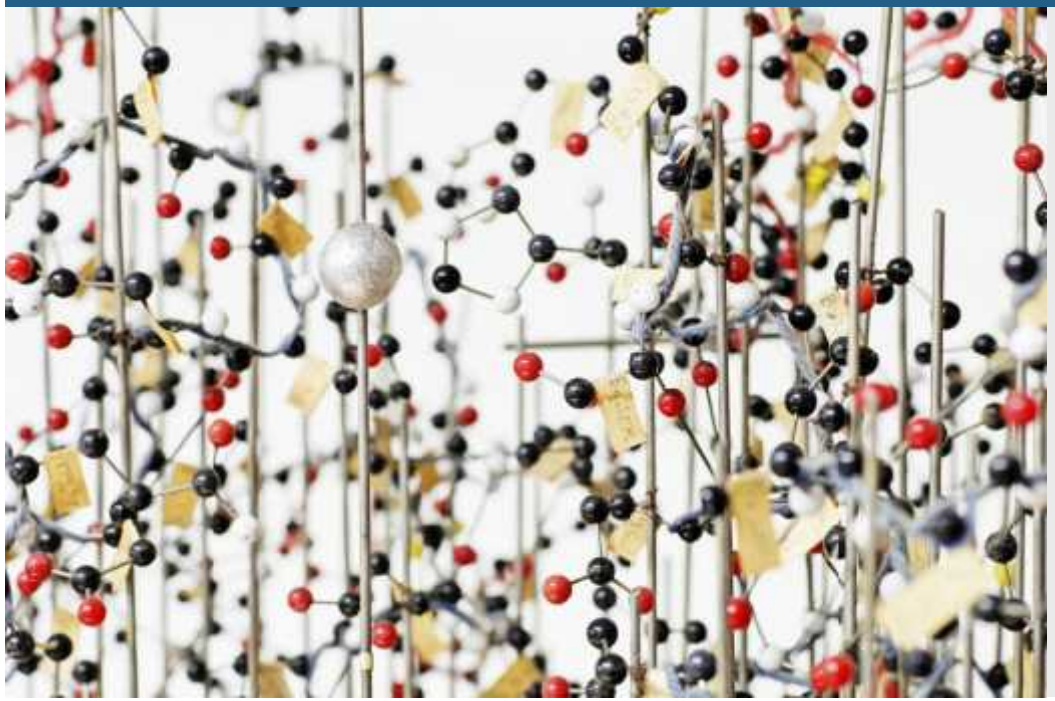
Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks



Primary Care Pilot

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Denmark 13/11/2013

REACTION

ICT 248590

Primary Care Clinical Field Trial

Research Question

To investigate the feasibility of using the REACTION Platform including remote monitoring, patient education and Risk Stratification to improve clinical outcomes and patient self-management for a diabetes population in primary care

- The REACTION platform enables collection of data from both remote monitoring equipment, patient input data via the patient portal and manual entry of data extracted from the EPR to create a comprehensive diabetes data management system
- Outputs allow for risk stratification to identify patients in the greatest need of medical intervention and provide educational feedback to support patient self-management

Objectives

Aim

- The aim of the study is to investigate whether improvements could be made in clinical outcomes, patient compliance and self-management, and patient/clinician satisfaction through an assessment and intervention program

The objectives of the study are to

1. Improve professional compliance by following defined Map of Medicine and NICE guidelines to identify and target interventions
2. Improve patient outcomes as measured by HbA1c, Cholesterol, …… home blood pressure and home blood glucose measurements
3. Improve patient understanding and compliance with therapeutic regimes
4. Measure patient and clinical perception and satisfaction

Primary Care Clinical Trial Activities

- **Clinical Pre-Pilot – Sep 2012**
- **Clinical Pilot – Jan 2013**
  - –Home Physiological Measurements
  - –Activity/Diet Data
  - –Compliance Data
  - –Risk Stratification
- **Interim Evaluation – June 2012**
- **Long Term Risk Sep 2012 – 2013**
  - –Data Extraction for type 1 and type 2
  - –Validation of models
- **Short Term Risk Dec 2013**
  - –Pattern Management
  - –Semantic Search
- **ePatch ECG**
  - **–Pre-Pilot – May 2013**
  - **–Pilot – Oct 2013**

Pre-Pilot Phase

- Friends and family testing - involved users that were not from the target population, they included researchers, friends and neighbours of those working within the study. 3 participants
- Field Testing - involved patients from the target sample – 7 participants

Objectives

- Test reliability and robustness in a non-lab environment
- Test functionality of the equipment in a non-lab environment
- Test usability and functionality of patient portal
- Test usability and functionality of clinical portal
- Receive usability feedback
- Train clinical users on equipment and clinical interface
- Refine monitoring and clinical protocols

Pilot Phase – Jan 2013 Sample

Patient Selection. All patients on the diabetes register are eligible to be included

