Remote Accessibility to Diabetes Management and Therapy in Operational healthcare Networks.

REACTION (FP7 248590)

D8-1 Clinical protocol for MDI compliance

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Manuel Perez	2011-05-31	Minor changes, typos and formatting corrections

1. Executive summary

Care of diabetes in the community (out-of-hospital/outpatient) is becoming ever more demanding and necessary. Where once diabetics, both Type I and Type II, were cared for mainly by hospital based services, there has been a steady move toward community based care. The relative number of Type II diabetics is increasing. Diabetics have complex and debilitating co-morbidities. More young people and children are presenting with Type II diabetes and this will increase if obesity in childhood and young adulthood continues to increase. Member states of the EU have differing health care structures and service stratagems but all face the same conundrum: a growing health problem that cannot be coped with let alone afforded by present service design and patient pathways.

Compliance (also adherence, concordance, or capacitance) describes the degree to which a patient correctly follows medical advice. Most commonly, it refers to medication or drug compliance. It is an essential part of a successful health outcome but is largely the responsibility of the patient.

It has been estimated that almost 40% of all prescriptions are taken incorrectly. A WHO study[1] suggested that increasing the effectiveness of adherence interventions may have a far greater impact on the health of the world population than any improvement in medical treatment and that monitoring of medication compliance has been shown to result in a 50%[2] improvements in compliance.

Examples of the rate and consequences of non-compliance for selected medical disorders are as follows:

- Diabetes non-compliance (98% in US) is the principal cause of complications related to diabetes including nerve damage and kidney failure
- Hypertension non-compliance (93% in US, 70% in UK) is the main cause of uncontrolled hypertension-associated heart attack and stroke
- Asthma non-compliance (28-70% worldwide) increase the risk of severe asthma attacks requiring hospitalization[3.]

The objectives of this deliverable are to:

1. Establish a compliance monitoring application for MDI (Multiple Daily Injection) insulin pens therapy and assess its impact on the patient's clinical pathway.
2. To establish a compliance monitoring program using a medication dispenser in order to determine its impact on the patient's clinical pathway.

   Or in the event that the insulin pen is not available due to Novo Nordisk not joining the project then:

3. Establish compliance monitoring using manual recording of time and dose of the insulin injection and the patient will be instructed to use the smart phone (or similar user terminal) to send the data to the REACTION platform and assess its impact on the patient's clinical pathway.

2. Background

2.1.1 Purpose, context and scope of this deliverable

Chronic diseases are the largest cause of death world-wide and cardiovascular disease in particular accounts for 17 million deaths because of heart disease and stroke in 2002. It is suggested that the solutions to these problems are inhibited by economic factors and the orientation of health systems toward acute care. If the impact of this level of chronic disease is to be reduced then the following must be addressed: the care of chronic disease needs a higher priority; better control of risk factors; care of patients by a healthcare system that espouses a multi-professional and multi-sectorial approach[4]. General practice is key to making disease management programmes effective. The latter are described in NSFs and NICE guidelines and their delivery measured by QOF points in the nGMS. A meta-analysis of the literature on the effectiveness of interventions in chronic disease management programmes concluded that most improved care but little evidence of which model of care was most effective – clinically and economically.

2.1.2 Current Practice

Patients in a primary care setting are usually (but not exclusively) Type 2 Diabetes patients who have been diagnosed in middle or older age. Most of these patients are started on diet and exercise pathways initially and for some very disciplined patients whose diet was high in sugar previously this is often enough for a number of years.

However most patients do not have the discipline or the will power to sustain these efforts and often lapse back into bad dietary habits and inactivity. Therefore there is a progression onto oral therapies, gradually increasing in dose and drug regime until there comes a point where insulin is inevitable. There are several regimens and insulin available so wherever possible we match the appropriate regime is matched to the patient.

Traditionally, concordance is assessed by reviewing patient medication e.g. how often patients are ordering their medications. Is the patient ordering appropriately –i.e. if they are supposed to be taking 1 gram of metformin twice daily they should be ordering 112 tablets every month (224 every two months – the most common period for ordering repeats in our practice).

Community pharmacists can be partners in this by ensuring that patients are not only ordering these prescriptions but are also putting them into pharmacies to be dispensed.

However only the patient knows if they are taking the drugs as prescribed or not. A steep rise in a patient's blood results in that should blood glucose rise steeply it may suspected that a patient is not taking their medication. Our community colleagues – District nurses and other professionals who go into the home can help by asking patients how and where they store their medication – this may identify stockpiling of unused medicines. This is common in the elderly population who may have some degree of cognitive impairment. There is also a small cohort of patients who drink alcohol to excess and who may not be taking afternoon or evening medications on a regular basis.

2.1.3 Definition of Compliance

Compliance (also adherence, concordance, or capacitance) describes the degree to which a patient correctly follows medical advice. Most commonly, it refers to medication or drug compliance. It is an essential part of a successful health outcome but is largely the responsibility of the patient.

2.1.4 Issues with Compliance

It has been estimated that almost 40% of all prescriptions are taken incorrectly. A WHO study[1] suggested that increasing the effectiveness of adherence interventions may have a far greater impact on the health of the world population than any improvement in medical treatment and that monitoring of medication compliance has been shown to result in a 50%[2] improvements in compliance. Another study looking at randomised control trial found that the most common compliance challenges included paying for medications, remembering doses, reading prescription labels, and obtaining refills[5].

Types of noncompliance may include:

- not having the prescription filled
- taking an incorrect dose
- taking the medicine at the wrong time
- forgetting to take one or more doses
- stopping the medication too soon

2.1.5 Impact of non-compliance

Examples of the rate and consequences of non-compliance for selected medical disorders are as follows:

- Diabetes non-compliance (98% in US) is the principal cause of complications related to diabetes including nerve damage and kidney failure
- Hypertension non-compliance (93% in US, 70% in UK) is the main cause of uncontrolled hypertension-associated heart attack and stroke
- Asthma non-compliance (28-70% worldwide) increase the risk of severe asthma attacks requiring hospitalization[3.]

Non adherence has been estimated to cost the US economy up to $100 billion per year. In diabetes, non adherence to oral hypoglycaemic medications may partly explain why only 43% of patients with diabetes mellitus have glycosylated haemoglobin (HbA1c) below the 7% level recommended by the American Diabetes Association.

