DEFINE RCT: Guidance on identifying and recording acute exacerbations of asthma and referring events for adjudication

1. Consultations to be recorded on the GP Ambulatory Exacerbation CRF at the baseline and 12 months notes reviews (Medical Notes II)

- Record in this section any acute asthma-related episode which you feel **confident** is an **acute asthma exacerbation** and which was **definitively managed** in the GP surgery, emergency department or any other setting apart from a hospital inpatient ward.
- *Our protocol defines an acute asthma exacerbation as an acute asthma-related episode requiring treatment with antibiotics or systemic steroids, hospital admission or emergency department attendance.*
- *By definitively managed we mean the patient was prescribed treatment and/or provided with advice for the acute exacerbation and discharged home from that setting.*
- *Acute asthma exacerbations and other asthma-related episodes which required at least one overnight stay in hospital should be recorded on the **Hospital admission CRF**.*
- *For the 12 month notes review, please remember to document the relevant details of episodes recorded on the GP Ambulatory Exacerbation CRF on the **12M Medical Notes Contacts CRF** and record the reason for the consultation as 'Acute asthma exacerbation'. These details will be needed for the economic evaluation.*
- Information about acute exacerbations of asthma may be found in the following sections of the patient's electronic medical record (N.B. information relating to a single exacerbation may appear in more than one of these sections):

  1) Consultation notes – these will contain information about face-to-face and remote consultations with GP surgery staff.
  2) E-consults – these will contain information about patient queries submitted (and possibly also dealt with) via email by GP surgery staff.
  3) Discharge summaries – these will contain information about health care contacts in settings other than the GP surgery (e.g. primary care out of hours service, hospital).
  4) Appointment screen notes – these may contain information about why a particular appointment was requested, and may help provide explanations for antibiotic or oral steroid prescriptions which are either accompanied by a very brief consultation note or no consultation note at all.
  5) Tasks – these may contain information about requests requiring action from a member of GP surgery staff and help provide explanations for antibiotic or oral steroid prescriptions which are either accompanied by a very brief consultation note or no consultation note at all.
  6) Medications – check past medication issues for dates on which prescriptions for antibiotics or oral steroids were issued. Cross-checking these dates with information entered in the other sections listed above should help you find acute asthma exacerbation events.

1.1 Please record the following types of consultations as acute exacerbations of asthma if antibiotics or oral steroids were prescribed or consumed:

1. Consultations documented using **any of the following consultation codes**:
    - Acute asthma
    - Asthma attack
    - Asthma attack NOS
    - Status asthmaticus
    - Status asthmaticus NOS
    - Acute severe asthma

- Exacerbation of asthma
- Acute exacerbation of asthma
- Absence from work or school due to asthma

2. Consultations where the **free text** documents that the **clinician's impression is that the patient had an acute exacerbation of asthma or asthma attack** even if the consultation was not coded using any of the codes listed in point 1.
3. Consultations where the **free text** of the consultation documents any of the following **symptoms in the context of progressive worsening of asthma symptoms or the patient using their inhaler(s) more frequently than usual**:
    - Cough (especially 'chesty cough')
    - Wheeze
    - Chest tightness
    - Difficulty in breathing (may be shortened to DIB)
    - Shortness of breath (may be shortened to SOB)
    - Dyspnoea
4. Consultations where wheeze is documented as an **examination finding.**
5. Consultations where **nebuliser therapy** was prescribed or administered **in the context of progressive worsening of asthma symptoms or the patient using their inhaler(s) more frequently than usual**. Do <u>not</u> record the consultation as an acute exacerbation of asthma if the free text of the consultation or the patient's past medical history/prescription record indicates that the patient uses nebulisers on a regular basis (this can be the case in a minority of patients with severe asthma, especially if there is asthma-COPD overlap). These episodes may be recorded instead in the section on ambulatory management (baseline notes review) or medical notes contacts (12 month notes review).
6. Consultations where an **inhaler was administered during the consultation in the context of progressive worsening of asthma symptoms or the patient using their inhaler(s) more frequently than usual**.
7. Consultations where the **free text** of the consultation documents that the **patient took antibiotics or oral steroids from their rescue pack/home supply** for worsening asthma symptoms or an acute exacerbation of asthma, **whether or not** they consulted a health care professional about this first.
8. Consultations where the clinician prescribed antibiotics without oral corticosteroids but also advised the patient to take oral steroids **immediately** from their rescue pack/home supply in addition.
    - If the clinician advised the patient to take oral corticosteroids from their rescue pack/home supply <u>only if their condition did not improve or deteriorated</u>, **or** issued a prescription for oral corticosteroids but advised the patient to take these <u>only if their condition did not improve or deteriorated</u>, please check:
        i. The patient's medical record over the remaining duration of the notes review period (including consultation notes, e-consults, discharge summaries, appointment screen notes, tasks and past medication issues) to see if the patient informed the GP surgery or another health care setting that they had taken the oral corticosteroids. If there is documented evidence that the patient reported taking the oral corticosteroids, document the event as an acute exacerbation of asthma on the **GP Ambulatory Exacerbation CRF**. If there is no documented evidence that the patient reported taking the oral corticosteroids, document the event on the **GP Ambulatory Management CRF**.
        ii. The patient's **medication record** over the following **2-week period** to see if any further prescription for oral corticosteroids was issued during that time. If a prescription was issued (suggesting that the patient took the oral corticosteroids and requested a further prescription to replenish their supply), document the event as an acute exacerbation of asthma on the **GP Ambulatory Exacerbation CRF**. If a prescription was issued more than 2 weeks after the consultation <u>and</u> accompanied

by documented evidence elsewhere in the medical record that the prescription was issued to replenish the patient's supply after they took oral corticosteroids for the index event, please also record this on the **GP Ambulatory Exacerbation CRF**. If a prescription was issued more than 2 weeks after the consultation and not accompanied by documented evidence elsewhere in the medical record that the prescription was issued to replenish the patient's supply after they took oral corticosteroids for the index event, or if a prescription was not issued at any subsequent point during the notes review period, document the event on the **GP Ambulatory Management CRF**.

