CloseHER2Home

**CloseHER2 Home**

**A feasibility study of a community pharmacy-led pathway for the administration of subcutaneous trastuzumab for HER2 positive breast cancer patients.**

| | |
|---|---|
| STUDY Acronym | **CloseHER2 Home (C2H)** |
| Sponsor<br>Sponsor Ref | **University of Dundee/ Tayside Health Board**<br>1- 014-19 |
| NHST R&D Number | **2019ON14** |
| Funder | Roche |
| Chief Investigator | Andrew Radley |
| REC Number | 19/ES/0143 |
| ISRTCN | |
| Version Number and Date | Version 2: 13.09.2021 |

1– 014 - 19 1

PROTOCOL APPROVAL ..... 3
LIST OF ABBREVIATIONS ..... 4
SUMMARY/SYNOPSIS ..... 5
**INTRODUCTION ..... 7**
**1 BACKGROUND & RATIONALE ..... 8**
**2 STUDY OBJECTIVES & OUTCOMES ..... 9**
**4 STUDY DESIGN ..... 11**
4.1 INTERVENTION ..... 11
4.2 STUDY DESCRIPTION ..... 11
4.3 STUDY FLOWCHART ..... 13
4.4 STUDY MATRIX ..... 14
4.5 STUDY ASSESSMENTS ..... 14
4.5.1 Demographic and Background Data ..... 14
4.5.2 Process Evaluation Measures ..... 15
**4.6 STUDY SAFETY ASSESSMENTS ..... 15**
4.7 TISSUE ..... 16
4.8 INCIDENTAL FINDINGS ..... 16
4.9 study POPULATION ..... 16
4.10 NUMBER OF PARTICIPANTS ..... 16
4.11 INCLUSION CRITERIA ..... 17
4.12 EXCLUSION CRITERIA ..... 17
**5 PARTICIPANT SELECTION AND ENROLMENT ..... 18**
5.1 IDENTIFYING PARTICIPANTS ..... 18
5.2 CONSENTING PARTICIPANTS ..... 18
5.3 SCREENING FOR ELIGIBILITY ..... 19
5.4 INELIGIBLE AND NON-RECRUITED PARTICIPANTS ..... 19
5.4.1 Withdrawal procedures ..... 19
**6 DATA COLLECTION & MANAGEMENT ..... 20**
6.1 Data Collection ..... 20
6.2 Data Management System ..... 20
**7 STATISTICS AND DATA ANALYSIS ..... 21**
7.1 SAMPLE SIZE CALCULATION ..... 21
7.2 PROPOSED ANALYSES ..... 21
7.3 Missing data ..... 21
7.4 TRANSFER OF DATA ..... 21
**8 STUDY MANAGEMENT AND OVERSIGHT ARRANGEMENTS ..... 21**
8.1 STUDY MANAGEMENT GROUP ..... 21
8.2 INSPECTION OF RECORDS ..... 22
**9 GOOD CLINICAL PRACTICE ..... 22**
9.1 ETHICAL CONDUCT OF THE STUDY ..... 22
9.2 Confidentiality and DATA PROTECTION ..... 22
9.3 Insurance and Indemnity ..... 23
**10 ADVERSE EVENTS ..... 23**
10.1 DEFINITIONS ..... 23
10.2 RECORDING AND REPORTING AE ..... 24
**11 ANNUAL REPORTING REQUIREMENTS ..... 24**
**12 STUDY CONDUCT RESPONSIBILITIES ..... 25**
12.1 PROTOCOL AMENDMENTS, deviations and breaches ..... 25
12.2 STUDY RECORD RETENTION ..... 25
12.3 END OF STUDY ..... 25
**13 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS ..... 25**
13.1 AUTHORSHIP POLICY ..... 25
13.2 PUBLICATION ..... 25
13.3 PEER REVIEW ..... 26
**14 REFERENCES ..... 26**

**PROTOCOL APPROVAL**

**A feasibility study of a community pharmacy-led pathway for the administration of subcutaneous trastuzumab for HER2 positive breast cancer patients.**

**Signatures**

The undersigned confirm that the following protocol has been agreed and approved by the Sponsor and that the Chief Investigator agrees to conduct the study in compliance with this approved protocol and will adhere to the principles of GCP, the Sponsor SOPs, and any other applicable regulatory requirements as may be amended from time to time.

Andrew Radley

| | | |
|---|---|---|
| Chief Investigator | Signature | Date |
| | | |

**LIST OF ABBREVIATIONS**

| | |
|---|---|
| AE | Adverse Event |
| ARR | Administration-Related Reactions |
| BOPA | British Oncology Pharmacy Association |
| CEL | Chief Executive Letter |
| CI | Chief Investigator |
| CNORIS | Clinical Negligence and Other Risks Scheme |
| CPP | Community Pharmacy-led Pathway |
| CRF | Case Report Form |
| DCE | Discrete Choice Experiment |
| DMC | Data Monitoring Committee |
| GCP | Good Clinical Practice |
| HCP | Healthcare Professional |
| HER2 | Human Epidermal Growth Factor Receptor 2 |
| ICF | Informed Consent Form |
| IF | Incidental Findings |
| ISF | Investigator Site File |
| IV | Intravenous |
| LVEF | Left Ventricular Ejection Fraction |
| MUGA Scan | Multigated Acquisition Scan |
| NHS | National Health Service |
| NCA | North Cancer Alliance |
| PI | Principal Investigator |
| PIS | Patient Information Sheet |
| PSSRU | Personal Social Service Research Unit costs |
| REC | Research Ethics Committee |
| SACT | Systemic Anti-Cancer Therapy |
| SAE | Serious Adverse Event |
| SC | Subcutaneous |
| SMC | Scottish Medicines Consortium |
| SMF | Study Master File |
| SMG | Study Management Group |
| SOP | Standard Operating Procedures |
| SSC | Study Steering Committee |
| WOSCAN | West of Scotland Cancer Network |

**SUMMARY/SYNOPSIS**

| | | |
|---|---|---|
| **Study Title** | CloseHER2 Home | |
| **Study Design** | Feasibility study | |
| **Study Population** | Patients treated with subcutaneous trastuzumab for HER2 positive breast cancer in the North Cancer Alliance (NCA) | |
| **Sample Size** | Up to 50 patients will be recruited to a community pharmacy led pathway and up to 15 pharmacies may participate. Community pharmacies. Where >15 pharmacies express an interest, priority will be given to those used by participating patients. Up to 50 patients will be recruited to standard care. All participants receiving care through this pathway will be asked to participate in an interview. A range of staff members from each pharmacy will be asked to participate in an interview. | |
| **Planned Study Period** | 12 months | |
| **Clinical phase duration** | 20 weeks | |
| **Follow up phase duration** | None | |
| **Primary** | **Objectives**<br><br>To assess the acceptability of a community pharmacy-led pathway (CPP) for the administration of subcutaneous trastuzumab | **Outcome Measures**<br><br>Proportion of consenting patients completing 4 cycles of trastuzumab via the CPP, compared to the eligible cohort of patients and also the eligible patients who consented.<br><br>Process evaluation of CPP by qualitative methods including semi-structured interviews with participants receiving the intervention and standard care and staff delivering the intervention and staff delivering standard care |
| **Secondary** | **Objectives**<br><br>Develop programme theory with key stakeholders | **Outcome Measures**<br><br>Construct a Logic Model |

| | | |
|---|---|---|
| | Evaluate the quality and safety of the CPP | Assess compliance with professional and legal standards set out in the SACT governance framework and audit tool<br><br>Patient and staff evaluation via semi-structured interviews |
| | Evaluate the practicality of the CPP | Patient and staff evaluation via semi-structured interviews |
| | Undertake an economic assessment of the CPP and the conventional care pathway | Define the attributes associated with a valued service and assess the weighting given to these attributes using a discrete choice experiment methodology<br><br>Use NHS Reference costs to model both pathways |

**SUMMARY**

Prevalence of cancer in the UK is rising due to improvements in survival and the increasing ageing population. It is projected to increase by approximately one million people per decade from 2010 to 2040. This has significant implications for the delivery of health services to this population. Within NHS Tayside, prescriptions for anti-cancer therapy have doubled in the last 10 years with significant impact on capacity. Novel pathways of treatment are required for cancer treatments to relieve the pressure on chair/bed space.

Breast cancer is the most common cancer in the UK, accounting for 15% of cancer diagnoses. Of these, up to 25% are HER2 positive tumours for which treatment with trastuzumab is recommended, after an initial course of systemic chemotherapy. Since 2014, trastuzumab has been approved for use in Scotland as a subcutaneous flat dose preparation administered over 2-5 minutes. Local experience and updated safety data suggests that trastuzumab could potentially be administered in a clinical setting out-with large cancer centres. Breast cancer patients have indicated their preference for the subcutaneous preparation, rather than an intravenous infusion, due to the convenience of administration, which allows them to get back to living a normal life after completing chemotherapy. This convenience is limited by the need to attend a cancer centre which is a significant distance from home or work. Community

pharmacies are found in convenient locations and community pharmacists are ideally placed to provide an alternative to the conventional treatment pathway.

The Close HER2 Home study will examine the feasibility of a community pharmacy-led pathway for breast cancer patients receiving subcutaneous trastuzumab therapy. The study will undertake a process and economic evaluation of a pharmacist-led pathway. The study aims to recruit up to 50 patients who have completed their chemotherapy and are prescribed single agent treatment with trastuzumab within NCA Health Boards. The eligible patients will consent to receive 4 cycles of trastuzumab administered in a community pharmacy or to receive standard care.

**INTRODUCTION**

Breast cancer is the most common cancer in UK and accounts for 15% of all new cancer diagnoses. [1] The overexpression of human epidermal growth factor receptor 2 (HER2) is found in 15-20% of breast cancer cases. HER2-positive tumours exhibit aggressive behaviour and a corresponding survival disadvantage. [2] The introduction of the monoclonal antibody against HER-2, Trastuzumab (Herceptin®), led to significant improvements in disease-free and overall survival [3,4] and is now standard treatment for HER2 positive breast cancers. [5,6,7]

A subcutaneous formulation of trastuzumab was approved for use in breast cancer by the Scottish Medicines Consortium (SMC) in 2014. [8] This has superseded its intravenous (IV) predecessor for virtually all patients receiving trastuzumab for breast cancer because of its improved safety profile and patient preference.[9]

A few small studies suggest that observation is not required after the first dose of IV or SC[10,11] and a recent survey of British Oncology Pharmacy Association (BOPA) members demonstrated that the majority of centres do not observe patients for the requisite 2 hours beyond the third dose[12,13]. The majority of centres advise patients they can leave after 30 minutes or sooner which is also current practice in NHS Tayside.

