CASE REPORT FORMS

Management of Acute Severe Ulcerative Colitis (MASC)

Study period: 1st February 2019 – 31st January 2020

CRF version 3.0 (16th April 2019)
Case report form A – Patient Data at Admission

To be completed at admission / diagnosis of ASUC

Inclusion criteria
- Patient with previous diagnosis of ulcerative colitis, hospitalized for acute severe colitis (ASUC)

OR
- Patient without a previous diagnosis of ulcerative colitis, hospitalized for acute severe acute colitis, in whom infectious/ischemic colitis has been discarded

Note that the patient can be admitted for the treatment of ASUC or this could have developed whilst an inpatient

Exclusion criteria
- Patient younger than 16 years old
- Diagnosis of infectious or ischemic colitis in patients without previous diagnosis of UC

- Date of admission:
- Was the patient admitted primarily for the treatment of ASUC? Yes / No
  If "Yes": date of diagnosis (only the year) Date the colitis was defined as "severe" during hospitalisation:

- Truelove criteria AT DIAGNOSIS OF ASUC
Acute severe ulcerative colitis is defined as bloody stool frequency ≥6 per day <u>and at least ONE of the following: pulse rate >90 bpm, temperature >37.8 °C, haemoglobin < 10.5 g/dL, ESR > 30 mm/h or CRP >30 mg/l.

  Bloody stools/day ≥ 6: yes/no
  And
  Pulse >90 bpm: yes/no/unknown
  Temperature >37.8°C: yes/no/unknown
  Haemoglobin <10.5 g/dl: yes/no/unknown
  ESR >30 mm/h: yes/no/unknown
  CRP >30mg/l: yes/no/unknown

Demographics and Patient History
- Sex: Male/female
- Age (Patient age at entry to the MASC audit):

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- Was ulcerative colitis already diagnosed before admission? Yes/No, this is the first episode
  If "Yes": Year of diagnosis:
- Previous inpatient admission with a diagnosis of acute severe ulcerative colitis?: Yes/No
  If "Yes": How many previous admissions
- Admission ward: Gastroenterology/ Surgery/ Other
  If Other ward please specify:
- Previous appendectomy: Yes/No
- History of diabetes mellitus (Include diet, tablet and insulin controlled DM): Yes/No
- Smoking History: Never/Ex-smoker: stopped more than 6 weeks ago/Ex-smoker, stopped less than 6 weeks ago / Current smoker
- Weight (Kg)
- Height (cm)
- Location of Disease (Montreal Classification): E1- Proctitis/E2 - Left-sided colitis/E3 - Extensive Colitis (proximal to splenic flexure)

**Investigations at admission (+/- 24 hours)**
- Albumin at admission (g/L or mmol/L)
- Haemoglobin at admission (mg/L or g/dl or mmol/l)
- CRP at admission (mg/L or mg/dl)
- Faecal calprotectin at admission (ug/g or mg/kg)
- Colonic dilatation on abdominal x-ray at 3rd day of admission (>5.5cm in transverse colon):
  yes/no/x-ray not performed

**Concomitant Therapy**
- Concomitant therapy for ulcerative colitis immediately before admission: Yes /No
  If Yes:
  o  **Topical Steroids by mouth:** yes/no
    If yes, specify: budesonide/ budesonide MMX/beclomethasone dipropionate
    Dosage (mg/day)
  o  **Systemic steroids by mouth:** yes/no
    If yes, specify: methylprednisolone/hydrocortisone/prednisone, prednisolone/other
    Dosage (mg/day)
  o  **Topical Steroids via rectum:** yes/no
If yes, specify: Prednisolone suppositories / Prednisolone enema / Hydrocortisone suppositories / Hydrocortisone enema / Budesonide enema
Dosage (mg/day)
- Mesalazine: yes/no
  If yes: topical/Systemic (both options are possible)
- Thiopurines: yes/no
  If yes, specify: azathioprine / mercaptopurine/6-thioguanin
- Methotrexate: yes/no
- Calcineurin inhibitors: yes/no
  If yes, specify: Tacrolimus/Cyclosporine
- Tofacitinib: yes/no
- Biologics: yes/no
  If yes:
  - Anti – TNF: infliximab, adalimumab, golimumab, certolizumab pegol
  - Anti – integrin: vedolizumab
  - Anti – IL12/23: ustekinumab
  - Other biologicals, please specify