Current Population n = 205

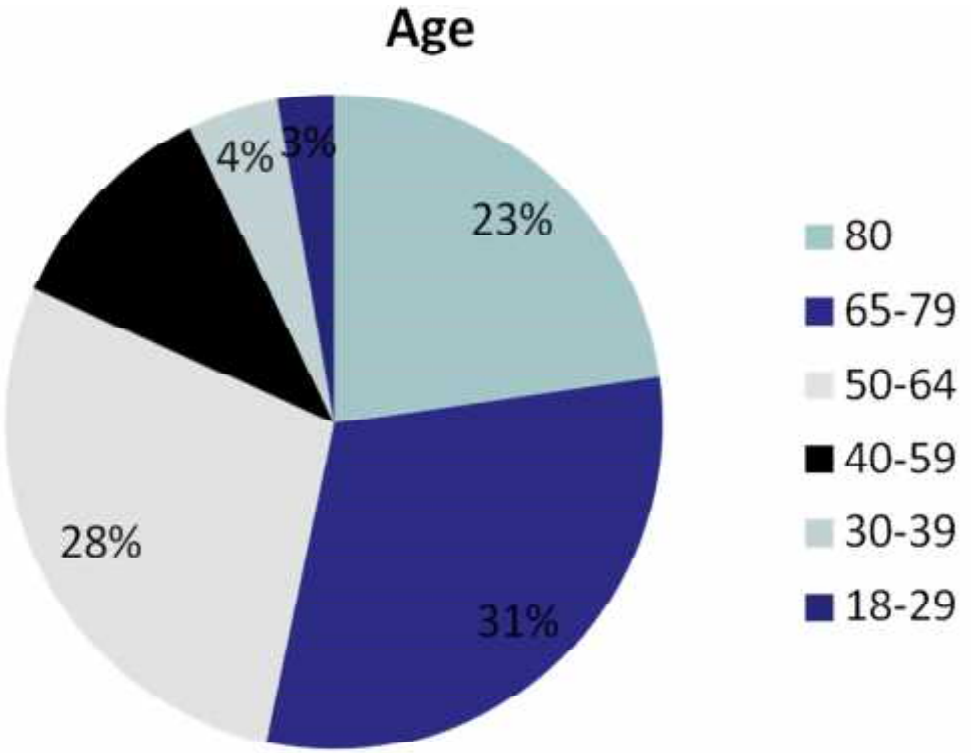
- Type 2 = 179
- Type 1 = 26

Age Range: 18 – 96

- 7% < 40
- 53% ≥ 65

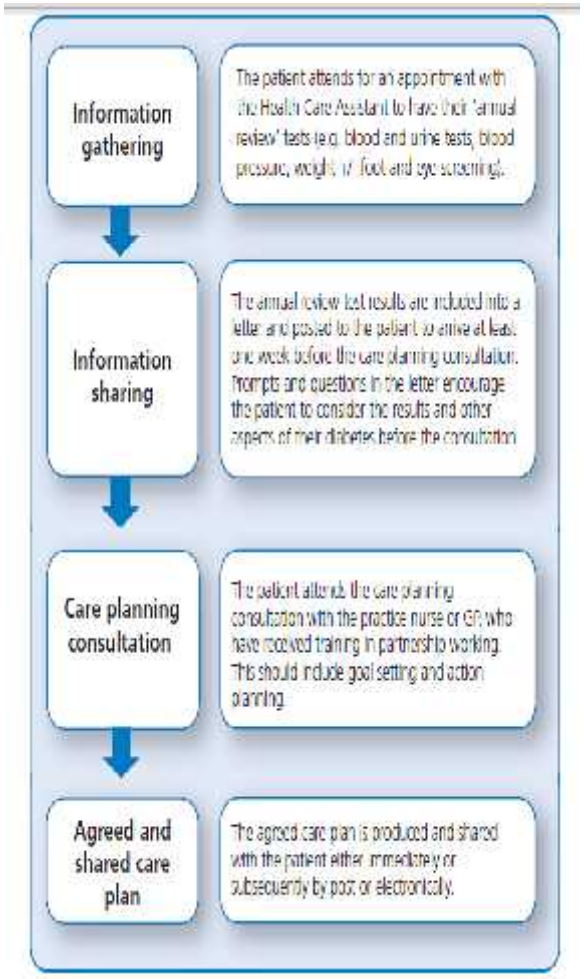
Gender

- Male = 62%



Primary Care Work Flow

NICE Workflow



Activity

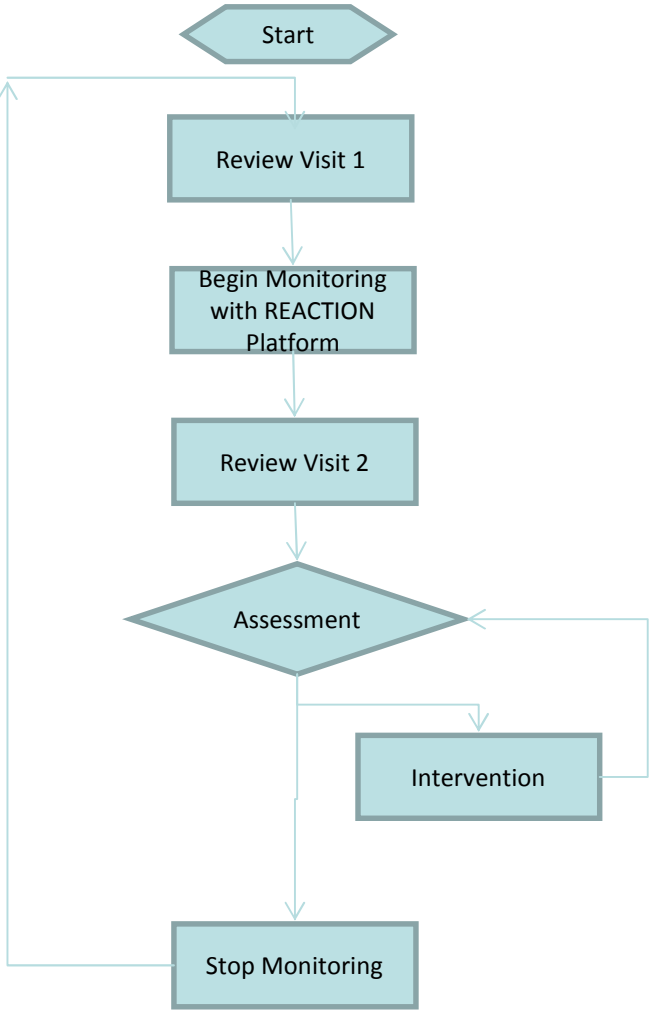
Clinic Tests
Monitoring data
Diet Data
Activity Data
Medication Data