A local audit was conducted within NHS Tayside to ensure this practice was safe. In the first two years of use 161 patients were treated with subcutaneous trastuzumab. In the first year of use there was a single ARR reported as requiring treatment with antihistamine for a local injection reaction. This occurred on the first dose and did not recur with subsequent cycles. To date, there have been no serious ARRs with subcutaneous trastuzumab in NHS Tayside. A similar audit is currently underway in the West of Scotland Cancer Network (WOSCAN) which will further inform in practice. This evidence suggests SC trastuzumab has potential to be safely administered by a novel treatment pathway out with the acute setting. This study will also provide data to inform practice about this point.

Preparation of SC trastuzumab is much simpler than IV, it is a 600mg flat dose ready for injection solution. This eradicates the risk of errors from dose calculation required

for weight-based IV dosing. Wastage is minimised compared with IV weight-based dosing where drug would be discarded if full vials could not be utilised for the calculated dose. Preparation in a controlled clean-room environment is not necessary therefore preparation and administration can be undertaken by a suitably trained healthcare professional, using aseptic technique, in a "near patient" area. This releases capacity in aseptic dispensing unit, reduces the impact on staff time and minimises the time patients spend on the oncology unit. A time and motion study reported switching from IV to SC reduces the time spent by patients on the oncology unit by two thirds and a similar reduction in health care professional (HCP) time. [14]

The PrefHer study, which treated participants with both IV and SC formulations, found the 89.9% of participants favoured the SC formulation [15], citing time saved and lower levels of pain/discomfort as the primary reasons for their choice. The advantages of minimal time spent at hospital and the ability to resume a normal life has been reinforced by an informal group of breast cancer survivors attending the Dundee Maggie's Centre and forms the fundamental aim of this work: to deliver cancer treatments closer to home.

## 1 BACKGROUND & RATIONALE

Improvements in diagnosis and treatment of cancer combined with an ageing population have led to a steady rise in the prevalence of cancer in the UK. This effect has been observed in NHS Tayside; a recent NHS Tayside report prescriptions for Systemic Anti-Cancer Therapy (SACT) have doubled in the last ten years.
As the most common cancer in women in Scotland, breast cancer accounts for a significant proportion of SACT prescriptions. Aetiology is multi-factorial, but increasingly the role of lifestyle factors – in particular obesity – have added to a rise in incidence, which is projected in increase by 27.5% over the next 10 years. [16] Breast cancer survival has doubled in the last 40 years due to improvements in treatment. This means more people are being diagnosed with breast cancer and those with the disease living longer, with more treatments becoming available. The combination of improving survival and increasing incidence is beginning to impact on health service resources and clinical capacity. To cope with the increasing demand the health service must look to deliver treatments in novel ways; utilising the clinical capacity of community pharmacies appears to be a rational and viable direction to take the delivery of cancer treatments.

As highlighted by the PrefHer study, the SC formulation of trastuzumab was favoured because the convenience afforded to patients allowed them to "get on with life". [15] The advantage is constrained where patients do not live (or work) conveniently close to their local cancer centre. Current practice requires patients to attend for treatment at an oncology outpatient area. All centres in the North of Scotland Cancer Alliance (NCA), have a population spread over a large geographical area. This can mean patients travel a considerable distance for a 5-minute injection.

In addition, a significant portion of patients who complete chemotherapy return to work necessitating time off to attend hospital for trastuzumab. Lack of car parking spaces and inadequate public transport are frequently highlighted reasons patients dislike attending hospital for treatment.

The Close HER2 Home study will evaluate a new pathway of care for patients prescribed trastuzumab for breast cancer. It is hypothesised that community pharmacies offer an ideal site for delivery of this care pathway and of similar care pathways.

The UK government "Commission of Future Models of Care Delivered through Pharmacy" and the corresponding policy document from Scotland "Prescription for Excellence" highlight a new role for community pharmacy in delivering therapy. [17,18] Prescription for Excellence recognised pharmacists as the clinicians responsible for NHS pharmaceutical care and plans for the implementation of all clinical pharmacists to be independent prescribers. It calls for the development of integrated multidisciplinary teams able to deliver complex care close to where the patient lives. The Integrated Care Strategy that is being pursued by NHS Boards aims to move the majority of care into primary care environments, with a large reduction in the types of care that are provided from hospital facilities.[19] Community pharmacy is a key delivery point for complex care in the future, working closely with hospital specialists and general practice colleagues to deliver high quality patient care within the new environment of integrated health and social care. This project acts as a test of change for community pharmacy and an exemplar of policy aspiration that could be used as a model of care for other interventions.

Similar pathways in which provision of hospital-only medicines are delivered in primary care are already under investigation: the SuperDOT-C study will compare a community pharmacy led pathway to the conventional hospital-based pathway for Hepatitis C virus therapy.[20] Following on from previous success, community pharmacists have received further commissioning in England to administer flu vaccines, [21]. With cuts to their budget in England, there is an urgent need for community pharmacy to demonstrate their value across the UK.[22] Thus it is just the right time to be evaluating new pathways of care responding to this significant clinical need utilising these technological and policy developments.

However, these novel pathways of care need to be evaluated for both for acceptability, efficacy, safety and cost-effectiveness compared to traditional pathways. This study will provide some preliminary evidence of the feasibility of a community pharmacy-led pathway for the delivery of subcutaneous trastuzumab, and examine the acceptability of this pathway to both patients and pharmacists.

## 2 STUDY OBJECTIVES & OUTCOMES

This feasibility study of a community pharmacy-led pathway (CPP) will use quantitative and qualitative measures to assess the CPP in terms of acceptability, quality, safety, practicality and cost.

**Table 1: Primary Objectives and Outcome Measures**

| **Primary Objective:** | **Outcome Measure:** | **Timepoint of outcome measured:** |
|---|---|---|
| To assess the acceptability of a community pharmacy-led pathway (CPP) for the administration of subcutaneous trastuzumab | Proportion of consenting patients completing 4 cycles of trastuzumab via the CPP, compared to the eligible cohort of patients and also the eligible patients who consented.<br><br>Process evaluation of CPP by qualitative methods including semi-structured interviews with participants receiving the intervention and standard care and staff delivering the intervention and staff delivering standard care | *At end of study*<br><br>*During the intervention period* |

**Table 2: Secondary Objectives and Outcome Measures**

| **Secondary Objective:** | **Outcome Measure:** | **Timepoint of outcome measured:** |
|---|---|---|
| Develop programme theory with key stakeholders | Construct a Logic Model | Prior to recruitment |
| Evaluate the quality and safety of the CPP | Assess compliance with professional and legal standards set out in the SACT governance framework and audit tool. [22,23<br><br>Number of AEs in each group<br><br>Patient and staff evaluation via semi-structured interviews | During intervention period<br><br>During intervention<br>Follow up |

| | | |
|---|---|---|
| Evaluate the practicality of the CPP | Patient and staff evaluation via semi-structured interviews | Follow up |
| Undertake an economic assessment of the CPP and the conventional care pathway | Define the attributes associated with a valued service and assess the weighting given to these attributes using a discrete choice experiment methodology<br><br>Use NHS Reference costs to model both pathways | *Throughout study period* |

## 4 STUDY DESIGN

### 4.1 INTERVENTION

The intervention under study is a new model of care for the administration of subcutaneous trastuzumab via a community pharmacy-led pathway (CPP). Patients prescribed a course of SC trastuzumab can elect to have four of their prescribed doses of in a community pharmacy administered by a pharmacist.

Participating patients and a selection of staff will be invited to participate in a semi-structured interview to assess the feasibility of the new pathway, when they have completed the intervention phase of the study.

### 4.2 STUDY DESCRIPTION

In the standard care pathway, patients prescribed trastuzumab attend for treatment at an oncology outpatient area in a hospital at 3-weekly intervals for the duration of treatment. Pre-treatment assessment and administration of trastuzumab is undertaken by a chemotherapy nurse as following the local protocol.

Patients will be informed of the study by their chemotherapy nurse of the study and by providing them with Patient Information Sheet, describing the intervention pathway. Patients who are interested will be referred to a research nurse or may contact the study team directly for further information and an informed consent appointment.

Eligible patients will be consented by a suitably qualified research nurse. Those who consent to the Community Pharmacy Pathway will be referred to a community pharmacist when they have completed chemotherapy but continue on single agent trastuzumab. Patients will attend the community pharmacy at 3-weekly intervals to receive their trastuzumab for 4 doses. Pre-treatment assessment and administration of trastuzumab will be undertaken by the pharmacist in their consultation room.

Following completion of the fourth cycle the patient will complete any remaining doses as per the conventional pathway.