2.1.6 Classification of Compliance

Patients can be classified into 1 of 3 general compliance categories[6] full compliers who take adequate amounts of medications to control the disorder

- partial compliers, who take many doses but not regularly enough to control the disorder
- non compliers who take few or no doses and whose disorder is unaltered

2.1.7 Standard measures of medication compliance

There are a number of standard measures for compliance. Claxton et al[6] go on to say that compliance data on patient self-reporting may be erroneous not simply because they may not admit to the numbers of occasions they have missed taking medication but are also to do with them not remember if they have or have not taken a dose. Prescription refills are considered questionable for assessment of dosing compliance because they provide no information on timing or quantity of intake. Pill counts are often erroneous because patients do not always retune bottles that have pills remaining. The accuracy of the pill count method is adequate when compliance is excellent because there is nothing to return. Electronic monitoring is considered accurate because it records the time and date of the actual dosing events.

2.1.8 Medication Monitoring Devices

2.1.8.1 Insulin Pens

Insulin pens are now becoming more prevalent for people on insulin therapy. Insulin pens are common in the United Kingdom, and are generally characterised by a different shape and the fact that they use an insulin cartridge as opposed to a vial. Some insulin pens use replaceable cartridges, and others use non-replaceable cartridges and must be disposed of after being used. The replaceable cartridges for insulin pens come in 3 and 1 ½ ml sizes, although 3 is more common and has become dominant. Prefilled insulin pens are disposed of when the insulin within the cartridge is used up. Prefilled pens are often marketed for type 2 diabetics who need to use insulin. Insulin pens are purported to be very easy to use. They are great for young diabetics who need to deliver insulin at school. Furthermore, many diabetics find insulin pens almost painless. They are also portable and discreet, as well as not being as time-consuming as syringes. An accurate dose can be pre-set on the dosage dial, which can be useful for diabetes sufferers who also have impaired vision[7].

2.1.8.2 Electronic Monitoring Device

Electronic Monitoring units vary in design from standard pill containers with a microchip processor chip embedded in the cap the medication boxes with compartments for individual doses to meters dose inhaler canisters that release puffs of medication. Most of the devices monitor medication dosing using special containers that store dosing information that transit data to special software.

Patients are shown how to use the devices and instructed not to open the unit except when medication needs to be removed for dosing[6].

3. Devices to be used within the Study

3.1.1 Novo Nordisk Insulin Pen

It is proposed that within the study a prototype insulin pen will be used provided by Novo Nordisk with built in wireless communication technology. The pen would be capable for registering time and dose of insulin intake and communicate the results via the patients BAN and a personal node, such as a mobile phone to a dedicated monitoring application on the Reaction platform.

Novo Nordisk is the only European company that can offer an insulin injection device which can accurately record the time and dose of the insulin intake.

The latest Novo Nordisk insulin pen is a prefilled insulin pen. The insulin pen is the world's most widely used prefilled insulin pen. The insulin pen is popular because it is simple to learn and use, and because it delivers insulin accurately [7].

Figure 1: Novo Nordisk Insulin Pen

When insulin is needed, a prefilled insulin pen is a commonly used injection system for insulin delivery. The insulin pen is a pre-filled insulin delivery device, eliminating the step of loading insulin into the delivery system. The insulin pen dose-setting mechanism does not allow a dose larger than that remaining in the insulin pen to be administered. It also permits dose corrections without loss of insulin and provides doses in one-unit increments up to 60 units per injection. Each insulin pen contains 300 units of insulin. The dose scale of the insulin pen automatically returns to zero after injection to allow visual confirmation of dose delivery.

The insulin pen is simple to learn and use, it delivers insulin accurately, and the insulin pen has a discreet and non-medical appearance.

Prefilled insulin pens offer several advantages over vial and syringe[8].

- easier to use
- more accurate in delivering insulin doses
- is more discreet in public
- more convenient in general.

3.1.2 Pivotell Plus Battery Operated Pill Dispenser

The following device has been selected as the unit that will be used to monitor oral compliance in the study. The Pivotell Plus is a battery operated pill timer dispenser with text and email notification. Spare internal cassettes are available for pre-filling by carers or a pharmacist. Refill frequency will depend upon the number of daily medications doses required: once a day medication requires refill every 28 days, twice a day medication requires refill every 14 days, four times a day medication requires refill every 7 days.

Features

- internal tray containing 29 sections
- tray rotates at pre-set times to dispense medication and sound alarm
- alarm continues for up to 60 minutes or until the dispenser is tilted tipping the dose out of the appropriate section
- notifies family member, friend or carer by text or e-mail message if medication is not taken on time
- circular plastic lid with lock
- clock can be set to 12 or 24 hour display and is self-adjusting for British Summer Time
- low power indicator

Figure 2: Pivotell Plus

The dispenser can hold up to 28 days supply of medication depending on how frequently medication is taken each day.

When it is time to take medication the internal tray rotates, the alarm sounds and the light flashes. The user then simply picks up the dispenser and tilts it to take the medication in the hand or suitable container. This cancels the alarm and flashing light. The dispenser will then wait until the next alarm time and repeat the process.

The Pivotell Plus dispenser will send a warning via e-mail and text message to a family member, neighbour or carer in the event that:

- Medication has not been taken on time
- The device has been left upside down
- There are only 4 doses remaining before the tray needs refilling
- There is a device error
- The batteries need replacing

A full events history of the dispenser is recorded in the Administration Centre which can be monitored by the family member acting as Administrator. This history includes the actual times that medication was dispensed by the user, and all other messages sent from the dispenser to the Administration Centre (including, for example, the times that the dispenser might have been left upside down) [9].

4. Project Setting

4.1.1 Chorleywood Health Centre - Description

Chorleywood Health Centre is a medium sized general practice based in an affluent area North West of London. The majority of its 6000 patients are elderly and patient care is well managed. The practice achieves high QOF scores, taking 96.4% of the total points available – 0.7% above national average.

The health centre uses the iSOFT Premiere clinical system to store its electronic patient records. This system is connected to Contract+ which is used to manage information required for the GMS contract.
The health centre is staffed by a multi-disciplinary team, including GP's nurses an onsite physiotherapist and counselling services. In addition a Diabetic Retinopathy clinic is held at the centre.

The practice is housed in a purpose built building which replaced its predecessor after a flood in 1997. The building was developed specifically to exploit technology and telecommunications to deliver health care and the team have been using technology as tools to help them with their work for some time. In addition to providing sufficient power points, network outlets, ISDN and telephone lines in each of its rooms, the practice also has a purpose built Telehealth room which houses video conferencing and digital imaging equipment. The practice runs a regular vascular clinic and uses the video conferencing equipment to link with the John Radcliffe Hospital in Oxford. It has a similar program for heart disease linked with Watford General Hospital.

