# Standard Operating Procedure: Pharmacy procedures for Medication Organisation Device project (NIHR HTA 09/34/03; Phase II Randomised controlled trial)

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## 1. ABBREVIATIONS

| | |
|---|---|
| NIHR | National Institute of Health Research |
| HTA | Health Technology Assessment |
| RCT | Randomised Controlled Trial |
| MOD | Medication Organisation Device |
| RFID | Radio frequency identification |
| OtCM™ | Objective therapy Compliance Monitoring |
| SOP | Standard Operating Procedure |
| RISP | Research Information Sheet for Practices |

## 2. INTRODUCTION

The aim of this study is to test whether Medication Organisation Devices (MODs) help patients to take their medication correctly. MODs are currently used by around 100,000 people in the UK, at a cost of several million pounds per year. Some MODs are supplied by the NHS under the Disability Discrimination Act, but in many cases patients or their carers bear the cost themselves. Although pharmacists, clinicians, patients and carers believe that MODs aid adherence to complex medication regimes; this proposal has not yet been tested in a randomised controlled trial.

Under this RCT, diverse measures will be used: Objective measures such as Objective therapy Compliance Monitoring (OtCM™) films which record when a pill has been removed from its packaging; subjective measures including questionnaires which ask patients about their medication-taking and attitudes towards their medication, quality of life, satisfaction with the trial and perceived changes in autonomy; and the views of their carer(s). In addition to this, post-RCT focus groups for participants and healthcare professionals will be arranged, with a view to using these qualitative data to further refine the design of the proposed definitive study. Data will be accessed in a number of formats including paper-based records, electronic audio recording, RFID-enabled devices, and computer-based data.

Six medical practices and their respective pharmacies will take part in this research project. The trial will take part in two main phases: a 3-week trial followed at exactly four weeks post initiation by a 3-month trial.

It is anticipated that 720 participants will be assessed for suitability, 576 will take part in the 3-week trial and 160 will go on to participate in a 3-month, 2 x 2 factorial trial comprising medication from: usual packaging weekly; MOD weekly; usual packaging monthly; MOD monthly. A simple flow chart is appended (Appendix 1).

**3. SCOPE**

This SOP is provided by the UEA Research team to each Pharmacy team to provide clear instruction for all trial procedures; facilitate project management and ensure appropriate management and confidential storage of materials and data for project NIHR HTA 09/34/03. It should be used in conjunction with local SOP documents (see Section 7).

**4. DEFINITIONS**

| | |
|---|---|
| MOD | Device used for organisation of medicines to facilitate correct taking of prescribed medicines. In this case MODs refer only to Nomad Clear, Nomad Clear XL and Venalink devices. Each of these is divided into compartments labelled with days of the week and times of the day. |
| RFID | Wireless non-contact system that uses radio-frequency electronic fields to transfer data from a tag attached to an object. |
| OtCM™ | Clear plastic film with printed microcircuit which adheres to the foil backing of drug blister packs and which, when the circuit is broken, records electronically the time and date of medicine –removal events. |

**5. RESPONSIBILITY**

Project management, assessment of participant ability, patient visits and data collation will be the responsibility of **researchers**.

Medication supply and delivery, attachment of monitoring devices, collection and storage of used monitoring devices and specific data collation and provision will be the responsibility of **pharmacists** in conjunction with researchers.

Individual researchers and pharmacy personnel are expected to behave in a professional manner and in accordance with Pharmacy and University rules and regulations and the project RISP agreement.

All researchers should be aware that as 'persons receiving healthcare', the subjects of this trial must be considered 'vulnerable' under the Safeguarding Vulnerable Groups Act (2006).

