Great Western Hospitals NHS
NHS Foundation Trust

Addendum to the TVCN Breast Cancer Chemotherapy Protocol (adjuvant): Trastuzumab SC

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Date Implemented	11.12.2014	Next Review Date	*11.12.2015*
Status		*Approved*	
Target Audience (who does the document apply to and who should be using it)		Day Therapy Centre, Dove Unit, Mobile Chemotherapy Unit and Coatewater Staff only	
Accountable Director		Medical Director	
Policy Author/Originator		Lead Chemotherapy Pharmacist	
Implementation Lead		Head of Chemotherapy Service	
If developed in partnership with another agency, ratification details of the relevant agency			

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Quality Impact

Great Western Hospitals NHS Foundation Trust strives to ensure equality of opportunity for all service users, local people and the workforce. As an employer and a provider of health care, the Trust aims to ensure that none are placed at a disadvantage as a result of its policies and procedures. This document has therefore been equality impact assessed in line with current legislation to ensure fairness and consistency for all those covered by it regardless of their individuality. This means all our services are accessible, appropriate and sensitive to the needs of the individual. The results are shown in the Equality Impact Assessment Tool at the end of this document.

Document Description

This document is a clinical guideline.

Special Cases

There are no special cases applicable to this document

Contents

1 Document Details

1.1 Introduction

HER2-Positive breast cancer represents between 15-25% of breast cancers. It has aggressive characteristics and necessitates an approach to treatment that often includes anti HER2 directed agents. The most commonly used of these is Trastuzumab (Herceptin®).

This document serves an addendum to the current Thames Valley Cancer Network (TVCN) adjuvant Breast Cancer Chemotherapy Protocol: SC Trastuzumab (Ref 1) for locally agreed observation times and ongoing monitoring.

1.2 Glossary/Definitions

The following terms and acronyms are used within the document:

DTC	Day Therapy Center
ECG	Electrocardiogram
FBC	Full Blood Count
GWH	Great Western Hospital
HER2	Human Epidermal Growth Factor number 2
LFT	Liver Function Test
LVEF	Left Ventricular Ejection Fraction
NCRI	National Cancer Research Institute
NHS	National Health Service
TVCN	Thames Valley Cancer Network
U&E	Urea & Electrolytes

1.3 Purpose of the Document

This document serves as an addendum to the current TVCN chemotherapy protocol for the use of Trastuzumab in adjuvant breast cancer. The document includes locally agreed changes to both post infusion observation times and guidelines for cardiac monitoring which advocates a new schedule of echocardiographic monitoring.

2 Main Policy Content Details

2.1 Network Trastuzumab Protocol

Refer to the TVCN Adjuvant Breast Chemotherapy Protocol: Trastuzumab SC (Ref 1) for indications, dose modifications, adverse effects and support medications.

2.2 GWH Trastuzumab Infusion Protocol

Observation time for SC Trastuzumab is based on whether the patient is Trastuzumab naïve or an existing IV Trastuzumab patient transferring to SC.