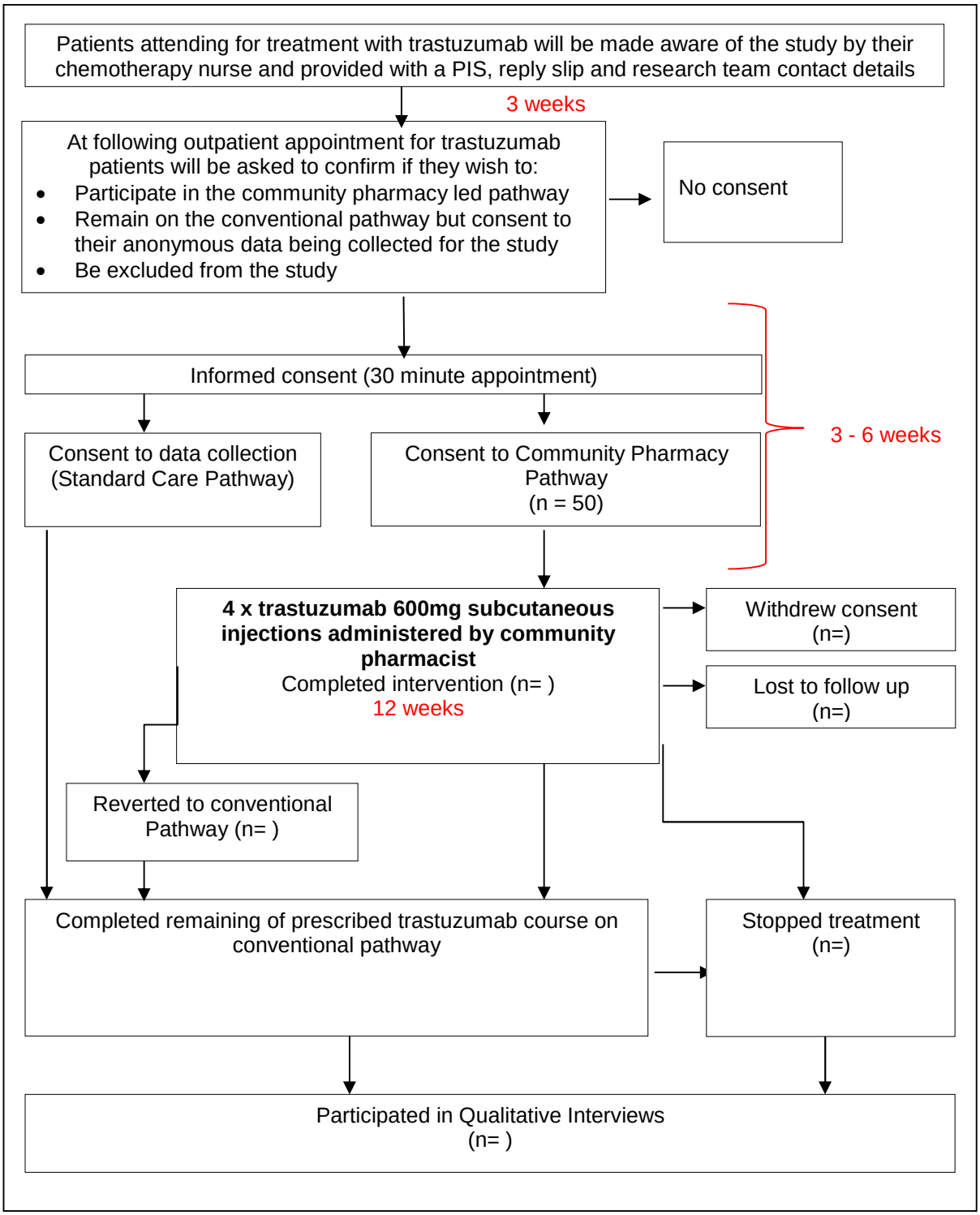
Patients who consent to the study, but choose standard care will continue to receive their treatment from the hospital, but will be asked to participate in qualitative interviews. Participants having standard care will be contacted by the study team (using details supplied by the patient on the reply slip) to arrange a convenient time to conduct a telephone, video or in-person semi-structured interview.

Staff from community pharmacies participating as study sites will be trained to deliver the study methodology. This will include completion of training in Good Clinical Practice, completion of study documentation, introduction to cancer and its treatment and administration and monitoring of trastuzumab treatment. An assessment will be made of training effectiveness and participant satisfaction during qualitative interviews.

All participants will remain under the care of the acute oncology service regardless of pathway and will continue to have access to the 24-hour Cancer Treatment Helpline and the local oncology triage service.

All community pharmacists participating in the study will receive training as described in this protocol and required by the Service Specification between the Healthboard and the pharmacy.

## 4.3 STUDY FLOWCHART



## 4.4 STUDY MATRIX

| | Baseline Visit (Week 1) | | Intervention Period (Weeks 3 – 12) | | Follow up (week 18±2) | |
|---|---|---|---|---|---|---|
| | Standard Pathway | CPP | Standard Pathway | CPP | Standard Pathway | CPP |
| Informed Consent, Demographics & Background Data (~30 mins) | x | x | | | | |
| Pre-assessment | x | x | x | x | x | x |
| Administration of trastuzumab in hospital outpatient unit | x | x | x | | x | x |
| Administration of trastuzumab in Community Pharmacy | | | | x | | |
| AEs, self-reported toxicity | | | x | x | | |
| Semi-structured Interview | | | | | x | x |

## 4.5 STUDY ASSESSMENTS

### 4.5.1 Demographic and Background Data

- Age, ethnicity, education, employment, socio-economic status (SMID) will be collected at baseline to describe the population who utilised the service .
- Distance from home and work address to hospital will be identified from postcode and recorded (postcode itself will not be documented).
- Baseline treatment toxicity assessment from nursing notes/care bundle (to enable investigating community pharmacy to assess if remaining stable, worsening or improving during intervention period).

### 4.5.2 Process Evaluation Measures

These measures are aimed at identifying feasibility and acceptability issues that may affect future wider roll out of the CPP.

**Observations**

Sites delivering standard care and the community pharmacy pathway will be visited by the CI/Research Pharmacist on at least one occasion to observe and a checklist completed:

- Appointment duration (waiting time and chair time)
- Healthcare professional (HCP) time taken for appointment
- Sites delivering the CPP will be visited to obtain:
    - Appointment duration (waiting time and chair time)
    - Healthcare professional (HCP) time taken for appointment
    - Quality and Safety Audit (Community Pharmacy sites only**)**

**Semi-structured Interviews**

Semi-structured interviews will be conducted with participants and health care professionals taking part in the study, using purposive sampling and representation from all participating pharmacies and the acute oncology service. The interviews will be conducted by the CI or Research Pharmacist using topic guides developed in line with the research aims and programme theory. All interviews will be recorded as digital audio files and transcribed in full for thematic analysis. They will be identifiable only via unique study code. These data will contribute to assessment of the feasibility and acceptability (including barriers and facilitators); identifying any unintended consequences of participation. Transcripts will be inductively analysed to identify themes emergent from the interviews. A deductive analysis will also be undertaken to compare findings with programme theory. Anonymised data will be analysed using a software product such as NVIVO.

## 4.6 STUDY SAFETY ASSESSMENTS

There are no additional safety assessments required in the CPP; the service specification in included in Appendix.

**Standard care** for patients receiving subcutaneous trastuzumab includes:

- Cardiac assessment every 4 months (LVEF by MUGA or Echocardiogram)
- Full blood count and biochemistry every 4 months (to coincide with venous cannulation for MUGA scan)
- Patient self-reported toxicity assessment against criteria for recognised side effects of trastuzumab conducted every 3-weeks prior to treatment administration

Pharmacists operating the CPP will review toxicity at each 3-weekly patient visit. Cardiac assessment and blood tests will take place prior to and following the CPP as per standard of care.

Pharmacists delivering the Community Pharmacy Pathway will be trained to treat administration related reactions including the use of adrenaline (epinephrine). In addition, they must adhere to the relevant General Pharmaceutical Council standards and have standard operating procedures (SOPS) in place which cover:

- Infection control (including hand hygiene)
- Sharps disposal
- CPR
- Anaphylaxis
- Chemical (cytotoxics and biologics) spill
- Chaperone
- Information governance including Data Protection & confidentiality

### 4.7 TISSUE

No tissue will be collected.

### 4.8 INCIDENTAL FINDINGS

Any incidental findings (IF: previously undiagnosed condition) considered to be clinically significant will be reported to the participant's GP by the CI, PI, or research pharmacist with the consent of the participant and in consultation with the study clinical lead.

### 4.9 STUDY POPULATION

This pilot study will be open to patients treated by a cancer centre in the North of Scotland Cancer Alliance (NCA) who are prescribed subcutaneous trastuzumab for the treatment of HER2 positive breast cancer.

Staff from participating cancer centres (at least one chemotherapy nurse and one oncology pharmacist) and all participating community pharmacists will be invited to participate in a process evaluation. For cancer centres, invitation to participate will be co-ordinated by the lead site pharmacist for oncology (PI) or their delegated investigator.

### 4.10 NUMBER OF PARTICIPANTS

Up to 50 patients will be recruited to the CPP with up to 15 pharmacies. For this pilot study, Tayside, Grampian, Highland and Fife Healthboards will be invited to participate in the CPP. Community pharmacy sites will be identified by an expression of interest (EoI) process facilitated by Community Pharmacy Scotland (CPS). Community pharmacies identified by the EoI process will be assessed for suitability against professional and legal standards (Appendix 3). Where there is a high level of interest,

priority will be given to pharmacies already used and identified by participating patients.

### 4.11 INCLUSION CRITERIA

**Community Pharmacy Pathway Participants:**

- Adult patients, ≥ 16 years of age
- Able to provide informed consent
- Prescribed a course of trastuzumab for the treatment of breast cancer
- Tolerated at least one dose of subcutaneous trastuzumab administered by a chemotherapy nurse in the acute setting
- Have a minimum of 4 cycles outstanding in the prescribed course.

**Study Registration Participants**:

- Adult patients, ≥ 16 years of age
- Able to provide informed consent
- Prescribed a course of trastuzumab for the treatment of breast cancer

**Staff Participants**

- NHS employee involved in the treatment of breast cancer patients who cared for patients participating in the CPP
- Community Pharmacist who participated in the CPP
- Able to provide informed consent

### 4.12 EXCLUSION CRITERIA

**Community pharmacy pathway:**

- Unable to provide informed consent
- History of severe allergic or immunological reactions
- Less than 4 cycles outstanding in the prescribed course of trastuzumab

**Study Registration Participants**:

- Unable to provide informed consent
- History of severe allergic or immunological reactions
- Less than 4 cycles outstanding in the prescribed course of trastuzumab

**Staff Process Evaluation**

- No involvement in the study
- Unable to provide informed consent

Individuals who are participating in another interventional study, or who are enrolled in an observational study, will be co-enrolled where the CIs of each study agree that it is appropriate.

# 5 PARTICIPANT SELECTION AND ENROLMENT

## 5.1 IDENTIFYING PARTICIPANTS

**Community Pharmacy Pathway/Study Registration Participants:**

Potential participants will be recruited from oncology outpatient departments within NCA. Individuals will be identified from the "Chemo List" function of the electronic prescribing and administration system (ChemoCare) by the research pharmacist, the PI or their delegate on a weekly basis until recruitment is complete. Identified patients will be flagged to the nurse responsible for administering their trastuzumab who will provide them with a patient information sheet (PIS) when they attend for treatment.

Interested individuals may be referred to the study team by their chemotherapy nurse or may contact the study team directly via the details provided in the PIS.

**Staff Participants**

Cancer centre staff participants will be identified by the site PI and invited to participate in service evaluation interviews. Interested staff participants will be given a PIS that explains their role.

All community pharmacists (and their staff) participating in the CPP will be invited to participate in service evaluation interviews. Interested individuals will be given a PIS and give written consent prior to interview.

## 5.2 CONSENTING PARTICIPANTS

**Community Pharmacy Pathway/Study Registration Participants:**

Potential participants who express an interest to their nurse will be given an appointment (in person or by telephone) with an Oncology Research Nurse at least 24 hours after receiving the PIS; normally to coincide with their next appointment for treatment 3 weeks later. The Research Nurse is familiar with the study methodology and trained in obtaining informed consent. They will review the information in the PIS with the potential participant and those who wish to enter the study will be asked to complete a consent form.