When was the treatment started? (year, month)
When was the last dose given before admission? (DD-MMM-YYYY)

Case report form B – Medical management
To be completed at discharge or 90 days after the date of admission, whichever is sooner

Initial management
- Was there any form of nutritional support? Yes/no
  if yes: conventional enteral nutrition: yes/no
  immune-enhanced enteral nutrition: yes/no
  parenteral nutrition: yes/no
  if yes: exclusive parenteral nutrition: yes/no
- Were stool cultures obtained on admission? Yes / no
  If yes: were they positive/negative
  If positive: specify bacteria
- Were parasites and ova evaluated on admission? Yes / no
If yes, were they present: yes/no

- Was Clostridium difficile infection evaluated on admission? Yes / no
  
  If yes, was it present: yes/no
  
  If yes, was antibiotic treatment given: yes/no

- Were prophylactic antibiotics prescribed? Yes / no

- Was cytomegalovirus (CMV) infection ruled out? Yes / no
  
  If yes:
  - Technique: Immunohistochemistry / PCR (viral load) on colonic biopsy / serology / PCR (viral load) in blood
  - Did the patient receive antiviral therapy? Yes / no
    
    If yes: oral/iv

- Was prophylaxis with low molecular weight heparin initiated? Yes / no

**Endoscopy**

- Was endoscopy performed during the admission? Yes / no
  
  o Date of endoscopy:
  
  o Type of examination: flexible rectosigmoidoscopy / complete colonoscopy
  
  o Most severe Mayo endoscopic score for the rectum (0 – 3)
  
  o Most severe Mayo endoscopic score anywhere above the rectum (0 – 3)
  
  o Most severe UCEIS score for the rectum:
    - Vascular pattern (normal/patchy obliteration/obliterated)
    - Bleeding (none/mucosal/luminal mild/luminal moderate or severe)
    - Erosion and ulcers (none/erosions/superficial ulcer/deep ulcer)
  
  o Most severe UCEIS score anywhere above the rectum:
    - Vascular pattern (normal/patchy obliteration/obliterated)
    - Bleeding (none/mucosal/luminal mild/luminal moderate or severe)
    - Erosion and ulcers (none/erosions/superficial ulcer/deep ulcer)

**Initial Medical Treatment**

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- **Type of steroids used:** methylprednisolone/prednisone/prednisolone/hydrocortisone/beclomethasone dipropionate/budesonide, budesonide MMX/other/none
  
  If "none": why? (free text)

- **Initial dose of steroids (mg/day)**

- **Route of administration of steroids:** Oral/iv
  
  o In case of iv steroids: bolus/continuous perfusion

- **Date of beginning of the treatment with steroids (date):**

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**Progress at day 3-5 after starting treatment for ASUC**

- Albumin at day 3-5 (g/L or mmol/L)
- Haemoglobin at day 3-5 (g/L or g/dl OR mmol/l)
- CRP at day 3 (mg/L or mg/dl)
- Stool frequency at day 3
- Blood stool frequency at day 3
- Stool frequency at day 5
- Blood stool frequency at day 5

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**Response and rescue medical therapy**

- Response (evaluated by the gastroenterologist at discharge): steroid-refractory/steroid-responsive

  If steroid-refractory: Rescue Medical Therapy / Surgery (Please fill out CRF C)

  If Rescue Medical Therapy: Cyclosporine/Infliximab

  If Cyclosporine
  
  o Date of first dose:
  o Date of last i.v. dose:
  o Response (adequate/inadequate)
  o Starting Dose: 2 mg/kg or 4 mg/kg
  o Maximum blood levels of Cyclosporine during induction:
    <150 ng/mL, 150-250 ng/mL, 250-350 ng/mL, >350 ng/mL
    / Not available