5. Aims of the Pilot

The clinical aim of this study is to:

1. Assess the potential cost/benefit from using insulin pens with wireless communication capabilities for compliance monitoring patients on Insulin Therapy
2. Evaluate the ability of the REACTION platform to launch personalised, easy to use compliance monitoring applications using commercially available insulin pens and standard mobile phones or smart phones
3. Study the benefit of having applications embedded in the communication networks rather than embedded in millions of single products.
4. Evaluate the impact on the patients' health status based on compliance monitoring of patients on oral therapy
5. Evaluate the ability of the REACTION platform to launch personalised, easy to use compliance monitoring applications.

Aims 1 – 3 can only be completed in the event that the insulin pen is available and that Novo Nordisk has joined the project. In the event that the pen is not available:

The compliance study will be carried out with manual recording of time and dose of the insulin injection and the patient will be instructed to use the smart phone (or similar user terminal) to send the data to the REACTION platform.

The clinical work in this subtask will be performed by CHC. Novo Nordisk will supply FlexPen® MDI pens and insulin and IN-JET will evaluate the economic benefits and usability aspects.

6. Clinical Protocol

6.1.1 Overview

Monitoring will include 2 different cohorts. A maximum of 100 patients will be enrolled. One group will be reminded by personalised alerts when noncompliant. The other group will not. All patients will be tested for glycosylated haemoglobin HbA1c every two weeks. The HbA1c level is proportional to average blood glucose concentration over the previous four weeks to three months and will thus represent an aggregated quality measure of the patient's level of glycaemic control. Development in HbA1c levels over a 9 month period will be analysed and compared to the patient case history, with particular focus on registered hyper- and hypo-glycaemic episodes.

Patients identified as having management issues during the 3 week screening program will be provided with a monitoring device as described in Table. Patients within the intervention cohort will receive intervention based on the clinical protocols described in D.8.2.2 and below. Data will be monitored and when non-compliance is identified they will be contacted by the clinical team. Patients with in the control arm will not be exposed to any intervention

Duration of Participation
The intervention will last for 3 months and will be repeated at 6 months and 18 months. Pharmacy refill data of all patients are available from 6 months before, until 6 months after the start of the intervention.

Primary outcome measure will be calculated from:
1) data collected as a percentage of medication taken as prescribed, and as percentage of medication taken within the correct time interval,
2) refill data, taking the number of days for which oral antidiabetics are dispensed during the study period divided by the total number of days of the study period.
3) Differences in adherence between the intervention groups and control group are studied using refill data.
4) Differences in adherence between the two intervention groups are studied using the percentage data.

6.1.2 Patient Selection / Sample

Patients will be selected from the chronic disease register at Chorleywood Health Centre diagnosed with Diabetes Type 1 & 2. Currently there are a total of 204 patients on the disease register. Those that meet the inclusion criteria will be invited to take part. This number is expected to be 100 including a maximum of 17 patients on insulin therapy.

User Group	Patient Numbers
Diabetes Type 1	34
Diabetes Type 2	170
Diabetes Insulin (incl within Type 1&2)	17

Table: 1 Sample Size

6.1.3 Patient inclusion criteria

- The patient must be registered with CHC
- The patient must be on the CHC Diabetes register
- Patients using oral or insulin therapy

7. Monitoring Protocols

7.1.1 Parameters to be Measured

User Group	Blood Sugar	BP	Weight	Spo2	Continuous Blood Sugar	Medication Dispenser	Radio Linked Insulin Pen	Activity	Diet
Oral Therapy	X	Optional	X	Optional	Optional	X	N/A	X	X
Insulin Therapy	**X**	**Optional**	**X**	**Optional**	**Optional**	**Optional**	**X**	**X**	**X**

Table 2: Parameters to be Measured

7.1.2 Refilling of Devices

Patients with the Pivotell Plus pill timer dispenser will require the devices to be refilled at:

Once a day medication: 28 days
Twice a day medication: 14 days
Four times a day medication: 7 days

The two main pharmacies that serve the community will be responsible for filling the medication dispensers which will either require the patient to collect directly or will be delivered to the patient by the research team at CHC. Where this is not possible CHC will liaise with the patient directly to organise their medication for them.

Patients with the Novo Nordisk insulin pen will be given refills to last for 28 days and will be required to attend the Health Centre to collect the repeat doses.

7.1.3 Reviewing Patient Data

The CHC Research Nursing team will be responsible for reviewing patient data received from the monitoring equipment via the reaction Platform. The CHC research team will require access to a PC with internet access to view the patients monitoring information.

The team will review the monitoring data once per day – Monday to Friday. Patients will be informed that even though they are sending data each day, a nurse may not view this data each day.

7.1.4 Intervention Protocols

In order to respond to the monitoring data in a timely and organised way, a series of monitoring protocols have been developed. These include:

- No data received
- Compliance
- Non Compliance
- Technical Issue

The following process flow diagrams provide an overview of the processes contained within each of these protocols. These protocols will continue to evolve as the Reaction platform evolves and will be validated at each stage.

