# Guidelines on treating children with COVID-19 and/or COVID-19-like symptoms

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COVID-19 Public Health Response Team

Department of Child and Adolescent Health, Mater Dei Hospital

Primary Health Care

Maltese Paediatric Association

Malta College of Family Doctors

Association of Private Family Doctors

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### Preamble

This document was commissioned following the need to establish a framework and guidelines for medical practitioners who treat and care for children in the scenario that schools are due to re-open for the new scholastic year. This document is meant to guide practitioners in their practice and is not intended to supplant the clinical judgement or discretion of a medical practitioner in his/her care of a sick child with COVID-19 and/or COVID-19-like symptoms. For this reason, these guidelines are for medical practitioners only and should not be used or interpreted by lay persons. These guidelines cover all children up to the age of sixteen years.

As stated in the guidelines provided to schools, it is of paramount importance that children return to their education this upcoming scholastic year. This document aims to provide medical practitioners with the necessary information and tools to keep children at school as much as possible whilst safeguarding their health as well as that of their families and school staff.

For urgent consultations on these guidelines, medical practitioners may contact the COVID-19 Public Health Response Team on 79004731 or 79600383 or email on covid19.health@gov.mt. This guidance will be updated and communicated on the basis of emerging evidence.

### General Information on COVID-19

Coronaviruses are viruses which cause respiratory symptoms ranging from the common cold to more serious illnesses such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). They are a family of viruses which are present both in humans and in animals. They are spread from one person to another through:

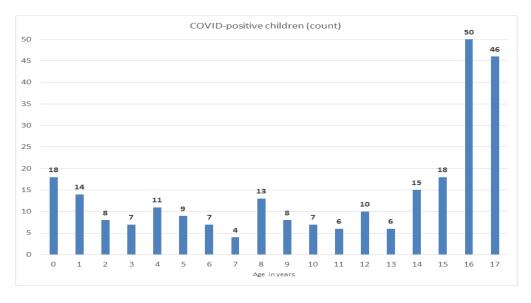
- 1. Coughing and sneezing (via droplets)
- 2. Hands which have become contaminated with the virus after touching contaminated surfaces or
- 3. Through direct contact with a person infected with the coronavirus (such as caring for a sick person)

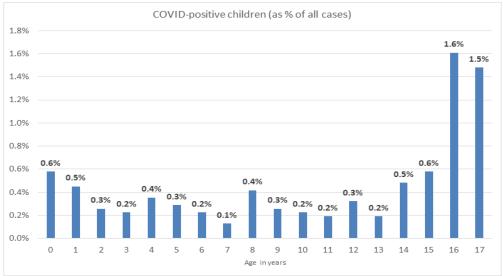
For further information on how the virus is transmitted, the symptoms of the illness and what to do if sick or have symptoms, refer to:

https://deputyprimeminister.gov.mt/en/health-promotion/covid-19/Pages/symptoms.aspx https://deputyprimeminister.gov.mt/en/health-promotion/covid-19/Pages/resources.aspx

### COVID-19 in children and transmissibility of COVID-19 in school settings

The burden of disease of COVID-19 on persons aged less than 18 years is low, at around 1-5% <sup>1,2</sup>. The graphs below show the distribution of COVID positive cases in 0-18 years olds in Malta (count and percentages of all COVID-19 cases in Malta). In Malta persons under 18 years of age account for 8.26 % of all COVID-19 cases.