  If Infliximab
  
  o Dose of first infusion: 5 mg/kg/10 mg/kg/other (specify)
  o Date of first dose:
  o Response (adequate/inadequate)
  o Was tuberculosis ruled out before starting infliximab? Yes/no
• If Yes: Methods (multiple choice): contact history / plain X ray / PPD / IGRA
• If any of them was positive, did the patient receive prophylaxis against TB?
  o First blood determination of levels of infliximab (µg/mL):
  o Date of the first blood determination of levels of infliximab
  o Second blood determination of levels of infliximab (µg/mL):
  o Date of the second blood determination of levels of infliximab
  o Was a second dose of infliximab administered during the admission? Yes / No
    ▪ Date of second infusion
    ▪ Dose of second infusion: 5 mg/kg/10 mg/kg/other (specify)
  o Was a third dose of infliximab administered during the admission? Yes / No
    ▪ Date of third infusion
    ▪ Dose of third infusion: 5 mg/kg/10 mg/kg/other (specify)

If 'Other' rescue medical therapy please specify medication:

If steroid-steroid responsive: Despite responding to steroids was a decision made to start rescue medical therapy whilst an inpatient? Yes / No
  If No: Was surgery necessary? Yes (please fill out CRF C) / No
  If Yes: If Rescue Medical Therapy: Cyclosporine/Infliximab
    If Cyclosporine
      o Date of first dose:
      o Date of last i.v. dose:
      o Response (adequate/inadequate)
      o Starting Dose: 2 mg/kg or 4 mg/kg
      o Maximum blood levels of Cyclosporine during induction:
        <150 ng/mL, 150-250 ng/mL, 250-350 ng/mL, >350 ng/mL / Not available
    If Infliximab
      o Dose of first infusion: 5 mg/kg/10 mg/kg/other (specify)
      o Date of first dose:
- Response (adequate/inadequate)
- Was tuberculosis ruled out before starting infliximab? Yes / no
  
  If Yes:
  - Methods (multiple choice): contact history / plain X ray / PPD / IGRA
  - If any of them was positive, did the patient receive prophylaxis against TB?

- First blood determination of levels of infliximab (μg/mL):
- Date of the first blood determination of levels of infliximab
- Second blood determination of levels of infliximab (μg/mL):
- Date of the second blood determination of levels of infliximab
- Was a second dose of infliximab administered during the admission? Yes / No
  - Date of second infusion
  - Dose of second infusion: 5 mg/kg/10 mg/kg/other (specify)

- Was a third dose of infliximab administered during the admission? Yes / No
  - Date of third infusion
  - Dose of third infusion: 5 mg/kg/10 mg/kg/other (specify)

- Was a third line medical therapy administered (Cyclosporine ➔ Infliximab or Infliximab ➔ Cyclosporine)? Yes / no
  - Type of third line medical therapy: Cyclosporine / infliximab
  - Date of initiation:
    - Was surgery necessary? Yes / no
      If yes, fill CRF C

- Any other complication of the medical management that did not need surgical treatment? Yes/no
  
  If yes, please detail (more than one option is possible):
pneumonia/central line infection/ urinary tract infection/ other
infectious (Specify)/cardiac complications/neurologic complications/
renal complications/ other no infectious (specify)
Case report form C – Surgical data and postoperative complications

To be completed at surgery (surgical data) and at discharge (postoperative complications)

- Date of Surgery
- Indication for Surgery: Colitis refractory to medical treatment/toxic megacolon/perforation/bleeding
- Type of procedure: proctocolectomy/proctocolectomy and pouch/total colectomy/subtotal colectomy/right side resection/left side resection
- ASA: I/II/III/IV/V
- Most senior surgeon present at operation: Colorectal Trainee/Colorectal consultant/general surgery trainee/General surgery consultant
- Operative approach: open/mini-invasive

If mini invasive,
- please detail: Laparoscopic/Laparoscopic single incision/ hand-assisted/Robotic
- site of specimen extraction: ileostomy site/Pfannenstiel/other transverse incision/median line incision
- conversion to open surgery? Yes/No