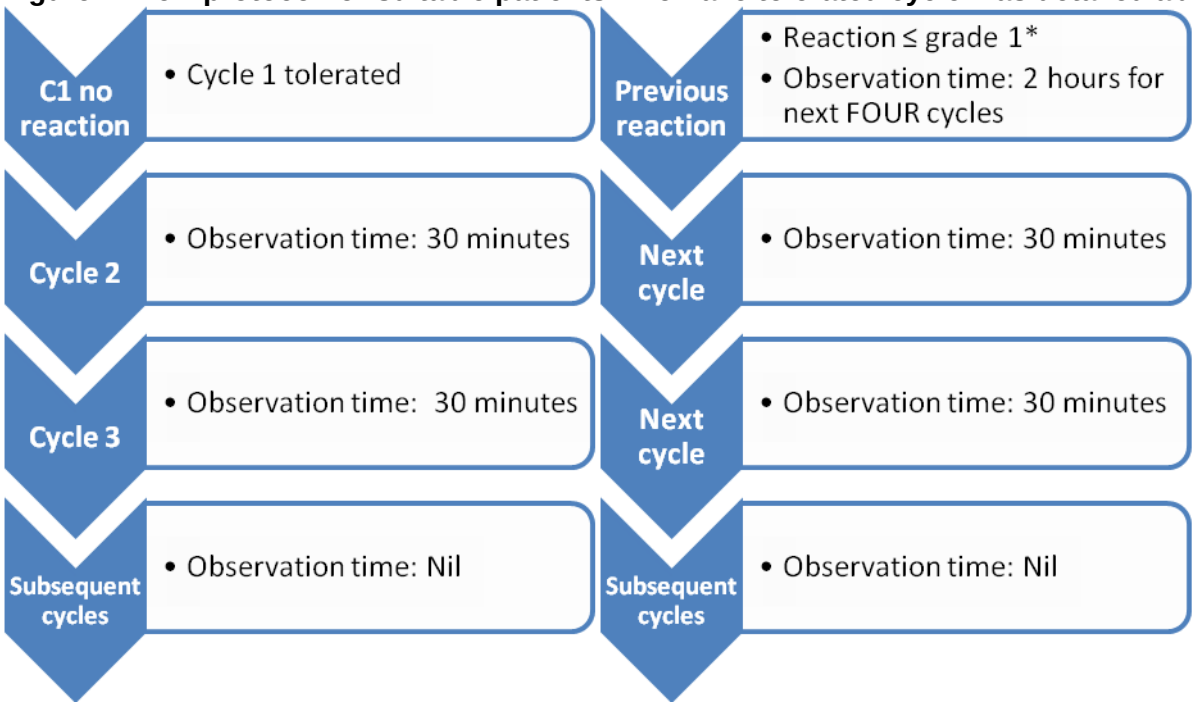
2.2.1 New Patients

Table 1 below is the reduced observation time protocol suitable for new patients (not currently receiving Trastuzumab).

Table 1: SC Trastuzumab dose schedule (new patients)

Dose: 600mg subcutaneous over 2-5 minutes Observation time: 4 hours

Figure 1: New protocol for suitable patients who have tolerated cycle 1 as detailed above



*For reactions >grade 1, please refer to the clinican responsible for the patient for guidance.

2.2.2 Existing IV Trastuzumab patients

Table 2 below is the infusion protocol to be used in the case of existing IV Trastuzumab patients who are transferring to SC Trastuzumab with up to a five week gap in between.

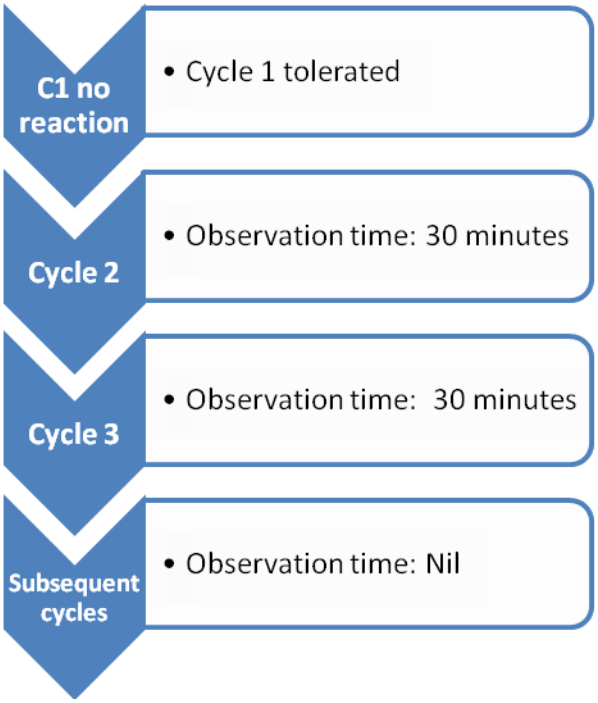
For patients transferring from IV to SC with more than a five week gap, please refer to Table 1 for observation times.

