Consensus statement:

'Drug Treatment in Community Settings for COVID19 patients'

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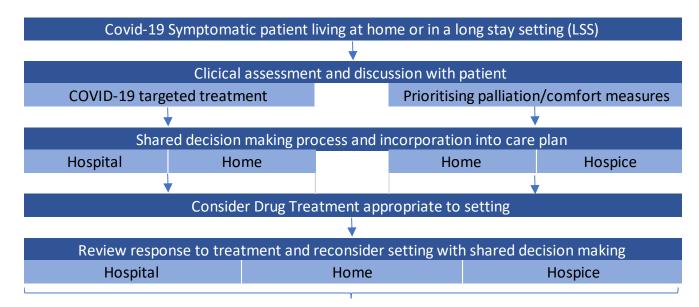
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Role of Clinician in supporting informed decisions

The Covid-19 pandemic began in England in February 2020. Its effect on older people living in their own homes and in long term care settings has been disproportionate compared to other population groups. We now have the opportunity to learn lessons from different regional responses to wave 1 of the pandemic to be able to adapt this response in a second wave. During the 2020 'Integrated Care: Supporting the Care Home Sector' Clinical Summit, there was a call to clarify the position on the use of home oxygen, dexamethasone, anticoagulants and fluid management for patients who wish to remain in their own homes or in long term care facilities. The key consideration of any treatment of an individual should be a personalised care approach with informed decisions around care. This is a key feature of the NHS constitution, the Long-Term Plan¹, and the subject of a letter from the Medical Director and Chief Nurse during the pandemic².

The decision to use drug treatment for COVID19 should be made on the basis of informed consent gained through a discussion with the individual, those who hold the health and welfare Lasting Power of Attorney (LPA) or through a best interest decision, based on the consideration of an individual's mental capacity (assessed using the mental capacity assessment under the Mental Capacity Act). Where possible, the patient's family and/or carers must be included in a best interest shared decision. Whilst home-based treatment approaches enable care in the comfortable surroundings of an individual's home and may enable family and friends to visit, there are limitations in terms of clinical monitoring and escalation compared to the inhospital setting. Discussions should ensure the similarities and differences of treatment approaches are clear to inform personalised decision-making. This discussion should be made at the time or as part of a documented advance care plan.

This consensus statement on community based COVID-19 treatments does not aim to replicate hospital care, nor advocates using these as an initial treatment approach for patients who wish for hospital care when required. This statement also does not cover the use of Remdesivir which is a treatment which is used in hospitals for COVID19 patients with pneumonia requiring supplemental oxygen under close medical supervision. The home-based treatments outlined in this document may not offer the same chances of survival as inpatient hospital care. This document summarises consensus on treatment options for a very specific cohort of patients, who opt for active treatment (as opposed to palliation alone), but who have made a previous or current informed decision to refuse hospitalisation in preference for a home-based approach. The decision should be reviewed where clinically indicated or where patients/families indicate their wishes have changed



Treatment and treatment venue are changeable at any point in patient treatment

Figure 1. Treatment venue decision pathway. Patients at home are defined as patients living in a home setting with the right care support or in a long stay setting.*

This consensus statement has been drawn up with the support of primary, secondary and integrated care clinicians and aims to support the use of drug treatments which may be considered when managing a patient with COVID-19 in a community setting, for whom hospital admission is not part of their preferred treatment plan. These four main treatment options are not exclusive but are meant to be considered as a package of measures for individuals with COVID-19. It is important to consider the stage of the disease, the competency of those caring, as well as the limitations and potential risks of the setting and the clinical support network.

^{*} Hospice as a place of care may not be a realistic choice for many dying with COVID - depends on several factors including local availability of hospice beds and whether Hospices are equipped to receive CVID positive patients. This must be considered before any decisions around transfer to hospice from another care setting

1. Oxygen

COVID-19 is a condition which typically causes pneumonia. Severe cases of COVID-19 can be associated with respiratory failure which may not improve with supplemental oxygen as discussed in the BMJ Article and infographic³.