Shared via the patient portal

Review
Long Term Risk
Short Term Risk

Clinical Action
Referral
Patient Self Management

REACTION Workflow



Protocol – Organisation

- Patients invited to take part at 6 month and 12 month appointments – offered as usual service
- Administrative support for enrolment/training is given by a non clinical care assistant
- Patients are seen by the diabetes nurse for 1st review visit – 30 min appt
- Patients seen by GP for follow up review – 10 min appt
  - Review Remote Monitoring Data
  - Record outcome on EPR
- Risk stratification is completed through review by GP
- Interventions are conducted by Nurse and GP

Protocol – Review Visit 1 - Revised

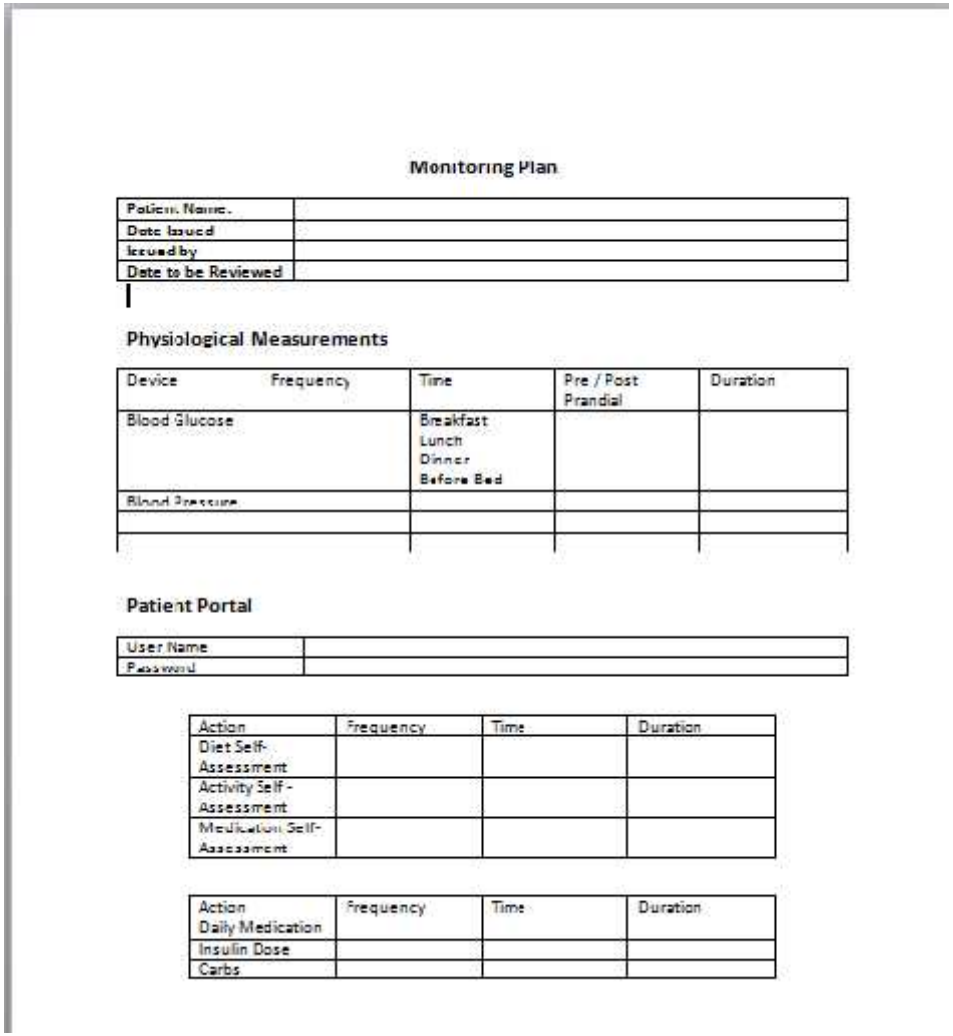
- Appt times increased to 30 minutes
- Usual clinic tests taken
- Patient is enrolled onto the program
- Above carried out by nurse

Protocol – Review Visit 1 - Revised

- Patients instructed in the self monitoring of blood glucose and blood pressure
- Given monitoring plan
- Given access to patient portal
- Above carried out by non clinician immediately after appointment

Protocol – Home Monitoring

- Patient asked to self - monitor fasting Blood Glucose and Blood Pressure for 14 days
- Complete activity Self assessment
- Complete diet Self assessment
- Complete medication compliance
- Given access to patient portal



Monitoring Plan

Patient Name:	
Date Issued	
Issued by	
Date to be Reviewed	

Physiological Measurements

Device Frequency	Time	Pre / Post Prandial	Duration
Blood Glucose	Breakfast Lunch Dinner Before Bed		
Blood Pressure			

Patient Portal

User Name	
Password	

Action	Frequency	Time	Duration
Diet Self-Assessment			
Activity Self - Assessment			
Medication Self-Assessment			

Action Daily Medication	Frequency	Time	Duration
Insulin Dose			
Carbs			

Protocol – Clinical Monitoring

- Patients are monitored for missing data or extreme values during the 2 weeks by non clinical staff
- Risk profiles are generated using risk engines (UKPDS) and clinical guidelines
- Results are reviewed by GP and Nurse
- Patients are stratified into High, Medium and Low Risk groups
- Interventions are planned

Protocol – Risk Stratification Model

Risk Factor	Low	Medium	High	
HbA1c	<7%	7-8%	>8%	
Total Cholesterol	<4 mmol/L	4-5 mmol/L	>5 mmol/L	
LDL	<2 mmol/L	2-3 mmol/L	>3 mmol/L	
HDL	>1	0.9 - 1	<1	
Blood Pressure	<140/80 <130/70 Renal	140-150/80-85	>150/85	
Fasting Blood Glucose	<7	7-10 mmol/L	>10 mmol/L	
History				
Renal – EGFR >90 age N/A	CKD1 60-89 mL/min	CKD2 30-59 mL/min	CKD3 15-29 mL/min	CKD4 < 15 mL/min
Creatinine - Male	<110 μmol/L	<150 μmol/L	>150 μmol/L	
Creatinine - Female	<92 μmol/L	<150 μmol/L	>150 μmol/L	
CVD – Amputation, Medium to high foot risk, history of atrial fibrillation or Stroke (CVA)				
CHD – UKPDS , MI or Stent/CABG (heart surgery)				

