Case Report Form CovidSurg-Cancer-Bladder

NB: Additional data points may be required for specific cancer types

NIHR Global Health Research Unit on Global Surgery | CovidSurg

Patient **REDCap ID**:_____

Age: 0-4w | 4-52w | 1-9y | 10-16y | 17-19y | 20-29y | 30-39y | 40-49y | 50-59y | 60-69y | 70-79y | 80-89y | 90y+ **Sex**: Female | Male | **ASA Grade**: 1 | 2 | 3 | 4 | 5 **Weight** (<52 weeks only):_____ kg

WHO/ECOG Performance status: 0 | 1 | 2 | 3 | 4 | 5 | Unknown

BMI:

□ Underweight (<18.5)
□ Normal/healthy weight (18.5-24.9)
□ Overweight (25-29.9)
□ Moderately obese (30-34.9)
□ Severely obese (35-39.9)
□ Very severely obese (≥40)

Comorbidities:

□ Current smoker
□ Asthma
□ Current cancer disease
□ CKD (Moderate/Severe)
□ COPD
□ Congenital abn (cardiac)
□ Congenital abn (non cardiac)
□ Congestive heart failure
□ Dementia
□ Diabetes Mellitus
□ Hypertension
□ Myocardial Infarction
□ Peripheral Vascular Dis
□ Stroke/TIA
□ Other: _____

Cancer-specific details:

Tumour type: □ Bladder □ Prostatic urethra

Was a Transurethral Resection of Bladder Tumour (TURBT) performed? □ Yes □ No **Date of TURBT:** ___/__/____

Why was no TURBT performed?

□ Patient choice □ Risk to patient □ No capacity □ Other:_____

Was the TURBT performed as an emergency?

□ Yes, for bleeding □ Yes, other reason □ No, planned/elective op

Baseline **T-stage (based on clinical, radiological and pathological information)**

T stage: Carcinoma in situ | Ta | T1 | T2 | T3 | T4 | Unknown
N stage: N0 | N1 | N2/3 | unknown **M** stage: M0 | M1 | unknown

Date of cancer **diagnosis**: ___/__/____

Date of **initial treatment decision** : ___/___/____

Was the post-TURBT MDT (tumour board) or surgeon's decision for definitive surgical treatment i.e cystectomy

Yes – decision for surgical Rx (optimal treatment option) | Yes – decision for surgical Rx (compromised option due to COVID-19) | No – decision for non-surgical Rx (optimal treatment option) | No – decision for non-surgical Rx (compromised option due to COVID-19)

Definitive treatment planned after TURBT

□ Endoscopic surveillance □ Intravesical BCG □ Intravesical chemotherapy □ Curative surgery □ Radiotherapy □ Palliative radiotherapy □ No further treatment planned □ Other:_____

Did this represent a compromised treatment option?

□ Yes, compromised by COVID □ Yes, compromised unrelated to COVID □ No optimal treatment option

Did the patient have a cystectomy related to this cancer during the 3-month study window? No / Yes

If a cystectomy WAS performed: Date of cystectomy: ___/__/____

Urgency of surgery: Immediate | Urgent | Expedited | Elective

Cystectomy performed in: Dedicated COVID-free hospital | Dedicated COVID Rx hospital | Undesignated hospital type with ED | Undesignated hospital type without ED | Other:_____

COVID-19 CRITCON level: 0 | 1 | 2 | 3 | 4 | 5

Did the patient have a ***resolved* COVID-19 infection** before the time of cystectomy? Yes – lab test/CT thorax | Clinical suspicion | No

Was **COVID-19 screening** performed preoperatively?

Laboratory test | CT thorax | Other: _____

Did patient have mandatory self-isolation before cystectomy?

Yes, > 2 weeks | Yes - < 2 weeks | No

COVID-19 suspected at time of surgery? Yes | No

Tests performed to investigate SARS-CoV-2 status:

	CT (neg)	CT (pos)	Swab (neg)	Swab (pos)
4-7 days prior surgery	□	□	□	□
1-3 days prior surgery	□	□	□	□

Did any change to treatment occur due to the COVID-19 pandemic (operated patients)**?**

No change to care, no neoadjuvant Rx | No change – neoadjuvant equivalent to pre-COVID | Delay to definitive Rx | Expedited definitive surgery | Change in choice of operation | Op performed in alt. hospital | IR procedure before surgery, not typically indicated | Neoadj treatment, not typically indicated | No Neoadj, typically indicated | Neoadj treatment longer than typical | Neoadj treatment shorter than typical | Adj treatment, not typically indicated | No adj, typically indicated | Other:_____

If a cystectomy WAS performed:

If **emergency cancer surgery** was required, why?

□ Gastro-intestinal obstruction □ Bleeding □ Sepsis □ Tumour progression □ Organ perforation □ Other:_____

Anaesthesia: Local | Regional | General

Operation performed? _____

Approach: Open | Minimally invasive | Converted to open

Operation components performed

□ Radical cystectomy □ Partial cystectomy □ Ileal conduit □ Orthotopic substitution □ Other:_____

Did this represent a change to your typical operative approach in the pre-COVID-19 era?