Where a participant requests to speak with a member of the study team the consent process will not be completed until the participant has spoken to the study team and had all their questions answered to their satisfaction.

For adults who lose capacity their previous wishes will remain legally binding and this will remain valid unless the protocol changes significantly. If this occurs and further consent is required from a participant who has lost capacity, the appropriate person will be asked for their consent. In all cases the CI or delegate will consult with carers and take note of any signs of objection or distress from the participant – the participant will be withdrawn if they raise objection. Where appropriate the participant will be withdrawn from any further clinical intervention and agreement will be sought from a carer to allow data collection.

The informed consent process will be conducted in compliance with TASC SOP07: Obtaining Informed Consent from Potential Participants in Clinical Research.

### 5.3 SCREENING FOR ELIGIBILITY

All patients attending for subcutaneous trastuzumab will be screened for eligibility by the research pharmacist, site PI or a delegated oncology pharmacist (who would access the system in the course of their daily work) on a weekly basis. Patients with less than 4 cycles remaining or meet the exclusion criteria being deemed ineligible.

### 5.4 INELIGIBLE AND NON-RECRUITED PARTICIPANTS

Ineligible participants will be thanked for their interest in the study and given a clear explanation as to why they are ineligible for study participation.

#### 5.4.1 Withdrawal procedures

The right to refuse to participate without reasons will be respected.

All participants will be free to withdraw at any time from the study without giving reasons and without prejudicing further treatment. Participants will be informed that they have the right to withdraw from the study at any time and can do so by informing a healthcare professional involved in their treatment or a member of the research team. Participants who withdraw from the CPP, will have their next appointment for treatment arranged with their local oncology outpatient unit where any remaining doses will be given via the conventional pathway.

After the participant has entered the study they remain under the care of the local oncology service whose clinicians may stop or give alternative treatment to that specified in the protocol at any stage if it is considered to be in the participant's best interest; the reasons for doing so will be recorded.

# 6 DATA COLLECTION & MANAGEMENT

## 6.1 DATA COLLECTION

- Data will be collected by staff appointed to the study and participating community pharmacists (investigators).
- Data sources will be the CRF, ChemoCare, medical/nursing notes, laboratory reports and semi structured interviews.
- Data will be collected at baseline, at each CPP appointment (week 3, 6, 9 and 12) and at follow up (week 18 ± 2).
- Baseline treatment toxicity assessment from nursing notes/care bundle (to enable investigating community pharmacy to assess if remaining stable, worsening or improving during intervention period). Please refer to Appendix 2 for clinical data to be collected. The clinical data will not be analysed but will be copied to the participant's clinical notes when they return to the acute sector to ensure continuity.
- Age, ethnicity, education, employment, socio-economic status (SMID) will be collected to describe the population who utilised/declined the service. This information will be collected by the PI's and entered into the CRF at the referral (baseline) stage.
- Distance from home and work address to hospital will be identified from postcode and recorded (postcode itself will not be documented) to compare the travel time burden on patients for CPP versus conventional pathway. This information will be extracted by the PI at baseline and entered into the CRF.
- Sites will be visited by the CI/PI on at least one occasion to observe:
    - Appointment duration (waiting time and chair time)
    - Healthcare professional (HCP) time taken for appointment
- Sites delivering the CPP will be visited to obtain:
    - Appointment duration (waiting time and chair time)
    - Healthcare professional (HCP) time taken for appointment
    - Quality and Safety Audit (CPP sites only**)**

## 6.2 DATA MANAGEMENT SYSTEM

Data management will be conducted in compliance with TASC SOPs on Data Management, including TASC SOP53 Data Management Systems in Clinical Research.

The data management system (DMS) will be Excel as approved by Sponsor.

The DMS will be based on the protocol and CRF for the study and individual requirements of the investigators. The CRF will collect only information that is required to meet the aims of the study and to ensure the eligibility and safety of the participant. The study database will be compliant with TASC SOP53 Data Management Systems in Clinical Research.

The database is managed in line with all applicable principles of medical confidentiality and data laws. Anonymised patient data will be stored on University of Dundee research database. The Data Controllers will be the University of Dundee and NHS Tayside, the Data Custodian will be the CI.

The CI may delegate CRF completion but is responsible for completeness, plausibility and consistency of the CRF. Any queries will be resolved by the CI or delegated member of the STUDY team.

Database lock will be conducted in compliance with TASC SOP32 Locking Clinical Study Databases.

## 7 STATISTICS AND DATA ANALYSIS

### 7.1 SAMPLE SIZE CALCULATION

A Sample size is not required for this feasibility study.

### 7.2 PROPOSED ANALYSES

This study is designed to be descriptive and not to detect statistically significant differences between the CPP and conventional pathway of care, therefore only descriptive statistics will be used to describe the population.

The primary outcome is the number of patients who complete four cycles of trastuzumab via the CPP (numerator) as a proportion of all who consented to the CPP (denominator) and also as a proportion of the estimated cohort available to consent.

Qualitative analyses have been previously described in this protocol. Nvivo software may be employed to aid analysis of anonymous qualitative interviews if available.

### 7.3 MISSING DATA

The nature of this study is to assess the applicability of this model in the real world, so incomplete data that impacts the primary outcome will be assumed to be consistent with failure of intervention. Every effort will be made to obtain missing data.

### 7.4 TRANSFER OF DATA

Referral and transfer of necessary patient identifiable data between acute sites and community pharmacy will be by secure NHS.net email. Anonymised study data will be kept within NHS Tayside.

Anonymous CRFs will be collected by study team at the end of the intervention.

## 8 STUDY MANAGEMENT AND OVERSIGHT ARRANGEMENTS

### 8.1 STUDY MANAGEMENT GROUP

The study will be co-ordinated by a Study Management Group (SMG), consisting of:

Study co-ordinator (TCTU)

Chief Investigator

Principal Investigators (Lead Pharmacists at NCA sites or their delegate)

Clinical Lead (Oncology consultant)

Research pharmacist

Research Nurse

### 8.2 INSPECTION OF RECORDS

The CI, PIs and all institutions involved in the study will permit study related monitoring, audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.

## 9 GOOD CLINICAL PRACTICE

All study staff (study team, site leads, community pharmacists and research nurses) will be trained in Good Clinical Practice, according to local agreements and sponsor approvals. CV's will kept in the site file.

### 9.1 ETHICAL CONDUCT OF THE STUDY

The study will be conducted in accordance with the principles of good clinical practice (GCP).

In addition to Sponsorship approval, a favorable ethical opinion will be obtained from the appropriate REC and appropriate NHS R&D approval(s) will be obtained prior to commencement of the study.

### 9.2 CONFIDENTIALITY AND DATA PROTECTION

The CI and study staff will comply with all applicable medical confidentiality and data protection principles and laws with regard to the collection, storage, processing and disclosure of personal data.

The CI and study staff will also adhere to the NHS Scotland Code of Practice on Protecting Participant Confidentiality or equivalent.

All trial records and personal data will be managed in a manner designed to maintain participant confidentiality. All records, electronic or paper, will be kept in a secure storage area with access limited to appropriate trial staff only. Computers used to collate personal data will have limited access measures via user names and passwords.

Personal data concerning health will not be released except as necessary for research purposes including monitoring and auditing by the Sponsor, its designee or regulatory authorities providing that suitable and specific measures to safeguard the rights and interests of participants are in place.

The CI and trial staff will not disclose or use for any purpose other than performance of the trial, any personal data, record, or other unpublished, confidential information disclosed by those individuals for the purpose of the trial. Prior written agreement from the Sponsor will be required for the disclosure of any said confidential information to other parties.

Access to collated personal data relating to participants will be restricted to the CI and appropriate delegated trial staff.

Where personal data requires to be transferred, an appropriate Data Transfer Agreement will be put in place.

Published results will not contain any personal data that could allow identification of individual participants.

### 9.3 INSURANCE AND INDEMNITY

The University of Dundee and Tayside Health Board are Co-Sponsoring the study.

**Insurance**: The University of Dundee will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study.

Tayside Health Board will maintain its membership of the Clinical Negligence and Other Risks Insurance Scheme ("CNORIS") which covers the legal liability of Tayside in relation to the study.

**Indemnity:** The Co-Sponsors do not provide study participants with indemnity in relation to participation in the Study but have insurance for legal liability as described above.

## 10 ADVERSE EVENTS

### 10.1 DEFINITIONS

| | |
|---|---|
| Adverse Event (AE) | Any untoward medical occurrence in a clinical research participant which does not necessarily have a causal relationship with study participation |
| Serious Adverse Event (SAE) | A serious adverse event is any untoward medical occurrence that:<br>• results in death<br>• is life threatening<br>• requires hospitalisation or prolongation of existing hospitalisation |

| | |
|---|---|
| | • results in persistent or significant disability or incapacity<br>• is a congenital anomaly or birth defect<br>• Or is otherwise considered serious |

### 10.2 RECORDING AND REPORTING AE

All SAEs will be recorded on the AE Log in the CRF and will be assessed for severity by the CI or delegate. SAEs will be recorded from the time a participant consents to join the study until the participant's last study visit for both arms of the study.

The Investigator will make a clinical judgment as to whether or not an AE is of sufficient severity to require the participant's removal from the study. A participant may also voluntarily withdraw from treatment due to what he or she perceives as an intolerable AE. If either of these occurs, the participant should, if required, be offered an end of study assessment and be given appropriate care under medical supervision until symptoms cease, or the condition becomes stable. SAEs will be followed up until 30 days after participant's last visit.

The CI or delegate will ask about the occurrence of SAEs and hospitalisations at every visit during the study. **SAEs which are both unexpected and related to study participation** will be submitted on an HRA NCTIMP Safety Report form to the REC by the CI, within 15 days of becoming aware of the SAE, and copied to the Sponsor Research Governance Office.

Worsening of the condition under study will not be classed as an AE, but will be defined as an outcome. Pre-specified outcome(s) will not be classed as an AE but as an outcome. Elective admissions and hospitalisations for treatment planned prior to randomisation, where appropriate, will not be considered as an AE. However SAEs occurring during such hospitalisations will be recorded.

## 11 ANNUAL REPORTING REQUIREMENTS

Annual reporting will be conducted in compliance with TASC SOP 15: Preparing and Submitting Progress and Safety Reports in CTIMPs and Non-CTIMPs, as a condition of sponsorship and as a condition of a favourable opinion from a REC. An HRA Annual Progress Report for NCTIMPs will be prepared and submitted by the CI to REC, and copied to the Sponsor, on the anniversary date of the REC favourable opinion.

Any safety reports additional to SAE reports, for example, reports of a DMC, will be sent by the CI to REC, with a Safety Report Form, and to the Sponsor.