During the first wave of the pandemic some primary and community-based clinicians were using flow rates of up to 4L/min in the community to support patients with mild to moderate hypoxia. These flow rates can be achieved through the supply and distribution of emergency oxygen concentrators via a 4hr emergency oxygen request. The supply of home oxygen and assessment of patients is usually overseen by a specialist home oxygen team with clinical pathways in line with national guidance and determined by a local system or network and it is important that decisions are supported by local policy.

There are several important questions to consider alongside a local policy which has been agreed by a system or network. An example of this policy agreement is attached produced by the London Region during the height of the first wave of the pandemic.

1.1. Points for consideration when supplying Oxygen therapy outside acute settings during COVID 19 pandemic.

This list is not exhaustive but serves to help areas (such as PCNs, CCG, STPs, ICS, services) to consider what processes they will need to put in place to deliver a robust service to patients requiring oxygen therapy outside of acute settings.

The London Clinical Network has produced a helpful guide for this process 'Oxygen therapy outside acute settings during the COVID 19 pandemic v3.3'⁴. Local areas who do not already have this in place may wish to consider adapting this into a Standard Operating Procedure for their own use, bearing in mind:

- Who is your local:
 - Respiratory clinical lead
 - Hospital at home or older persons' clinical lead
 - Palliative Care lead
 - Home oxygen Service Assessment and Review (HOSAR) Lead You will need to identify and gain support from these people to ratify a pathway
- Do you have local emergency and home oxygen prescribing guidelines?
- Do you have a clinical oxygen protocol specific to the setting of care and cohort of patients which is consistent with principles of good medical oxygen practice?
- Who is the nominated responsible clinical lead ensuring governance for oxygen therapy outside hospital (i.e. in line with principles of good medical practice)?
- How do you as an area/region want to manage the supply and availability of oxygen equipment outside the hospital setting? Emergency home oxygen

- delivery can take up to 4 hours from ordering; how will this be achieved and managed?
- Do you have the details for the local HOS-AR service and oxygen supplier?
 Can you access a Home Oxygen Order form (HOOF), Initial Home Oxygen
 Risk Mitigation Form (IHORM), and Home oxygen Consent form (HOCF)? Do you know where to send these documents?
- Are staff prescribing and monitoring oxygen therapy outside the hospital setting appropriately trained and is this training up to date?
- Do you need to consider extending traditional working hours of your local HOSAR team? Do you have access to a clinical expert for example an on call respiratory consultant to provide advice and support?

1.2. Core standards of Oxygen administration

ndic.	escription of the Core	Standar	Exceptions	Definitions
No	Standard	d (%)		and
				Instructions
1	Oxygen therapy is prescribed on the patient prescription charts or electronic prescription record and this prescription specifies target oxygen saturation, oxygen flow rate, delivery device and monitoring frequency	100%	Emergency. To be documented at later point.	
2	Every patient has a set target oxygen saturation	100%		
3	The clinical indication for oxygen therapy is clearly documented within the medical record	100%		
4	Pulse oximetry is recorded four times a day for all patients receiving oxygen therapy this is subject to increase or reduction in frequency with increase in severity or palliation, respectively. Supported by the use of the COVID-19 pulse oximetry diary ⁵ .	100%		

5	Each patient has had a risk assessment completed before oxygen therapy is prescribed and this documented in the clinical notes; if risks outweigh benefits oxygen therapy should not be prescribed. Oxygen therapy should not be prescribed to current smokers due to the risks to themselves and others.	100%	
6	Oxygen tubing and masks should be checked daily by carers; faulty equipment should be replaced and not used	100%	
7	Staff responsible for the safe storage of oxygen must have been assessed as competent to move and handle oxygen equipment (support from oxygen suppliers and local Respiratory teams). This includes specific support around the care for patients in receiving oxygen safely and comfortably). Staff must be appropriately trained and supported in using oxygen monitoring equipment. Guidance can be found on the NHS YouTube video 'Adult Pulse oximetry Monitoring Covid-19 Diary 6.	100%	

1.3. Patients with suspected or confirmed COVID 19 whose preferred place for treatment is within their home, or care home