For patients transferring from IV Trastuzumab that have had a previous reaction to Trastuzumab, observation time will be decided on an individual patient basis; please refer to the clinician responsible for the patient.

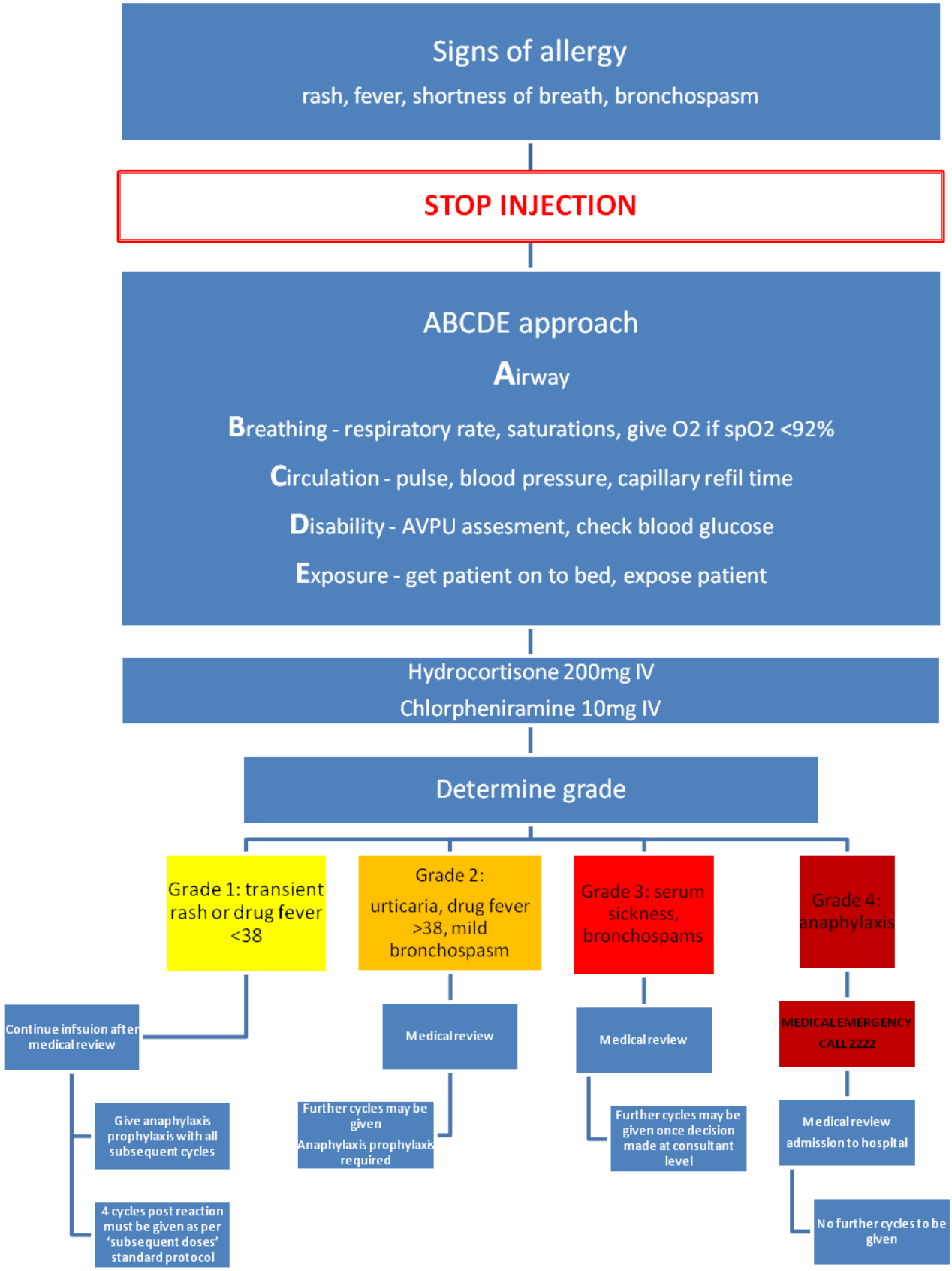
Table 2: SC Trastuzumab dose schedule (existing IV patients)