Protocol – Review follow up

- Patient results are shared and discussed with the patient
- Care Plan agreed and shared either via the patient portal or paper
- Intervention takes place if necessary

Protocol – Intervention

Intervention	Reaction Tool Kit

Decision on Therapy – Lifestyle
• Referral to self management courses
  • Diabetes Education
  • Dietician
  • Activity
	Diet Self Assessment
	Activity Self Assessment
	Education
	Recording Carb Intake

Decision on Therapy – Blood Glucose Control	Blood Glucose Monitoring
Decision on Therapy – Oral Therapy	Blood Glucose Monitoring Medication Compliance
Insulin Therapy	Blood Glucose Monitoring Insulin Diary
Complications/RISK • Cardiovascular Team • Renal Team • Ophthalmology • Vascular Surgeon • Neurologist • Obs Gynae – pregnant patients only	Monitoring of Co-morbidities: •Blood Pressure •Weight •SpO2 •Step Up Patients • Video Conferencing

Managing Patient Information Clinical Portal

Managing Patient Information – Clinical Portal

- Data collection by monitoring devices (and optional manual entry of physiological data)
- Data analysis (e.g. above/below thresholds, patterns) and presentation of the results
- Integration of data from various sources
- Administrative functions (user management, equipment management, etc.)
- Data collected about diet, physical activity and medication compliance
- Generates and sends notifications (alerts, reminders) to the user
- Definition of the care plan

Sharing Information – Patient Portal

Sharing Information – Patient Portal

- Patients can view graphical trend and tabular data
- Patients can view educational material recommended by the healthcare professionals
- Patients can manually enter physiological data and lifestyle data
- Patients can view their own care plan on patient portal
- Personalized user settings
- Decision support for patients (lifestyle advice, recommended educational resources)
- Introduction of Skype capabilities
- Ability to book appointments and order repeat prescriptions on patient portal

Evaluation – MAST Methodology

Measuring Outcomes

- Measure compliance as defined by Map of Medicine and NICE guidelines to identify and target interventions
- Improve patient outcomes as measured by HbA1c, Cholesterol, …… home blood pressure and home blood glucose measurements
- Improve patient understanding and compliance with therapeutic regimes
- Measure patient and clinical satisfaction

MAST Domains

- Clinical Outcomes
- Professional Perception
- Patient Perception
- Resource Usage and Organisational Impact

Evaluation – Measuring Project Outcomes

Clinical Evaluation

- Identify Risk/Risk Stratification
  - Comparative analysis of GP Judgement vs algorithm
- Measure Interventions - % of whole population
- Record Types of Intervention
- Measure Compliance Levels
- Measure Time to control
- Medication Compliance

Evaluation – Measuring Project Outcomes

Professional Perception – Evaluation

- Clinical Portal – Usability
- Device - Usability
- Long Term Risk Model – Usability
- ePatch – Usability
- Semantic Search – Usability
- Pattern Recognition – Usability

Evaluation – Measuring Project Outcomes

Patient Perception – Evaluation

- Focus Groups – Nov/Dec - 2013
  - Measure perception of service
  - Measure perception of tools
- Usability study of Patient Portal – Dec 2013
  - 20 patients to be selected
- Questionnaires – All Patients
  - Patient Perception Questionnaire

Evaluation – Measuring Project Outcomes

Resource and Organisational – Evaluation

- Impact on existing pathways
- Impact on clinical time
- Impact on resource usage
- Economic Reporting