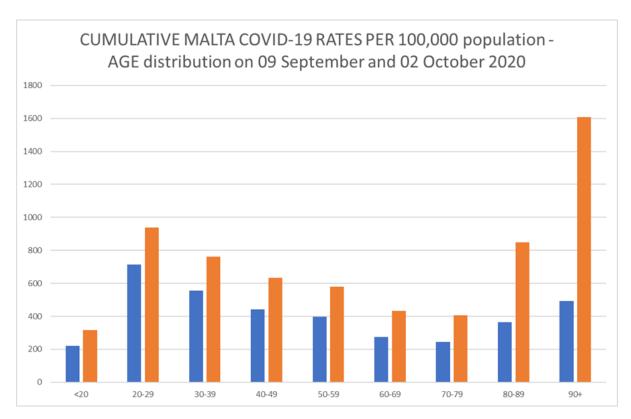




<sup>&</sup>lt;sup>1</sup> Ladhani SN, Amin-Chowdhury Z, Davies HG, Aiano F, Hayden I, Lacy J, Sinnathamby M, de Lusignan S, Demirjian A, Whittaker H, Andrews N, Zambon M, Hopkins S, Ramsay ME. COVID-19 in children: analysis of the first pandemic peak in England. Arch Dis Child. 2020 Aug 12:archdischild-2020-320042. doi: 10.1136/archdischild-2020-320042. Online ahead of print.

<sup>&</sup>lt;sup>2</sup> Ludvigsson JF. Systematic review of COVID-19 in children shows milder cases and a better prognosis than adults. Acta Paediatr. 2020 Jun;109(6):1088-1095

The graph below shows the age distribution of positive COVID-19 cases in Malta as on the 2<sup>nd</sup> October 2020. A shift towards older persons was noticeable over the summer months. This pattern may shift again once schools re-open, especially since children tend to be cared for by their grandparents after school hours and many grandparents will also provide school transport for their grandchildren. For this reason, and since there may be an increase in COVID-19 infections in the colder months, it is very important that elderly grandparents take all the necessary precautions when caring for their grandchildren.



From the literature it has been shown that the case fatality rate in children is also very low at around 0.3-0.5%<sup>3,4</sup>. Literature states that around 15% of COVID-19 positive children, adolescents and young adults less than 18 years attending school are asymptomatic<sup>5,6</sup>.

<sup>&</sup>lt;sup>3</sup> Ladhani SN, Amin-Chowdhury Z, Davies HG, Aiano F, Hayden I, Lacy J, Sinnathamby M, de Lusignan S, Demirjian A, Whittaker H, Andrews N, Zambon M, Hopkins S, Ramsay ME. COVID-19 in children: analysis of the first pandemic peak in England. Arch Dis Child. 2020 Aug 12:archdischild-2020-320042. doi: 10.1136/archdischild-2020-320042. Online ahead of print.

<sup>&</sup>lt;sup>4</sup> de Souza TH, Nadal JA, Nogueira RJN, Pereira RM, Brandão MB. Clinical manifestations of children with COVID-19: A systematic review. Pediatr Pulmonol. 2020 Aug;55(8):1892-1899

<sup>&</sup>lt;sup>5</sup> de Souza TH, Nadal JA, Nogueira RJN, Pereira RM, Brandão MB. Clinical manifestations of children with COVID-19: A systematic review. Pediatr Pulmonol. 2020 Aug;55(8):1892-1899

<sup>&</sup>lt;sup>6</sup> Patel NA. Pediatric COVID-19: Systematic review of the literature. Am J Otolaryngol. 2020 Sep-Oct;41(5):102573.

However, in Malta, the asymptomatic to symptomatic ratio is just over 1 in 4 (n= 159; asymptomatic 43; symptomatic 116). A possible reason for this is due to Malta's high testing rates and also due to increased testing of contacts in Malta.

Evidence shows that the risk of transmission between children is very low, with children being much more likely to get infected from household contacts rather than from school. ECDC contends that symptomatic children transmit as much as adults, but a number of studies have shown a very low transmission rate from infected children to other children and to adults <sup>7,8,9,10,11,12</sup>, as well as from adults to children in the education setting, with the risk being quantified at 0.3%, 1% and 1.5% respectively in one study<sup>13</sup>. However, one should note that experience in schools is still very limited and it is therefore not possible to determine the extent of transmission of COVID-19 in school settings more accurately.

