

NHS Greater Glasgow & Clyde
Management of Non-Cytotoxic Intrathecal & Intraventricular Injections (NCIIIs)
NHSGGC Register of Authorised Specialties/Clinical Areas, NCIIIs, Dose Ranges and Upper Limits



As recommended by the Scottish Government HDL(2006)11, Guidance for the Safe Handling of Intrathecal and Intraventricular Injections, NHS Greater Glasgow & Clyde (NHSGGC) have developed a local policy which outlines all relevant governance arrangements. This policy was approved by the NHSGGC Area Drug and Therapeutics Committee (ADTC) in February 2009, and updated July 2014.

The relevant documents are attached below and are available on all clinical areas authorised to use these agents, the anaesthetics website and the Clinical Governance website.

[Scottish Government HDL\(2006\)11 Guidance for the Safe Handling of Intrathecal and Intraventricular Injections.](#)

[NHSGGC Organisational Policy for the Management of Non-Cytotoxic Intrathecal and Intraventricular Injections.](#)

The following pages record the specialties/clinical areas, NCIIIs, dose ranges and upper limits which are authorised for use within NHSGGC. This information is not transferable to other clinical areas and no other medicines can be used via the intrathecal or intraventricular route if not recorded in this register. If you would like to use a particular medicine via the intrathecal or intraventricular route which is not on this list, you must submit a request in writing in advance of use, with supporting evidence and with an Unlicensed Medicines Request form (where appropriate) to the Designated Lead for the specialty/clinical area and the Leads for Implementation (below). The Designated Lead should consult with nominated pharmacy and nursing leads before making a decision on whether to approve/not approve the request. This decision will be formally authorised by the appropriate Clinical Director, who retains overall responsibility. Refer to section 3.7.1 of the policy for further details. This application must be copied to Dr Gordon McGinn or Catherine McLaughlin, or deputies (contact details below).

For further information or advice, please contact:

Leads for Implementation:

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Deputies:

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NHSGGC Specialties/Clinical Areas Authorised to Use NCIII

Sectors / Specialties	Specialty/Clinical Area	Comments	Page
Surgery and Anaesthetics (All Sectors) For Neuro-Anaesthetics, see under Regional Services	Theatres, Anaesthetic Rooms and Operating Departments	For obstetric, gynaecology and paediatric theatres, see under Women and Childrens' Directorate	3 – 4
	ENT		5
	Chronic Pain Service		6
Women and Children's	Obstetrics and Gynaecology		7 – 8
	Paediatrics and Neonates		9 – 10
	ADMIRAL Study / LONGWING Study in Paediatric Patients with Dravet's Syndrome		11 – 12
Regional Services	Palliative Care Intrathecal Service		13 – 14
	Spinal Injuries, Neurosciences & Neuroradiology		15 – 18
	Neuro Rehabilitation Unit (previously PDRU)		19
	WAVE Study & RO7234292 (RG6042) In Patients with Manifest Huntington's Disease	Spans Old Age Psychiatry and Spinal Injuries, Neurosciences & Neuroradiology – see under Mental Health	20
Mental Health	Old Age Psychiatry	Spans Old Age Psychiatry and Spinal Injuries, Neurosciences & Neuroradiology (as administered by neuroanaesthetists), Older People Mental Health and Glasgow and Clyde Community Services	20
Pharmacy Prescribing and Support Unit (PPSU)	Aseptic Services		21
	Pharmacy Distribution Centre		21
	Site Based Pharmacy Departments	See Under Relevant Specialty/Clinical Area	

NHSGGC Surgery & Anaesthetics:

Authorised NCIII List for Theatres, Anaesthetic Rooms and Operating Departments (**under review**)*

NCIII Approved for Use	Licensed Status: Licensed Medicine / Off-Label / Unlicensed Medicine	Aseptic Manipulation / Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit
Intrathecal Bupivacaine 0.25%	Off-label	No – agent used via other routes therefore not subject to NCIII controls within and on leaving pharmacy	Yes	10-15mg	20mg
Intrathecal Bupivacaine 0.5% (Plain or Heavy)	Plain: Off-label Heavy: Licensed medicine	As above**	Yes	10-20mg	25mg
Intrathecal Diamorphine	Off-label	As above	Yes	Up to 400micrograms	400micrograms, rarely up to 800micrograms in major surgery
Intrathecal Fentanyl	Off-label	As above	Yes	15-25 micrograms	30 micrograms
Intrathecal Levobupivacaine 2.5mg/ml	Licensed medicine (doses above 15mg are off-label)	As above	Yes	10-20mg	25mg
Intrathecal Levobupivacaine 5mg/ml	Licensed medicine (doses above 15mg are off-label)	As above	Yes	10-20mg	25mg
Intrathecal Morphine PF	Licensed medicine but unlicensed route	As above	Yes	Up to 400micrograms	400micrograms, rarely up to 1mg in major surgery
Intrathecal Prilocaine 2% (Hyperbaric)	Licensed medicine for spinal anaesthesia	As above	Yes	40-80mg	80mg

* On very rare occasions, this may also include administration in critical care areas.

** Heavy bupivacaine exclusively used via intrathecal route (confirmed by Dr Phil Oates and Ruth Forrest). Consider implementation of NCIII controls.