Interim Results – Sample

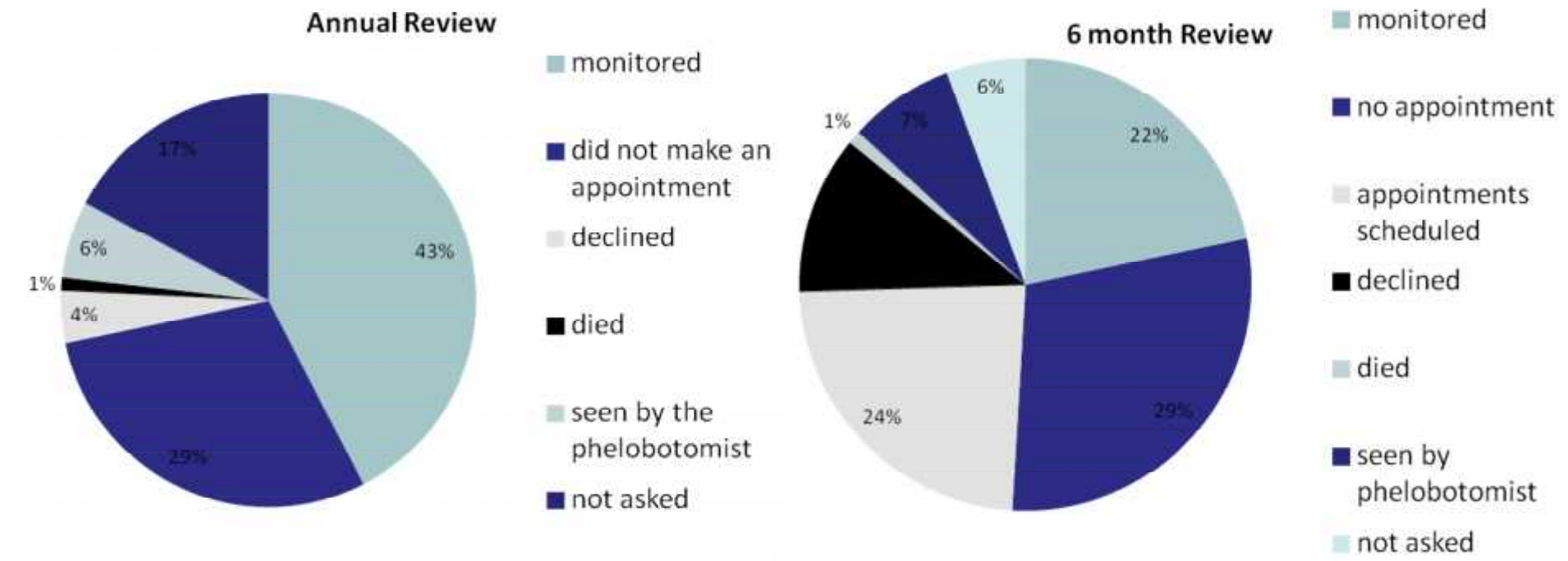
Patient demographics

- 44% of population has been monitored
- Average age of subjects enrolled – 65
- Average duration of diabetes – 9 years
- 68% men/32% women

At baseline, patients controlled their diabetes with:

- Insulin-oral therapy combination 17%
- Oral 49%
- Insulin 22%
- Diet and exercise 15%

Interim Results – Monitoring Statistics



Interim Results – Device Assignment

- Home Gateway – Black box
  - 9 patients – Avg 1 hour in patient home
  - Installation by clinician and non clinical researcher
  - Selected as they had access to Broadband

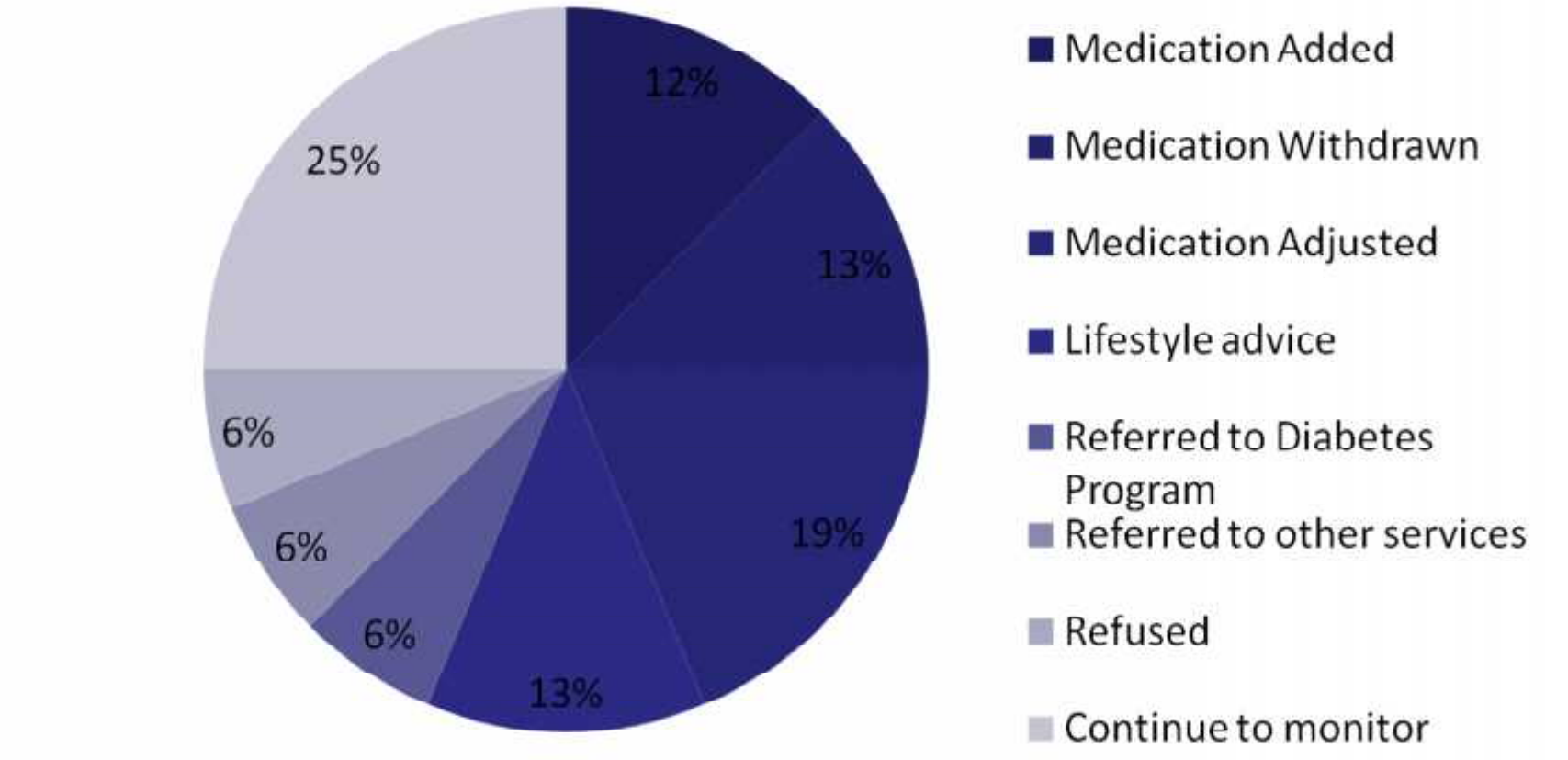
- Patient Gateway
  - 87 patients
  - 8 installations by clinician – Avg 45 hour in patient home
  - 79 patient self installs – Avg 10 min training at health centre