2.Consultations to be recorded in the GP Ambulatory Management CRF at baseline and 12 months (Medical Notes III):

2.1 Events to be referred for clinical adjudication (applicable to 12 month notes review only)

Please refer the following events for clinical adjudication:

2.1.1 Events where the clinician prescribed antibiotics without oral corticosteroids for any **upper or lower respiratory tract infection other than pneumonia** AND there is **no indication** in the consultation code or free text of **ANY** of the following:

a) the clinician's impression was that the patient had an acute exacerbation of asthma
b) antibiotics were prescribed in the context of symptoms suggestive of asthma (cough, wheeze, chest tightness, difficulty in breathing, shortness of breath, dyspnoea),
c) antibiotics were prescribed in the context of the patient reporting more frequent inhaler use as a result of progressive worsening in asthma symptoms.
d) prescription or administration of nebuliser therapy, or administration of an inhaler during the consultation **in the context of** progressive worsening in asthma symptoms
e) wheeze on examination

If there is any indication in the consultation code or free text that the clinician's impression is that the patient had pneumonia, there is no need to refer the event for adjudication but you should still record It on the 12M Medical Notes Contacts CRF.

If the consultation code or free text documents that the clinician's impression is that the patient had an acute exacerbation of COPD, there is no need to record the episode on the CRF or refer the episode for clinical adjudication.

2.1.2 Events where the clinician prescribed antibiotics without oral corticosteroids and the **only** documented evidence suggestive of asthma is **EITHER:**

1) patient advised to increase their inhaled corticosteroid or ICS-LABA (combination inhaler) dose (*patients may be asked to do this even if the clinician's impression is that the patient has a respiratory tract infection but not an acute exacerbation of asthma*)

OR

2) Peak expiratory flow rate (PEFR) at least 20% lower than best PEFR or previously recorded PEFRs or predicted PEFR (if neither best nor previous PEFRs are documented in notes) (*this finding may still be present in patients who have a respiratory tract infection which is not clinically suspected to be an acute exacerbation of asthma*).

Specifically, there must be **no documented evidence** of **ANY** of the points listed in **section 2.1.1 a) to e)** alongside either of the above.

If there is documented evidence of **both 1) and 2)** in the **absence** of any of the points listed in **section 2.1.1 a) to e)** then the event should also be referred for adjudication.

To refer an event for clinical adjudication:

- Create a **Word document** detailing **all** relevant information from the patient's electronic medical record for clinical adjudication. Please provide information which documents the **entire illness episode** for which the patient consulted. This may include information from consultation notes, e-consults, discharge summaries, appointment screen notes or tasks.
- **Please remove any patient identifiers or details which indicate which arm of the trial the patient was randomised to from your Word document.**
- In Open Clinica:

  1) Record the 'reason for contact' as 'other' and specify the reason as "possible exacerbation requiring adjudication"

  2) Answer 'yes' to 'Does episode require clinical adjudication?'

  3) Select the reason why the episode requires clinical adjudication. You may select **one** of the following options:

     1) Antibiotics prescribed without oral corticosteroids for an upper or lower respiratory tract infection other than pneumonia, and no documented evidence to suggest an acute asthma exacerbation (see section 2.1.1 of the guidance notes for further details)

     2) Antibiotics prescribed without oral corticosteroids for an upper or lower respiratory tract infection other than pneumonia and only documented evidence of asthma is advice to increase ICS or ICS-LABA dose, or reduction in peak expiratory flow rate (PEFR) or both (see section 2.1.2 of the guidance notes for further details). N.B. Please include documentation of the patient's best PEFR, previous PEFRs, or predicted PEFR if you have selected this reason based on the patient's PEFR reading. If none of these are available in the electronic medical record, please include information on the patient's age, gender and height so that a predicted PEFR can be calculated.

  4) **Tick the box** asking you to confirm that you have **de-identified and blinded** all information being submitted for clinical adjudication.

  5) Upload your **de-identified and blinded** Word document to Open Clinica.

2.2 Consultations where the patient was initially assessed in a particular health care setting (e.g. GP surgery) and immediately referred to another health care setting for further assessment the same day (e.g. hospital).

If you answer the question 'Was the patient admitted to hospital?' as 'Yes' but there is no available hospital discharge summary in the patient's electronic medical record for you to complete the hospital admissions section of the CRF, please if possible check the notes again at a later date (e.g. up to 2 months after the date when the hospital admission is indicated to have taken place) and if there is still no discharge summary flag this to the study/data team to check whether the patient has provided details of the hospital admission in their REDCap questionnaire.

2.3 Consultations related to the patient's asthma or problems caused by their asthma which were definitively managed in GP surgeries or other ambulatory settings but which are not acute exacerbations of asthma.

Flowchart: Identifying acute asthma exacerbations and events to refer for independent adjudication