**If you have any concerns regarding individual participants or any procedures or safeguarding issues arising from this trial then you must immediately contact either the trial manager (Clare Aldus XXX or XXX) or Chief Investigator (Debi Bhattacharya XXX).**

## 6. PROCEDURE

### 6.1 Contact details

For any general queries, however seemingly trivial please contact us:

| | | |
|---|---|---|
| Project Manager | Clare Aldus | XXX XXX |
| Researcher | Sathon Boonyaprapa | XXX XXX |
| Researcher | Trish Boyton | XXX XXX |

### 6.2 Providing a one month supply of medicines for the three week trial

All participants (likely to be ~576 across all practices) who are eligible for the 3-week trial will be provided with a one-month supply of their medication. Duplicate labels should be prepared for each medication. One label should be applied to the medicines and the second given to the researcher as a record of medicines dispensed at Visit 1. This medication and duplicate labels will be collected from the pharmacy at a pre-arranged, mutually convenient time by the researcher. The researcher will deliver the medication to the participant in person at Visit 1 (see Appendix 1). For each participant the trial will start from the date of delivery of this medication and this is important to the pharmacist because it determines the start date for the 3-month trial for eligible participants (i.e. 28 days from the start of the 3-week trial).

### 6.3 Enrolling participants in the NHS repeat dispensing scheme and removing them from the scheme

All participants who are eligible for the 3-month trial (likely to be 160 across all practices) will be signed up to the scheme to manage the request and collection of

repeat prescriptions (see local SOP). Researchers will ensure that participants complete the repeat dispensing scheme proforma and will pass the signed documentation to the pharmacist for implementation. Some of the participants will already be included in this scheme. It will be the responsibility of the pharmacist to ensure that all patients are enrolled in the scheme.
After the trial, researchers will inform pharmacists which participants, if any, have requested to be removed from the NHS repeat dispensing scheme and it will be the responsibility of the pharmacist to action these requests.

**6.4 Storage and disposal of medicines removed from participants**

Once the one-month supply of medication has been delivered by the researcher to the participant, all old supplies of prescribed solid oral dose forms will be placed in tamper evident packaging and stored at the home of the participant. This is to avoid confusion for the trial participant, regarding which medication package should be used. No medicines belonging to trial participants will be stored at the pharmacy. However, it is possible that in a few cases, drugs which are out of date or no longer needed by participants will be returned to the pharmacy by the researcher for disposal. Disposal should be carried out according to usual pharmacy procedures. It is also possible that patients express opinions to you about the method of medication removal. On gaining their permission, please record these comments.

**6.5 Preparing medications for participants according to allocation**

Researchers will ascertain that participants are capable of using the OtCM$^{TM}$ films and which is their preferred MOD-type and then record this information on Administration form 2 (Appendix 3). Researchers will provide participant names to the pharmacist, inform them which are allocated to which arm of the trial (MOD weekly, usual packaging weekly, MOD monthly, usual packaging monthly) and the preferred MOD-type for each participant.

MODs to be used are Venalink, Nomad Clear and Nomad Clear XL.
Medications to be measured under the trial are as tabulated (Table 1). All these products must be from designated manufacturers as the OtCM$^{TM}$ films are very specific to particular pack sizes.

Table 1. Medication to be used for the trial

| ID | Medicine name | Format | Dose | Units per blister | Manufacturer |
|---|---|---|---|---|---|
| Si40 | Simvastatin | tablet | 40mg | 14 | Almus |
| As75 | Aspirin | tablet | 75mg | 28 | |
| Le25 | Levothyroxine | tablet | 25mcg | 28 | Almus |
| Le50 | Levothyroxine | tablet | 50mcg | 14 | Almus |
| Le100 | Levothyroxine | tablet | 100mcg | 14 | Almus |
| Ra5 | Ramipril | capsule | 5mg | 14 | Almus |
| Ra10 | Ramipril | capsule | 10mg | 14 | Almus |
| Be2.5 | Bendroflumethiazide | tablet | 2.5mg | 14 | Almus |
| Om20 | Omeprazole | capsule | 20mg | 7 | Almus |
| Am5 | Amlodipine | tablet | 5mg | 14 | Teva |
| Am10 | Amlodipine | tablet | 10mg | 14 | Almus |
| La15 | Lansoprazole | capsule | 15mg | 7 | Almus |
| La30 | Lansoprazole | capsule | 30mg | 7 | Almus |
| At25 | Atenolol | tablet | 25mg | 14 | Almus |
| At50 | Atenolol | tablet | 50mg | 14 | Almus |
| Me500 | Metformin | tablet | 500mg | 14 | Almus |
| Fu20 | Furosemide | tablet | 20mg | 14 | Almus |
| Fu40 | Furosemide | tablet | 40mg | 14 | Almus |