Interim Results – Technical Challenges

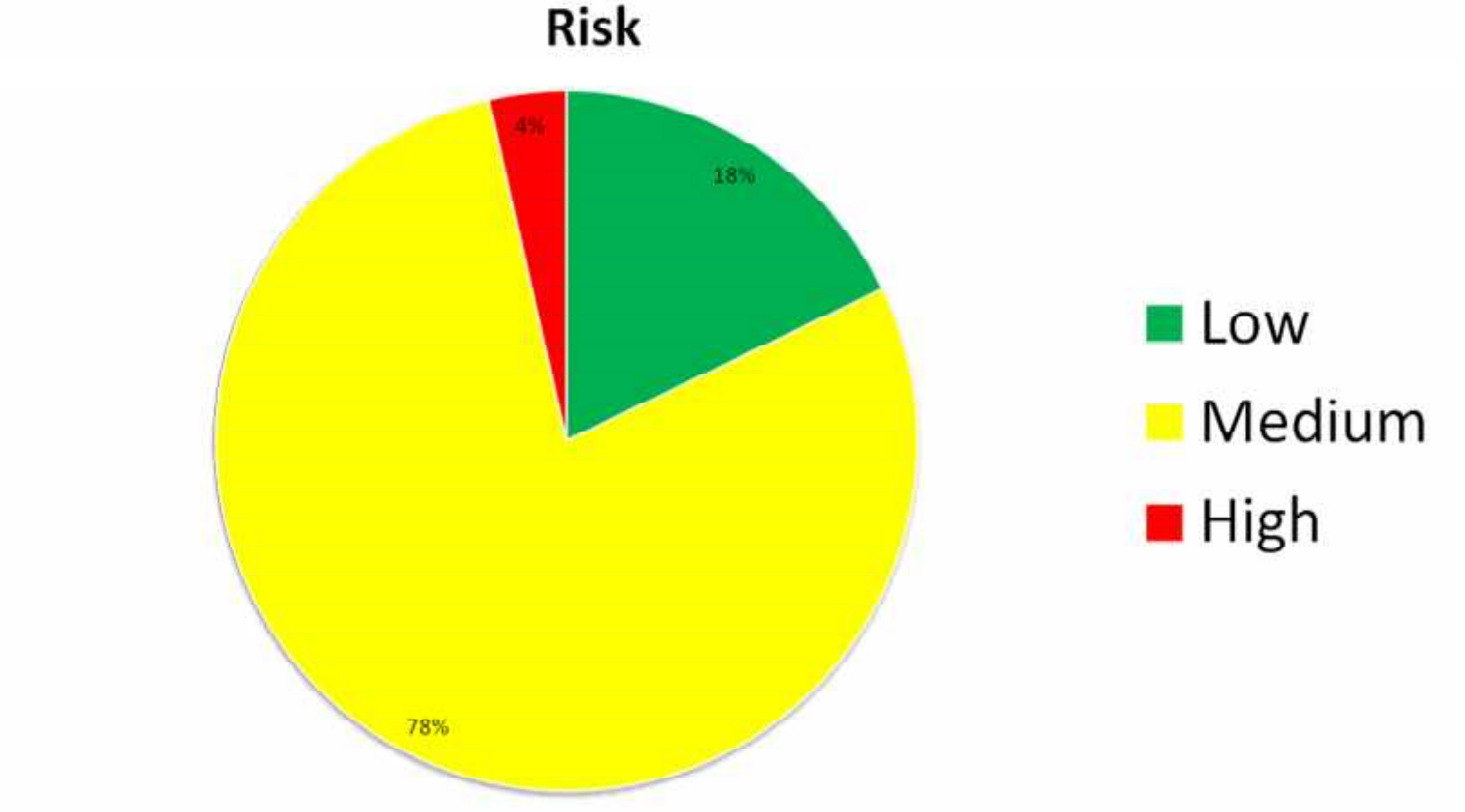
- All
  - Blood Glucose Testing
- Patient Gateway
  - Mobile Connectivity
- Home Gateway (Blackbox)
  - Connectivity
  - Broken Wi-Fi Antennas
  - Installation Logistics
  - Automatic Updates

Interim Results – Clinical Outcomes Intervention Rate

- Intervention rate – 24%



Interim Results – Risk Profile



Interim Results – Intervention

- O% of Low Risk received an intervention
- 52% of Medium Risk received an intervention
- 100% of High Risk received an intervention

Long Term Risk Assessment Models

- A Long Term Risk Assessment Model consists of a mathematical formula that accepts a set of parameters as input and provides an estimate of the probability of developing a particular complication

- Example: probability of Retinopathy worsening

$$p(Retinopathy) \approx -0.71 \cdot GROUP + 0.48 \cdot HBA00 + 0.25 \cdot RETPAT00$$

Variables	Description
GROUP	Type of glucose control (Strict = 1, Normal = 0)
HBA00	Haemoglobin A1c at Baseline
RETPAT00	Retinopathy Severity Level at Baseline

7 different models, validated on retrospective data

	Probability of correctly predicting risk calculated on		
Model	**DCCT sample**	**Type I validation cohort**	**Type II validation cohort**
Adverse Cardiac Event	0.7257	0.7759	0.863
Hypoglycemia	0.6694	0.6078	-
Ketoacidosis	0.6745	0.8824	-
Microalbuminuria	0.7421	-	0.7288
Proteinuria	0.833	-	-
Neuropathy	0.6661	0.8	0.7442
Retinopathy	0.6573	0.6635	0.4911

Interim Results – Long Term Risk

- For the type I diabetes patients, 5 predictive models reached predictive performances similar to the ones obtained on the original DCCT data
  - Adverse Cardiac Event
  - Hypoglycaemia
  - Ketoacidosis
  - Neuropathy
  - Retinopathy
- The other two models did not have enough cases to provide meaningful results