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<sup>&</sup>lt;sup>7</sup> ECDC Technical Report. COVID-19 in children and the role of school settings in COVID-19 transmission. 6 August 2020 [accessed on 10 September 2020]. Available from:

https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-schools-transmission-August 2020.pdf <sup>8</sup> Danis K, Epaulard O, Bénet T, et al; Investigation Team. Cluster of coronavirus disease 2019 (Covid-19) in the French Alps, February 2020. Clinical Infectious Diseases. 2020 Jul 28;71(15):825-832. doi:10.1093/cid/ciaa424 <sup>9</sup> Heavey L, Casey G, Kelly C, Kelly D, McDarby G. No evidence of secondary transmission of COVID-19 from children attending school in Ireland, 2020. Euro Surveillance: European communicable disease bulletin. 2020 May;25(21) [accessed on 10 September 2020]. Available from:

https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.21.2000903

<sup>&</sup>lt;sup>10</sup> Dub T, Erra E, Hagberg L, Sarvikivi E, Virta C, Jarvinen A, et al. Transmission of SARS-CoV-2 following exposure in school settings: experience from two Helsinki area exposure incidents. medRxiv. 2020:2020.07.20.20156018.

<sup>&</sup>lt;sup>11</sup> Yung CF, Kam KQ, Nadua KD et al. Novel coronavirus 2019 transmission risk in educational settings. Clinical Infectious Diseases. 2020 Jun 25. doi: 10.1093/cid/ciaa794

<sup>&</sup>lt;sup>12</sup> Laura Heavey, Geraldine Casey, Ciara Kelly, David Kelly, Geraldine McDarby. No evidence of secondary transmission of COVID-19 from children attending school in Ireland, 2020 Euro Surveill. 2020 May;25(21):2000903.

<sup>&</sup>lt;sup>13</sup> Macartney K, Quinn HE, Pillsbury AJ et al. Transmission of SARS-CoV-2 in Australian educational settings: a prospective cohort study. Lancet Child and Adolescent Health. Published online Aug 3 2020. doi: 10.1016/S2352-4642(20)30251-0

## Clinical assessment of children presenting possible COVID-19 and/or Influenza-Like-Illness<sup>14</sup> symptomatology

A significant proportion of children with COVID-19 are asymptomatic (15% <sup>15,16</sup>), even though they are still potentially infectious. Evidence is also showing that the severity and presence of symptoms do not necessarily correlate to the severity of the viral infection. Experience has shown that the most frequent symptoms in children are fever and cough, although other symptoms may be present such as tiredness, sore throat, runny / blocked nose, headache, muscle pain and loss of smell and taste. Vomiting and diarrhoea are also important symptoms that are also more common in children. The elucidation and identification of symptoms in children may be more difficult and practitioners need to retain a high index of suspicion in situations where there is:

- Sudden onset of fever
- New continuous cough (coughing > 1 hour or 3 prolonged coughing episodes in 24 hours)
- Loss of or change in taste and/or smell
- Possible exposure from a household contact with respiratory symptoms

If a child has a fever and localising signs of infection (e.g. urinary tract infection), then this could be considered the cause of the fever as long as signs and symptoms are typical of the underlying condition. If no localising signs are found, then one would be more suspicious of COVID-19 and more likely to refer for PCR testing.

It should be noted that as children start to enter into adolescence (from a mean age of 11 years), their clinical picture and risk of transmission starts emulating more and more the clinical symptomatology and transmission patterns in adults.

<sup>&</sup>lt;sup>14</sup> https://www.who.int/influenza/surveillance monitoring/ili sari surveillance case definition/en/

<sup>&</sup>lt;sup>15</sup> de Souza TH, Nadal JA, Nogueira RJN, Pereira RM, Brandão MB. Clinical manifestations of children with COVID-19: A systematic review. Pediatr Pulmonol. 2020 Aug;55(8):1892-1899

<sup>&</sup>lt;sup>16</sup> Patel NA. Pediatric COVID-19: Systematic review of the literature. Am J Otolaryngol. 2020 Sep-Oct;41(5):102573.

### Criteria to refer for swabbing for PCR testing

Not all unwell children should be referred for a swab test. Children with mild symptoms of a common cold and/or allergies do not warrant referral for a PCR test, especially if these symptoms are a common occurrence for that particular child. Whilst it is difficult to establish clear criteria for swabbing, screening for COVID-19 effectively would significantly curb the potential spread of the virus in schools. The most recent case definition published by WHO for the surveillance for COVID-19 is shown below. This case definition is intended only for surveillance purposes. Clinical discretion must always remain paramount.