Researchers will provide information on which are the preferred MODs for participants and sufficient MODs and OtCM$^{TM}$ films to pharmacies in a timely manner. Pharmacy staff will fill and check MODs according to local SOPxxxx and Local SOP:xxxxxxxxx respectively and provide MODs and medication in usual packaging to participants according to allocation. Pharmacists will apply OtCM$^{TM}$ films to all MODs and usual packaging for all medications tabulated (Table 1) according to manufacturer's specifications and training.

**6.6 Delivery or collection of medicines on a weekly or monthly basis**

Pharmacists will be responsible for arranging delivery of medicines to the homes of all those allocated to weekly supply. Weekly delivery may lead to additional delivery costs for the pharmacy. Additional delivery costs incurred will be reimbursed. Funding has been secured and details of the mechanism of reimbursement will be provided to individual pharmacies by researchers. Pharmacists and participants will be responsible for arranging delivery or collection of medicines to those allocated to monthly supply according to participants' usual procedure. Duplicate labels should be printed for all

medications. One label is to be applied to the medication in the usual manner and the other to be applied to Administration form 3 or administration form 3 follow-on sheets.

The OtCM™ films applied to the medicine in usual packaging and MODs carry data which are critical to the success of the project. It is important that, whenever possible, pharmacists and delivery staff reiterate the importance of retaining all used packaging and returning it to the pharmacy.

**6.7 Arranging collection and storage of used packaging**

Participants will be expected to take their medicines as prescribed and then to collect and return all used packaging to the pharmacist. The OtCM™ films are not individually identified as belonging to a person or a particular medicine type. **It is very important that used packaging is collected and stored in a systematic manner in the clearly labelled receptacle provided for each participant.**

For medicine deliveries: Pharmacists should inform the delivery driver that he or she should 1) collect used packaging in the receptacle provided and 2) deliver it to the pharmacy for storage. Additional costs incurred for collection will be reimbursed.

For medicine collections: Pharmacists should either collect packaging from participants or their representative at the point of issue of new medication or remind them to continue to retain and return the packaging at their next visit. Researchers will periodically collect retained packaging from the pharmacy.

**6.8 Administration form 3**

One aspect of this study is to determine differences between MODs and usual packaging. This involves, for example, recording differences in the time taken to dispense medication by each system and numbers of alleged near misses. Researchers will provide pharmacists with Administration form 3 (Appendix 4) for recording these data for each participant. This form will be completed by the pharmacy for each participant and will be stored in the project folder within the pharmacy.

### 6.9 Study information

During and after the trial researchers will collect all returned packaging and administration forms from pharmacies.

### 6.10 Providing feedback to researchers

It would be beneficial to the design of a future definitive trial to obtain positive and negative feedback concerning the design and execution of the trial. Pharmacists will be invited to take part in a focus group after the trial.
Other feedback can be included in Administration form 3 or on separate sheets to be attached to Administration form 3.