If converted:
- Were flexures taken down laparoscopically? Yes/no
- Main reason for conversion: Access/adhesions/dilated colon/Bleeding/ Visceral injury/ Failure to progress/ To deal with rectal stump transection (due to active disease)/ Difficult mesentery (to deal with mesenteric blood supply on outside)

- Operation duration (minutes from incision to skin closure)
- intra-operative blood transfusion: yes/no
- intra-operative complications: none/vascular injury/ bowel injury (e.g. duodenum)/ injury to other organs or structures (e.g. ureter)
- rectal stump treatment: no rectal stump / open mucous fistula/ mucous fistula closed in the subcutaneous/ closure at the pelvic brim/low closure at the pelvic floor
- postoperative admission to intensive care unit: no admission to ICU/planned from operating theatre/ unplanned, from Ward /unplanned, from operating theatre
Post-operative complications
- Where there any post-operative complications? None / One / More than one
  If One:
    Type of complication: abdominal infectious complication, extra-abdominal infectious complication, bleeding, medical no infectious complication
    Clavien-Dindo grade: Grade I / Grade II / Grade IIIa / Grade IIIb / Grade IVa / Grade IVb / Grade V
  If More than one:
    Type of worst complication: abdominal infectious complication, extra-abdominal infectious complication, bleeding, medical no infectious complication
    Clavien-Dindo grade of the worst complication: Grade I / Grade II / Grade IIIa / Grade IIIb / Grade IVa / Grade IVb / Grade V

Comprehensive complication index (CCI):
- rectal stump leak (if rectal stump was closed): no/yes, no radiological or surgical intervention needed/yes, radiological drain needed/yes, surgery needed date of diagnosis
- intra-abdominal or pelvic collection: yes/no if yes, date of diagnosis
- surgical site infection: none/superficial SSI/deep SSI/organ space SSI
- reoperation: yes/no if yes: date cause: rectal stump complication/bowel obstruction/stoma-related complications/wound complications/bleeding/other (specify)
Case report form D – Discharge and Follow-up

To be completed at discharge and at the end of follow-up (minimum 90 days after the date of admission)

- date of discharge:
- weight (kg) at discharge
- where was the patient discharged? Home/other recover facility
- date of last follow-up during the study period:
- weight (kg) at last follow-up:
- readmission (minimum follow-up 90 days): yes/no
  
  if Yes: Date of readmission
  
  cause of readmission, please select all that apply: IBD flare/post operative complication (specify)/ Admitted for colectomy surgery/other (specify)

- mortality (minimum follow up 90 days): yes/no
  
  if yes: Date of death
  
  cause: post operative complication (specify)/other medical complication (specify)/related to IBD/other /specify)

- total days of hospitalization (including readmissions)
- in case of a newly diagnosed ulcerative colitis was the diagnosis confirmed by the pathologist during the admission or the follow up? Yes/No
  
  If yes: UC diagnosed in a biopsy obtained by endoscopy: yes/no
  
  UC diagnosed in the specimen resected during surgery: yes/no

- Did the patient undergo surgery before the first discharge? Yes/No

If NO surgery before first discharge

- Date of first outpatient visit after discharge
- Partial Mayo score after 60-90 days
  
  o Stool frequency (0-3)
  o Rectal bleeding (0-3)
  o Physician’s global assessment (0-3)
  o Date of assessment

- Was oral cyclosporine prescribed? Yes/no
  
  o Dose (mg/day)

- Was azathioprine prescribed? Yes/no
  
  o Date of initiation
  o Dose (mg/kg) or mg/day

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- Were steroids stopped before discharge? Yes / no
  - Date of withdrawal
- Did the patient receive prophylaxis against *pneumocystis jiroveci*? Yes/no (previously *P. carinii*)
- Cumulative dose of infliximab during the first 90 days after diagnosis (mg/kg)