Continued/

Site-Based Leads, Contacts and Local Information (under review)

Site	Designated Lead	Nominated Pharmacy Lead	On-Site Pharmacy Contact(s)	Nominated Nursing Lead	Information Folder Location	Location of Intralipid 20% for Local Anaesthetic Toxicity
VI ACH	Dr Alan Gillespie	Ruth Forrest, Lead Clinical Pharmacist ITU & Theatres	Scott Nicol	Juliet Sullivan	Theatres (1) Pharmacy (1) ACH Th (1) - Stored electronically via Shared Drive ACH Pharm (1)	Theatres Arrest Trolleys
QEUH Theatres	Dr Gordon McGinn	Ruth Forrest	Joanne Barton	Julie Garnett May Hodgson	Theatres (1) Pharmacy (1)	Arrest trolleys, ITU, theatres & HDU
GGH Theatres	Dr Malcolm Watson	Ruth Forrest	Gayle Rothnie Erin Flynn Angela McCafferty	Alison Deas	Theatres (1) Pharmacy (1)	Theatres Arrest Trolleys
GRI Theatres	Dr Geraldine Gallagher	Ruth Forrest	Rakesh Kishore Pamela MacTavish Morna Ball Nicola Cairns Angela McCafferty	Sr Carole Morley and/or Juliet Sullivan	Theatres (1) Pharmacy (1)	Theatres
Stobhill ACH Theatres	Dr Barry Evans	Ruth Forrest	As for GRI Theatres	Juliet Sullivan	Stored electronically via Shared Drive	Emergency Trolley Drawer labelled 'Local Anaesthetic Toxicity'. Theatres, End of Theatre Corridor (beside tea room).
RAH Theatres	Dr Liz James	Ruth Forrest	Fiona MacGregor Jonathan Yates Annmarie Crowe		Theatres (1) Pharmacy Medicines Information (1)	Inpatient Theatres and HDU
IRH Theatres	Dr Duncan Thomson	Ruth Forrest	Joanne Berrich Aileen Begley		Theatres (1) Pharmacy Dispensary (1)	Theatres and ICU
VoL Theatres	Dr Liz James	Ruth Forrest	To be confirmed		Theatres (1) Pharmacy Medicines Information (1)	Theatres

Authorised NCIII List for ENT Theatre (last updated 25.01.2022):

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity
ENT Theatre	<p>Dr Louise Melia Designated ENT Surgical Lead, Approved by Mr John Marshall, CD for ENT, 24.01.22</p> <p>Dr Anna McCormack Consultant Anaesthetist QEUH</p> <p>Dr Daphne Varveris trained and authorised</p> <p>(Only used by above consultants)</p> <p>Confirmed by Dr Varveris, 21.01.2022</p>	Ruth Forrest Lead Clinical Pharmacist ITU & Theatres	Ruth Forrest Carlene Burleigh, Alison O'Prey, Carolyn Caulfield		Intrathecal fluorescein 5%	Imaging CSF leaks	Unlicensed medicine	Yes, made in pharmacy at RHC Aseptic Unit and ordered on named-patient basis on agreed request form.	No	0.5ml	0.5ml	ENT Theatres	N/A

Authorised NCIII List for Chronic Pain Service (under review)

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity		
Different combinations of the agents below may be used, depending on patient needs. These combinations will be unlicensed, under strict control of, and prescribed only by Dr Lars Williams.															
CPS VI ACH	Dr Gordon McGinn Consultant in Anaesthetics & Pain Management, Pain Management Service, NHSGGC	Ruth Forrest Lead Clinical Pharmacist ITU & Theatres	Scott Nicol / Ruth Forrest		Intrathecal bupivacaine	Intractable pain which cannot be managed by other traditional and existing means of pain relief	Licensed medicine	Yes, made in pharmacy at PPU WIG and ordered on named-patient basis on agreed request form.	No	Up to 30mg	30mg/ 24 hours**	Chronic Pain Department ACH VI (1)	Theatres & Day Surgery Unit VI		
CPS Stobhill ACH					Intrathecal clonidine	As above	Licensed medicine but unlicensed route	As above	As above	As above	2-8 micrograms/kg/hour	Max daily dose: 1mg Max conc: 2mg/ml	Chronic Pain Department ACH Stobhill (1)	Theatres Stobhill	
CPS Inverclyde					Intrathecal diamorphine	As above	Licensed medicine but unlicensed route	As above	As above	As above	5-10mg/day	5-10mg/ 24hours**			Chronic Pain Department Inverclyde (1)
					Intrathecal fentanyl	As above	Licensed medicine but unlicensed route	As above	As above	As above	As above	Up to 100micrograms/day	Max conc: 2mg/ml Up to 100micrograms/day		
					Intrathecal hydro-morphone	As above	Unlicensed medicine	As above	As above	As above	As above	Up to 20mg/day	Max conc: 35mg/ml** Up to 20mg/day		
					Intrathecal levo-bupivacaine	As above	Licensed medicine	As above	As above	As above	As above	Up to 30mg/day	Max conc: 40mg/ml** Up to 30mg/day		
					Intrathecal morphine PF	As above	Licensed medicine but unlicensed route	As above	As above	As above	As above	Up to 30mg/day	Max conc: 50mg/ml** Up to 30mg/day		
					Intrathecal phenol 5% in glycerol			Removed 28.08.2014							
** In exceptional circumstances, it may be necessary to use a higher daily dose or concentration. These doses must be verified by Dr Lars Williams.															