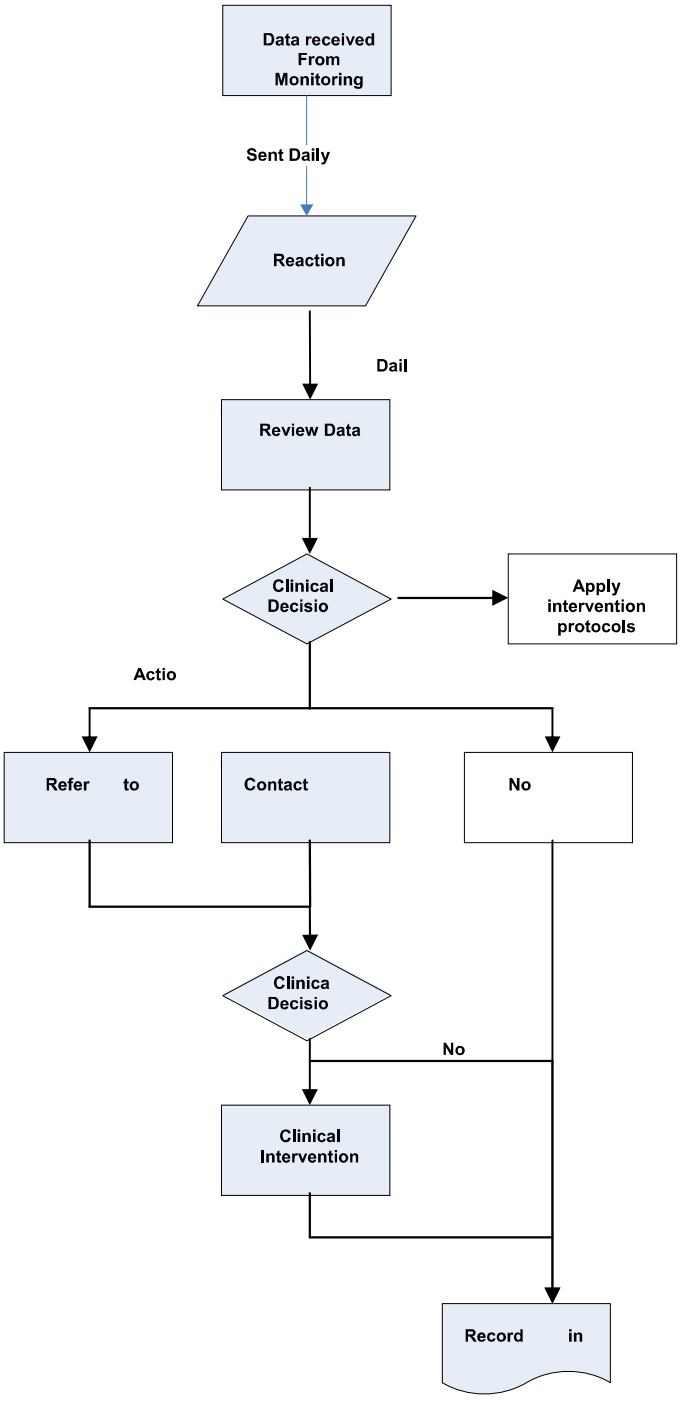

Figure: 3 Overview of Monitoring Protocols

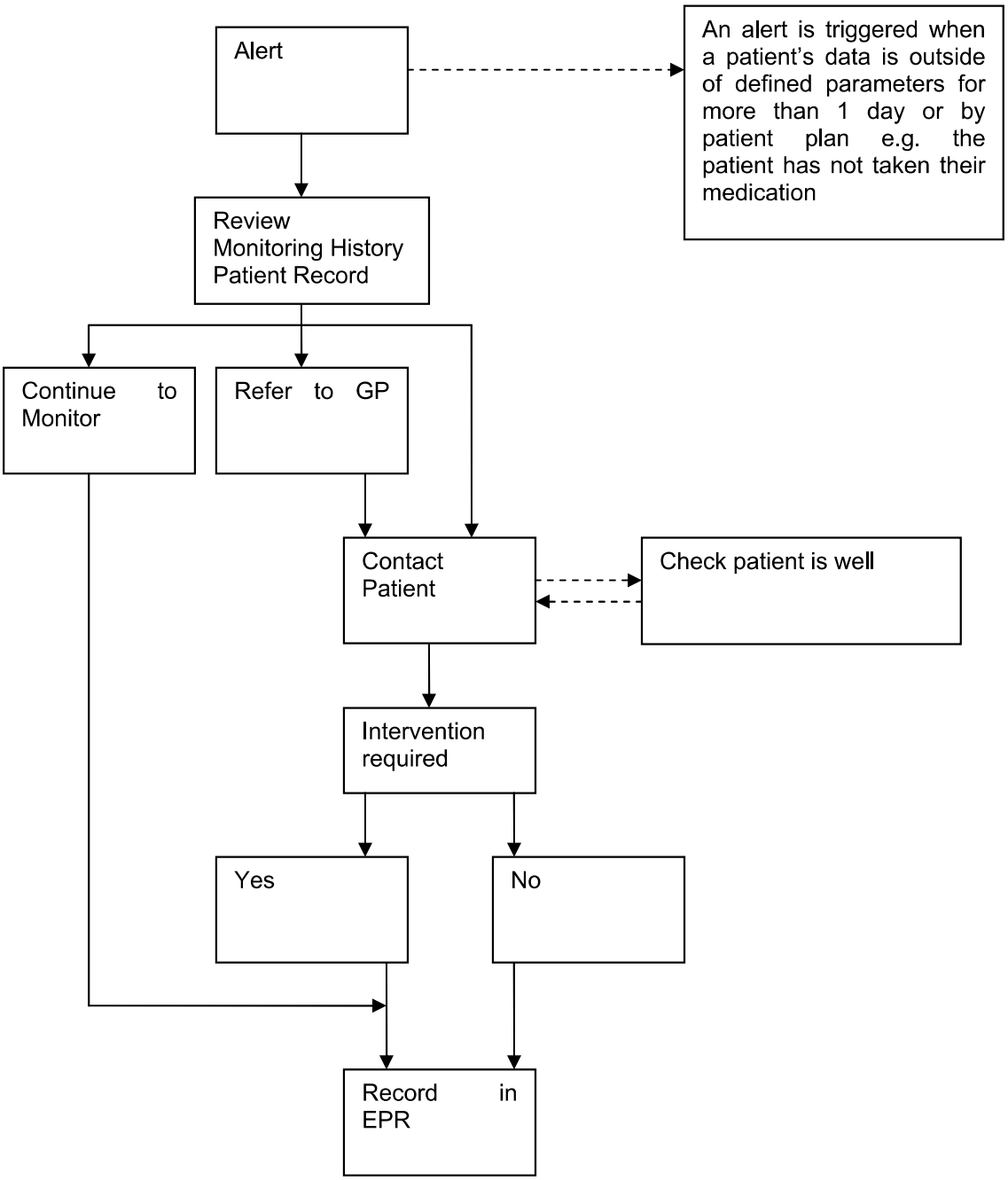

Figure 4: Monitoring Alert Protocol

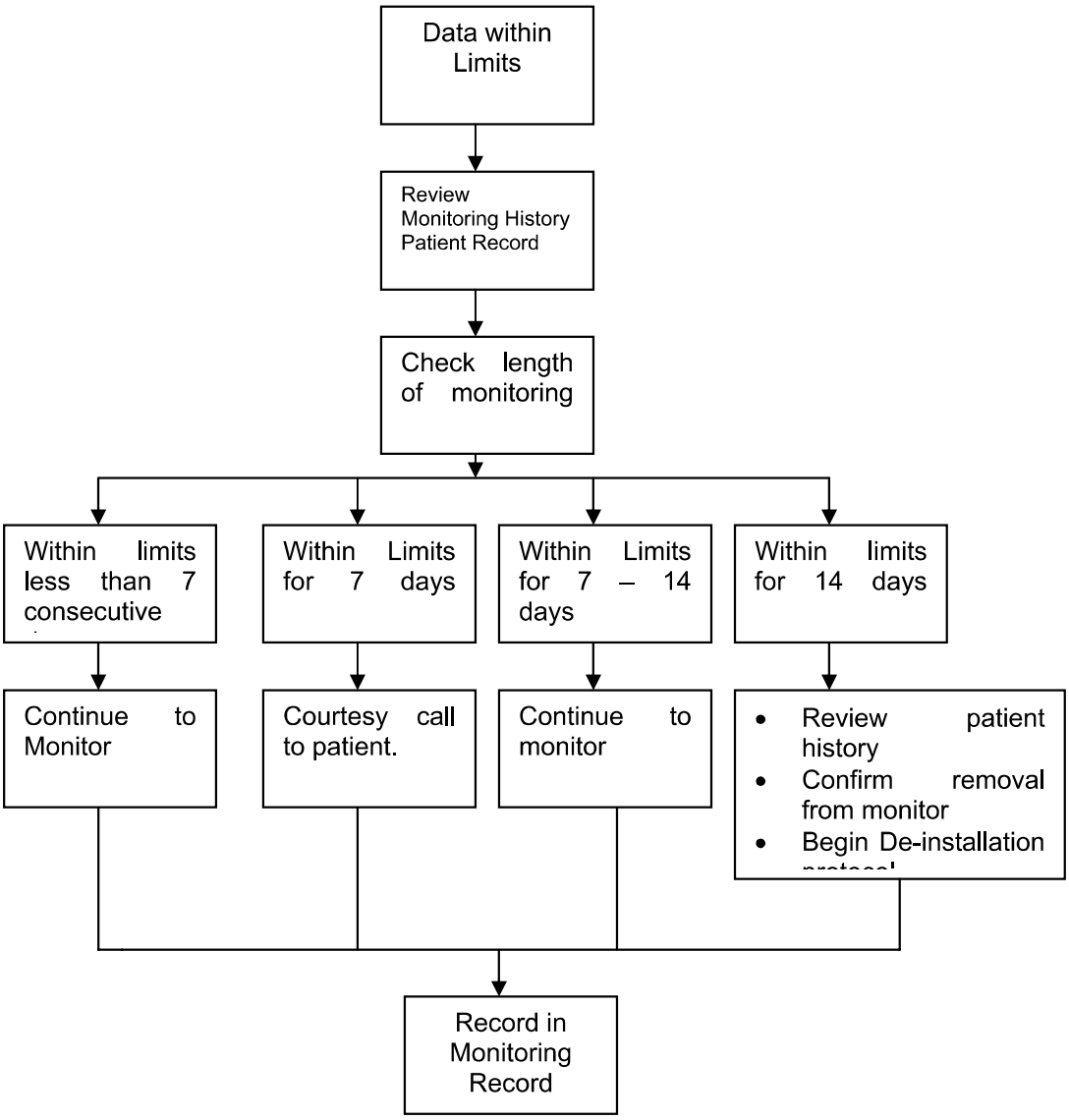

Figure 5: Within Limits Protocol

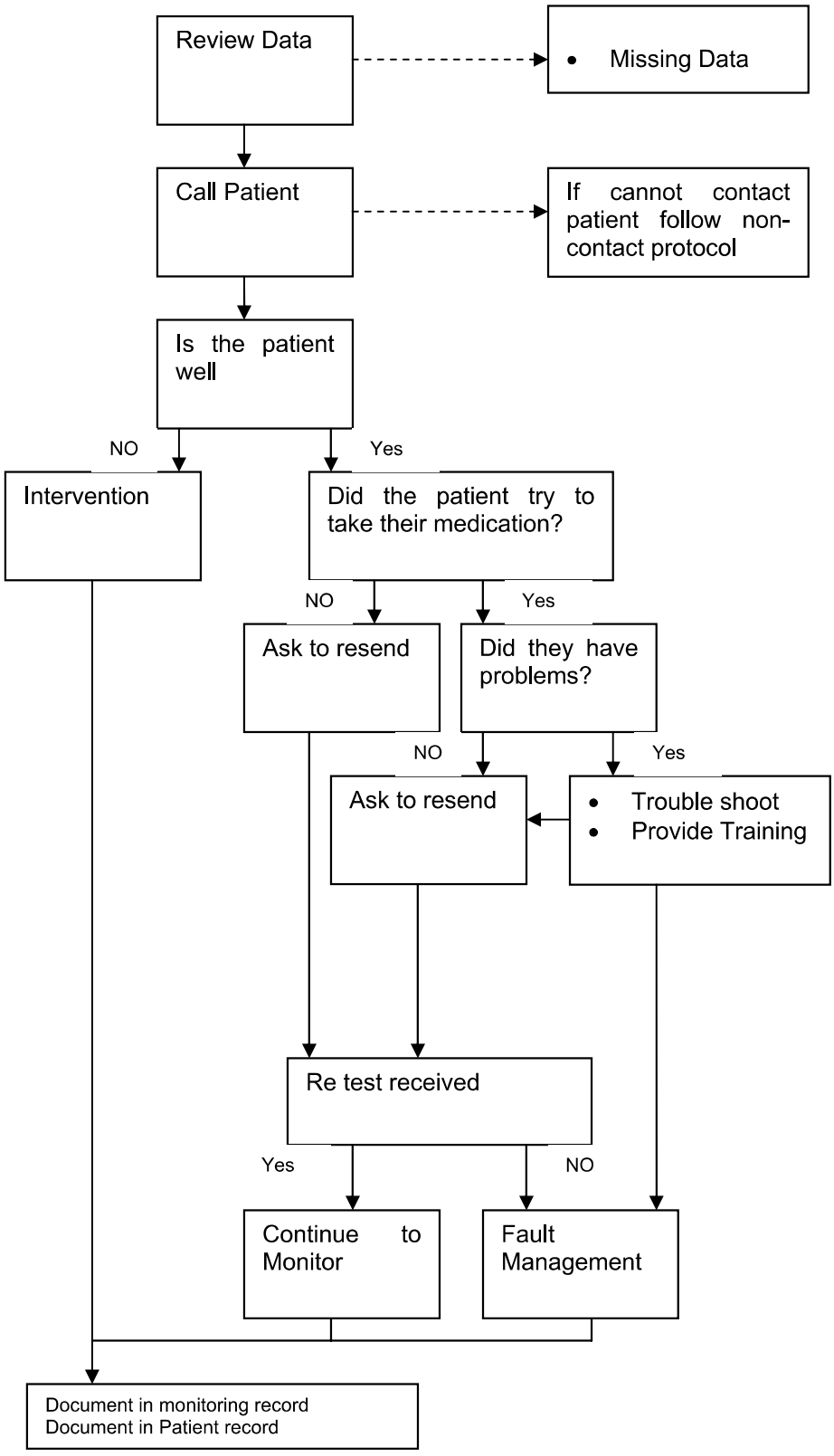

Figure 6: Technical Triage Protocol

7.1.5 Recording Data

Results from the monitoring data will be recorded either on the Reaction Monitoring Platform (when available) or on a monitoring form which will document the outcome of each monitoring session. Any actions taken by the CHC Nurses will be recorded on this form as well.