**Was rescue therapy continued as maintenance therapy after hospital discharge? Yes / No**

If Yes:
- Was anti-TNF maintenance therapy prescribed (yes/no)
  - If "yes":
    - "which anti-TNF?" (infliximab / adalimumab/golimumab/certolizumabpegol)
    - "which dose?" and "frequency of administration" (copy questions already present in CRF)

If "No":
- Was anti-TNF therapy newly prescribed after discharge (yes/no)
  - If "yes":
    - "which anti-TNF?" (infliximab / adalimumab/golimumab/certolizumabpegol)
    - "which dose?" and "frequency of administration" (copy questions already present in CRF)

**Complications after discharge**

Did the patient experience any complications after discharge? No / One / More than one

If One:
- Type of complication: abdominal infectious complication, extra-abdominal infectious complication, bleeding, medical no infectious complication, other (specify)
- Clavien-Dindo grade of complication after discharge: Grade I / Grade II / Grade IIIa / Grade IIIb / Grade IVa / Grade IVb / Grade V

If More than one:
- Type of worst complication: abdominal infectious complication, extra-abdominal infectious complication, bleeding, medical no infectious complication, other (specify)
- Clavien-Dindo grade of the worst complication that occurred after discharge: Grade I / Grade II / Grade IIIa / Grade IIIb / Grade IVa / Grade IVb / Grade V
- Comprehensive complication index of complications that occurred after discharge (CCI):
If one or more complications after discharge:

- rectal stump leak after discharge (if rectal stump was closed): no/yes, no radiological or surgical intervention needed/ yes, radiological drain needed/ yes, surgery needed
date of diagnosis

- intra-abdominal or pelvic collection after discharge: yes/no
  if yes, Clavien-Dindo grade
date of diagnosis

- surgical site infection after discharge: none/ superficial SSI / deep SSI / organ space SSI
  if yes, Clavien-Dindo grade
date of diagnosis

- reoperation after discharge (minimum follow up 90 days): yes/no
  if yes : date
  cause: rectal stump complication/bowel obstruction/stoma-related complications/wound complications/bleeding/other
  (specify)

Unit Questionnaire

We will contact sites at a later stage to request information on your centre.

<table>
<thead>
<tr>
<th>Is your centre a:</th>
<th>University hospital/ tertiary centre; District general hospital;</th>
</tr>
</thead>
<tbody>
<tr>
<td>In your centre does exist an IBD digestive Unit (gastroenterologist)?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>How many IBD specialists (Gastroenterology, Internal Medicine) are in your hospital?</td>
<td>(number)</td>
</tr>
<tr>
<td>Is there a dedicated IBD Nurse specialist in your hospital?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>How many beds does the Gastroenterology Department have in your hospital?</td>
<td>(number)</td>
</tr>
<tr>
<td>How many admissions per year does the Gastroenterology Department have in your hospital?</td>
<td>(number)</td>
</tr>
<tr>
<td>Is there an outpatient facility (Day Hospital) where IBD treatments can be</td>
<td>Yes/No</td>
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<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
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<tr>
<td>administered intravenously?</td>
<td></td>
</tr>
<tr>
<td>In your centre does exist a formal multidisciplinary team for IBD?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>In case a multidisciplinary IBD team exists, do you meet regularly</td>
<td>No/Once a month/Twice a Month/Every week/ Other (specify)</td>
</tr>
<tr>
<td>How many consultant-level surgeons perform colorectal resection operations at your site?</td>
<td>(number)</td>
</tr>
<tr>
<td>How many surgeries for ASUC per year at your site?</td>
<td>(number)</td>
</tr>
<tr>
<td>How many consultant-level surgeons perform IBD resections at your site?</td>
<td>(number)</td>
</tr>
<tr>
<td>How many consultant-level specialist colorectal surgeons are at your site</td>
<td>(number)</td>
</tr>
<tr>
<td>How many beds are in your hospital in total (all specialties)?</td>
<td>(number)</td>
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<tr>
<td>How many general surgical beds are in your hospital?</td>
<td>(number)</td>
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<tr>
<td>How many high dependency (HDU) and intensive care (ITU) beds are in your hospital?</td>
<td>(number)</td>
</tr>
</tbody>
</table>