NHSGGC Women & Childrens' Directorate:
Authorised NCIII List for Obstetrics and Gynaecology (under review)

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIII's Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity
QEUH Maternity Theatres	Dr Regina O'Connor Ext 61659/8	June Grant, Lead Clinical Pharmacist Obstetrics and Gynaecology / Peter Mulholland, Neonatal Pharmacist SGUH	Peter Mulholland & Joanne Barton	May Hodgson Anaesthetic Sister	Intrathecal diamorphine 0.4mg and bupivacaine 0.5% 1.5ml to 2.2ml (heavy)	To provide anaesthesia for operative deliveries	Unlicensed medicine	No – agent used via other routes therefore not subject to NCIII controls within and on leaving pharmacy	Yes	1.9ml – 2.6ml of solution	2.6ml, rarely up to 2.9ml of solution	Obstetric Anaesthetic Office (1)	Resus Trolley, Gyn 2 Theatre. From January 2010: Obstetric Resus Trolley
PRM Obstetric Anaesthetics	Dr Fiona Bryden for Obstetric Anaesthetics 01412114620 (on anaesthetists register)	June Grant, Lead Clinical Pharmacist Obstetrics and Gynaecology	As above		Intrathecal bupivacaine 0.5% Heavy 1.5ml to 3ml diamorphine 300micrograms.	To provide anaesthesia for operative deliveries	Licensed Mixtures with diamorphine off label	No, also used via other routes therefore not subject to NCIII contols within and on leaving pharmacy.	Yes	At the discretion of the anaesthetist but dose above 3.3ml used rarely.	Doses above 3.3ml used rarely	Consultant Anaesthetist Room, Theatre Lobby, Labour Ward (1)	Theatres and emergency trolley in HDU Level 3 PRM
					Intrathecal levo-bupivacaine 0.25% and 0.5%	Generally for analgesia for labour and occasionally used for anaesthesia	Licensed	As above	Yes	2.5mg-15mg	15mg	As above	Theatres and emergency trolley in HDU, level 3 PRM
GRI Gynaecology	Dr Rosie Snaith, Consultant Anaesthetist Gynaecology	June Grant, Lead Clinical Pharmacist Obstetrics and Gynaecology	As above	Carole Morley	As under PRM Obstetric Anaesthetics for intrathecal bupivacaine and intrathecal levo-bupivacaine	To provide anaesthesia for gynaecological procedures	Licensed	No, also used via other routes therefore not subject to NCIII contols within and on leaving pharmacy.	Yes	2.5mg-15mg	15mg	Consultant Anaesthetist Room, Theatre Lobby, Labour Ward (1)	Theatre 4 Level 2 PRM
					Intrathecal diamorphine	As above	Licensed medicine but unlicensed route	As above	Yes	Up to 300micrograms	300micrograms		
					Intrathecal morphine PF	As above	Licensed medicine but unlicensed route	As above	Yes	100 – 300 micrograms	300micrograms		

Authorised NCIII List for Obstetrics and Gynaecology (continued) (under review)

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIII Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity
RAH Maternity	Liz James, Consultant Anaesthetist and Lead Anaesthetist Clyde (based at RAH) 0141 314 6609	June Grant, Lead Clinical Pharmacist Obstetrics and Gynaecology / Maria Tracey	Maria Tracey / Annmarie Crowe		Intrathecal bupivacaine 0.25%	To provide anaesthesia for operative deliveries	Licensed medicine but unlicensed route	No – agent used via other routes therefore not subject to NCIII controls within and on leaving pharmacy	Yes	10-15mg	20mg	Theatres (1)	Maternity Theatre
					Intrathecal bupivacaine 0.5% (plain or hyperbaric)	As above	Plain: Licensed medicine but unlicensed route Heavy: Licensed medicine	As above	Yes	10-15mg	20mg		
					Intrathecal diamorphine 5mg ampoule reconstituted to 1mg/ml	As above	Licensed medicine but unlicensed route	As above	Yes	200-300 micrograms	400 micrograms		
					Intrathecal fentanyl 50microgram/ml	As above	Licensed medicine but unlicensed route	As above	Yes	15-25 micrograms	25 micrograms		
					Intrathecal levo-bupivacaine 2.5mg/ml	As above	Licensed medicine	As above	Yes	10-15mg	20mg		
					Intrathecal levo-bupivacaine 5mg/ml	As above	Licensed medicine	As above	Yes	10-15mg	20mg		
					Intrathecal morphine PF	As above	Licensed medicine but unlicensed route	As above	Yes	Up to 200micrograms	200 micrograms		
					Intrathecal bupivacaine 0.5% heavy with 400microgram diamorphine	As above	Off label	As above	yes	1.9-2.6ml solution	2.6 ml rarely up to 2.9ml		