• Ensure there is a robust pathway for provision of oxygen in these circumstances, that includes accessibility to senior staff with expertise in

- oxygen therapy including the local respiratory team, HOSAR service, Hospital at Home team, palliative care clinicians, primary care clinicians and older persons' team.
- Do you need to make arrangements with respiratory consultants at your local secondary care facility so they can be contacted for advice and guidance?
- Have you a supply of oxygen saturation probes to enable appropriate monitoring and care
- If a clinician feels at any time that a change of plan to hospitalisation may be beneficial and/or the patient's wishes change this escalation should be arranged.
- Any care plan must consider what to do in the event of flow rates being too high to sustain oxygen delivery in this setting and whether consequent escalation is appropriate.
- How will equipment be accessed quickly whilst waiting for delivery from supplier?
- Again, consideration of extended HOSAR staff hours of work or availability of an on-call staff member for advice may be useful
- Who will complete the HOOF for the patient? Are staff trained in completion of HOOF, IHORM, HOCF? Who is best to deliver this training?
- Is there a training in place in assessing risks around oxygen therapy?
- Who will review the patient clinically and be responsible for adjustment of flow rate +/- removal
- Fire risk must be considered when using high flow oxygen as noted in the Oxygen Supply and Fire Safety CAS alert: 'Use of high flow open circuit oxygen devices carries a risk of increasing ambient oxygen concentration. If this exceeds 23% this poses a potential fire risk'⁷

1.4. Patients with suspected or confirmed COVID 19 at the end of life

Oxygen is unlikely to be helpful in majority of cases but those who are hypoxic may gain symptomatic benefit. Use of oxygen in these situations should be based on symptom relief, not oxygen saturation levels. Nasal cannulae are more comfortable and less intrusive than face masks. This consensus statement recommends the consideration of the NICE 'COVID-19 rapid guideline: managing symptoms (including at the end of life) in the community'8 as well as Ruth Ting's journal: 'Palliative care for patients with severe covid-19'9 when treating patients with COVID-19 at the end of life.

2. Dexamethasone

NICE have published <u>guidance on the use of dexamethasone</u> ¹⁰ following the findings from the Recovery trial on the 3rd September. There was a statistically significant reduction in all-cause mortality at 28 days in the hospital setting using 6mg Dexamethasone for up to 10 days. Dexamethasone was used in the hospital setting for patients who were diagnosed with **severe** or **critical** COVID-19 with the <u>WHO</u> <u>criteria</u> ¹¹ They were also supported with the use of supplementary oxygen with or without invasive mechanical ventilation and with higher concentration of oxygen. There was no evidence that dexamethasone provided any benefit among patients who were not receiving respiratory support at randomization, and the results were consistent with possible harm in this subgroup. The Chief Pharmaceutical Officer and National Medical Director have also published a recent <u>letter</u> ¹² (13th November 2020) on the use of corticosteroids including dexamethasone and hydrocortisone.

2.1 Severity criteria for Dexamethasone administration

Dexamethasone is recommended for patients who meet the WHO criteria 13 "severe" or "critical" COVID-19. The WHO recommend this should apply "even if they cannot be hospitalised or receive oxygen because of resource limitations" The UK MRHA also acknowledges that there may be occasions where severe and critical COVID-19 patients are not hospitalised 14 and recommends that the WHO guidance for treatment should be applied 15.

Dexamethasone is not recommended in non-severe COVID-19 as there is a possibility harm is greater than benefit, as noted in the NHS England and Improvement's November 2020 statement on COVID-19 corticosteroid prescription¹². Concomitant Treatment with oxygen should be considered (see consensus statement on oxygen).

The <u>NICE guidelines</u>¹⁰ include treatment considerations such as gastroprotection which should be considered prior to prescribing Dexamethasone (COVID-19 prescribing briefing,2020). When prescribing Dexamethasone to patients who are diabetic, close blood monitoring should be observed.