# 12 STUDY CONDUCT RESPONSIBILITIES

## 12.1 PROTOCOL AMENDMENTS, DEVIATIONS AND BREACHES

The CI will seek approval for any amendments to the Protocol or other study documents from the Sponsor, REC and NHS R&D Office(s). Amendments to the protocol or other study docs will not be implemented without these approvals.

In the event that a CI needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF, documented and submitted to the Sponsor. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to the appropriate REC and lead NHS R&D Office for review and approval.

In the event that a breach of GCP or protocol is suspected, this will be reported to the Sponsor Governance Office immediately

## 12.2 STUDY RECORD RETENTION

Archiving of study documents will be for five years after the end of study.

## 12.3 END OF STUDY

The end of study is defined as the point at which all patients and staff participating in the process evaluation have been interviewed. The Sponsor, CI and/or the SC have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely. The CI will ensure that any appropriate follow up is arranged for all participants.

A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study.

# 13 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

## 13.1 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team and their respective employers.

## 13.2 PUBLICATION

The clinical study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.

Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

### 13.3 PEER REVIEW

The study has been peer reviewed internally, by Directors of Pharmacy for Scotland, by a patient engagement group and the Funder (Roche).

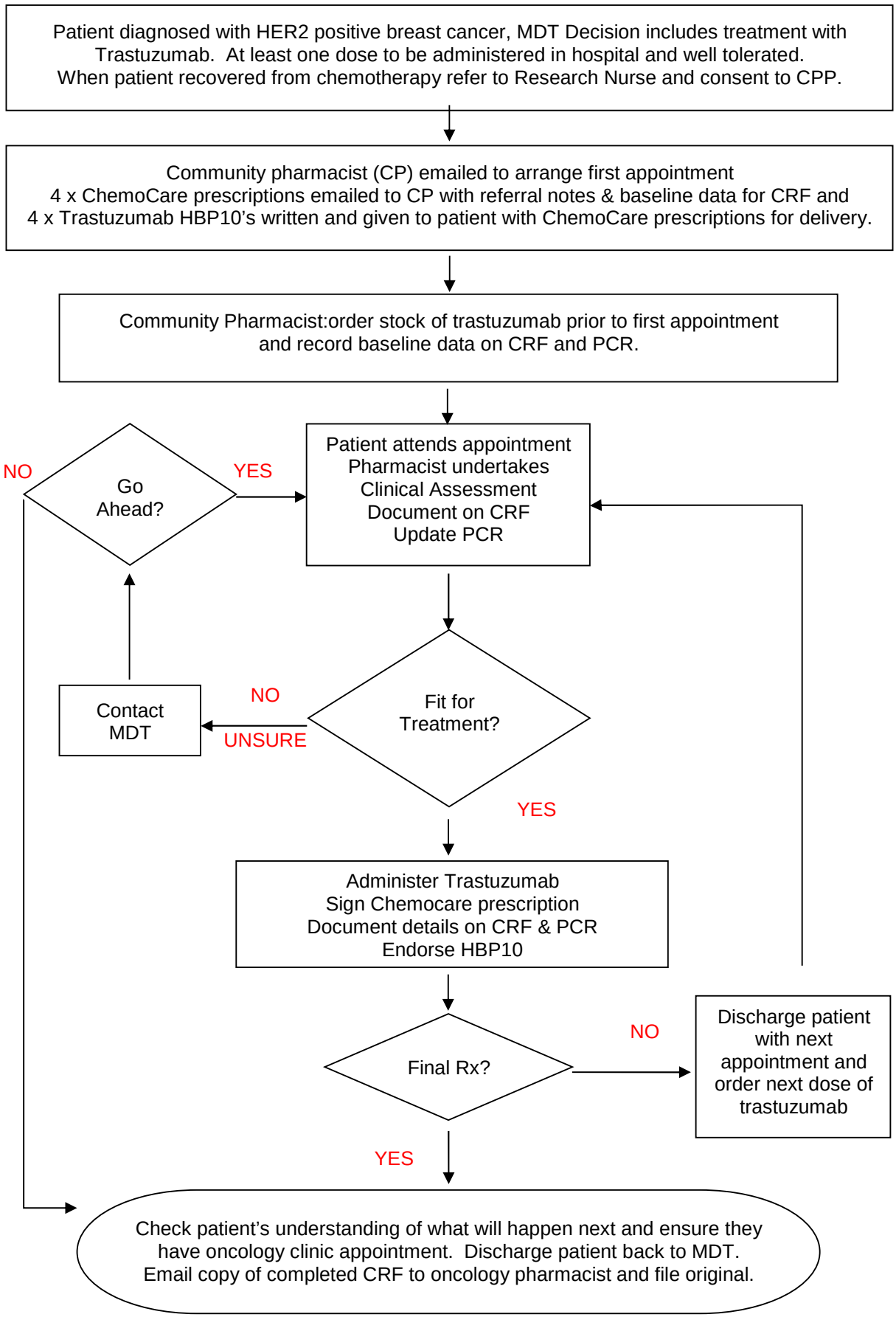
## 14 REFERENCES

1. Cancer Research UK, [November 2016] Available from URL: http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer#heading-Zero.
2. Slamon DJ, Clark GM, Wong SG, Levin WJ, Ullrich A, McGuire WL. Human breast cancer: correlation of relapse and survival with amplification of the HER-2/neu oncogene. Science. 1987;235:177
3. Slamon DJ, Leyland-Jones B, Shak S, Fuchs H, Paton V, Bajamonde A, et al. Use of chemotherapy plus a monoclonal antibody against HER2 for metastatic breast cancer that overexpresses HER2. N Engl J Med. 2001;344:783
4. Marty M, Cognetti F, Maraninchi D, Snyder R, Mauriac L, Tubiana-Hulin M, et al. Randomized phase II trial of the efficacy and safety of trastuzumab combined with docetaxel in patients with human epidermal growth factor receptor 2-positive metastatic breast cancer administered as first-line treatment: the M77001 study group. J Clin Oncol. 2005;23:4265
5. Denduluri N, Somerfield MR, Eisen A, Holloway JN, Hurria A, King TA, et al. Selection of Optimal Adjuvant Chemotherapy Regimens for Human Epidermal Growth Factor Receptor 2 (HER2)–Negative and Adjuvant Targeted Therapy for HER2-Positive Breast Cancers: An American Society of Clinical Oncology Guideline Adaptation of the Cancer Care Ontario Clinical Practice Guideline. J Clin Oncol. 2016;34:2416
6. Senkus E, Kyriakides S, Ohno S, Penault-Llorca F, Poortmans P, Rutgers E, et al. Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol 2015;26 (Suppl. 5) v8-30
7. Cardoso F, Costa A, Senkus E, Aapro M, Andre F, et al. ESO–ESMO International Consensus Guidelines for Advanced Breast Cancer (ABC 3). Ann Oncol 2017;8:16–33, 2017
8. https://www.scottishmedicines.org.uk/General/SMC_Advice_Site_Search_Results?q=%28trastuzumab%29+AND+path%3A%2Fcontent%2FSMC_Advice%2FAdvice*+AND+type%3APAGE&p=0&style=smc_advice_results [March 2017]
9. Datapharm: Herceptin 600 mg solution for injection in vial: Summary of Product Characteristics updated 29 March 2016. [November 2016]. Available from URL: http://www.medicines.org.uk/emc/medicine/28179
10. Price L, Brunt AM Trastuzumab infusion reactions in breast cancer. Should we routinely observe after the first dose? Eur J Hosp Pharm Published Online First: 16 March 2017.

11. Karmali S, Hughes N, Galiauskas R, Cook J, Murphy K, Bird BR R and Murphy CG G. Is 6 hour monitoring for administration related reactions after first administration of subcutaneous trastuzumab necessary? A single institution audit [abstract]. In: 39th Annual San Antonio Breast Cancer Symposium; December 6-10, 2016; San Antonio. Publication Number: P3-12-04. Available from URL: https://www.sabcs.org/Portals/SABCS2016/Documents/SABCS-2016-Abstracts.pdf?v=1
12. http://www.wales.nhs.uk/sites3/Documents/456/Herceptin%20sc%20protocol%20v1GDCB.pdf and http://stlukescanceralliance.co.uk/wp-content/uploads/2015/10/Trastuzumab-Herceptin-subcutaneous-for-early-breast-V3-5.15.pdf
13. Unpublished data (BOPA survey results and NHS Tayside trastuzumab audit) available on request from protocol author
14. Burcombe R, Chan S, Simcock R, Samanta K, Percival F, Barrett-Lee P. Sucutaneous Trastuzumab (Hereptin®): A UK Time and Motion Study in Comparison with Intravenous Formulation for the Treatment of Patients with HER2-Positive Early Breast Cancer. ABCR 2013;2:133
15. Pivot X, Gilgorov J, Müller V, Curigliano G, Knoop A, et al. Patients' preferences for subcutaneous trastuzumab versus conventional intravenous infusion for the adjuvant treatment of HER2-positive early breast cancer: final analysis of 488 patients in the international, randomized, two-cohort PrefHer study. Ann Oncol 2014;25:1979
16. http://www.isdscotland.org/Health-Topics/Cancer/Publications/2015-08-18/2015-08-18-Cancer-Incidence-Projections-Report.pdf
17. Smith J, Picton C, Dayan M. Now or Never: Shaping pharmacy for the future. Royal Pharmaceutical Society 2013. London. [November 2016]. Availbe from URL: https://www.rpharms.com/promoting-pharmacy-pdfs/moc-report-full.pdf
18. Prescription for Excellence: A vision and action plan for the right pharmaceutical care through integrated partnerships and innovation. Scottish Government 2013. Edinburgh. [November 2016]. Available from URL: http://www.scotland.gov.uk/resource/0043/00434053.pdf
19. http://www.gov.scot/Publications/2016/02/86 [November 2017]
20. https://clinicaltrials.gov/ct2/show/NCT02706223 [November 2016]
21. https://www.england.nhs.uk/2016/05/recommission/ [November 2016]
22. http://www.bbc.co.uk/news/health-37715393 [November 2016]
23. http://www.sehd.scot.nhs.uk/mels/CEL2012_30.pdf [April 2016]
24. http://www.healthcareimprovementscotland.org/our_work/cancer_care_improvement/programme_resources/systemic_anti-cancer_therapy.aspx [April 2016]

## Appendix 1: CloseHER2Home Standard Operating Procedure

### 1.1 Process Flow Diagram



## 1.2 Procedure and Responsibilities

Patients can be referred to the community pharmacy pathway on completion of intravenous chemotherapy. The current service is part of a study pilot therefore patients will have signed an informed consent form in order to participate.