**NHSGGC Women & Children's Directorate:
 Authorised NCIII List for Paediatrics & Neonates (RHC) (under review)**

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity
Paediatric Theatres (Anaesthetics)	Dr Pam Cupples / Dr Graham Bell Tel: 201 0186	Steve Bowhay Lead Clinical Pharmacist Paediatrics and Neonates	Steve Bowhay		Intrathecal levo-bupivacaine ampoules 0.25% and 0.5%	Spinal anaesthesia	Licensed medicine	No. Also used via other routes therefore not subject to NCIII controls within and on leaving pharmacy.	Yes	Up to 1.5mg/kg	Extremely unlikely to exceed 15mg total		Th recovery resus. trolley
					Levo-bupivacaine and clonidine	Spinal anaesthesia	Unlicensed medicine		Yes	Up to 1.5mg/kg for levo-bupivacaine Up to 1 microgram/kg for clonidine (always with levo-bupivacaine)	Up to 15mg of levo-bupivacaine Up to 1 microgram/kg clonidine (always with levo-bupivacaine)		
Fraser of Allander Neurology Unit – Neurology & FANU Intrathecal Baclofen Service (ward 1C, occasionally in OP Clinic and IP Wards in RHC).	Dr Iain Horrocks, Consultant Paediatric Neurologist Clinical Lead: Dr Stewart MacLeod, Consultant Paediatric Neurologist	As above	As above		Intrathecal baclofen	Spasticity and hypertonia	Licensed medicine	Yes, made in RHC Pharmacy	No	Up to 1000 micrograms	1000 micrograms Higher doses may be rarely be required in severe generalised spasticity or dystonia which must be approved by a consultant paediatric neurologist or consultant in paediatric neuro-disability.	Dr Valerie Orr's Office (1) Pharmacy (1) Policy and register available via GGC Prescribing website, under Medicines Policies.	N/A
					Application to prescribe/ administer approved for Dr Iain Horrocks and Dr Sarah Abernethy (Cons Paed Neurologists) by Dr Valerie Orr/Dr Nick Heaney, 20.12.17.	Intrathecal nusinersen	Compassionate use in Spinal Muscular Atrophy Type 1	ULM Compassionate use	Yes, made in RHC Pharmacy	No	9.6mg - 12mg	12mg	Register of authorised personnel held by Designated Lead.

**NHSGGC Women & Children's Directorate:
 Authorised NCIII List for Paediatrics & Neonates (RHC): (continued) (under review)**

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity
Fraser of Allander Neurology Unit – Neuro-surgery	Miss Patricia Littlechild, Consultant Neuro-surgeon, INS, QEUH Deputy: Dr Roddy O’Kane, Consultant Neuro-surgeon, INS, QEUH	Steve Bowhay Lead Clinical Pharmacist Paediatrics and Neonates	Steve Bowhay Lead Clinical Pharmacist Paediatrics and Neonates		All agents as described for adult patients - refer to Neurosciences information on page 13 and 14.								N/A
Pain Team	Dr Tony Moores Deputy: N/A	Steve Bowhay Lead Clinical Pharmacist Paediatrics and Neonates	Steve Bowhay Lead Clinical Pharmacist Paediatrics and Neonates		Intrathecal baclofen	Spasticity	Licensed medicine	Yes, made in RHC Pharmacy	No	As above	As above		
PRM Neonates	Dr Andrew Powls, Neonates, Tel 2115210	Steve Bowhay, Lead Clinical Pharmacist Paediatrics & Neonates	June Grant		No agents authorised - patient would be referred to Neonatal Surgical Unit at RHC to receive.	Under guidance of specialists at RHC							

NHSGGC Women & Children's Directorate:

Authorised NCIII List for Paediatrics & Neonates (RHC): (continued) (final approval and added to the register 10.06.2022):

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation/Preparation Required	Storage in Clinical Area Authorised	Approved * Dose Range	Upper Limit *	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity
Women and children. Clinical trials - RHC Neurology department	Dr Iain Horrocks Administration / PI: Dr Andreas Brunklaus Deputy: Prof Sameer Zuberi Approved by Dr Alan Mathers (CoM) Dr Phil Davies (CD) Jamie Redfern (Director)	Stephen Bowhay Samantha Carmichael	Scott Nicol Kirsty Mcleish Sarah Casey	Patricia Clark Hayley Cranston	Investigational drug product - STK-001 33 mg/mL - a concentrate for solution for injection intended for dilution with artificial cerebrospinal fluid (aCSF) solution followed by IT administration. STK-001 is being investigated as part of the ADMIRAL Trial protocol no: STK-001-DS-102.	Treatment for Dravet's syndrome in children aged between ≥2 and <18 years at Screening	Investigational Medicinal Product (IMP)	Yes – will be prepared in the Aseptic Unit at the RHC.	No	*(a) 3 proposed dose cohorts: 30mg, 45mg, 70mg. Each patient to receive 3 doses in total (Day 1, Week 8, Week 12) with option to include another 2 cohorts based on SMC safety data analysis and recommendations	In each dose cohort the upper limit will be the dose agreed for that cohort i.e. in the 30mg dose cohort – upper dose limit will be 30mg. Maximum dose escalation between any 2 cohorts is 1.8 times the lower dose, with a maximal dose level of 70mg per administration	Folder and documents will be stored in both the Clinical Trials Office main pharmacy QUEUH, and Aseptic Pharmacy RHC. Drug will be stored in Aseptic Pharmacy RHC.	N/A
Extension to Admiral Trial under discussion called Longwing Study STK-001-DS-502 18.01.2022													
Women and children. Clinical trials - RHC Neurology department	Dr Andreas Brunklaus	Stephen Bowhay Samantha Carmichael	Scott Nicol Kirsty Mcleish Sarah Casey	Patricia Clark Hayley Cranston	Investigational drug product - STK-001 33 mg/mL - a concentrate for solution for injection intended for dilution with artificial cerebrospinal fluid (aCSF) solution followed by IT administration. STK-001 is being investigated as part of the LONGWING Trial protocol no: STK-001-DS-502.	Treatment for Dravet's syndrome in children aged between ≥2 and <18 years at Screening	Investigational Medicinal Product (IMP)	Yes – will be prepared in the Aseptic Unit at the RHC.	No	*(b) Patients will receive IT administration of study drug STK-001 at the dose level they received while participating in Study STK-001-DS-102, or at a dose level recommended by the SMC (Protocol Section 6.5.3).	The highest dose administered may not exceed that evaluated previously in Study STK-001-DS-102.	Folder and documents will be stored in both the Clinical Trials Office main pharmacy QUEUH, and Aseptic Pharmacy RHC. Drug will be stored in Aseptic Pharmacy RHC.	N/A