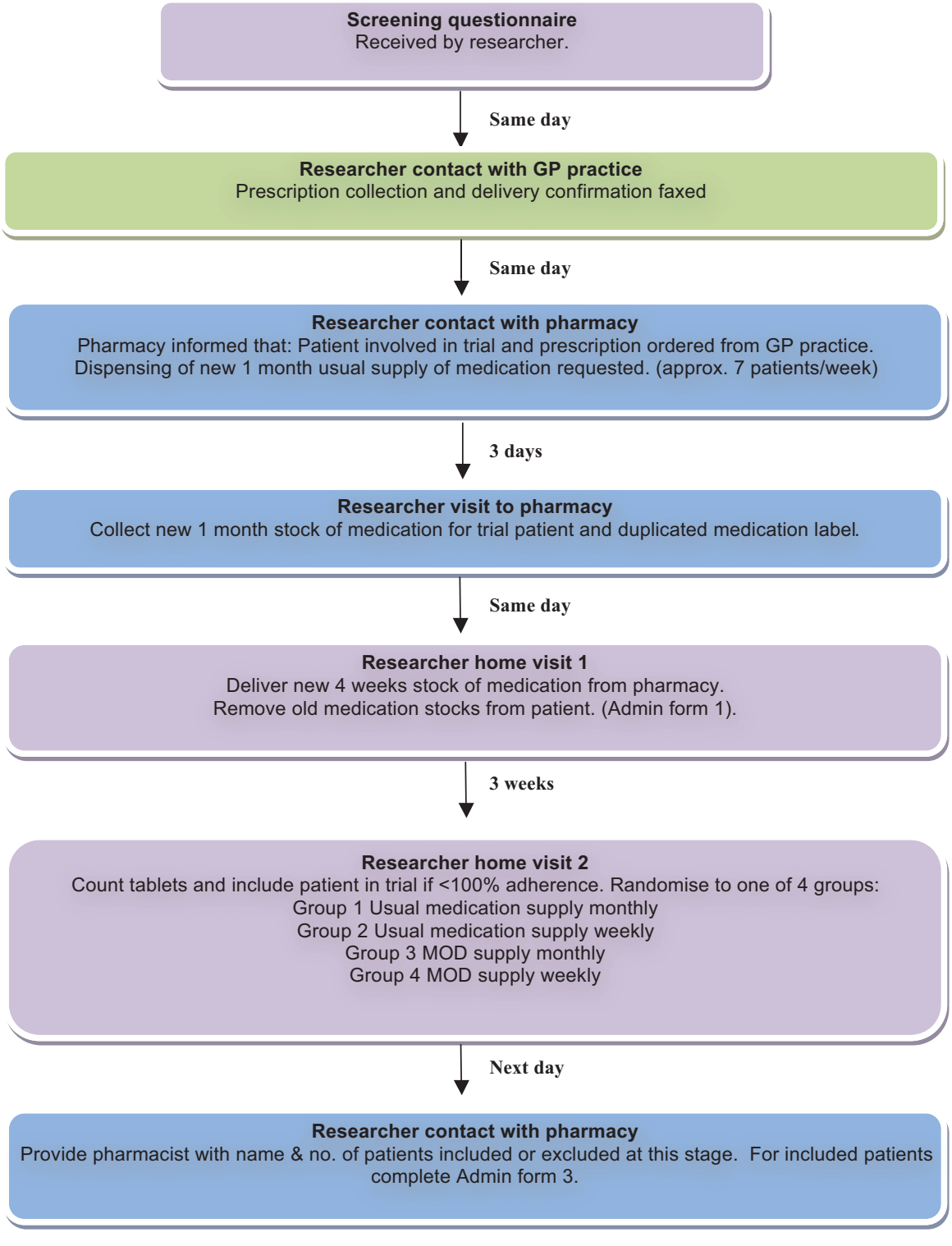
### 6.11 Post-trial discussion with participants.