Interim Results – Long Term Risk

- For Type II diabetes patients, 3 predictive models out of seven performed well on the new data
  - Adverse Cardiac Event
  - Microalbuminuria
  - Neuropathy
- The Ketoacidosis model was not applicable on Type II patients
- Not enough cases for evaluation of the models related to Hypoglycemia and Proteinuria
- The Retinopathy model provided results close to random guessing

Interim Results SUTAQ – Patient Perception

Enhanced Care

- Provided enhanced care that was over and above what they consider to be their normal care
- More actively involved
- Improved sharing of information

Access to services

- Not helped in accessing services

Privacy and Discomfort

- Most of those that agreed to take part did not have concerns

Personnel Concerns

- No concerns over who was looking at data or safety of data

Replacement for usual care

- Not a substitution for normal health
- Not as suitable as regular face to face

Satisfaction – good

Interim Results – Patient Perception

- “Devices easy to use”
- “Helped monitor intake of foods”
- “Able to enter manual data when the kit did not work well”
- “Was easy to use and was helpful to see own data”
- “Made me more Proactive”
- “Tool to help me and others in the long term”
- Not a replacement for normal care – “I still have diabetes and must use all resources at hand to improve my care and treatment”
- “Would like to be able to enter comments about the measurements”

Interim Results – Patient Challenges

- **Review Visit Attendance**
  - Patient attendance to review visits is variable
  - Some only attend once per year - QOF
- **Blood Glucose Monitoring**
  - Type 2 patients not used to blood glucose monitoring
- **Patient compliance to monitoring plan**
  - Low compliance with diet, activity and medication questionnaires – either paper based or patient portal <10 % completed to date
- **Low usage of Patient Portal** < 10%
  - Elderly population – even with access to PC there is low confidence in using
    - "Do not want to"
    - "Clinicians can look at it"
  - Difficult to estimate usage
  - Those that have used it report it to be useful

Interim Results – Professional Perception

Benefits

- Helps facilitate and inform conversations with patients
- Improved clinical compliance levels
  - Review of clinical management
  - Care plans
- "Improved ability to target those patients that need additional support which may reduce workload by not having to manage those that are not in need"
- Devices are "easy to use"
- Improvements in clinical portal are making information easier to manage but "needs to be integrated with existing EPR" to avoid duplication of data

Interim Results – Professional Perception

Challenges

- Impact on workload
  - Recruitment and Traning
  - Managing incoming data – Who reviews data?
  - Managing incoming data – intelligent rule definitions
  - Confidence in making decisions based on incoming data
  - Increase in interventions = increase in appointments

- Duplication of data entry EPR and REACTION Clinical Portal

Interim Results – Revised Protocol

Change to recruitment and training

- More targeted time spent with patient training
  - More time for patients to ask questions
  - Focus on blood glucose testing
- Reduced the need for home visits and support calls
- Less impact on clinical time
- Higher enrolment rate
- Improved home monitoring compliance

Patient Data Management – Rules

Alerts

- Most clinical portals provide a simple alerting system
  - Is patient data above or below defined thresholds?
- Generates alerts on a screen

- Many tend to be false alerts
  - Time consuming to review data
  - Clinicians begin to ignore

- Systems need to be based on clinical workflow
  - Monitoring of Acute Exacerbations
  - Monitoring of Trend

Patient Data Management – Basic Rules

Use Case 1:

- Is physiological data from the devices being received each day? – or is there missing data?

- If data is not being received the device status should be checked for connectivity issues and the patient should be contacted by phone to determine if there is a reason for the missing physiological data. Reasons for missing data

  - Patient forgot or did not want to take a measurement
  - Patient Training issue
  - Device error
  - Transmission error
  - Clinical Web Server Error

Patient Data Management – Basic Rules

Use Case 2:

- Is the physiological data extreme? – e.g. blood glucose < 4 or > than 14 AND/ OR Blood Pressure < 90/10 OR > 210/110

- If the physiological data is an extreme value the clinician will make a clinical judgement as to whether they should contact the patient or continue to monitor. Reasons for extreme values could include:

  - Device error
  - Patient training issue
  - Clinical reason
  - Transmission error
  - Clinical Web Server Error

Patient Data Management – Advanced Rules

Use Case 3:

- It is found that the patients' Blood Glucose levels are too high, the patient has previously had medication which has made them have hypos. Patient is prescribed an additional medication. Clinician wants to monitor their BP and BG for 1 month

  - Extreme values
  - Missing values
  - Is the average blood glucose of 14 days > 7 mmol/L
  - Is the average blood pressure of 14 days => 140/80 OR
  - Does the patient have a history of kidney, eye, cardiovascular AND is the average blood pressure of 14 days > 130/80

Next Steps

- Clinical Evaluation – January 2014
- Integration of data with EPR - talks with EPR provider
- Improved data analysis and information visualization methods
- Advanced patient management and notification
- Integration of
- Semantic search
- Long Term Risk Tool into clinical portal

ePatch Pre-Pilot

Aim

- To investigate the usefulness and feasibility of using the ePatch® in a Primary Care setting from a clinician's perspective
- To understand the usability and satisfaction from a patient's perspective