For guidance on identification of severity of a patient's condition, this statement recommends the use of '<u>A living WHO guideline on drugs for covid-19'</u> ¹³. Criteria for severe COVID-19 diagnosis include, but are not limited to:

- acute respiratory distress syndrome (ARDS)
- sepsis or septic shock¹⁶
- other conditions that would normally need life-sustaining therapies such as ventilation or vasopressor therapy
- signs of severe respiratory distress
- oxygen saturation <90% (or deteriorating) on room air

• increased respiratory rate (>30 breaths per minute in adults and children over 5 years

2.2. Steroid Class effect

It is considered that alternative glucocorticoids could be used with similar efficacy to dexamethasone and may have less glucogenic potential. The total daily dose equivalences are Prednisolone 40 mg, Methylprednisolone 32mg and Hydrocortisone 160mg. It is recognised however in the Community setting that oral steroids i.e. Dexamethasone and Prednisolone are likely to be used more than intravenous administration.

The use of steroids in older people requires regular monitoring and has the potential to worsen symptoms of delirium as well as inducing diabetogenic consequences, it is recommended that patients who are started on steroids are monitored for their blood sugars on a daily basis and that their care plan includes regular medical review.

2.3. Dosing guidance

This statement recommends that clinician review the <u>emc dosing guidance on</u> <u>Dexamethasone 2mg tablet administration</u>¹⁷ and the <u>emc dosing guidance on</u> <u>Prednisolone 5mg tablet administration</u>¹⁸ before prescription.

3. Anticoagulants

Nice have recently issued the 'COVID-19 rapid guideline: reducing the risk of venous thromboembolism in over 16s with COVID-19'¹⁹. Specific guidance supports the understanding that patients in community settings with COVID-19 pneumonia do have an increased risk of VTE and that pharmacological VTE prophylaxis should be considered for them to ensure that they receive the same care as patients admitted to hospital.

An assessment of the risks of VTE and bleeding needs to be made and consideration of VTE prophylaxis if the benefit outweighs the risk of bleeding. This rapid Nice Guidance recommends treatment with Low Molecular Weight Heparin (LMWH) or for patients who cannot have this use of fondaparinux or unfractionated heparin (UFN). The use of direct-acting anticoagulants (DOAC) is recommended for a further area of research, We recognise, however, that in community settings DOACs may be more suitable as an alternative to a parenteral mode of delivery.

Patients with any acute medical illness being treated in a hospital setting often meet criteria on risk stratification for prophylactic doses of anticoagulation to reduce the likelihood of acquiring venous thromboembolism (VTE). This prophylactic dose of is usually provided as a once daily injection of a low molecular weight heparin (LMWH). Alternatively, daily oral treatment can be offered with a direct oral anticoagulant (DOAC).

COVID-19 is associated with an increased risk of VTE, greater than expected from the presence of an acute respiratory illness. Strategies to reduce VTE in patients with COVID-19 treated in community settings are important to minimise harm. A recent survey of practice by the Society for Acute Medicine as part of its annual benchmarking audit (SAMBA), found variation in the approach to anticoagulation for patients with COVID-19, with some hospitals using higher doses than licensed prophylactic dose²⁰. While such enhanced approaches may seem appropriate, there is as yet no trial evidence that shows higher prophylactic doses of anticoagulation are clinically and cost effective.

To reduce unwarranted variation in community practice for prophylactic anticoagulation in COVID-19 and in line with the Rapid NICE guidance, this consensus statement advises the application of standard VTE prophylaxis as set out below. This statement may be superseded by trial evidence in this setting.

3.1. Considerations before prophylactic anticoagulant administration

When administering prophylactic anticoagulants, the following criteria must be considered to confirm patient eligibility for treatment.

- Are there facilities in place for baseline blood tests to be taken for appropriate prescribing
- Can the location of care support subcutaneous injection to deliver LMWH?
 Otherwise, consider oral prophylaxis with DOACs
- If DOACs are chosen as the most appropriate treatment, the following must be considered: Which drug is most appropriate? What is the patient's renal function? Are there any interactions this DOAC could have with patients existing medication and adverse response reporting must be in place
- Does the patient have any bleeding risk factors including, but not limited to*:
 - Active major bleeding (or within 3 months prior to admission)
 - Acquired bleeding disorders
 - Uncontrolled hypertension
 - o Concurrent use of anticoagulants
 - Acute stroke
 - Thrombocytopenia
 - Uncontrolled inherited bleeding disorders (such as haemophilia)
 - Trauma patient
 - Surgery
 - LP/epidural/spinal anaesthesia within the previous 4-6 hours or expected within the next 12 hours
 - Other procedures with high bleeding risk
 - PT (prothrombin time) >6 seconds above upper limit of normal (ULN) or APTT (activated partial thromboplastin time) >6 seconds above ULN and NOT due to coagulopathy
 - Haematological disorder affecting platelet function