Community Pharmacies identified via expression of interest process will be audited to ensure compliance with the Clinical Pharmacy Oncology Service Specifications and standards prior to operating the service.

Prior to operating a subcutaneous trastuzumab service the community pharmacists must have documentary evidence of their competence to operate the service, including completion of British Oncology Pharmacy Association (BOPA) Breast Cancer Module, the relevant NHS SACT Learn Pro Module and attendance at a training day run by the study team. This will include hands-on training for injection preparation and administration. Initially, a nurse experienced in the administration of trastuzumab will provide training and offer sessions for pharmacists to attend hospital for further practical training if desired. It is anticipated in the longer term, pharmacists experienced in administering trastuzumab could offer training to their peers.

**The Oncology Pharmacist (Principal Investigator)**

- The oncology pharmacist will confer with the patient and identify a participating pharmacy close to the patient's home address or preferred location (e.g workplace).
- The oncology pharmacist will record the patient's baseline results onto the care bundle.
- The oncology pharmacist will ensure the next 4 scheduled cycles of trastuzumab have been prescribed and pharmaceutically verified in line with local SACT SOPs to ensure compliance with CEL 30 (2012) standards.
- The oncology pharmacist will contact the selected community pharmacy and a copy of the referral email/letter will be sent to the patient' GP practice.
- The oncology pharmacist will email (via nhs.net) the referral pack to the community pharmacy. The referral pack includes:
  - ChemoCare Prescriptions x 4
  - Roche/Alliance Healthcare Order Form and Instructions
  - Trastuzumab Care Bundle (or CloseHER2home Case Report Form)
  - First cycle checklist
- The oncology pharmacist will issue 4 (or more if appropriate) HBP10 prescriptions for each cycle of treatment to the patient to deliver to the community pharmacist prior to their next appointment.
  - Where the oncology pharmacist is an independent prescriber, they will write the prescriptions.
  - If the oncology pharmacist is not an independent prescriber they must make arrangements locally to ensure HBP10s are written.
- The oncology pharmacist will co-ordinate the first appointment with the community pharmacy. It will be recommended the patient visit the pharmacy prior to their next appointment to meet the pharmacist and staff, deliver HBP10s and confirm appointment for next dose of trastuzumab.
- The oncology pharmacist will be the main point of contact for community pharmacists participating in the service and will answer or refer queries within a reasonable time frame.
- The oncology pharmacist will contact the study team with any queries relating to the operation of the service during the pilot study.

**The Community Pharmacist (Investigator)**

At referral the community pharmacist will:
- Ensure they have received the referral pack from the onocology pharmacist
- Ensure the ChemoCare and HBP prescriptions are valid.
- Update the patient care record (PCR).

- Order the first dose of subcutaneous trastuzumab 600mg vial using the order form included in the referral pack.
- Contact the oncology pharmacist if they have any queries or encounter any supply issues

At the first appointment the community pharmacist will:
- Accept the HBP10s from the patient and store them securely.
- Confirm contact details for the patient and agree best method of contact for issues around their care; update the patient care record (PCR) if required.
- Complete the first cycle checklist with the patient.

At all consultations the community pharmacist will:
- Check they have:
  - A printed valid ChemoCare prescription for the date required.
  - A valid HBP10.
  - A dose of trastuzumab and the required ancillaries for administration prior to the patient attending.
- Assess the patient tolerance of treatment and fitness for treatment as described in the care bundle.
  - If there is uncertainty around fitness for treatment, this should be discussed prior to administration of trastuzumab.
  - All grade 2 toxicities or deterioration in performance status should be discussed with the MDT. The oncology pharmacist should be contacted in the first instance but if unavailable, the local cancer triage service should be contacted. Details for the triage service will be held by the patient.
- If the patient is fit for treatment, administer trastuzumab as described by the process described in the care bundle.
  - Batch number and expiry for each vial received must be documented on the care bundle to aid product recall.
- Consider the most appropriate course(s) of action for any arising pharmaceutical care issues. Provide or refer for supportive medicines for symptomatic relief.
- Document actions on the patient care record (PCR).
- Agree next appointment date and time (three weeks hence) with the patient. If the next appointment cannot be agreed within 28 days, contact the oncology pharmacist for advice.
- Where the patient has completed their final cycle of treatment, contact the oncology pharmacist to arrange the patient's next appointment for treatment or review with the MDT.
- Sign the ChemoCare Prescription to acknowledge administration. Store securely until patient has completed treatment.
- Endorse the HBP10 and send to practitioner services.
- Order the next dose of trastuzumab.

**The Health Board**

Service cost under negotiation.

**Trastuzumab Ordering Process:**
Herceptin Subcutaneous (trastuzumab) Vial 600mg/5ml are ordered via Alliance Healthcare. Current documentation will be supplied at service start up.

## 1.3 Pharmacist Checklist

<table>
<tr><td colspan="2">First Cycle Checklist for Trastuzumab (Herceptin) 600mg solution for Injection</td></tr>
<tr><td colspan="2">☐ Check the patient has the HBP10s and store them securely.<br>☐ Contact the oncology pharmacist immediately if the patient does not have HBP10's<br>☐ Confirm contact details for the patient and agree best method of contact for issues around their care. Update the patient care record (PCR) if required.<br>☐ If not previously done, the patient may be registered for the Chronic Medication Service<br><br>Complete the following checklist at each cycle and discuss any queries with the oncology pharmacist.</td></tr>
<tr><td><u>Concordance</u><br><br>Does the patient require information about their treatment?<br>□ Yes □ No</td><td><u>Actions</u><br><br>Check the patient's understanding of what their treatment is for and how it is administered. Clarify any discrepancies. The patient may have already received multiple cycles and have a good understanding treatment.<br><br>If required, supply written information:<br><br>Herceptin Patient Information Leaflets are available from the electronic medicines compendium:<br>http://www.medicines.org.uk/emc/<br><br>Macmillan Treatment Information:<br>Treathttps://www.macmillan.org.uk/cancerinformation/cancertreatment/treatmenttypes/biologicaltherapies/monoclonalantibodies/trastuzumab.aspx#<br><br>The oncology pharmacist from can be contacted if you need more information or support (see contact details as the end of this document).</td></tr>
<tr><td><u>Interactions & Precautions</u><br><br>Is the patient aware to check with their pharmacist if any newly prescribed, over-the-counter (OTC) or complementary/alternative medicines (CAM) interacts with their treatment?<br>□ Yes □ No</td><td>No clinically significant interactions between trastuzumab and concomitant medicinal products used in clinical trials have been observed.<br><br>Interactions between complementary and alternative medicines (CAM) cannot be ruled out. It is very difficult to find consistent, high quality studies which show beyond doubt that a CAM is effective and safe. It is therefore recommended that CAM is not taken while receiving systemic anti-cancer therapy.<br><br><u>Actions</u><br>Advise the patient to always check with a pharmacist that any new medicine is safe to take with their treatment.</td></tr>
</table>

| | |
|---|---|
| **Adverse Effects**<br><br>**Is the patient aware of the common side effects of their therapy?**<br><br>□ **Yes** □ **No**<br><br>**Is the patient experiencing any side effects?**<br><br>□ **Yes** □ **No**<br><br>**Is the patient aware that side effects should be reported?**<br><br>□ **Yes** □ **No** | Baseline toxicities of treatment (side effects) will be recorded in the patient's care bundle in the referral pack.<br><br>Refer to the care bundle for advice on how to grade toxicities.<br><br>**Administration Related Reactions**<br><br>Local injection site reactions include redness, pain or itching are common and minimized by alternating injection sites with each dose administered.<br><br>If required, local reactions can be treated with oral antihistamines (e.g. chlorphenamine, cetirizine) and topical hydrocortisone 1% cream. **Reactions which do not resolve within 48 hours should be reported to the oncology pharmacist.**<br><br>Rare administration-related allergic reactions have occurred with the intravenous formulation of trastuzumab. While this has not been reported in long-term follow up of clinical trials of subcutaneous trastuzumab staff administering trastuzumab must be able to recognise anaphylaxis and take swift action to treat the patient. Familiarise yourself with your anaphylactic treatment procedure and ensure treatment is readily available in the administration area.<br><br>**A suspected anaphylactic reaction to should be treated immediately with epinephrine/adrenaline and an ambulance called.**<br><br>**Other Side Effects**<br><br>Less common side effects include diarrhoea, muscle or joint pain, high blood pressure and tiredness.<br><br>Low grade toxicities can be treated for symptomatic relief. Where the patient is registered for the minor ailments scheme (MAS), they can access treatments permitted for MAS.<br><br>**If you are unsure about the severity of the side effects or how to grade them, you can contact the oncology pharmacist for advice. Contact details are at the end of this questionnaire.**<br><br>**Cardiotoxicity**<br><br>Trastuzumab-induced cadiotoxicity is a well-recognised potential side effect of treatment. Patients are counselled on the risks of treatment by their consultant as part of the process of consent. Cardiac function is assessed before treatment and monitored by multigated acquisition (MUGA) scan or Echocardioagram (ECHO) every 4 months.<br><br>Patients should be asked prior to each treatment if they have any symptoms suggestive of cardiotoxicity. These are detailed on the care bundle and include dyspnoea (shortness of breath) and oedema (fluid gathering, swollen ankles). |

| | |
|---|---|
| | If the patient experiences any new-onset symptoms like these or any other suggestive of cardiotoxicity, refer them promptly to the oncology pharmacist.<br><br>**As with any patient attending a pharmacy, if the patient shows signs or symptoms of a heart attack, call an ambulance immediately.**<br><br>**Actions**<br><br>Check the patient's understanding of the side effects of their treatment.<br><br>Ask if they are experiencing side effects as described in the care bundle at each appointment. Assess the severity of their side effects using the grading and take action accordingly.<br><br>Document side effects/toxicities in the care bundle and PCR.<br><br>If required, discuss side effects with the oncology pharmacist.<br><br>For toxicities of ≥2, contact the oncology pharmacist or oncology triage if out of hours.<br><br>Remind the patient to report any side effects they experience even if they are not sure what has caused them.<br><br>Remember to report any adverse drug reactions through the MHRA Yellow Card Reporting Scheme. |
| **Monitoring**<br><br>**Can the patient tell you the date of their next MUGA scan or ECHO?**<br>□ **Yes** □ **No** | Action:<br><br>Note the date of the next cardiac scan on the care bundle. The patient should have follow up arranged before completing the fourth treatment in community pharmacy. Contact the oncology pharmacist if they do not.<br><br>Record any care issues in the patient's care plan and agree desired outcome and actions. |
| **At any stage you can contact the patient's oncology team via their designated pharmacist below. You can also talk to the study team on the contact details below.**<br><br>Contact Details: [NHS Tayside] [NHS Grampian] [NHS Highland]<br><br>Oncology Pharmacist(s) direct number and email: [TBC]<br><br>Telephone/Pager (Mon-Friday 0900 - 1700):[ TBC]<br><br>**Out-of-hours contact the Cancer Treatment Helpline: 0800 917 7711**<br><br>**CloseHER2Home Study Team:**<br>Lisa MacLeod, Research Pharmacist (Tuesday – Friday)<br>Email: l.m.macleod@stir.ac.uk Telephone: 07758161328<br>Andrew Radley, Chief Investigator Telephone: 01382 425681 | |