Acute onset of fever and cough

OR

Acute onset of 3 or more of the following sign or symptoms:

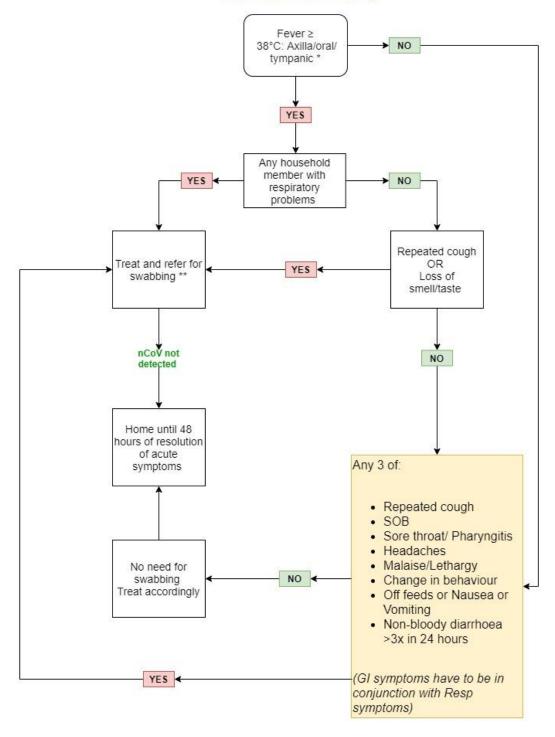
fever, cough, weakness/fatigue, headache, myalgia, sore throat, dyspnoea, anorexia/nausea/vomiting, diarrhoea and altered mental status.

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Current evidence shows that there is more likely transmission between household members than in the school setting. Thus, a child with a fever/other suggestive symptoms living with a symptomatic household member should be more actively considered for swabbing. It is important to keep in mind, that, depending on demand, the process from referral for a swab test to the receipt of the result may take a few days to be completed and so the child would need to remain indoors until the result is out and the child fully recovers. Parents should always be encouraged to seek advice from the child's caring physician before requesting a swab test. If parents refuse to swab their child when medically indicated, then the child is to remain home for 14 days and not return to school until 48 hours after acute symptoms fully resolve. The medical practitioner should document this in the medical certificate issued for the child and should record this in his/her medical notes.

The following flow chart was developed to assist medical practitioners in reaching a decision on whether to swab or not.

### Guidelines: Referring children <16 years old for SARS-CoV-2 Swabbing



These guidelines are for doctors only. Review, treatment and referral of sick children should NEVER be delayed and always take priority over swabbing.

Issued by Paediatric Infectious Disease Service, MDH Adapted from WHO COVID-19 case definition, 7/08/2020

<sup>\*</sup> No need to refer for swabbing if fever is due to an obvious bacterial infection unless COVID-19 infection still suspected;

<sup>\*\*</sup>Quarantine of Covid positive children will be guided by public health doctors.

### New swabbing methodologies

To date, the gold standard test is the nasopharyngeal swab for PCR testing. Most children have tolerated this test well. As an alternative, deep nasal and oropharyngeal sampling for PCR testing have detection rates that are comparable to the nasopharyngeal swab and may be more acceptable for some parents and children.

New technologies are being developed such as saliva testing and antigen tests for screening purposes. These are currently being evaluated for specificity/sensitivity and feasibility of implementation of such tests locally and different settings.

It is important to emphasise that antigen/antibody testing is not a clinically confirmatory test for COVID-19 and currently these modalities do not replace a PCR test. These tests should therefore not be used on their own, as the basis for public health or clinical decisions or for treatment. Patients should be guided accordingly.

### Medical certification for school absence

Children who are unwell should invariably stay home and should return to school only after 48 hours following resolution of acute or infective symptoms. Given the prevailing epidemiological situation, each absent child from school would need to be certified for each day of school absence before returning to school, irrespective if the child is suffering from a COVID-19-like symptoms or from any other illness. Certification and return to school do not require a negative swab and unnecessary swabbing is to be avoided. It is up to the caring physician to decide whether a swab test is necessary, guided by the criteria outlined previously. Once the child is reviewed by the medical practitioner, certification with a date in advance of when they can return to school could be provided if deemed appropriate by the physician. If deemed appropriate, on-line certification is also possible, where an SMS or e-mail would be considered an acceptable means for certification in line with Medical Council recommendations. If a child tests positive for COVID-19, then Public Health protocols would be implemented.