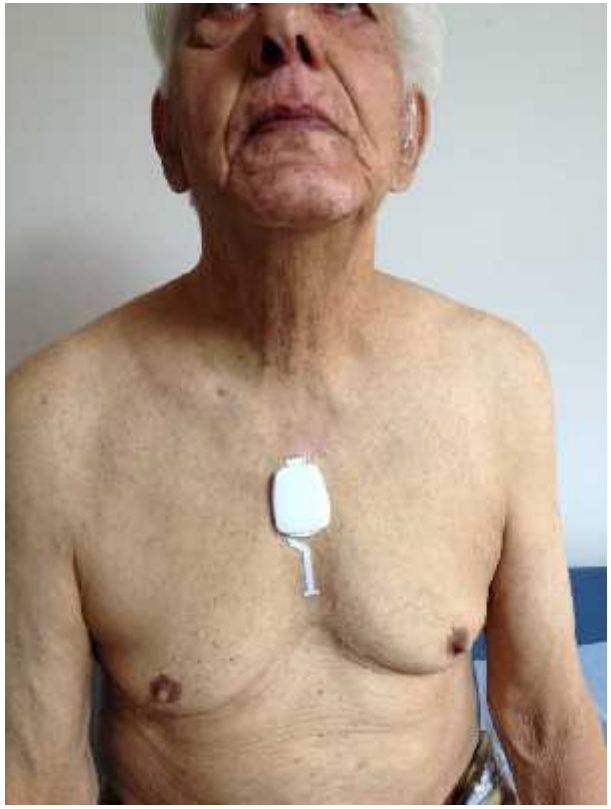
Methods

- 5 patients who attend the Warfarin clinic at Chorleywood Health Centre were invited to take part in the demonstration

ePatch Pre-Pilot

- The ePatch® fitted to patient and asked to wear for 24 hours
- Patient instructed not to shower or get the sensor wet while wearing it
- Patients asked to return to the health centre the next day to have the sensor removed
- Patients asked to complete a questionnaire

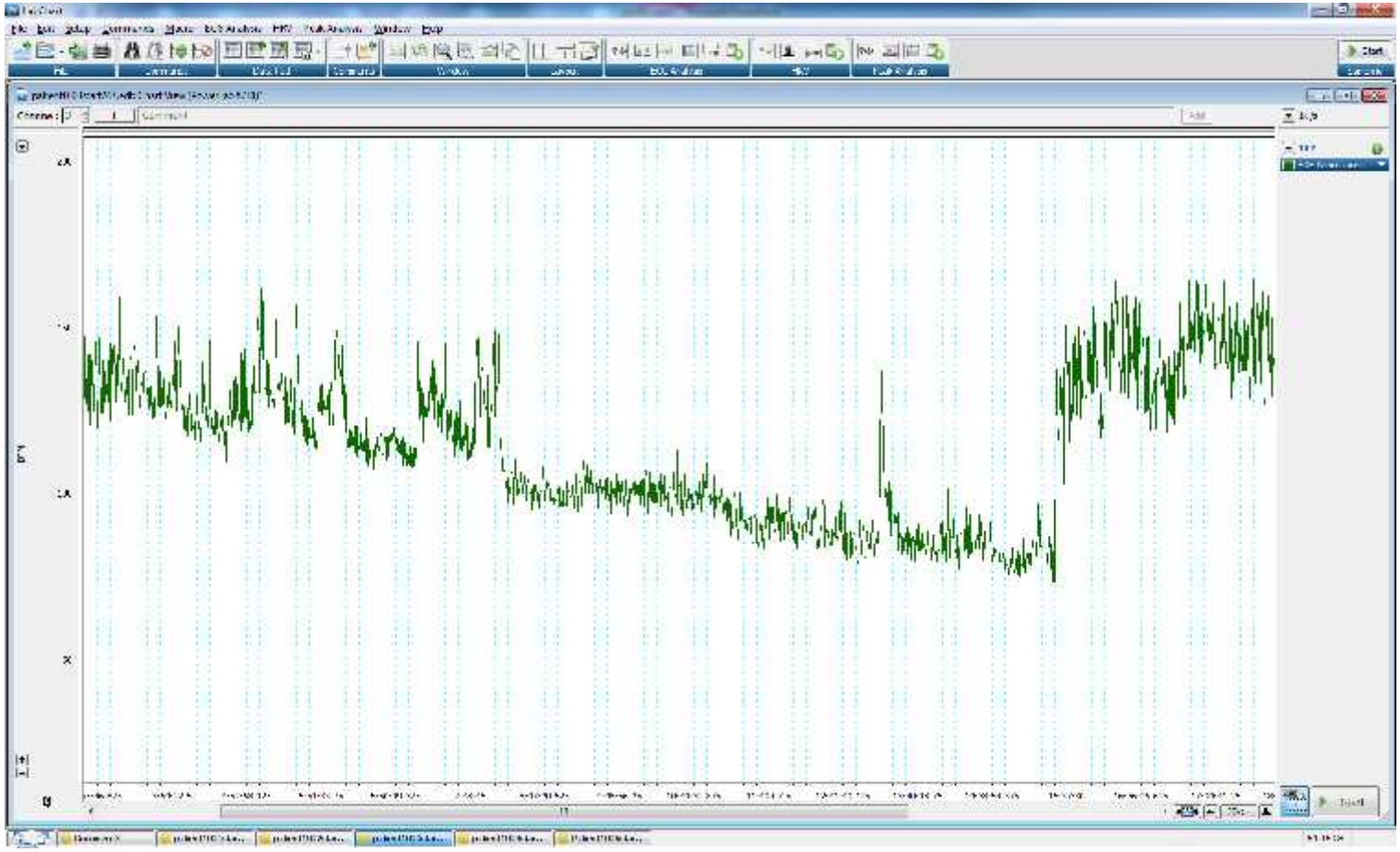
ePatch Pre-Pilot



pt1005 – woken up at 4:30 am by two cats in bed

pt1005

pt1003 trend curve



Patient Feedback

- All of the patients said the ePatch® was very comfortable to wear
  - "Don’t know I've got it on, especially in bed. I have had boxes and in bed they are very uncomfortable"
  - “Unaware of wearing it”
- All patients said that they felt the ePatch® was very discreet
  - “The ePatch would be very obvious if worn with an open top neckline”
  - “Possibly it being so unobtrusive you can forget you've got it on e.2. Buttoning up shirt and putting clothes over the head”
  - “Unnoticeable”
- None of the patients reported any problems while wearing the ePatch®

- All of the patients were very satisfied with the ePatch®