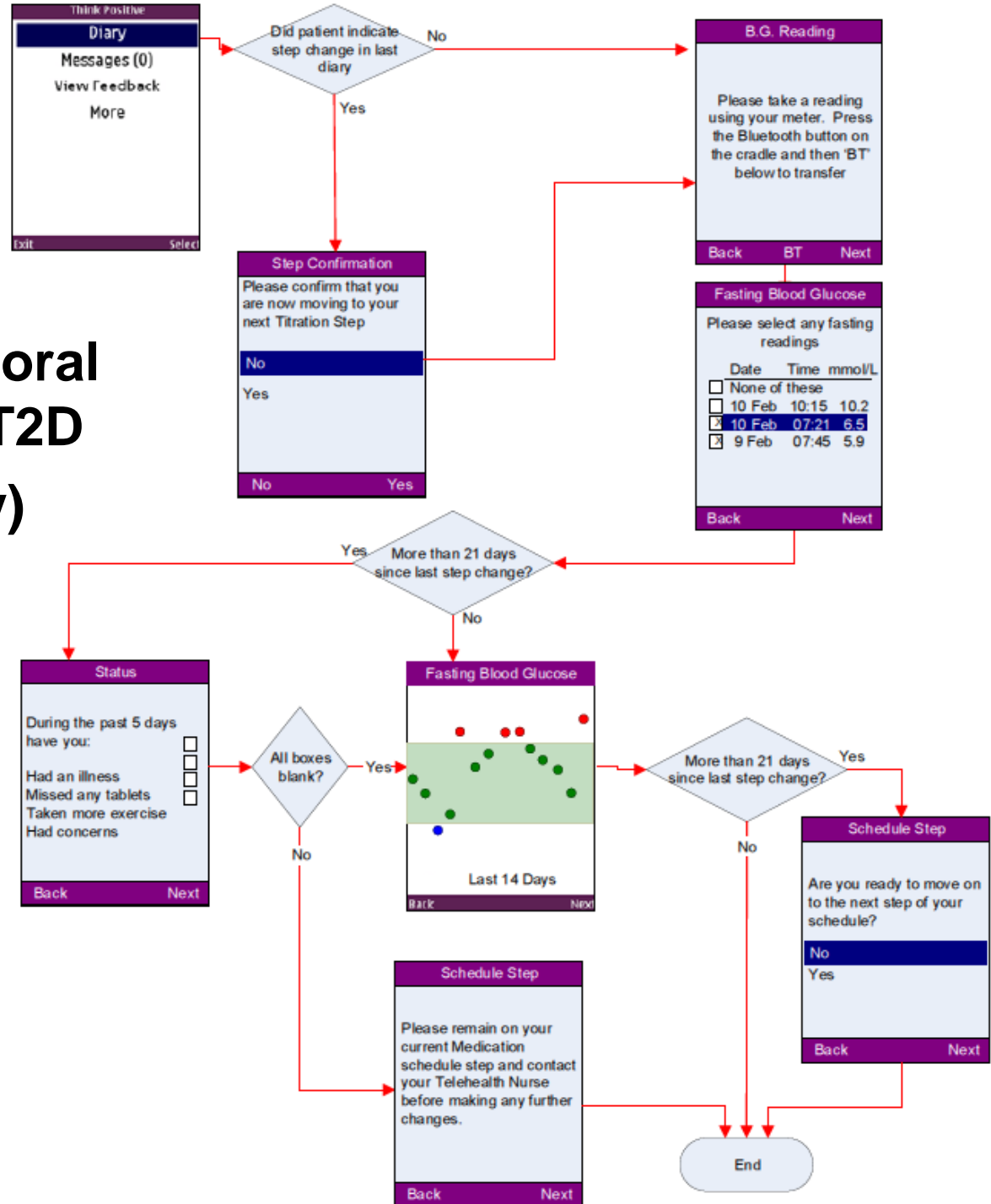
- Patients with uncontrolled type 2 diabetes recruited from 15 general practices and followed for 6 months
- A telehealth nurse working remotely reviewed results and provided telephone support and advice according to set criteria
- Practice Nurses saw a reduction in time to support insulin titration
- Most patients could use the equipment and were enthusiastic about the extra support
- **Blood glucose control improved, as reflected by a mean decrease in HbA_{1c} of 0.66% ($P = 0.05$), with the mean insulin dose increasing by 17 units ($P = 0.006$)**



Turner J, Larsen M, Tarassenko L, Neil A and Farmer A.
Informatics in Primary Care (May 2009)

Larsen M, Turner J, Neil A, Farmer A. and Tarassenko L.
Journal of Telemedicine & Telecare (December 2010)

Self-titration of oral medication in T2D (MATS study)



The objectives of clinical trials

Perspective from industry

- Main objective – effectiveness and safety: Demonstrate that the new device/test offers measurable clinically important benefits to patients (improved outcomes)
- Regulatory: What new results are required to support regulatory approval?
- [Reimbursement: Provide economic evidence (cost-effectiveness) to support reimbursement decisions (financial impact of outcomes)]
- Market adoption: What type of data will help to market the device/test to healthcare professionals (and patients)? How important is it for the trial to be conducted by a key opinion leader?

“Intelligent tests”

Diagnostic tests with software

- Software is regulated as a medical device:
 - if it provides the only means to acquire data from a medical device/ diagnostic test for aiding in the diagnosis or treatment of a patient
 - if it replaces a diagnostic or treatment decision made by a physician
- Blood-glucose + (mobile phone) software is designated as:
 - Class I: if software only transmits and stores the data
 - Class II: if software is used to analyse device-generated data for the purpose of aiding in the diagnosis or treatment of a patient
- Class I: elastic bandages, hand-held surgical instrument
- Class II: powered wheelchairs, infusion pumps
- Class III: implantable pacemakers, *HIV diagnostic tests*

Issues for discussion

- The tension for high-grade medical evidence and the pace of technological development
 - Whole-System Demonstrator technology designed in 2007 (when contract awarded to t+ Medical) is now obsolete at the end of 2011 (when results should become available)
 - Contrast this with whzan (South Central SHA Innovation Newsletter)

Whzan

This is a low cost telehealth solution developed jointly by Solcom Ltd and the South Central SHA. It offers a new approach to telehealth using an Android Smart phone or tablet PC and internet cloud architecture. **This is now in patient use having been developed from scratch in less than 1 year.**



Issues for discussion

- The tension for high-grade medical evidence and the pace of technological development
- How different are medical devices/diagnostic tests from drugs?

Drummond, Griffin, & Tarricone (2009): “Six Reasons Why Devices Are Different”

1. Many are diagnostic (not therapeutic)
2. Difficulty in doing RCTs (learning curve with new device)
3. Efficacy depends on how devices are used (e.g. skill of surgeon)
4. Implementation may have wider economic implications (training, healthcare delivery infra-structure)
5. Lack of equivalent evidence for competing products
6. Prices more likely to change over time

Issues for discussion

- The tension for high-grade medical evidence and the pace of technological development
- How different are medical devices/diagnostic tests from drugs?
- Design of control group with “multi-component” intervention: device/diagnostic test, feedback to user, integration into clinical pathways
- Primary outcomes versus secondary outcomes versus *post-hoc* analysis