Monitoring Results

- Compliance
- Non - Compliance
- No data received
- Other: free text option

Monitoring Outcomes

- No action taken
- Close watch
- Call Patient
- Escalate to GP
- Emergency Response Required
- Technical Issue
- Other: free text option

7.1.6 Out of hours monitoring

While patients will be asked to take a measurement 7 days per week, their data will only be viewed Monday – Friday between 9 am and 5pm. There will be no out of hour provision for the monitoring of data during demonstration 1.

8. Implementation

The following section provides an overview of the implementation strategy which will be used to recruit and manage patients, equipment and information during the study.

8.1.1 Patient Recruitment

Those participants meeting the inclusion criteria will be sent a letter of invitation which will describe the project and invite the patient to an induction meeting to be held at CHC. Letters will be sent out by 2nd class post.
2 days after the letters have been sent, a follow up phone call will be made to each patient who has been contacted. The call will be used to:

- Further explain the project
- Describe what the impact will be on the patient e.g. time / disruption during installation as well as monitoring requirements
- Answer patients questions
- Confirm whether the patient is willing to participate and can attend the demonstration induction meeting.
- Confirm dates / availability for induction meeting

Details and results of the phone calls will be recorded on a Recruitment Control Form.
Responsibility for the follow up calls will be with the CHC Research Team.

8.1.2 Patient Induction Meeting

All participants will be invited to attend a Patient Induction Meeting. This meeting will be held at CHC. This meeting will last 1 ½ hours and will be used to:

- Describe the demonstration – Power Point Presentation
- Introduce the demonstration team. Team members to be present will include:
    - CHC Research Team
    - Dr Russell Jones
- Describe the patients role in the program and any benefits to the patients
- Demonstrate the technology
- Provide an opportunity to “have a go on the technology”
- Describe Data Sharing Issues and Consent form
- Answer any questions

8.1.3 Withdrawal of Patients

Patients will be informed at each stage that they have the right to withdraw from the demonstration at any time. Patients who deteriorate during the monitoring phase of the demonstration will be withdrawn from the demonstration. Should a patient withdraw voluntarily or due to deterioration within the first 2 weeks of the start of the demonstration they will be replaced.

8.1.4 Stock Control of Monitoring Equipment

All monitoring equipment received from the supplier at CHC will be checked off against agreed numbers within 1 day of receipt. All equipment will be entered onto a stock control Form. This Form will document the deployment, cleaning and testing history of each piece of equipment.
The monitoring stock will be stored in plastic storage boxes together with a copy of the stock control Form and will be stored in the research office at CHC.
Each time a piece of monitoring stock is issued to a patient; details must be entered onto the stock control Form.

8.1.5 Decontamination of Monitoring Equipment

All monitoring equipment will be cleaned, decontaminated, recalibrated and disposed of in accordance with the manufacturers' instructions, MHRA guidelines and all other clinical and operational standards.

The CHC Research Team will be responsible for the cleaning and decontamination of equipment.
All "dirty" equipment will be stored in a separate area away from other "clean" equipment.
Decontamination wipes will be used to clean and disinfect the surface areas of all equipment.
Once cleaned, equipment will be placed in clear plastic bags and stored in the "clean" equipment area.

8.1.6 Booking the installation of Monitoring Equipment

Patients will be contacted by the CHC research team 1 week prior to the installation and appointments will be made with each patient to carry out the installations.

Installations will normally be carried out within the hours of 9am and 5pm, Monday - Friday, however where there is a specific requirement, out of hours installation will take place.

8.1.7 Pre-Installation of Monitoring Equipment

Prior to installation all devices will be tested in CHC and fresh batteries will be installed in all devices. All equipment will be decontaminated as per decontamination procedures.

Patient information will be entered onto the monitoring software system using information contained on the referral form and monitoring equipment will be assigned to the patient

An installation form will be prepared by the person doing the installation. This form contains information concerning:

- Name and address and contact details of patient
- Date and time of Installation
- Pertinent information
- Description and serial number of equipment to be installed

- Confirmation and details of site inspection
- A check that a consent form has been completed
- Confirmation of Patient Training
- Confirmation that Patient Information Form has been provided
- Confirmation that patient Support information has been provided e.g. contact numbers
- Confirmation of successful test transmission
- Signature of Installer to confirm the above
- Signature of patient to confirm the above
- Questionnaire?
    - Patient satisfaction?
    - Quality of Life?
    - Usability?

8.1.8 Installation Process

During the installation, the installer will:

- Provide an overview of the demonstration
- Review and fill in the consent form (if not already completed)
- Ensure the patient is aware that the equipment is not an emergency device and if they feel unwell during the time they are being monitored they should contact their GP or dial 999 in an emergency as per usual
- Carry out a site inspection to ensure a suitable location is found for the medical devices e.g. scales
- Install the medical devices as required
- Train the patient on using the medical devices
- Watch the patient use the medical devices
- Carry out further training if required
- Provide the patient with a medical device user guide
- Provide the patient with contact information
- Send a test transmission and confirm receipt either via laptop with mobile internet connection or contact CHC and confirm with one of the research team
- Complete the installation form and ask the patient to sign
- Return installation form to CHC

8.1.9 Equipment / Resources required for Installation

- Disinfectant Hand Gel
- Monitoring Equipment that has been assigned to the patient
- 1 complete set of Spare Monitoring Equipment
- Spare set of batteries for each piece of equipment (as required)
- Clear Plastic Bags X 3
- Gloves
- Laptop with mobile internet connection (optional)
- Consent form
- Installation form
- Patient User Guide
- Questionnaire
- Support Contact Details

A follow up call will be made to each patient within 24 hours of installation to confirm that the patient does not require any further support or training and to answer any questions that may have arisen since the installation of the equipment. If required a further site visit will be made. This call and visit if required will be carried out by one of the CHC Research team.

Results of these calls will be recorded for evaluation purposes (section on the Installation form)

8.1.10 De-installation Contact

Patients will be contacted by the CHC research team 1 week prior to the due date of de-installation. Appointments will be made with each patient to carry out the de-installations.
De- Installations will normally be carried out within the hours of 9am and 5pm, Monday - Friday, however where there is a specific requirement, out of hours de- installations will take place.

8.1.11 De- Installation Process

During the de - installation, the installer will:

- Collect all monitoring equipment and place in a clear plastic bag.
- Review the de-installation form to ensure all equipment has been collected
- Carry out a site inspection to ensure no damage has occurred during the de-installation process
- Sign the de-installation form

- Ask the patient to sign the de-installation form
- Return de-installation form to CHC
- Unassign equipment from the patient on the monitoring system

8.1.12 Technical Support

In the event of a technical fault being identified by the CHC research nurses during the review of patient data, the technical issue protocol will be followed in order to determine if the problem is a local medical device problem or a wider communications problem.