* The study is planned to consist of 3 cohorts (Cohorts 1, 2, and 3) with the option to include 2 additional cohorts. The proposed dose levels for each cohort are 30 mg, 45 mg, and 70 mg per drug administration - It is planned that each patient will receive 3 drug administrations in total - one on Day 1, Day 57 (week 8), and Day 85(week 12). The dose will depend on the cohort the patient is enrolled into to; for example patients enrolled into the

30mg dose cohort will receive 3 doses in total of 30mg per dose, and those enrolled into the 45mg dose cohort will receive 3 doses in total of 45mg per dose and so on. The proposed cohort dose levels however may be adjusted based on safety review, additional preclinical and/or clinical data, and/or regulatory authorities' recommendation.

The maximal dose escalation between any 2 cohorts will be 1.8 times the lower dose, with a maximal dose level of 70 mg per drug administration. The safety monitoring committee (SMC) may recommend, based on all available safety and PK data, that dose cohorts over 30 mg receive only one dose. An additional one or two optional cohorts may also be enrolled up to a maximum dose of 70 mg per drug administration in order to:

- Escalate or deescalate to a lower and/or to an intermediate dose level of STK-001;
- Repeat a dose level if a safety signal (not meeting a stopping rule) indicates that further dose escalation may affect the safety of study patients; or
- Further characterise PK parameters.

See Clinical Trial Protocol Number STK-001-DS-102 for further information.

* (b) The SMC will meet, at a minimum every 4 months to review all available safety data from this trial, as well as any data from other ongoing trials with STK-001 (as defined in the SMC Charter). The SMC will meet upon the occurrence of dose-limiting toxicities (DLTs) to recommend the acceptability of continued dosing. The occurrence of any of the pause/stopping rules listed in Section 6.6.2 of protocol STK-001-DS-502 at any dose level in patients receiving STK-001 will result in a pause and no further study drug will be administered until a review by the SMC is completed. At the time of the regular review meetings or on an ad-hoc basis, the SMC may advise on the optimal dose level for patients in this Open Label Study based on the emerging benefit/risk profile from the totality of data available from interventional studies of STK-001. The highest dose recommended may not exceed that evaluated previously in Study STK-001-DS-102.

Approval Obtained:

- **Board / NCIII Level Approval:**
- Chief of Medicine W&C - Dr Alan Mathers - approval received, 31.12.21
- Dr Gordon McGinn as joint-lead for implementation of the policy – approval received 02.06.22
- Catherine McLaughlin as joint-lead for implementation of policy – approval of all arrangements being in place received 10.06.2022, and added to the register
- **Paediatric Neurology:**
- Dr Andreas Brunklaus - request received, approval received 31.05.22
- Nominated deputy contact for Dr Brunklaus in case of emergency – Prof Sameer Zuberi – approval received 30.05.22
- Dr Iain Horrocks - Designated Lead for Neurology on NCIII policy – approval received 20.01.2022
- CD for Neurology – Dr Phil Davies – approval received 30.05.22
- Lead Medical Director/General Manager (or deputies), Jamie Redfern - approval received 30.05.22
- **Pharmacy:**
- Steve Bowhay Lead Clinical Pharmacist - approval received, 31.12.21
- **Aseptic Unit Approval:**
- Scott Nicol – approval received 01.06.22
- **Nursing links:**
- Patricia Clark- approval received 31.05.22
- Hayley Cranston – approval received 01.06.22
- **Clinical Trial approval:**
- Dr Sam Carmichael- approval received 31.05.22
- Kirsty McLeish – approval received 02.06.22

NHSGGC Regional Sector:

Authorised NCIII List for Palliative Care Intrathecal Service (last updated 07.11.22)