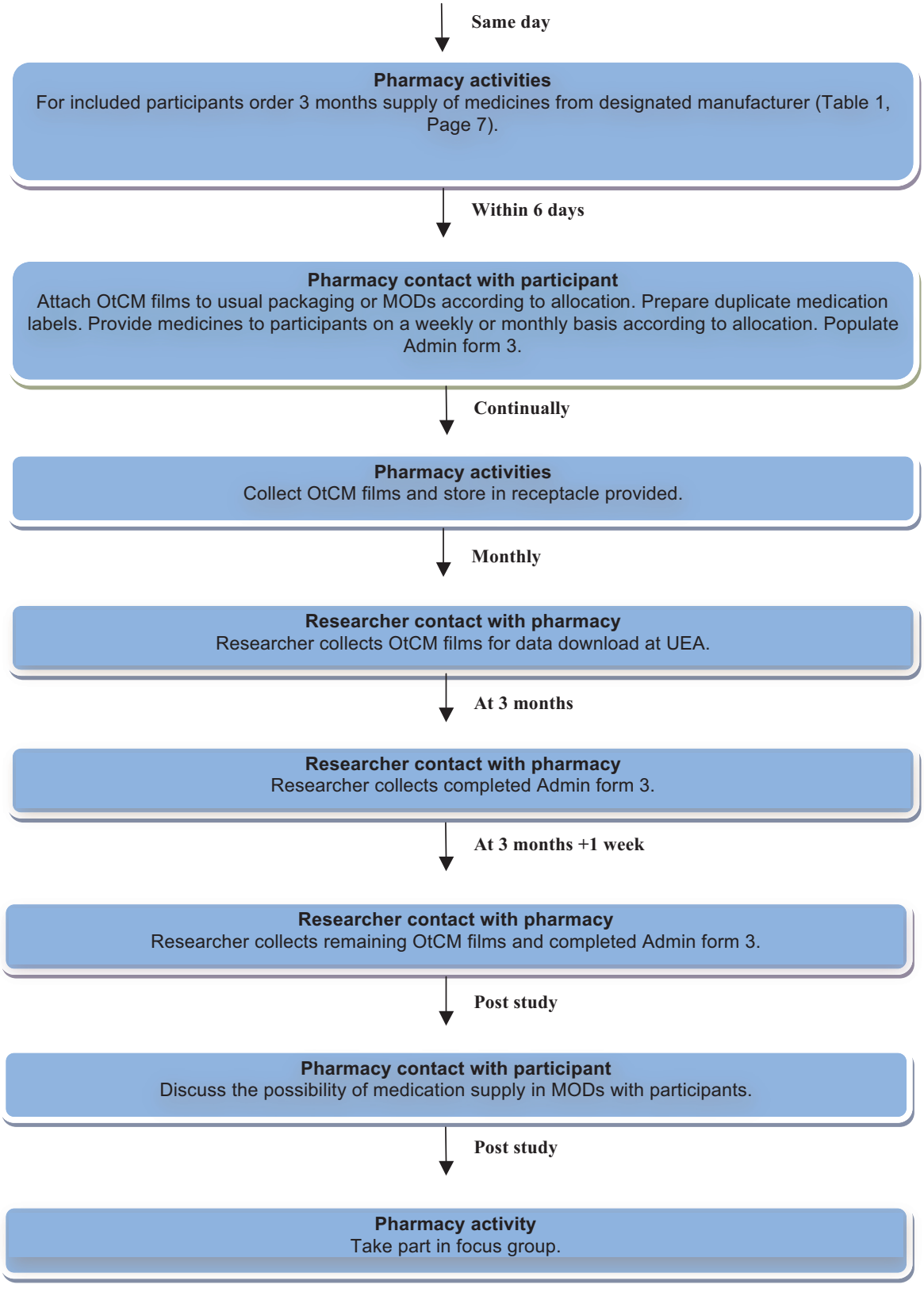
As a direct result of this trial, participants may feel that they would like to be assessed for suitability for receiving medicines in MODs. Researchers will refer participants expressing this wish to pharmacists for professional advice. Pharmacists may then wish to refer these participants to the Norfolk Medicines Support Service if appropriate.