If a child is turned away from school due to a temperature of between 37.2°C and 37.5°C and does not have any other symptoms, it is advised that the child would remain at home for 24 hours with parents checking temperature every 6 hours without administering anti-pyretics after consultation with their doctor. If no spikes in temperature are noted, then the child can return to school the next day with a doctor's note, without requiring swabbing.

No school or child-care facility should be allowed to request COVID-19 swabbing or any COVID-19 antigen or antibody test (or ask for a negative result) prior to accepting a child back to school following absence due to illness. A medical certificate confirming that the child is fit to return to school and presented on the child's return to school should suffice.

Given that many children may remain at home (due to shielding or quarantine reasons) and that many parents may also opt to keep their children at home, school absence would need to be justified and clearly and meticulously documented by all schools in conjunction with the educators and parents. This is important to prevent children from being absent for unofficial

or unjustifiable reasons or absent without the explicit knowledge of their parents or custodians (especially in older children), with particular attention to those most vulnerable from a socioeconomic aspect.

For clarity's sake there are only 3 occasions why children should remain home for medical reasons and not attend school physically. These are:

Reason	Responsibility
Child and/or household members in	Public Health
quarantine	
Sick child	Caring medical practitioner
Child who requires shielding (unless	Caring hospital consultant paediatrician
appropriate measures can be put in place for	
the child to attend school safely)	

### Children who may require shielding

At the start of the pandemic, Public Health produced a non-exhaustive list of clinical conditions which was used, at the time and with the limited evidence available, to classify certain persons as vulnerable because they were considered as having a higher risk of serious complications if they were infected with COVID-19. Whilst this served its purpose at the start of the pandemic, it is now being advised that the need to shield children should be based on a discussion and indepth assessment between the caring hospital consultant paediatrician, the child's parents and school management. As much as is possible, children who are deemed to require shielding should still be able to attend school physically and the benefit of attending school should be weighed with the need to keep children and young people with certain underlying conditions safe. Alternative arrangements and measures may be implemented by the school to allow the child to physically attend school, e.g. primary school children could be asked to wear masks in the presence of a child requiring shielding.

Moreover, this measure should not be used to increase truancy or absenteeism, particularly for the children who are most vulnerable (either for medical and/or social reasons).

Annexes 1 and 2 contain a certificate with an updated list of clinical conditions which are to be used to guide hospital consultant paediatricians for the assessment of children who may require shielding. The certificate does not divulge the illness or medical condition that the child is suffering from. Also, this protocol does not delve into the type or suitability of shielding as this needs to be determined between the caring physician, the parents and school. Hospital consultant paediatricians are to contact parents of children who may require shielding to determine whether a certificate should be issued. Parents who are in doubt or who have not been contacted by their hospital paediatrician, may consult their family doctor who in turn will advise the parents accordingly, in line with the list of conditions in Annex 2. Family doctors may also consult directly with hospital consultant paediatricians.

Children living with household members who require shielding or are sick do not require shielding themselves and can/should attend school.



### STATEMENT CONFIRMING BENEFIT FROM SHIELDING FROM COVID-19 INFECTION

TO BE COMPLETED BY HOSPITAL CONSULTANT PAEDIATRICIAN.