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit**	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity
NHSGGC	<p>Dr Alison Mitchell Consultant in Palliative Medicine, West of Scotland Cancer Centre Tel 301 7042</p> <p>Dr Gordon McGinn, Consultant Anaesthetist and Joint-Lead for NCIII Policy</p> <p>Deputy: Rachel English CNS Interventional cancer pain service CNS Tel 301 7042</p> <p>Leads reviewed and updated by Dr Mitchell 20.01.2022 and 26.05.2022</p>	<p>Paul Gallagher Palliative Care Pharmacist West of Scotland Cancer Centre Tel 301 7044</p> <p>Elayne Harris, Macmillan Lead Pharmacist Palliative Care</p>	<p>Paul Gallagher Tel 301 7044</p> <p>Elayne Harris Tel 07876478140</p> <p>Nicola Cairns Tel 301 7411</p> <p>Carla Forte Tel 301 7029</p> <p>Grant Martin, tel 301 7640</p>	<p>Rachel English Tel 301 7042</p> <p>Lisa Mohapatra</p>	Intrathecal bupivacaine	Intractable cancer related pain	Licensed medicine	Yes – prepared in WoSCC	Only by prior arrangement, on an individual patient basis and for logistical reasons only at weekends and out-of-hours.	Up to 60mg/day	60mg/day** (rarely up to 120mg/day**) Maximum concentration of 40mg/ml Maximum vial strength available	WoSCC: Palliative Care Shared Folder and on WOSCAN	GGH Theatres and HDU
					Intrathecal clonidine	As above	Licensed medicine but unlicensed route Concentrate is unlicensed (ULM Ref 201231)	As above	As above	Up to 600 micrograms/day	600micrograms/day Maximum concentration of 2mg/ml Maximum vial strength available		
					Intrathecal diamorphine	As above	Licensed medicine but unlicensed route	As above	As above	5-10mg/day	5-10mg/day Maximum concentration of 30mg/ml Maximum amp strength to be used 30mg		
					Intrathecal fentanyl	As above	Licensed medicine but unlicensed route	As above	As above	Up to 1mg/day	1mg/day Maximum concentration of 50micrograms/ml Maximum vial strength available		
					Intrathecal hydro-morphone	As above	Licensed medicine but unlicensed route	As above	As above	Up to 10mg/day	10mg/day Maximum concentration of 10mg/ml Maximum vial strength available		

Continued/

NHSGGC Regional Sector:

Authorised NCIII List for Palliative Care Intrathecal Service, continued (last updated 07.11.22)

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit**	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity
					Intrathecal levo-bupivacaine	As above	Licensed medicine	As above	As above	Up to 60mg/day	60mg/day (rarely up to 120mg/day**) Maximum concentration of 7.5mg/ml Maximum vial strength available		
					Intrathecal morphine PF	As above	Licensed medicine but unlicensed route	As above	As above	Up to 15mg/day	Up to 15mg Maximum concentration of 40mg/ml Maximum vial strength available		
					Intrathecal ropivacaine	As above	Licensed medicine	As above	As above	Up to 60mg/day	60mg/day (rarely up to 120mg/day**) Maximum concentration of 10mg/ml Maximum vial strength available		
					Intrathecal ziconotide	As above	Licensed medicine	As above	As above	2.4-9.6 micrograms	21.6micro-grams/day Maximum concentration of 100micro-grams/ml Maximum vial strength available		

** In exceptional circumstances, it may be necessary to use a higher daily dose or concentration. These doses must be verified by a clinician level 1 and the leads for implementation should be informed.

**NHSGGC Regional Sector:
 Authorised NCIII List for Spinal Injuries (last updated 26.05.22):**

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity
Philipshill	Dr Margaret (Mariel) Purcell (endorsed as new Designated Lead by Dr Colin O'Leary, CD, 13.01.22) Deputy, Dr Mahanada Jigajinni In training: Mr Andrea Des Etages To be trained: Dr Ronali McLean	Claire Saleh	Claire Saleh / Scott Nicol	SCN Karen McCarron Ext 62563 Deputy: CN Susan Donnelly	Intrathecal phenol 5%	Intractable spasticity	Unlicensed medicine	No, due to instability, it must be prepared and administered immediately prior to use.	No, must be ordered on a named patient basis and issued to the administrator immediately prior to use. Supplied via QEUH Dispensary CD Room to RHC Aseptic Unit immediately prior to use.	Up to 5ml of phenol 5% in glycerol (2 injections in total, 1 injection for each side of the body)	5ml of 5% phenol in glycerol for left side of body and 5ml of 5% phenol in glycerol for right side of the body	Spinal Injuries Outpatient Department Office and online via GGC Medicines, Medicines Policies page	N/A
Philipshill, Edenhall and Spinal Injuries Outpatients Department	As above	As above	As above	As above	Intrathecal baclofen	Spasticity	Mixture of licenced and unlicensed products	Ordered on prescription on a named patient basis. All products subject to NCIII controls.	No, must be ordered on a named patient basis and issued to the administrator immediately prior to use. Supplied via RHC Pharmacy immediately prior to use.	Not applicable.	1000micro-grams/day. Occasionally higher doses may be necessary and prescriptions must be checked by 2 consultants.	As above	N/A
					Intrathecal levo-bupivacaine 7.5mg/ml	Chronic pain	Licensed medicine 10ml vials, draw up 6 x 10ml into pump (1 pt)	Not currently but explore the potential to make in pharmacy.	No, must be ordered on a named patient basis and issued to the administrator immediately prior to use. Supplied via RHC Pharmacy immediately prior to use.	Patient currently gets 30mg/day	No definite upper limit. All intrathecal levobupivacaine prescriptions must be checked by 2 consultants.	As above	Ward 61 INS Also held in: Labour suite, A&E Resus, PICU, RHC A&E, 4C, 11A, 11C, Gyn Th, Ortho Th L2 and T02 Gen Th