Dose: 600mg subcutaneous over 2-5 minutes Observation time: 2 hours

Figure 2: New protocol for suitable patients who have tolerated cycle 1 as detailed above



2.3 Management of allergic reactions



2.4 Anaphyalxis prescribing on ARIA

ARIA gives two options for management of allergic reaction to medications

- Anaphylaxis prophylaxis: Dexamethasone 20mg IV, Ranitidine 50mg IV, Chlorpheniramine 10mg IV
- Anaphylaxis treatment: Hydrocortisone 100mg IV, Chlorpheniramine 10mg IV

For patients who have had previous reactions (grade 1-3) anaphylaxis prophylaxis for subsequent cycles is required.

If patients experience significant side effects with the dexamethasone bolus then this should be dicussed with the treating clinician and may be omitted at the clinicans discression.

2.5 Reloading patients with SC Trastuzumab

Reloading is not necessary with SC Trastuzumab. For patients that have missed a dose of subcutaneous Trastuzumab, the next 600mg dose (the missed dose) should be administered as soon as possible.

The interval between consecutive doses of SC Trastuzumab should not be less than three weeks.

This may be different for patients participating in a clinical trial; please check with the research team for trial patients.

2.6 Monitoring for patients receiving SC Trastuzumab

Individual monitoring requirements are summarised in Table 3 and detailed below.

Table 3:Summary of monitoring requirements for SC Trastuzumab treatment

Test	Time			
	Baseline	4 months	8 months	Continuing monitoring
Echocardiogram	X	X	X	Every 4 months whilst on tx. After completion of tx per 2.6.1
FBC, U&E, LFT, Ca	X	X	X	At clinicians discretion
Weight	X	X	X	Every 4 months whilst on tx.

2.6.1 Echocardiographic monitoring in adjuvant breast cancer

The recommended schedule for monitoring as agreed between all consultants in the Oncology department at GWH with a responsibility for patients receiving SC Trastuzumab is as per Table 4.

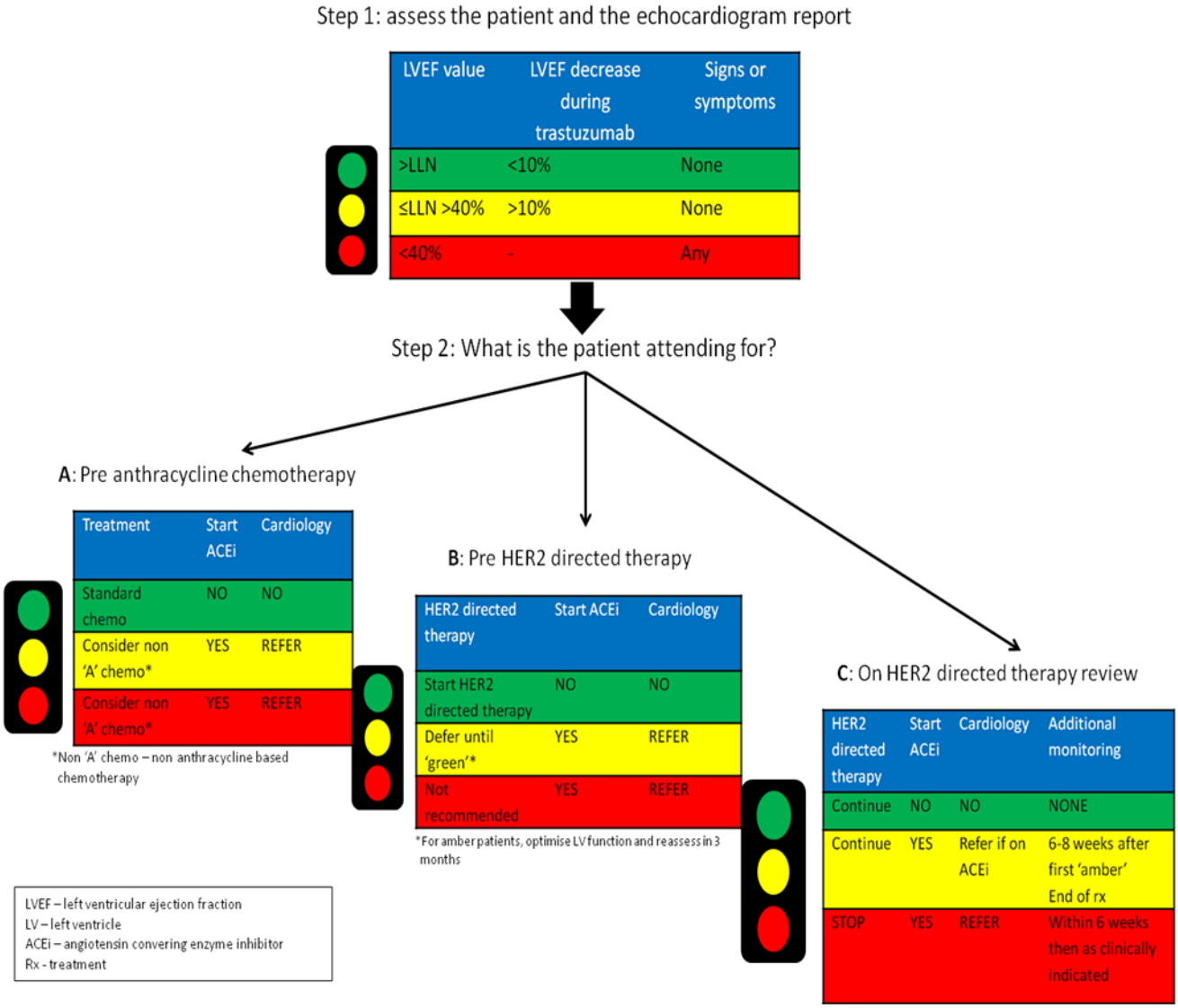
Table 4: Echocardiographic monitoring schedule