3.2. Dosing

^{*}If clinicians have the facilities to calculate CrCl, a CrCl<30mL/min should be considered a bleeding risk factor

A standard dose of pharmacological VTE prophylaxis now recommended by NICE for most patients, but that dose adjustments may be needed for patients at extremes of body weight and those with renal impairment, to ensure appropriate dosing. Patients with extremes of body weight or abnormal renal function may need the dose to be adjusted and that summary of product characteristics and locally agreed protocols should be used to inform that decision as per NICE guidance.

Decisions to use a treatment dose of VTE need to be made with the relevant investigations and locally agreed pathways of care.

3.3. Anticoagulant administration

This consensus statement recommends the consideration of the Royal College of Physicians guide: 'Clinical guide for the prevention, detection and management of thromboembolic disease in patients with COVID-19'21 for the use of prophylactic anticoagulant administration for COVID-19 positive symptomatic patients in the community.

4. Fluid Management

Dehydration and acute kidney injury (AKI) in patients with COVID-19 is common (Nadim et al., 2020) and is associated with an increased risk of dying. Causes may include volume depletion, haemodynamic changes, viral infection leading directly to kidney tubular injury, thrombotic vascular processes, glomerular pathology or rhabdomyolysis. It may be associated with haematuria, proteinuria and abnormal serum electrolytes (both increased and decreased serum sodium and potassium).

Maintaining optimal fluid status is critical in reducing the incidence of AKI. Insensible losses in COVID-19 can be high due to factors such as fever, high respiratory rate or diarrhoea. Additionally, other factors such as hypoactive delirium, decline in mobility and/or fatigue may adversely impact on patient's capabilities in keeping up with their fluid requirements. Risk factors that increase the risk of AKI include pre-existing chronic kidney disease, heart failure, liver disease, diabetes, history of AKI, age 65+ years.

Fluid status should be assessed by clinical examination and clinical monitoring, by pragmatic assessment of fluid intake and, where possible, appropriate investigations including blood tests and the addition of appropriate investigations. Routine medications should be reviewed, and consideration given to adjusting medications that can cause/worsening AKI or dehydration (e.g. diuretics). Continued assessment and monitoring of hydration and/or AKI should take please at least every 48 hours or more often if clinically indicated. Glucose levels should be checked in those with AKI, especially if also receiving dexamethasone/other steroids.

If volume depletion (hypovolaemia) and/or fluid needs cannot be met orally, then supplementation with subcutaneous or intravenous fluids should be considered for patients with COVID-19. Choice of fluids should be based on biochemistry, fluid status and local availability.

This statement was made with reference to the NICE '<u>COVID-19 rapid guideline: acute kidney injury in hospital</u>'²² guidance.

4.1. Subcutaneous fluid management guidance

This consensus statement was made with the consideration of the Herefordshire and Worcestershire Action Notice (Interim) to Accommodate COVID-19 Working Practice document on Subcutaneous Fluids in the Community²³.

This statement recommends the use of the '<u>Care Pathway for Administration of Subcutaneous Fluid in the community</u>²⁴ pathway (used in conjunction with the Worcester Health and Care '<u>Subcutaneous Fluid Administration by Subcutaneous Infusion</u>'²⁵) as well as the NHS Leeds Clinical Commissioning Group's '<u>Primary Care Request for Clinically Assisted Hydration (Sub-Cutaneous Fluid) Flow Chart</u>'²⁶ under the '<u>Leeds Older People with Frailty and COVID-19</u>: <u>Enhanced Care at Home Pathway</u>'²⁷ page.

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