**Notes:**

### 1.4 Guide for the Administration of Subcutaneous Trastuzumab

Check the patient's ChemoCare prescription:

- Correct patient (name, CHI)
- Drug
- Dose
- Date of administration
- Route and method of administration
- E-signature for confirmation and authorisation of prescription

Collect together all the equipment you will need:

- Surface wipe (Clinell, orange)
- Gloves (1 pair, nitrile)
- Apron
- Chlorhexidine/Alcohol swabs(s)
- 23 gauge blue safety needle (for vial to syringe transfer)
- 25 gauge orange needle (for administration)
- 5ml luer lock syringe
- Sterile gauze swabs
- Sharps bin (orange lid)
- Subcutaneous Trastuzumab 600mg / 5ml solution for injection vial

Preparation of injection:

- Clean the preparation area with a surface wipe
- Wash your hands
- Wipe the top of the medicine bottle with the alcohol wipe and leave to dry
- Open the syringe package and put on the clean surface.
- Attach a blue safety needle to the syringe.
- Insert the needle into the top of the bottle at an angle of 90°.
- Pull back the plunger and withdraw the full volume of trastuzumab into the syringe.
- Detach the syringe leaving the needle in the vial
- Attach the sheathed orange needle to the syringe.
- Lay the prepared syringe on the clean surface.

Administering the subcutaneous injection

- Ask the patient to remove garments to expose the injection site area. If the area is visibly dirty, clean the area with a chlorhexidine/alcohol swab. Wait for the alcohol to evaporate before proceeding.
- Holding the needle upwards, tap the syringe gently to move any air bubbles towards the needle.
- Push the plunger gently to remove the air bubble.
- The injection site of SC trastuzumab should be alternated between the left and right thigh. New injections should be given at least 2.5cm from the old site and never into areas where the skin is red, bruised tender or hard.
- A fold of skin should be gently pinched with the thumb and forefinger. The needle should be inserted at a 30 degree angle to achieve uniform placement in the subcutaneous space.
- SC Trastuzumab should be administered slowly at a rate that is comfortable for the patient.

- All 5mls should be administered to one site (it is not necessary to split the volume, trastuzumab SC has been formulated to allow the administration of the 5mls in one injection site.)
- Administration should take between 2-5 minutes i.e. give at a rate of 1-2ml/min
- Once the trastuzumab has been given the needle should be held in place for 30 seconds to prevent backtracking.
    - Do not massage the area after injection.
- Dispose of used equipment into the sharps bin.

**Appendix 2: Trastuzumab Care Bundle**

| **CloseHER2home Care Bundle** | |
|---|---|
| Action Required | Completed / Comments |
| **Notification of new patient**<br>**Stock Ordered**<br>**Stock Received** | **Received: ☐ Date:**<br>**Completed: ☐ Date:**<br>**Completed: ☐ Date:** |
| **Prescriptions received** | **Completed: ☐ Date:** |
| **Dates and time of first treatment to be administered in community pharmacy** | **Day:**<br>**Date:**<br>**Time:** |
| **Trastuzumab verbal/written information given to patient** | |
| **Patient has required contact information** | **Community Pharmacy ☐**<br>**Triage Alert Card ☐**<br>**Research team ☐** |
| Date and time of next treatment<br>**Stock ordered: ☐ Date:**<br>**Stock received: ☐ Date** | **Day:**<br>**Date:**<br>**Time** |
| Date and time of next treatment<br>**Stock ordered: ☐ Date:**<br>**Stock received: ☐ Date** | **Day:**<br>**Date:**<br>**Time** |
| Date and time of next treatment<br>**Stock ordered: ☐ Date:**<br>**Stock received: ☐ Date** | **Day:**<br>**Date:**<br>**Time** |
| **Patient has an appointment for MUGA scan** | **Day:**<br>**Date:**<br>**Time** |
| **Date and time of next treatment to be given in hospital (Ninewells or Perth Royal Infrimary)** | **Day:**<br>**Date:**<br>**Time:** |
| **Further relevant information / comments:** | |

**Patient ID:**

| **Clinical Assessment (To be completed each cycle)** | | | | | | |
|---|---|---|---|---|---|---|
| **Criteria** | **Example** | **Date** | **Date** | **Date** | **Date** | **Date** |
| WHO Performance Status<br>See Table Below | 0 | | | | | |
| Residual toxicity from chemotherapy?<br>Document details below | 0 | | | | | |
| Any previous local reaction to trastuzumab (Y/N) | N | | | | | |
| Injection site reaction | 0 | | | | | |
| Flu like symptoms | 0 | | | | | |
| Headaches | 1* | | | | | |
| Dyspnoea (Shortness of breath or cough) | 1* | | | | | |
| Ankle oedema (Ankle Swelling) | 0 | | | | | |
| Other<br>Please specify e.g. pain | 0 | | | | | |
| Injection site (Alternate left/right thigh) | L | | | | | |
| Time taken to complete appointment<br>From arriving on premises to leaving | 21 mins | | | | | |
| Pharmacist Signature: | *E. Xample* | | | | | |
| Further relevant information/comments: *e.g. *Pre-dates trastuzumab treatment, no worsening of symptoms. Headache relieved by occasional paracetamol)* | | | | | | |

| Grade | WHO Performance Status: Explanation of activity |
|---|---|
| **0** | Fully active, able to carry on all pre-disease performance without restriction |
| **1** | Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work |
| **2** | Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours |
| **3** | Capable of only limited self-care, confined to bed or chair more than 50% of waking hours |
| **4** | Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair |

| Grade | Common Toxicitiy Criteria for Adverse Effects (CTCAE): General Guideline<br>Full Guidance: https://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_8.5x11.pdf | |
|---|---|---|
| **0** | Nil | |
| **1** | Mild | Monitor, suggest symptomatic treatment where appropriate |
| **2** | Moderate | Discuss with Oncology MDT |
| **3** | Severe | Refer patient promptly to oncology MDT |

**Contact Details: [NHS Tayside] [NHS Grampian] [NHS Highland]**

**Oncology Pharmacist(s): [TBC] [TBC] [TBC]**

**Telephone/Pager (Mon-Friday 0900 - 1700):[ 01382 660111 pager TBC] [TBC] [TBC]**

**If unavailable contact [Oncology Triage on pager 3115 or 3454] [TBC][TBC]**

## Out-of-hours patients or pharmacists should contact the Cancer Treatment Helpline: 0800 917 7711

**CloseHER2Home Study Team (Monday to Friday, 0900 - 1700):**
**Lisa MacLeod, Research Pharmacist**
**Email: l.m.macleod@stir.ac.uk**
**Telephone: 07758161328**

**Andrew Radley, Chief Investigator**
**Telephone: 01382 425681**

## Appendix 3. Draft Service Specification for Community Pharmacy Oncology Service

SERVICE SPECIFICATION

# PHARMACEUTICAL CARE OF PATIENTS RECEIVING SYSTEMIC ANTICANCER THERAPY (SACT) AND/OR SUPPORTIVE TREATMENTS FOR CANCER: COMMUNITY PHARMACY ONCOLOGY SERVICE

### BACKGROUND

Improvements in diagnosis and treatment of cancer combined with an ageing population have led to a steady rise in the number of people with cancer in the UK. Many more people are surviving cancer, which can now be regarded as a long-term condition in many cases. The health service must look to deliver standard treatment and supportive care using established primary care routes. Utilising community pharmacies as a route to deliver these treatments is a rational and viable direction that builds on established service models such as immunisation. The North of Scotland Cancer Alliance (NCA) cancer centres serve a large geographical area, meaning patients can travel a considerable distance for treatment. In addition, lack of car parking spaces and inadequate public transport are frequently highlighted as reasons patients find it challenging to attend hospital for treatment. Improvements in treatment mean many tumour types should be managed in the same way as other chronic diseases and as such treatment in the acute setting is not ideal. Providing patients with an alternative and safe care pathway which enables them to get on with their lives, after a cancer diagnosis is the core principal of a Community Pharmacy Oncology Service.
The UK government "Commission of Future Models of Care Delivered through Pharmacy" and the corresponding policy document from Scotland "Prescription for Excellence" highlight a new role for community Pharmacists in delivering therapy. Prescription for Excellence recognises Pharmacists as the clinicians responsible for NHS pharmaceutical care and calls for the development of integrated multidisciplinary teams able to deliver complex care close to where the patient lives. Community pharmacy is a key delivery point for this, working closely with hospital specialists and general practice colleagues to deliver high quality patient care within the new environment of integrated health and social care. This service proposes an exemplar of policy aspiration that could be used as a model of care for other interventions.

### 1. Service Objectives

1.1. To raise awareness and support early diagnosis of cancer proactively.
1.2. To improve access to cancer services for individuals in marginalised groups: ethnic minorities, people with learning difficulties, people with mental health difficulties, homeless persons and substance misuse clients.
1.3. To deliver safe and comprehensive pharmaceutical care for patients receiving SACT and/or supportive therapy for cancer.
1.4. To minimise risk and ensure the best possible clinical outcomes are achieved by patients through successful partnerships making a positive contribution to patient adherence for cancer and other co-morbidities.
1.5. To offer a convenient patient pathway ensuring minimal impact of treatment on patients' lives that improves overall patient experience

### 2. Service Description

2.1. The Community Pharmacy Oncology Service ("the service") will allow named patients to use their community pharmacy as the service delivery point for their cancer treatment. The pharmacy will provide patient assessment, healthcare and wellbeing advice supporting medicines optimisation, dispensing and where required, administration of SACT/supportive therapy, with sign-posting and referral according to patient need.