I, Dr/Prof.	, Medical Council N	, Medical Council No,		
have been caring for	ID No,			
aged years, since				
I certify that the above-mentioned of	child is at moderate to high risk of	a severe COVID-19 infection as		
he/she suffers from one of the condi-	tions that necessitates shielding as l	listed in Annex 2. This certificate		
is valid until further notice.				
Other comments (including any s	pecific measures for shielding at	school):		
Signature	Hospital Cor	nsultant Paediatrician Stamp		
Parent/Custodian Signature	Name in capitals	ID number		
Date				

### Possible additional measures for shielding in schools

- Minimise contact with other children and staff
- Maintain interpersonal distances of greater than 2m
- Choosing a seating plan which would decrease exposure of the child to other children and staff
- If aged under 11 years, students in same class and bubble also wear masks
- Use of physical barriers such as Perspex
- More frequent hand washing and sanitizing
- Enhanced cleaning
- Use of private transport

#### **Resources:**

Mandatory Standards and Guidances – Ministry for Health Malta https://deputyprimeminister.gov.mt/en/health-promotion/covid-19/Pages/mitigation-conditions-and-guidances.aspx

COVID-19 – 'shielding' guidance for children and young people (Royal College of Paediatrics and Child Health)

https://www.rcpch.ac.uk/sites/default/files/generated-pdf/document/COVID-19---%2527shielding%2527-guidance-for-children-and-young-people.pdf

Coronavirus (COVID-19): shielding advice and support (Scotland)

https://www.gov.scot/publications/covid-shielding/pages/highest-risk-classification/

Who's at higher risk from corona virus (NHS)

https://www.nhs.uk/conditions/coronavirus-covid-19/people-at-higher-risk/whos-at-higher-risk-from-coronavirus/

### Annex 2 - Paediatric conditions that may necessitate shielding September 2020<sup>17</sup>

The following are paediatric conditions for which children may be asked to shield. Advice to shield depends mainly on community transmission of SARS-CoV-2 and public health advice on when extremely vulnerable or less vulnerable people should shield. Degree of vulnerability is not the same for all conditions listed below, is also dependent on the severity of the condition and will be determined by the caring consultant.

Advice for shielding is also affected by:

- a) the complexity of the underlying condition,
- b) guidance given by the caring hospital consultant,
- c) age of the child, and the mental capacity of the child with respect to the ability to perform hand hygiene, respect social distancing and put on and take off a face mask safely and
- d) the capacities of schools to provide help with shielding of vulnerable children: schools need to be well prepared for this and work to provide inclusive education to all children irrespective of any underlying condition the child might have. There should be no form of discrimination against children who suffer from a condition that makes them vulnerable.

Conditions that may put children more at risk\* to COVID-19 are as follows:

\*Not all children with these conditions have the same risk to COVID-19 and the need for shielding may vary depending on the epidemiology of SARS-CoV-2.

<sup>&</sup>lt;sup>17</sup> Based on Covid-19 –shielding guidance for children and young people. RCPCH: 22nd September 2020

### Immunodeficiency disorders

- Primary or secondary immunodeficiency disorders if on prophylactic antibiotics or immunoglobulins AND on immunosuppressants (such as steroids for >4 weeks, or biologics) OR with a concurrent co-morbidity (significant lung disease, renal impairment, chronic liver disease).
- Following a bone marrow transplant for a primary immunodeficiency disorder AND
  are still within 12 months of the transplant OR are on immunosuppressants or
  immunoglobulins or have significant lung disease or ongoing Graft versus Host disease.
- HIV infection AND with a CD4 count less than 200 or had an opportunistic infection within the last 6 months or have detectable viral load or are not on any antiretroviral treatment.

### Oncology

- Are on induction chemotherapy for Acute Lymphoblastic Leukaemia (ALL) or Non-Hodgkin's lymphoma or are on chemotherapy for Acute Myeloid Leukaemia (AML) or for relapsed and/or refractory leukaemia or lymphoma.
- Are post autograft transplant in the last 6 months or post allogeneic transplant within the last 12 months or until immune reconstituted.
- Are on CAR-T therapy or within 6 months from administration or until immune system has recovered.
- Are on chemotherapy for any cancer diagnosis or within 6 months of its completion or are on long term maintenance steroids.
- Have completed treatment for cancer but have ongoing significant respiratory, cardiac, renal or neurological conditions.

#### Cardiology

- Fontan, single ventricle physiology, especially with evidence of failure, and or end organ damage.
- Persistent cyanosis (oxygen saturations <85% persistently)
- Pulmonary Arterial Hypertension (PAH) especially those on pulmonary vasodilator therapy.
- Infants under 1 year with unrepaired congenital heart disease requiring surgery or catheter intervention e.g. VSD, AVSD or tetralogy of Fallot.
- Severe cardiomyopathies requiring medication.
- Congenital heart disease on medication to improve heart function.