## 7. REFERENCES

PCRN RISP agreement
Project protocol NIHR HTA 09/34/03
Local SOP:xxxxxxxxxx (Label and assemble MOD packs)
Local SOP:xxxxxxx (Accuracy check MOD packs)
Local SOP:xxxxxxxxxx (Manage the request and collection of repeat prescriptions)

## Appendix 1. Flow diagram of project




Same day
Pharmacy activities
For included participants order 3 months supply of medicines from designated manufacturer (Table 1, Page 7).
Within 6 days
Pharmacy contact with participant
Attach OtCM films to usual packaging or MODs according to allocation. Prepare duplicate medication labels. Provide medicines to participants on a weekly or monthly basis according to allocation. Populate Admin form 3.
Continually
Pharmacy activities
Collect OtCM films and store in receptacle provided.
Monthly
Researcher contact with pharmacy
Researcher collects OtCM films for data download at UEA.
At 3 months
Researcher contact with pharmacy
Researcher collects completed Admin form 3.
At 3 months +1 week
Researcher contact with pharmacy
Researcher collects remaining OtCM films and completed Admin form 3.
Post study
Pharmacy contact with participant
Discuss the possibility of medication supply in MODs with participants.
Post study
Pharmacy activity
Take part in focus group.

Appendix 2. Administration form 1 (example)

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UEA University of East Anglia

NHS Norfolk

Admin No:

**Consent for medication removal and return preferences**

Patient name:_____

Address: _____

| Date | Medication (Name, form and strength) | Quantity | Notes (e.g. out of date) |
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I give my permission for researchers to remove medicines (listed above) from my use by placing them in a sealed bag for the duration of the trial. I agree not to open the bag until researchers tell me that the trial is complete. If, in an emergency, I open the bag I will let the researchers know.

SIGNATURE OF PATIENT:_____

SIGNATURE OF RESEARCHER:_____

DATE:_____

Admin form 1 Removal of medicines consent form vs 1.2 23042012

Appendix 3. Administration form 2 (example)

## What are the effects of pill boxes?

Admin No: | | | | | | |

University of Aberdeen | UEA University of East Anglia | NHS Norfolk

**Please circle the name of the pillbox which you would prefer to use**

Nomad Clear

Nomad Clear XL

Venalink™

I confirm that I have been shown how to use the pill box identified above.

Participant Name .....

Participant Signature ..... Date.....

I confirm that this trial participant is able to use the selected pill box satisfactorily.

Researcher Name.....

Researcher Signature..... Date.....

Appendix 4. Administration form 3 front side (example)

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Admin No:

**PHARMACY RECORD (MODS)**

Patient name and Address

START DATE:_____

Delivery ☐ Collection ☐

Monthly ☐ Weekly ☐

Supply type: Nomad Clear™ ☐ Nomad Clear XL™ ☐ Venalink™ ☐ Usual ☐

Please record the time taken to dispense (Dispenser) and check (Pharmacist).

| Date | DISPENSER | | | PHARMACIST | | |
|---|---|---|---|---|---|---|
| | Start time | Finish time | Monthly/Weekly? | Start | Finish | Monthly/Weekly? |
| | | | | | | |
| | | | | | | |
| | | | | | | |

Please record the average time taken for activities involved with attaching OtCM™ films to packaging: .....

Please record any comments regarding OtCM™ system below:

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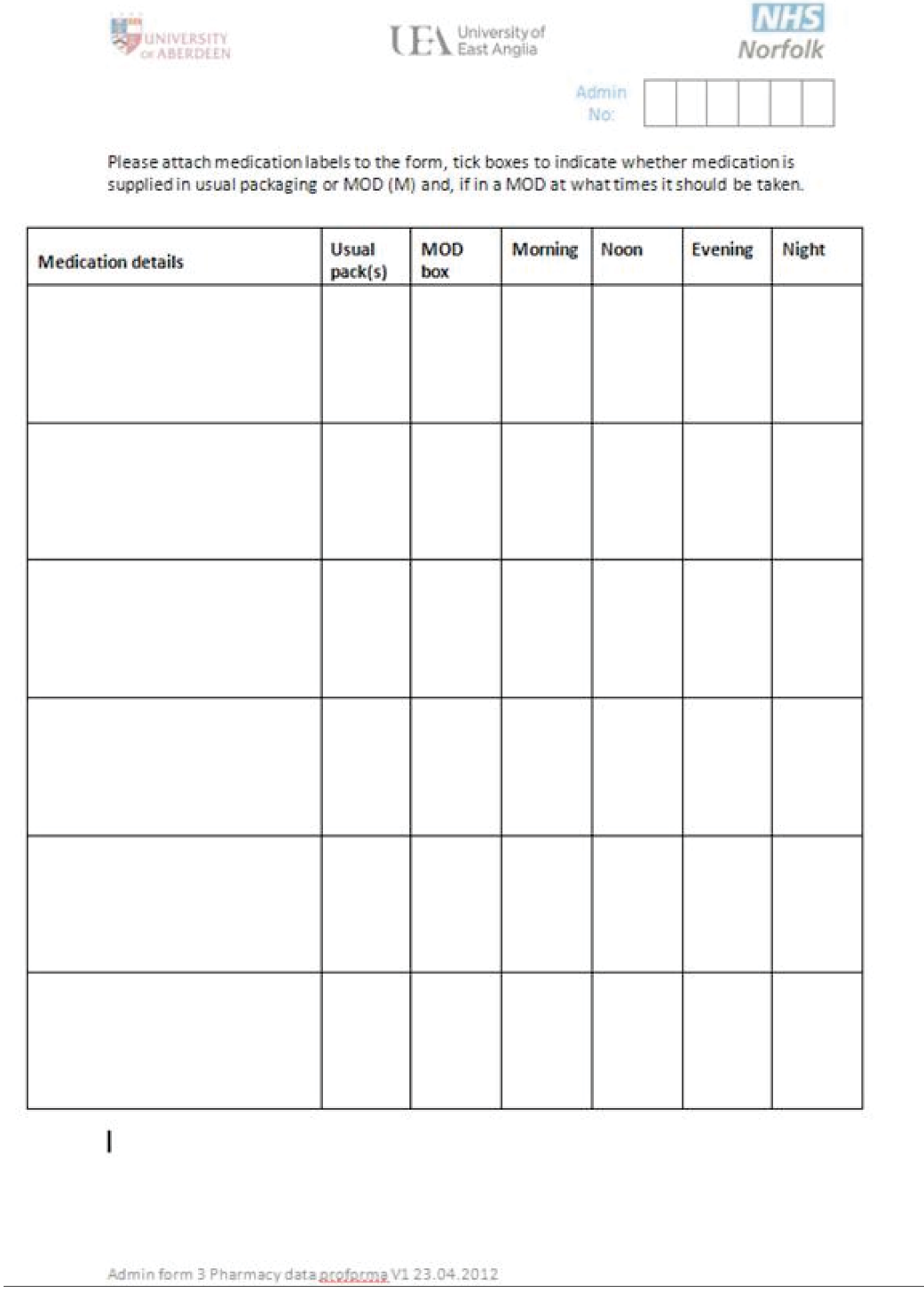
Please record any pharmacist-observed or patient-alleged near-misses

| Date | Time | Name of medicine | Type of Near Miss* | Additional comments |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

*D = Wrong drug; N = Wrong patient name; E = Out of date; P = Misread prescription; F = Wrong form; Q = Wrong quantity; L = Wrong label; S = Wrong strength; M = Missing item; X = Transposed labels

Admin form 3 Pharmacy data proforma V1 23.04.2012

Appendix 4. Administration form 3 reverse side (example).



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NHS Norfolk

Admin No:

Please attach medication labels to the form, tick boxes to indicate whether medication is supplied in usual packaging or MOD (M) and, if in a MOD at what times it should be taken.

| Medication details | Usual pack(s) | MOD box | Morning | Noon | Evening | Night |
|---|---|---|---|---|---|---|
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Admin form 3 Pharmacy data proforma V1 23.04.2012