Patient Group Direction Development Checklist [Covid19 End of Life Care PGD]

This appendix is used by Mountbatten clinicians to record the issues considered and the decisions made throughout the PGD development and implementation process, as set out in NICE Medicines Practice Guideline 2 (Patient Group Directions).

Roles and Responsibilities	Identified lead and/or group		Comments
Decision to develop a PGD	Paul Howard after liaison with the Isle of Wight Primary Care Network clinical directors and CCG Medicines Lead		PGDs only for use within Mountbatten: Hospice Medicines Safety and Optimisation Team (MSOT) PGDs for use across the other locality services: Island Medicines Optimisation Committee (IMOC)
PGD development group	*Lead author*	Paul Howard	The PGD development group generally includes multi-professional representation
	Co-authors	[removed]	
	External advisors	[removed]	
PGD approval group	Island Medicines Optimisation Committee		PGDs only for use within Mountbatten: CCG Primary Care Prescribing Committee (PCPC) PGDs for use across the other locality services: Island Medicines Optimisation Committee (IMOC)
PGD implementation	Training and implementation is delegated to the corresponding governance and education leads for: - Mountbatten Community Palliative Care Lead - St Mary's Ambulance Service - St Mary's Community Nurses		Implementation is generally overseen by the hospice MSOT. Training aspects are supported by Mountbatten's Education and Research committee. PGDs intended for use across other locality services are supported by those organisation's corresponding groups (e.g. the St Mary's Hospital Trust Clinical Standards Group).

Stage	Specific considerations		Issues considered and decisions made	RAG
Decision to develop a PGD (1/2): Use of a PGD versus (or alongside) alternative approaches.	Are any alternatives to a PGD more suitable? For example: pre-emptive prescribing, non-medical prescribing, homely remedies, and/or prescribing support tools such as JAC and SystmOne protocols.		The PGD is to be used in parallel with non-medical prescribing and JAC and SystmOne prescribing protocols	
	Will a PGD offer an advantage for patient care without compromising safety?		The PGD will minimise delays in accessing symptom relief for those already triaged as irrecoverably dying	
	Ensure legal requirements are met for each medicine (Human Medicines Regulations 2012)		Yes	
	Avoid PGDs for medicines:	with complex regimens or titration schedules	Not applicable	
		that require frequent dose adjustments after the medicine is in the patient's possession	Not applicable	
		for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis	Not applicable	

	Will the PGD include more than one medicine? The risks and benefits of including 2 or more medicines should be considered on a case-by-case basis		Keeping all of the medication together in a single PGD allows the options to be presented in a format that resembles the familiar 'just in case' scheme as closely as possible, and presents 1st and 2nd line options together.	
	Outcome: suitability of a PGD versus, or alongside, alternative approaches.		PGD appropriate as one of a set of integrated measures to address the Covid19 pandemic	
Decision to develop a PGD (2/2): Implications specific to the medication itself.	Does the medicine have a UK marketing authorisation? NB: PGDs *cannot* be used to supply unlicensed 'specials'.		Yes	
	Is the medicine a controlled drug, black-triangle medicine, or being used off-label?	Controlled drug	Morphine sulfate is a CD2 Midazolam is a CD3	
		Black-triangle medicine	No	
		Off-label use	**Off-label route** (morphine, midazolam, levomepromazine and hyoscine butylbromide) **Off-label indication** (morphine for breathlessness; hyoscine butylbromide for chest secretions; midazolam for breathlessness)	
		If yes, is use clearly justified by best clinical practice, in line with General Medical Council guidance;	Yes; use is consistent with both GMC guidance and local policies in relation to off-label medicines use	
		If yes, is the status of the medicine is clearly indicated in the PGD?	Yes; have retained the '†' symbol used to denote off-label indications and routes throughout the IoW palliative care guidelines and supporting documents	
	If an antimicrobial, have St Mary's microbiology team been consulted to ensure that use:	Is clinically essential and clearly justified by best practice guidance	Not applicable	
		Does not jeopardise local and national strategies to combat antimicrobial resistance and healthcare-associated infections	Not applicable	
	Is advice from IMOC or the CCG medicines team needed? (E.g. financial or formulary implications; implications for other groups).		Yes, discussed with CCG medicines lead and SMH chief pharmacist. No formulary impact at present but there is uncertainty about medicines supply during the pandemic that may require alternative medicines to be considered	
Developing the PGD.	Who will be the lead author and what support do they require?		[removed]	
	Record any references and sources used		Generic end of life care basis as described in: - IoW Palliative Care Symptom Control Guidelines - Wessex Palliative Care Guidelines Issues specific to Covid19 end of life care: - Clinical experience shared by the Italian Palliative Care Society - Wessex Regional Palliative Care Specialty Network - Liaison with other Palliative Care Formulary Editors	