- Post heart transplantation.
- Congenital heart disease and significant co-existing conditions e.g. chronic kidney disease or chronic lung disease.
- Severe and or symptomatic heart failure, particularly those on heart failure therapy.

### Dermatology

High dose steroids, defined as ≥ 0.5mg/kg/day, for at least 4 weeks, within the last 4 weeks.

### Haematology

- Sickle cell disease with additional co-morbidities or with a history of at least one chest crises needing intensive care treatment or at least two chest crises necessitating treatment.
- Thalassaemia or other inherited or congenital anaemia with severe iron overload and additional co-morbidity.

#### Neonatal

- Ex-premature infants with continuing oxygen and/or intermittent non-invasive ventilation requirements.
- Any infant who is eligible for palivizumab.

### Neurology

- Patients with significant difficulty with swallowing (e.g. myotonic dystrophy patients).
- Patients at significant risk of decompensation during infection (e.g. mitochondrial disease).
- Patients with symptomatic heart failure, particularly those on heart failure therapy (e.g. Duchenne muscular dystrophy).
- Patients with myasthenic syndromes.

### Gastroenterology, Hepatology & Nutrition

- Paediatric inflammatory bowel disease (IBD) patients with ANY of the following:
  - Whilst on intravenous or oral steroids ≥20mg prednisolone (or >0.5mg/kg) or equivalent per day.
  - Have started biologic therapy plus immunomodulatory or systemic steroids within previous six weeks.
  - Have moderate to severely active disease not controlled by moderate risk treatments who may require an increase in treatment.

- Intestinal failure patients requiring Home Parenteral Nutrition (HPN) with any of the following:
  - Primary immunodeficiency or immunodeficiency induced by drugs as part of their therapy.
  - Other significant conditions or other organ involvement (renal, haematology, cardiac, GI, respiratory, diabetes mellitus).
  - Social cofactors (eg heavily reliant on support from healthcare professionals/carers).
- Liver disease with any of the following:
  - Decompensated liver disease.
  - Receiving post-transplant immunosuppression or on transplant waiting list.
  - Other significant conditions or other organ involvement (renal, haematology, cardiac, GI, respiratory, diabetes mellitus).
  - Active or frequently relapsing autoimmune liver disease where an increase in treatment is likely needed.

#### Renal

- Renal transplant especially if in the last 3 months.
- On a high level of immunosuppressive medication for active disease undergoing induction treatment: those who are currently receiving or completed treatment within 6 weeks of high dose steroids of 20 mg/day or above (or 30 mg/m2 /day) AND cyclophosphamide or rituximab or other immunosuppressants.
- Have renal disease and satisfy any of the following:
  - On haemodialysis
  - On 2 different immunosuppressants
  - Have active or frequently relapsing nephrotic syndrome

### Respiratory

- Have significant impairment in ability to cough and to clear airway secretions: including children with severe neurological diseases such as severe cerebral palsy, neuromuscular disabilities, severe motor impairment and severe metabolic disease.
- Require a cough assist device to help with clearance of airway secretions.
- Life-dependent on long term ventilation, both invasive (via tracheostomy) and non-invasive (CPAP and BiPAP).

• Severe lung disease requiring continuous or overnight supplementary home oxygen and/or intermittent non-invasive ventilation.

### • Children with:

- Cystic fibrosis and Primary ciliary dyskinesia.
- Severe bronchiectasis.
- Severe restrictive lung disease such as interstitial lung disease or obliterative bronchiolitis.
- Severe asthma: children treated with biological agents or maintenance oral steroids.
- Children with repaired congenital thoracic abnormalities such as congenital diaphragmatic hernia / trachea-oesophageal fistula only if significant airway or lung problem.

### Rheumatology / Paediatric ophthalmology

- On cyclophosphamide and/or high dose steroids, defined as ≥ 0.5mg/kg/day, for 4 or more weeks, within the last 4 weeks.
- Have unstable or flaring rheumatological disease.