- In the event that it is a local medical device issue, a member of the CHC research team will visit the patient within 24 hours (Monday – Friday) and either fix the problem on site or replace the equipment.

The patients will be asked (as per information provided to them on installation) to contact the Support Number in the event that they have a problem with the medical device or communications. This will be a single number for both device and communication faults and will be the CHC reception number.

The CHC reception team will log the call on a Fault Call Form and will forward the call to one of the CHC Research Team.

- A member of the support team with contact the patient within 2 hours of a call being logged. In the event that it is a local medical device issue, a member of the CHC research team will visit the patient within 24 hours (Monday – Friday) and either fix the problem on site or replace the equipment.

8.1.13 Out of Hours

Patients will be provided with an out of hour's call number for device or communication problems. Results of maintenance / faulty calls that are logged will be recorded on a maintenance / fault Form for evaluation purposes.

8.1.14 Faulty Equipment

In the event that equipment is found to be faulty. Equipment will be decontaminated as per decontamination procedures and returned to the supplier.

8.1.15 TRAINING

Staff training will take place in early June or as soon as equipment / software becomes available. All CHC Research Staff will be trained on:

- Medical Devices
    - Operation

  - Installation
  - Trouble Shooting
  - Decontamination
  - Maintenance

- Monitoring Software
  - Adding / Editing Patients
  - Adding / Editing equipment
  - Review Data
  - Setting alert limits
  - Trouble Shooting

- Clinical Protocols
  - No data received
  - Within Limits
  - Above Limits
  - Technical Issues

9. LEGAL & ETHICAL REQUIREMENTS

This demonstration will require ethical approval for phase 3 which is to be applied for in Month 16.

In England, review by an ethics committee is one of a series of safeguards intended to protect the people taking part in the research. Research Ethics Committees (RECs) review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. The RECs are completely independent of research sponsors (that is, the organisations funding and hosting the research) and investigators. This enables them to put participants at the centre of their research. Each year, RECs in England review around 6,000 research applications. On average, they give an opinion after 35 days: well within the maximum allowance of 60 days.

The REC safeguards are set out in a series of documents and guidance:

Declaration of Helsinki (World Medical Association, as amended 2008) [10].

Sets out ethical principles for medical research involving human subjects, including research on identifiable human material and data.

Research Governance Framework for Health and Social Care (2nd edition) (Department of Health, published 24 April 2005) [11].

Establishes a framework for the governance of research in health and social care. It applies to all research that relates to the responsibilities of the Secretary of State for Health (that is, research concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-departmental public bodies and the NHS), and research undertaken by or within social care agencies.

It includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and universities within the health and social care systems that might have an impact on the quality of those services.

Governance Arrangements for NHS Research Ethics Committees (GAfREC) (Department of Health, published July 2001) [12].

Provides a standards framework for the ethical review of all NHS and social care research proposals which is efficient, effective and timely, and which will command public confidence. It sets out general standards and principles for an accountable system of Research Ethics Committees (RECs) working together to shared high standards of review and operating process throughout the NHS. It should be read in conjunction with the Research Governance Framework for Health and Social Care, above.

Source: http://www.nres.npsa.nhs.uk/aboutus/protecting-participant-safety/ [13]

Below is a flowchart detailing the process of gaining ethical approval for the Reaction project in England.

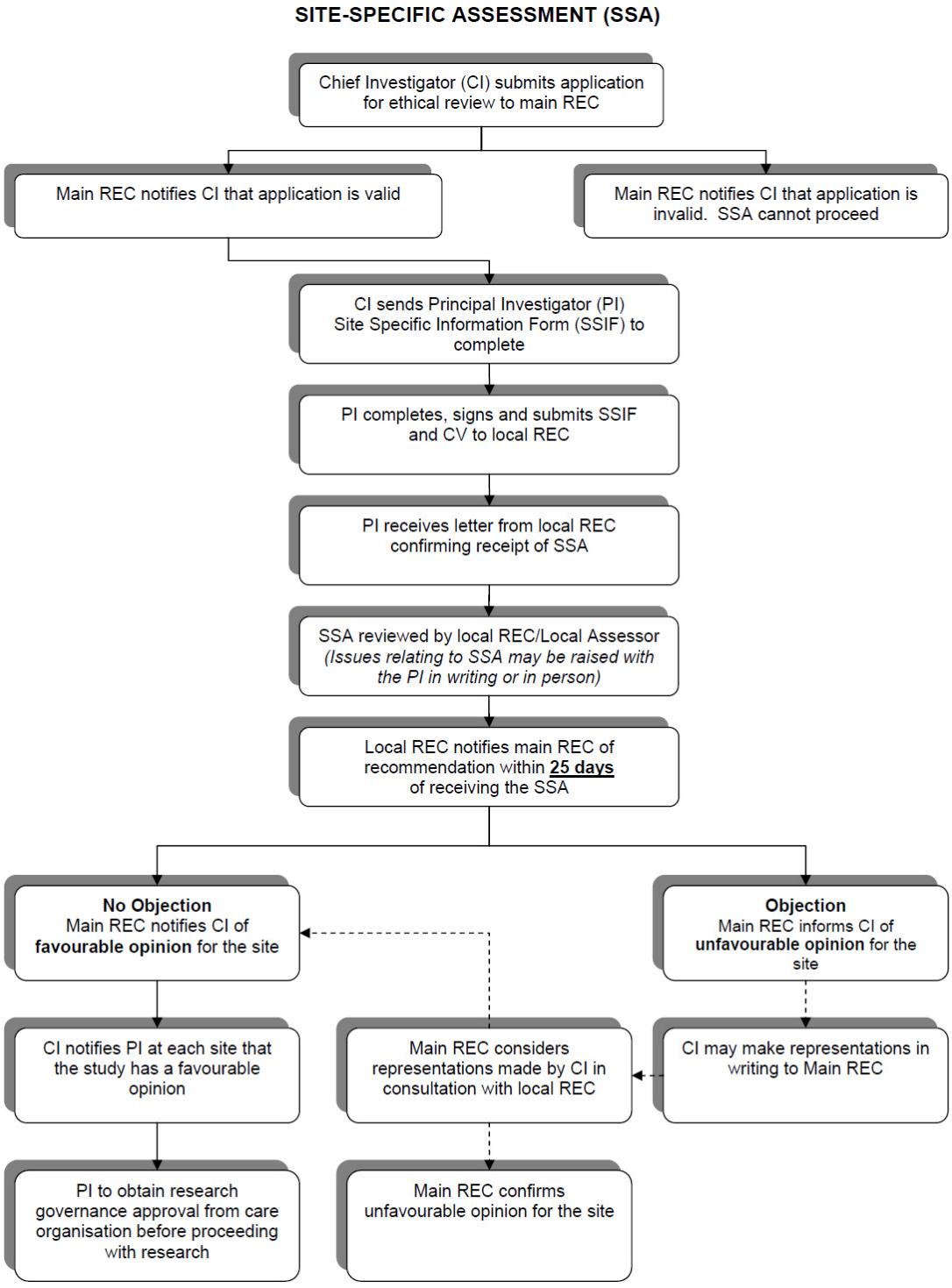

Figure 7: a flowchart detailing the process of gaining ethical approval for the Reaction project in England[1].