Prior to anthracycline based chemotherapy	Only if history of heart failure, myocardial infarction, significant arrythmia or other concern about baseline cardiac function
Prior to initiation of Trastuzumab	All patients
After 4 months of Trastuzumab therapy	All patients
After 8 months of Trastuzumab therapy	All patients
After completion of Trastuzumab therapy	Only if clinical concern regarding development of left vetricular failure or where further HER2 directed therapy is planned

If there is deterioration in LVEF while on Trastuzumab therapy then echocardiography should be more frequent, the NCRI guidelines recommend repeat assessment within 6-8 weeks of the appropriate intervention.

Figure 2 details the traffic light system for determining how to proceed when the LVEF is less than the lower limit of normal (LVEF ≤50%) or has dropped by 10 points between routine echocardiographic surveillance.

Figure 3: Traffic Light system for cardiac monitoring



2.6.2 Routine blood test monitoring in patients receiving SC Trastuzumab

Blood tests including FBC, U&Es, LFTs and Calcium studies should be performed at month 0, month 4 and month 8.

Further blood tests after this are at the clinicians discretion

2.6.3 Weight measurement in patients receiving SC Trastuzumab

Patient weight to be taken at baseline and every 4 months while on treatment.

3 Duties and Responsibilities of Individuals and Groups

3.1.1 Medical staff:

Consultants and Speciality Doctors treating patients with HER2 directed therapies are responsible for complying with the content of the policy and the prescribing of Trastuzumab.

3.1.2 Lead nurses within Cancer Services:

Dissemination of the information within the policy to nursing staff administering chemotherapy on the DTC, mobile chemotherapy unit, Dove and Coate Water. This may be extended to the supplier of home delivery services when appropriate.

3.1.3 Clinical trial (breast cancer) nursing staff:

Prospective audit of adverse reactions related to Trastuzumab and working to develop nurse led clinics which will use the protocol for clinical decision making.

3.1.4 Chemotherapy trained nurses:

Adhering to the protocol and escalating any concerns regarding protocol to medical staff.