		Underlying pharmacologic principles - Palliative Care Formulary - Maudsley Psychiatry Guidelines	
	Decide the review date (decide on a case-by-case basis; no longer than 3 years)	December 2020	
	Is the clinical and pharmaceutical content accurately described and supported by the best available evidence?	Yes. Sources used described above	
	Has the PGD template been fully completed?	Yes; some reformatting to put the core information on page 1 and to mirror the familiar just-in-case sheet format as closely as possible	
	Is any further external stakeholder or expert advice required? Any implications or opportunities for joint working with other organisations?	Yes, discussed as outlined above and agreed that we will share the PGD with others to consider implementing in their areas, subject to their local approval mechanisms	
	Who will lead on any training and educational plan required to implement the PGD safely and effectively (generally includes a register of people authorised to use the PGD)?	Because of the pandemic, formal group training is not practical. Therefore, have included a competency appendix based on NICEs PGD competency framework, for line managers or delegated others to use with clinicians who already have sufficient clinical experience to assess serious acute illness and recognise dying	
	Are any changes to the Medicines Competency assessment required?	No; deal with the competency assessment within the PGD's appendix 1	
	Are any additional resources required, e.g. diagnostic equipment?	No	
	Are arrangements for supply of the medicine(s) in place, including appropriately labelled packs and safe storage?	Both St Mary's Dispensary and Mountbatten Hospice will use a **Quality Check Form** to guide the pre-packing into tamper evident bags of: - Morphine sulfate (10mg/1mL) – 1 ampoule - Midazolam (10mg/2mL) – 1 ampoule - Levomepromazine (25mg/1mL) – 2 ampoules - Hyoscine Butylbromide (20mg/1mL) – 2 ampoules - Water for injections (10mL) – 1 ampoule - Syringes (2 x 1mL'; 2x2mL) - Needles (5 x drawing up; 5 orange) They will be prepared in batches of 10 bags. The Quality Check Form will be signed by the Packer and the Sealer-Checker; one of these	

		individuals will be a pharmacist; the other a pharmacist, pharmacy technician, registered nurse or doctor. Sharps bins will be carried separately. The CD stock register will cross-reference the individual tamper evident bag numbers.	
		The nurses and paramedics using the PGD will be employed by St Mary's or Mountbatten and will collect a tamper evident bag from St Mary's dispensary or Mountbatten Hospice, respectively. When collecting, they will record: - The date and time - the patients name - NHS number (or, if this is not known, their DoB, IW number or address) - The unique number on the tamper-evident bag - Their signature and name	
	Is the content consistent with the Summary of Product Characteristics *or* are off-label uses, doses or routes clearly identified?	Yes	
	Have all legal requirements have been met?	Yes	
	Does the PDG clearly outline applicable practical aspects of usage, e.g.: • not delegating responsibility • supplying an appropriately labelled pack • not splitting packs • ensuring the pack contains a Patient Information Leaflet • Identifying whether NHS prescription charges apply (if applicable)	Competency assessment specifically includes delegation PIL not applicable because all items are clinician administered The packs will be in tamper evidence bags NHS charges do not apply	
	Consider the best way of documenting: • date and time of supply and/or administration • patient consent to treatment • patient details (name, date of birth, allergies, previous adverse events) • how the patient met the criteria of the PGD • details of medicine given: name, strength, dose, frequency, quantity, route and site (if by injection); batch number and expiry date (if applicable) • a statement that supply or administration is by using a PGD • the health professional supplying or administering the medicine • relevant information that was provided to the patient or their carer	The 'key points' section describes the documentation required: - recording administration in the usual administration section (because this is already in use and familiar; it includes the date and time, preparation, dose, batch number, expiry, quantity remaining) - recording the other details in the patient's clinical record including an explicit statement that the medicines have been given using a PGD	
Submission for authorisation	A nursing, medical and pharmacist member of the Mountbatten MSOT approve the draft then submit it, in order, to:	Submitted for approval	

	• Mountbatten Senior Management Team for final approval of the draft • CCG Primacy Care Prescribing Committee for formal approval • Mountbatten Quality and Governance Committee to commence implementation		
PGD implementation: Once the authorising body approves PGD	The final signed version of the PGD is published to office 365 and the Medicines Procedures hardcopy folder[1]	[pending approval] – signed copy to be held by CCG Meds Op Team	
	Add the PGD review date and lead author to the PGD section of the Medicines Version Control Template to ensure that the PGD is reviewed and updated as required (alongside the decisions recorded in this template and any supporting literature and guidance).[2]	[pending approval]	
	Implement the above training and educational plan (if applicable), including any modifications required for the medicines competency framework	[competency framework ready for dissemination, pending approval]	
	Consider what monitoring arrangements are required (e.g. correlating the ordering of replacement pre-labelled packs with recording on the SystmOne PGD template).	[pending approval: use a SOP to ensure all steps of the process are clear to everyone involved]	

[1] If this replaces a previous version, the hardcopy of the latter is moved to the obsoleted SOP folder in the Pharmacy Office.
[2] Either in the 6 months leading up to the review date, or sooner if new legislation, evidence, guidance, drug safety information, untoward incidents, SPC or formulary changes require an unscheduled review.