[1] http://www.nres.npsa.nhs.uk/applications/guidance/trials-and-procedure-flowcharts/?esctl1507899_entryid62=67034

10. DATA PROTECTION

All patient information will be strictly protected in accordance with Caldicott Principles. Patients will be informed of how and when their data will be used and will be asked to sign a consent form to indicate their agreement.

11. Evaluation

While IN-JET will evaluate the economic benefits and usability aspects of the Novo Nordisk pen. This is still to be agreed and is dependent on the inclusion of the insulin pen within the study.

Chorleywood will evaluate the medication pill dispenser. As described previously described the primary outcome measure will be calculated from:

1) data collected as a percentage of medication taken as prescribed, and as percentage of medication taken within the correct time interval,
2) refill data, taking the number of days for which oral antidiabetics are dispensed during the study period divided by the total number of days of the study period.
3) Differences in adherence between the intervention groups and control group are studied using refill data.
4) Differences in adherence between the two intervention groups are studied using the percentage data.

Data will be collected from the pharmacy every 28 days.

Tables: 3, 4 and 5 provide an overview of additional evaluation protocol for the project with the aim of capturing data to identify if the project outcomes have been met. Each table provides a description of what data which will be captured by Chorleywood Health Centre, the purpose of the data and how it will be collected.

In addition, Chorleywood Health Centre has a responsibility to feed a summary of this information back to each participant. This will include a review of the clinical data captured as well as an overview of the outcomes of the project as a whole.

A mixture of Interviews, Questionnaires and Focus Groups will be used to elicit user feedback about the system. In addition, data collection systems will be in place to capture usability and clinical workflow validation.

11.1.1 Clinical Monitoring Data

This table describes the types of data we would like to collect via the Monitoring system. As well as data being stored on the monitoring system, data will be exported into the patients EPR. Data will be used to evaluate clinical management, participant compliance, Alert Rules and Technical issues.

Evaluation Matrix						
Indicator(s)	**Methods**	**Data Source/ collection method**	**Measure**	**Outcome**	**Timeframe**	**Resp. Party**
Participant Physiological Data	System	Patient / System	Clinical Management	Effectiveness of Clinical Management	Daily	CHC

Participant Habits Data	System	Patient / System	Habits Monitoring Data	Effectiveness of Social Care	Continuous / Daily	CHC
Participant Question Data	System	Patient / System	Clinical Management	Effectiveness of Clinical Management		CHC
No of Alerts	System	Patient / System	Above Physiological Parameters	Effectiveness of Clinical Management	Daily	CHC
Missing Data	System	Patient / System	No Physiological data received	Patient Compliance	Daily	CHC
Partial Missing Data	System	Patient / System	Partial Physiological data received	Patient Compliance	Daily	CHC

Table 3: Monitoring Data - Monitoring Data

11.1.2 Clinician / CHC Staff Data

This table describes the data we will collect from the Clinical / Admin team at CHC in order to evaluate their satisfaction and perception of using the system, and the impact on work load. Frequency and types of support requirements will be recorded formally to provide an indication of satisfaction. Outcomes of alerts will be used to monitor impact on clinical workload.

Evaluation Matrix						
Indicator(s)	**Methods**	**Data Source/ collection method**	**Measure**	**Outcome**	**Timeframe**	**Resp. Party**
Outcome of Alerts	CHC Clinical Team	System	No Contact Patient Contact Emergency Referral Referred to GP Other	Effectiveness of Solution / Workload	Daily	CHC
Clinician reported Web User Interface Issues	CHC Clinical Team	Manual	No of Support Calls Required	Effectiveness of Solution / Workload	Daily	CHC
Clinician Reported Training Issues	CHC Clinical Team	Manual	No of support calls required	Effectiveness of Solution / Workload	Daily	CHC
Clinician reported	CHC Clinical	System / Manual	No of support	Effectiveness of Solution /	Daily	CHC

Device Issues	Team / CHC Admin Team		calls required	Workload		
Clinician perception of system Web User interface	CHC Clinical Team	Manual - Questionnaire	Satisfaction	Satisfaction	Pre-pilot 1 month after start of project / end of project	CHC
Clinician perception of devices	CHC Clinical Team	Manual - Questionnaire	Satisfaction	Satisfaction	Pre-pilot 1 month after start of project / end of project	CHC
Clinician perception of "whole" system	CHC Clinical Team/ CHC Admin Team	Manual - Questionnaire	Satisfaction	Satisfaction	Pre-pilot 1 month after start of project / end of project	CHC

Table 5: Clinician / CHC Staff

11.1.3 Patient Data

This table describes the data we will collect from the patients. Comments and user observations will be recorded ad hoc during installation, de-installation and during any clinical / admin contacts. Frequency and types of support requirements will be recorded formally to provide an indication of satisfaction.

Evaluation Matrix						
Indicator(s)	**Methods**	**Data Source/ collection method**	**Measure**	**Outcome**	**Timeframe**	**Resp. Party**
Patient Reported Device Fault	Phone Call / In Person / Other	Manual	No of Support Calls	Patient Satisfaction	Daily	CHC
Patient perception of devices	Phone Call / In Person / Other	Ad Hoc / Questionnaire / Focus Group	Questionnaire	Patient Satisfaction	Daily / End of Demo	CHC
Patient perception "service model"	Phone Call / In Person / Other	Ad Hoc / Questionnaire / Focus Group	Questionnaire	Patient Satisfaction	Daily / End of Demo	CHC
Patient perception of	Phone Call / In	Ad Hoc / Questionnaire /	Questionnaire	Trust	Daily / End of Demo	CHC

privacy / security	Person / Other	Focus Group				

Table 5: Patient Data

12. Conclusion

This document has provided an overview of the MDI compliance Clinical Protocol, including the aims and objectives and methods which will be used to carry out the study. In addition, the document describes how the data will be viewed and responded to by the clinical teams. The actual practicalities of implementing and managing such a study within primary care are described including communication, installation and maintenance. Finally the document provides an overview of how we propose to conduct the evaluation of the service, technology and satisfaction from both the patient and clinical user perspective.

13. Table of figures and tables

Figures

Tables

14. Bibliography

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