3.1.5 Chemotherapy pharmacists:

Adhering to the protocol and referring to medical staff as appropriate.

4 Education and Training Requirements

It is important that there is a mechanism to ensure relevant staff are educated and trained in respect of the requirements of any documents, policies and associated procedures that affect them in their work.

4.1 Education and Training Plan

Education and training plan	Resources	Responsibility	Date / Frequency
Physicians who prescribe Trastuzumab	Email Breast MDT TSSG (breast) meetings	Consultant Oncologist Oncology Speciality Doctor	
Nurses who administer Trastuzumab	Email Staff room DTU Staff meetings DTU	DTC Sister Lead Chemotherapy Nurse	
Specialist nurses who support patients on Trastuzumab	Email Breast MDT TSSG (breast) meetings	Consultant Oncologist Oncology Speciality Doctor Lead Chemotherapy Nurse	

5 Communication plan

It is important that there is a mechanism to ensure relevant staff are aware of pertinent documents, policies and associated procedures that affect them in their work. Set out below is a communication action plan for this document.

5.1 Communication Action Plan

Communication task	Resources	Responsibility	Date / Frequency
Document to be uploaded to cancer services pages of intranet	n/a	Cancer Services Office Manager	When document approved
Notification of published document	To be included in cancer services (oncology) comms	Chemotherapy Working Group	When document approved

5.2 Distribution and communication channels

Distribution/communication channel	Contact
Cancer Services (oncology) Communications	Lead Chemotherapy Pharmacist
Cancer Services intranet	Cancer Services Office Manager

5.3 Monitoring Compliance and Effectiveness of Implementation

The arrangements for monitoring compliance are outlined in the table below: -

Measurable policy objectives	**Monitoring / audit method**	**Monitoring responsibility** (individual / group /committee)	**Frequency of monitoring**	**Reporting arrangements** (committee / group to which monitoring results are presented)	**What action will be taken if gaps are identified?**
All trastuzumab to be administered as per policy	20 consecutive trastuzumab prescriptions to be audited per year	Oncology Speciality Registrar, Oncology consultant	Annual	Departmental M&M meeting	Teaching sessions for chemotherapy nurses
No increase in adverse reactions after introduction of new policy	Prospective audit of adverse events	Lead chemotherapy nurse	Ongoing	Departmental M&M meeting	Review of individual events in real time analysis with results presented at morbidity and mortality meeting

5.4 Acute and Maternity Standards Criterion

This document does contain diagnostic testing procedures and / or screening procedures.

5.5 Diagnostic Testing Procedures / Screening Procedures

	Diagnostic Testing Procedures	**Name of Test** Echocardiogram
1	How the diagnostic test has been risk assessed	Standard test per SPC
2	How the diagnostic test is requested and recorded	Requested and recorded on CVIS
3	How the clinician treating the patient is informed of the result, including timescales and how this is recorded	Informed via CVIS, treatment not given until result viewed and approved by clinician. Recorded on Aria.
4	How the patient is informed of the result, including timescales and how this is recorded	Patient informed prior to next treatment being given, recorded in patient notes
5	Actions to be taken by the clinician including timescales and how this is recorded	Actions as per Echocardiogram traffic light system, recorded in patient notes, on Aria.
6	How the organisation monitors compliance with all of the above requirements	Monitored via IR1's, clinical screening

	Diagnostic Testing Procedures	**Name of Test** Routine blood tests and weights
1	How the screening procedure has been risk assessed	Standard test per SPC
2	How the screening procedure is requested and recorded	Requested on Medway, recorded on Medway and on notes in Aria
3	How the clinician treating the patient is informed of the result, including timescales and how this is recorded	Informed via Medway results, clinican referred by nurse or pharmacist if out of expected range per protocol. Recorded on Aria.
4	How the patient is informed of the result, including timescales and how this is recorded	Patient informed verbally in case of out of spec results, referred to clinican for review and recorded in patient notes and on Aria.
5	How the patient is followed up or referred including timescales and how this is recorded	Referred for review if required, recorded in patient notes, on Aria.
6	How the organisation monitors compliance with all of the above requirements	Monitored via IR1's, clinical screening

6 Review Date, Arrangements and Other Document Details

6.1 Review Date

This document will be reviewed every 2 years in accordance with the Trust's agreed process for reviewing documents.