Morphine removed from register as per email from SCN McCarron 19.01.2022

**NHSGGC Regional Sector:
 Authorised NCIII List for Neurosciences (under review):**

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity	
INS Ward 61 Ward 63 Ward 64 Ward 65 Ward 66 Ward 67 Ward 68 Neuro- theatres	Miss Patricia Littlechild, Consultant Neuro- surgeon, INS, SGUH Ext 62456 Deputy: Dr Roddy O'Kane, Consultant Neuro- surgeon, INS, SGUH Ext 62021	Claire Saleh	Claire Saleh / Scott Nicol	SCN Pauline Barrie	Intra-ventricular gentamicin vials 5mg/ml, very occasionally intrathecal	Bacterial meningitis	Licensed medicine	No – authorised for storage in ward 61. Subject to NCIII controls within and on leaving pharmacy.	Yes	Usually 5mg per day	5mg*	Ward 61 Beside Fridge.	N/A	
					Intra-ventricular vancomycin PFS 20mg/8ml	Bacterial meningitis	Unlicensed medicine	No – authorised for storage in ward 61. Subject to NCIII controls within and on leaving pharmacy.	Yes	Depends on space / age of child / pressure	Max 8ml			
					Vancomycin 125mg/50ml supplied in 50ml syringes	Shunt washing (intrathecal quality)	Unlicensed medicine	Yes, prepared in pharmacy PPU	Yes	N/A – for topical use only.				
					Amikacin	Bacterial meningitis	Licensed medicine but unlicensed use	Yes, prepared in pharmacy PPU.	No - ordered on named patient basis from pharmacy.	Rarely required. If used in future, it would be following failure of well-established therapies and would only be used following multidisciplinary consultation at a senior level with neurosurgeons, microbiology, pharmacy and nursing colleagues.				
					Intrathecal baclofen 10, 50, 500 & 2000micro-grams/ml	Spasticity	Licensed medicine	Yes, prepared in pharmacy PPU.	No - ordered on named patient basis from pharmacy.	Not applicable.	1000micro-grams/day. Occasionally higher doses may be necessary & prescriptions must be checked by 2 consultants.			Ward 61 Beside Fridge.
					Intrathecal baclofen 100, 200, 300, 400, 1000 & 3000micro-grams/ml	Spasticity	Unlicensed medicine							

* D/W Maya Rommer, INS Reg (on-call), 11.10.18 following an inquiry from another board – intraventricular gentamicin prepared using an intrathecal gentamicin 5mg/1ml ampoule, drawn up using a filter straw, diluted to 5ml with sodium chloride 0.9%, then 2ml sodium chloride 0.9% drawn up into a separate syringe, 7ml of CSF removed, the 5mg/5ml gentamicin solution administered, followed by the 2ml flush solution and then the drain is clamped off. (Occasionally the gentamicin solution is administered neat).

**NHSGGC Regional Sector:
 Authorised NCIII List for Neurosciences (continued):**

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity
Neuro-surgery OPD	Miss Patricia Littlechild, Consultant Neurosurgeon, INS, SGUH Ext 62456 Deputy: Dr Roddy O'Kane, Consultant Neurosurgeon, INS, SGUH Ext 62021	Claire Saleh	Claire Saleh / Scott Nicol	SCN Elaine Kennedy Sheila Matheson (trained and certified approved by Karen McCarron, 31.05.22)	Intrathecal baclofen 50, 500 & 2000micro-grams/ml	Spasticity	Licensed medicine	Yes, prepared in pharmacy PPU.	No - ordered on named patient basis from pharmacy.	Not applicable.	1000micro-grams/day. Occasionally higher doses may be necessary & prescriptions must be checked by 2 consultants.	Outpatients Department	N/A
					Intrathecal baclofen 100, 200, 300, 400, 1000 & 3000micro-grams/ml	Spasticity	Unlicensed medicine						
					Intrathecal clonidine	Removed from the register at the request of Miss Littlechild, 25.08.2014.							

**NHSGGC Regional Sector:
 Authorised NCIII List for Neurosciences (continued) (last updated 10.06.2022):**

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIII Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit	Folder/ Information Storage Location	Location of Intralipid for Potential LA Toxicity
Neuro-radiology	Dr Karthikeyan, Vanchilingam Updated 27.01.22 following discussion with Drs Wazim Izzath, Paul Armstrong, Mark Devlin and Alistair Leonard Miss Littlechild updated staff register (July 2017). Authorised Neurosurgeons can also administer Niopam® 300 and will obtain supplies as required from Neuro-radiology.	Claire Saleh	Claire Saleh / Scott Nicol	N/A	Intrathecal Iohexol (Omnipaque 300)	X-ray contrast medium for use in lumbar and thoraco-cervical myelography, cerebral angiography, peripheral angiography, venography, computer tomography enhancement, urography and arthrography, CT myelography; CT ventriculography: CT shunt assessment; baclofen pump assessment (currently the commonest use); CT for possible CSF leak. Fluoroscopic guided nerve root/facet joint injections.	Licensed Medicine	No. Also used via other routes and access required 24 hours a day therefore not subject to NCIII controls within and on leaving pharmacy.	Yes – potentially required in emergency out-of-hours situations. Stored in CT Room 2, CT Room 4 and Angiogram Room 1.	Omnipaque 300 6-10 ml	Omnipaque 300 10 ml	CT Room 2 with Omnipaque 300 Via GGC Medicines Policies webpage	N/A
					Intra-ventricular Iohexol (Omnipaque 300)		Licensed Medicine			Omnipaque 300 6- 10 ml	Omnipaque 300 10 ml		

NHSGGC Regional Sector:

Authorised NCIII List for Neuro Rehabilitation Unit (previously PDRU, last updated 10.06.2022):