2.2. The service will be provided by Pharmacists and support staff with the relevant knowledge, skills and competence as described in Section 4, Training.
The Responsible Pharmacist will ensure that all members of the pharmacy staff are aware of the operation of the service and full details must be available to relief and locum Pharmacists.
2.2.1. Relief and locum Pharmacists can participate in the service provided they meet the criteria outlined in this specification and have approval from the Responsible Pharmacist.
2.3. The pharmacy providing the service must adhere to the standards for safety, privacy and infection control as specified under Section 3: Premises.
2.4. Patients will be referred to the service when they are considered suitable and clinically stable as defined in the relevant treatment plan. The specialist multi-disciplinary team (MDT) will consent and refer patients to their choice of participating community pharmacy. The pharmacy will be provided with contact details for the specialist MDT responsible for the patient, who can be contacted about patient queries and clinical issues during working hours.
2.4.1. The point of contact will normally be the Specialist Clinical Pharmacist for the relevant tumour type who will provide support and advice about managing patients on the service.
2.4.2. The treatment plan will outline specifications for individual diseases or drugs as described in the appendices of this document.
2.4.3. Community Pharmacists will require: nhs.net email to ensure prompt access to clinical information including communications, appointments, out-of-hours reports and laboratory results.
2.5. Patients will continue to have access to the 24-hour triage telephone service for self-referral and issues which arise out of hours. Outcomes from triage calls will be reported to the community Pharmacist by the MDT via email for non-emergent issues and by telephone where the patient was admitted to the acute service.
2.6. A practitioner suitably qualified and trained to prescribe SACT or supportive therapy will issue the pharmacy with valid prescriptions for named patients. Community pharmacists will be furnished with the prescription at least 14 days before it is required.
2.7. Clinical verification (“screening”) of the prescription will be carried out in line with the relevant local or national NHS standard operating procedure (SOP). The SOP will incorporate the key pharmaceutical checks as specified in CEL 30 (2012) Appendix 3 and the British Oncology Pharmacy Association (BOPA) Verification Standards.
2.7.1. Clinical verification will normally be the responsibility of a specialist clinical Pharmacist. Responsibility for individual treatments is specified in the appendix of this document.
2.7.2. All Pharmacists operating the service are expected to be familiar with and have ready access to the current version SOP for clinical verification; awareness of the BOPA standards is essential.
2.7.3. The responsible pharmacy proprietor (e.g. Superintendent Pharmacist) must ensure effective clinical governance arrangements and oversight of the service with thorough and robust auditing measures including provisions to seek feedback from patients.
2.7.4. Suitable arrangements must be in place for effective use of Pharmacist resource to minimise undermining the quality of the service and managing risk with dispensing duties and specialist cancer service requirements.
2.7.5. The pharmacy must operate a clear and documented clinical quality improvement programme (or equivalent) to evidence how clinical care (as defined in the service spec) is regularly assessed and evaluated to make positive and lasting changes that safeguard patients from harm.

2.8. The acute MDT will coordinate an introductory appointment at a mutually convenient time with the patient and pharmacy.
  2.8.1. If not already registered, the patient can be registered for the Chronic Medication Service at this appointment.
  2.8.2. The pharmacy will agree with the patient regarding best method of contact for any issues around their care and responsibility for contacting the acute MDT if required. These details will be held in their patient care record (PCR) and treatment diary.
2.9. At each consultation the Pharmacist will:
  2.9.1. Assess the patient as described in the treatment protocol for fitness and tolerance for treatment.
  2.9.2. Ensure the correct dispensing of medicines has been made in line with the applicable prescription and treatment plan. Administer medications as prescribed as defined in the treatment plan.
  2.9.3. Consider the most appropriate course(s) of action for any arising pharmaceutical care issues.
  2.9.4. Help the patient understand their treatment and how to obtain the best possible clinical outcomes through education and support.
  2.9.5. Check if any other issues arising from the treatment and provide the appropriate signposting. e.g. social issues and if/how the treatment is impacting on their lifestyle.
  2.9.6. Document all actions on the patient care record (PCR) from the first consultation to ensure itemised record keeping standards that can be retrieved for audit and inspection purposes within 72 hours.
2.10. When a specified treatment course is completed or treatment is stopped, the patient will return to the acute MDT for re-assessment as outlined in the relevant treatment plan.

## 3. Premises & Environment

3.1. Relevant legislation and guidance:
  3.1.1. Pharmacists are referred to CEL 30 for general and specific advice on safe delivery of systemic anticancer therapy: http://www.sehd.scot.nhs.uk/mels/CEL2012_30.pdf.
  3.1.2. The pharmacy operating the service must have a private consultation room that complies with Health Protection Scotland standards, specifically those outlined in section 3.4 of the document “Infection Prevention and Control Guidance for NHS and Non-NHS Community and Primary Care Settings” available at http://www.documents.hps.scot.nhs.uk/hai/infection-control/publications/chp-g-2009-07-31.pdf
  3.1.3. Pharmacists are referred to the National Infection Control and Prevention Manual for standards and advice (http://www.nipcm.hps.scot.nhs.uk/)
  3.1.4. To further minimise risk of infection following accidental exposure, it is recommended that all Community Pharmacy staff involved in services that involve potential exposure to blood or contaminated sharps are immunised against hepatitis B.
3.2. The consultation room must have a suitable chair or bed and sufficient space to accommodate a chaperone and/or allow the patient to lie down in the event of fainting or anaphylaxis.
3.3. The pharmacy must have a pharmaceutical refrigerator. Temperature monitoring must be recorded daily and show evidence of action taken in the event of temperature excursions outside of the recommended ranges underpinned by an approved SOP

3.4. participate

## 4. Training

4.1. Each pharmacy will have a named Pharmacist and a deputy as a contingency who are responsible for the on-going management and delivery of the service. The service can only be provided when the named pharmacist or approved deputy is present and available.

4.2. All Pharmacists and support staff operating the service must be appropriately trained; non-treatment specific training must include:

4.2.1. Infection control (including hand hygiene).

4.2.2. Injection administration and technique

4.2.3. Basic Life Support training

4.2.4. Anaphylaxis Procedure

4.2.4.1. The Pharmacist and staff will be trained to deal with anaphylaxis and are required to have adrenaline/epinephrine readily available for use.

4.2.5. Pharmacists should have a CPD plan in place relevant to the service. Background knowledge and understanding of cancer is essential and membership of BOPA is desirable. Contractors must ensure relevant and effective measures to assess ongoing knowledge and competency.

4.2.6. For each treatment protocol, a mandatory training session will be conducted for Pharmacists who intend to operate the service. Pharmacists who complete training will be signed off as having the necessary knowledge and skill and competent to provide the service as outlined in the relevant treatment plan.

4.2.6.1. Each session will incorporate three key elements: disease (tumour type specific); drug(s) and where appropriate, administration technique.

4.2.6.2. All staff must have documentary evidence of training completed and this should be completed annually in light of any service feedback or input from the clinical improvement plan.

## 5. Governance

5.1. The pharmacy will operate a suitable staffing provision to ensure patients receive a professional and high quality service.

5.2. The Pharmacy must adhere to the relevant General Pharmaceutical Council standards and have SOPS in place which cover:

5.2.1. Infection control (including hand hygiene)

5.2.2. Cold chain storage

5.2.3. Sharps disposal

5.2.4. CPR

5.2.5. Anaphylaxis

5.2.6. Administration of Injectable Medicines

5.2.7. Blood

5.2.8. Chemical (cytotoxics and biologics) spill

5.2.9. Chaperone

5.2.10. Safeguarding

5.2.11. Customer care

5.2.12. Complaints handling

5.2.13. Information governance including Data Protection & confidentiality

5.3. The Pharmacist must have adequate insurance to participate in the service.

5.4. The Pharmacist must have membership of the Disclosure Scotland Protecting Vulnerable Groups (PVG) Scheme.

5.5. The acute MDT will provide a SOP for each treatment delivered as part of the service. Every member of staff involved in the provision of the service must be aware of and operate within the agreed procedure.

5.6. The Pharmacist will communicate with the acute MDT any clinically relevant issues anticipated to impact on patient safety or continuity of treatment using. Adverse events must be reported via Datix and the equivalent internal governance system.

5.7. Adverse drug reactions should be reported to the acute MDT and, where appropriate, the MHRA via the yellow care reporting system: https://yellowcard.mhra.gov.uk/

5.8. The pharmacy must operate a product and batch traceability system to facilitate in line with MHRA guidance to ensure swift recalls by the MHRA or manufacturer.

5.9. The pharmacy must have a complaints and incidents reporting procedure in place. Staff operating the service must be familiar with this procedure.

5.10. All requirements of the current Data Protection Act 2018 and future General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679 must be met in full.

5.11. The pharmacy/Pharmacist must hold an *nhs.net* email address to permit the transmission of identifiable patient personal information, where necessary.

5.12. The pharmacy will permit NHS personnel to audit the service with reasonable notice against the specifications in this document and the Health Improvement Scotland SACT Governance and Framework tool or future equivalent document: http://www.healthcareimprovementscotland.org/our_work/cancer_care_improvement/programme_resources/systemic_anti-cancer_therapy.aspx

## Appendix 4. Training Specification

*The following specification has been developed to guide the training and preparation of pharmacists working in study sites delivering the CloseHER2Home protocol:*

| Knowledge / Competency Required | How delivered? | How assessed/Evidenced? |
|---|---|---|
| 1. Knowledge of current treatment of breast cancer. Knowledge of governance arrangements for the safe handling and administration of systemic anti-cancer treatment (SACT). | - Presentation and discussion during the Study Training Day<br>- Through an E-learning package on SACT (Learn-Pro or other approved course to be specified at the training day). | - Participation in discussion and appreciative enquiry<br>- Certificate of attendance at study day<br>- Certificate of completion of self-directed learning module for SACT |
| 2. Knowledge of ethical and professional requirements for participating in a clinical study | Approved Good Clinical Practice (GCP) training course. | - Participation in discussion and appreciative enquiry<br>- Certificate of attendance at study day |
| 3. Ability to accurately and consistently use and complete study documentation | Explanation and examination of study documentation with group-based discussion | - Participation in discussion and appreciative enquiry<br>- Follow up in practice by Study Team |
| 4. Ability to safely and effectively administer a 5ml trastuzumab injection subcutaneously | - Observation of technique and explanation by a research nurse<br>- Through practice of the technique on clinical skills equipment<br>- Through work-shadowing nurses at local cancer centre | - Completion of training exercises at study day<br>- Through reflective discussion with study team and nurse delivering training/shadowing<br>- Certificate of participation by Study Team |
| 5. Ability to seek advice and manage pharmaceutical care issues with the patient | Explanation and discussion of study support documents at study day | Participation in discussion and appreciative enquiry |
| 6. Ability to safely deliver the service | Study Training Day and ongoing contact with PI | Observational audit by PI/CI |