6.2 Regulatory Position

This document is required for the NHSLA Risk Management Standards.

6.3 References, Further Reading and Links to Other Policies

The following is a list of other policies, procedural documents or guidance documents (internal or external) which staff should refer to for further details:

Ref. No.	Document Title	Document Location
1	TVCN Breast Chemotherapy protocol: Trastuzumab SC 21 day (adjuvant)	Intranet - Aria
2	GWH Guidance Document: Treatment options for patients with HER2-positive breast cancer	Intranet – Cancer Services
3	Cytotoxic Chemotherapy Policy	Intranet
4	CCS Operational Policy	Intranet
5	Management of cardiac health in Traztuzumab-treated patients with breast cancer: Updated United kingdom National Cancer Research Institute recommendations for monitoring. Jones et al 2009	British Journal of Cancer, March 10, 2009; 100(5): 684-692

6.4 Consultation Process

The following is a list of consultees in formulating this document:

Job Title / Department
Lead Chemotherapy Nurse
Senior Sister, Chemotherapy Day Suite
Research Sister (Breast Cancer)
Consultant Medical Oncologist
Consultant Clinical Oncologist

6.5 Comments

Any comments on this document should, in the first instance be addressed to the author.

Appendix A - Equality Impact Assessment Tool

1	Document Title:	Addendum to TVCN adjuvant Breast Cancer Chemotherapy Protocol: Trastuzumab SC	
		Yes/No	**Comments**
2	Does this document contain the Trust's statement on Equality?	Yes	
3	Does the document affect one group less or more favourably than another on the basis of:		
	• Age?	No	
	• Culture?	No	
	• Disability?	No	
	• Ethnic origins (including gypsies and travellers)?	No	
	• Gender?	No	
	• Gender re-assignment?	No	
	• Marriage and civil partnerships?	No	
	• Nationality?	No	
	• Pregnancy and maternity?	No	
	• Race?	No	
	• Religion or belief?	No	
	• Sexual orientation including gay, lesbian and bisexual people?	No	
4	Is there any evidence that some groups are affected differently?	No	
5	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	
6	Is the impact of the policy/guidance likely to be negative?	No	
7	If so can the impact be avoided?	No	
8	What alternatives are there to achieving the policy/guidance without the impact?	No	
9	Can the impact be reduced by taking different action?	No	

If you have identified a potential discriminatory impact of the document, please refer it to the Company Secretary, together with any suggestions as to the action required to avoid/reduce this impact.
For advice in respect of answering the above questions, please contact the Company Secretary or Policy Governance Officer

Reviewed by:	Sarah McGlue	Date:	08.07.2014
Post:	Lead Chemotherapy Pharmacist		

Appendix B – Quality Impact Assessment Tool

Purpose

To assess the impact of individual policies and procedural documents on the quality of care provided to patients by the Trust both in acute settings and in the community.

Process

The impact assessment is to be completed by the document author. In the case of clinical policies and documents, this should be in consultation with Clinical Leads and other relevant clinician representatives.

Risks identified from the quality impact assessment must be specified on this form and the reasons for acceptance of those risks or mitigation measures explained.

Monitoring the Level of Risk

The mitigating actions and level of risk should be monitored by the author of the policy or procedural document or such other specified person.

High Risks must be reported to the relevant Executive Lead.

Impact Assessment

Please explain or describe as applicable.