Department	Designated Lead & Staff Approved	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit	Information Location	Location of Intralipid for Potential LA Toxicity
QEUH: Neuro Rehabilitation Unit (NRU)	Dr Colin O'Leary (CD) and Dr Mariel Purcell (Spinal Injuries) Dr Teng Cheng Khoo approved 30.04.2021	Claire Saleh	Claire Saleh / Scott Nicol	Morag Austin, Lead Nurse for Neurology Specialties, Spinal Injuries Unit and Rehabilitation Medicine Morag Leighton, Senior Charge Nurse	Intrathecal phenol 5%	Intractable spasticity	Unlicensed medicine	No, due to instability, it must be prepared and administered immediately prior to use.	No, must be ordered on a named patient basis and issued to the administrator immediately prior to use. Supplied via NVH Pharmacy to RHC Aseptic Unit immediately prior to use.	Up to 5ml of phenol 5% in glycerol	5ml of 5% phenol in glycerol	Online	N/A
					Intrathecal baclofen (addition pending, awaiting detail from Mr O'Leary on approved dose range and upper limit, 30.04.21.	Spasticity	Licensed medicine	Yes, prepared in pharmacy Aseptic.	No - ordered on named patient basis from pharmacy.				

Additions to the staff register below include (confirmed by Lesley Murray, 07.06.2022):

- Dr Ali Ghanbari – 06/10/21 for IT baclofen and phenol
- Dr Harvey Mallory – 25/08/21 for IT baclofen
- Dr Teng Cheng Khoo – 22/04/21 for IT baclofen and IT phenol
- Dr Pilar Ines Alvial Palavicino – 28/01/21 for IT baclofen

**NHSGGC Mental Health:
 Authorised NCIII List for Old Age Psychiatry: WAVE / Precision HD Trial (last updated 20.01.2022)**

Department	Designated Lead	Nominated Pharmacy Lead(s)	Designated Contacts within On-Site Pharmacy Department	Nominated Nursing Lead(s)	NCIIIs Approved for Use	Indication	Licensed Status LM / ULM / LM but unlicensed indication	Aseptic Manipulation /Preparation Required	Storage in Clinical Area Authorised	Approved Dose Range	Upper Limit	Information Location	Location of Intralipid for Potential LA Toxicity
Old Age Psychiatry Huntington's Disease Clinical Trial WAVE Life Sciences Clinical Trial	Dr Matthew Sheridan Consultant Psychiatrist & Dr Bryan Dawson for Neuro- Anaesthetists Administering Plan for Dr James Herron to take over as PI 2023 – to be confirmed/ approved.	Sandee Beattie & Maria Nygren, Senior Clinical Trials Pharmacists	Scott Nicol, Aseptic Accountable Pharmacist	Linda Wilson / Karen Duffy (QEUH CRF)	Intrathecal WVE-003 (which sits within the class known as ASOs) & Intrathecal placebo	Study of WVE-003 in Patients with Huntington's disease (SNP3)	Trial medication	Yes, made in pharmacy and ordered on named-patient basis on agreed request form.	No - ordered on named patient basis from pharmacy RHC.	30 mg to 168 mg	168 mg	Via GGC Medicines, Medicines Policy webpage for GGC policy and register. Local information, guidance and policies kept in INS CRF.	N/A
Studies supported by:													
Dr Samantha Carmichael MRPharmS Lead Pharmacist Clinical Trials / R&D Clinical Research & Development, NHS Greater Glasgow & Clyde						Dr Erica Packard Mental Health Research Co-ordinator NHS Greater Glasgow and Clyde & Glasgow City HSCP Commonwealth House 32 Albion Street Glasgow G1 1LH							

Approval Obtained:

- **Board Level:**
- Dr David Dodds CoM – approved 06.10.2021
- Dr Samantha Carmichael, Lead Pharmacist Clinical Trials and R&D – approved 16.02.2022
- Dr Gordon McGinn – approved 05.01.2022
- Catherine McLaughlin – added to register 16.02.2022 as approval obtained from all relevant leads
- **Old Age Psych:**
- Dr Ashley Fergie, CD of OPS MH and OAPsych – approved 27.10.2021
- Dr Matthew Sheridan, PI/DL OAPsych – approved 06.10.2021
- Dr Martin Culshaw, Deputy Assoc MD MH – approved 07.10.21
- **Neurosurgery:**
- Dr Chris Hawthorne – approved 08.12.2021
- Dr Bryan Dawson – approved 10.11.2021
- Dr Mark Devlin – via email from Dr David Dodds, 04.11.21

NHSGGC Pharmacy Prescribing and Support Unit:

Designated Lead Aseptic Services: Scott Nicol, Lead Pharmacist Preparative Services, NHSGGC

Responsible for Policy Adherence with Respect to Ordering, Preparation, Issue, Transportation and Storage for NCIII's Prepared in Pharmacy

Designated Lead Pharmacy Distribution Centre: Gayle Robertson, Manager Clinical Technical Services Pharmacologistics, NHSGGC

Responsible for Policy Adherence with Respect to Ordering, Issue, Transportation and Storage for NCIII's Issued from the Pharmacy Distribution Centre

Designated Lead Pharmacy Dispensary/On-Site Distribution: Joanne Barton (**under review**) (Lead Pharmacy Technician Operations & Medicines Management)

Responsible for Policy Adherence with Respect to Ordering, Issue, Transportation and Storage for NCIII's Issued from the Pharmacy Acute Dispensaries and Distribution Areas