1.	Consider the impact that your document will have on our ability to deliver high quality care.	This document will mean that patients do not have to be observed for as long on DTC, thus creating a better patient experience and more capacity for other treatments. Reducing the number of echocardiograms required for patients will mean more slots can be used for other patients potentially reducing waiting times.
2.	The impact might be positive (an improvement) or negative (a risk to our ability to deliver high quality care).	Positive
3.	Consider the overall service - for example: compromise in one area may be mitigated by higher standard of care overall.	
4.	Where you identify a risk, you must include identify the mitigating actions you will put in place. Specify who the lead for this risk is.	
Impact on Clinical Effectiveness & Patient Safety		
5.	Describe the impact of the document on clinical effectiveness. Consider issues such as our ability to deliver safe care; our ability to deliver effective care; and our ability to prevent avoidable harm.	Day therapy services are stretched due to the lack of physical space to treat patients. Reducing observation times will mean that for every patient who starts trastuzumab an extra 4 hour slot will be created. For subsequent visits extra slots between 30 minutes and 90 minutes will be created.

Impact on Patient & Carer Experience		
6.	Describe the impact of the policy or procedural document on patient / carer experience. Consider issues such as our ability to treat patients with dignity and respect; our ability to deliver an efficient service; our ability to deliver personalised care; and our ability to care for patients in an appropriate physical environment.	Patients should experience a more efficient service on DTC. Increasing awareness of new therapies available will mean that patients will get more personalised cancer treatments.
Impact on Inequalities		
7.	Describe the impact of the document on inequalities in our community. Consider whether the document will have a differential impact on certain groups of patients (such as those with a hearing impairment or those where English is not their first language).	Some patients enjoy the time they get to spend with other cancer patients so for this group having a reduced observation time may mean they can spend less time exchanging experiences, however they could easily be directed towards other sources of support such as groups that meet outside the hospital environment.

Appendix C - Diagnostic Risk Assessment

DIAGNOSTIC TEST/PROCEDURE RISK ASSESSMENT

Test/procedure: Echocardiogram
Department: Oncology
Date of assessment: 08.07.2014
Review date: 08.07.2016
Name of assessor: Sarah McGlue

Risk Assessment: Diagnostic Tests			Likelihood				
			Rare	Unlikely	Possible	Likely	Certain
			1	2	3	4	5
Consequence	Catastrophic	5	5	10	15	20	25
	Major	4	4	8	12	16	20
	Moderate	3	3	6	9	12	15
	Minor	2	2	4	6	8	10
	Negligible	1	1	2	3	4	5

Test: Echocardiogram

Risk to Patient

	Degree of intervention required	Consequence of undertaking wrong test	Consequence of missed diagnosis	Not following up adequately	Not referring when indicated	Average risk score
Score	1	4	4	4	4	3.4

Risk to the Organisation

	Degree of intervention required	Consequence of undertaking wrong test	Consequence of missed diagnosis	Not following up adequately	Not referring when indicated	Average risk score
Score	1	8	8	6	6	5.8

THE OVERALL RESIDUAL RISK RATING			
1-3 : Low Risk	4-6 : Moderate Risk	7-12 : High Risk	15+ : Extreme Risk

DIAGNOSTIC TEST/PROCEDURE RISK ASSESSMENT

Test/procedure: Blood Tests and weight
Department: Oncology
Date of assessment: 08.07.2014
Review date: 08.07.2016
Name of assessor: Sarah McGlue

Risk Assessment: Diagnostic Tests			Likelihood				
			Rare	Unlikely	Possible	Likely	Certain
			1	2	3	4	5
Consequence	Catastrophic	5	5	10	15	20	25
	Major	4	4	8	12	16	20
	Moderate	3	3	6	9	12	15
	Minor	2	2	4	6	8	10
	Negligible	1	1	2	3	4	5

Test: Blood Tests and weight

Risk to Patient

	Degree of intervention required	Consequence of undertaking wrong test	Consequence of missed diagnosis	Not following up adequately	Not referring when indicated	Average risk score
Score	1	4	4	4	4	3.4

Risk to the Organisation

	Degree of intervention required	Consequence of undertaking wrong test	Consequence of missed diagnosis	Not following up adequately	Not referring when indicated	Average risk score
Score	1	8	8	6	6	5.8

THE OVERALL RESIDUAL RISK RATING			
1-3 : Low Risk	4-6 : Moderate Risk	7-12 : High Risk	15+ : Extreme Risk