□ No change to operative approach
□ Yes, chose to avoid minimally invasive surgery related to COVID
□ Yes, chose to avoid open surgery related to COVID

Surgical **intent**: Curative | Palliative

Environment in which patient cared for:

Operative theatre – Designated COVID theatre | Designated non-COVID theatre | No designation for theatre

ITU – Designated COVID treatment area | Designated non-COVID treatment area | No designation for this area

Postop ward– Designated COVID ward| Designated non-COVID ward| No designation for this ward

Post-operative histology:

T stage: Carcinoma in situ | Ta | T1 | T2 | T3 | T4 | Unknown
N stage: N0 | N1 |N2 | unknown **M** stage: M0 | M1 | unknown

Resection margin status: R0 | R1 | R2 | Unknown

Details of neoadj Rx: _____

Did surgeons contract COVID-19 (30-days): Yes | No

If NO operation was performed (by 3 months from study entry)

Is there **still** a plan for curative surgery? Yes | No

Why was no operation performed in the 3 months?

If still plan for surgery:

□ Patient choice to avoid surgery during pandemic
□ MDT decision to delay surgery due to risk to patient
□ Ongoing neoadjuvant treatment
□ No bed / intensive care space / theatre space
□ Change of recommendations in society guidelines
□ Other:_____

If no ongoing plan for surgery:

□ Patient choice to avoid surgery during pandemic
□ MDT decision to delay surgery due to risk to patient
□ Disease progression, surgery no longer indicated
□ Change in clinical status unrelated to cancer e.g. MI
□ Died awaiting surgery
□ Change of recommendations in society guidelines
□ Change to alternative treatment modality
□ Other: _____

Has the cancer been **re-staged**? No | Yes **If so**, date__/__/__

T stage: Carcinoma in situ | Ta | T1 | T2 | T3 | T4 | Unknown
N stage: N0 | N1 |N2 | unknown
M stage: M0 | M1 | unknown

Did any change to treatment occur due to the COVID-19 pandemic (non-operated patients)**?**

No change to care – delayed/cancelled other reason | Operation cancelled because of COVID-19 | Operation delayed because of COVID-19 | Change in Rx strategy | IR procedure before/instead of surgery, not typically indicated | Neodj treatment, not typically indicated | No Neoadj, typically indicated | Neoadj treatment longer than typical | Neoadj treatment shorter than typical | Less access to staging procedures | Less access to staging investigations | Other_____

Outcomes

COVID-19 post-operatively (30 days): Yes – lab test | Yes – CT thorax | Yes– clinical only | No

If yes: Inpatient | Required Admission | Community

Mortality: Died on table | d0-7 | d8-30 |

Alive still in hosp 30d | transferred | discharged to rehab | discharged home **Re-operation**: Yes | No

Timing of reoperation

□ During index admission □ Readmission with complications

Post-op intensive care: No | planned from theatre | unplanned from theatre | unplanned from ward

If a cancer operation WAS performed:

Complications:

□ Acute kidney injury
□ ARDS
□ Anastomotic leak
□ Blood transfusion
□ Cardiac arrest
□ Coma >24h
□ Deep Vein Thrombosis
□ Graft/prothesis/flap fail
□ Myocardial infraction
□ Pneumonia
□ Respiratory failure
□ Sepsis
□ Septic shock
□ Stroke/TIA
□ SSI superficial/deep
□ SSI organ space
□ UTI
□ Wound dehiscence

(If no/unplanned from ward): **Would post-operative ICU bed have been planned pre-COVID-19 era?** Yes, not available ~ COVID| Yes, not available (other)| No Total **length of hospital stay**: ____days

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Case Report Form CovidSurg

*NB: Complete this CRF <u>only</u> for patients that are eligible for **both** studies (operated cancer patients with COVID-19 infection)*

CovidSurg

Patient **REDCap ID**:_____

COVID-19 Patient Information

BCG/Tuberculosis(TB) status
Vaccine - <15yrs ago | Vaccine – 15>yrs ago | TB diagnosis <15yrs ago | TB diagnosis >15yrs ago | Close contact with individual with known TB <15yrs ago | Close contact with individual with known TB >15yrs ago | No previous BCG vaccine/TB exposure | BCG vaccination/TB exposure unknown

Findings at admission:

- ☐ Abdominal pain
- ☐ Dyspnoea
- ☐ Cough
- ☐ Diarrhoea
- ☐ Fatigue
- ☐ Fever >38C
- ☐ Haemoptysis
- ☐ Myalgia
- ☐ Nausea/vomiting
- ☐ Sputum
- ☐ Other:_____

COVID-19 Preoperative Investigations

Last available data from before surgery:
Resp rate: _____ rpm **Heart rate**:_____ bpm
Systolic BP:_____ mmHg Diastolic BP:_____ mmHg

Tests performed to investigate SARS-CoV-2 status:

	CT (neg)	CT (pos)	Swab (neg)	Swab (pos)
4-7 days prior surgery	☐	☐	☐	☐
1-3 days prior surgery	☐	☐	☐	☐
Day of surgery (preop)	☐	☐	☐	☐
After surgery (during index admission)	☐	☐	☐	☐
After discharge from index admission (within 30 days of surgery)	☐	☐	☐	☐

How was SARS-CoV-2 confirmed?

- ☐ Positive swab – result received before surgery
- ☐ Positive swab – result received after surgery
- ☐ CT scan of chest confirming COVID-19 – before surgery
- ☐ CT scan of chest confirming COVID-19 – after surgery
- ☐ Clinical diagnosis/chest X-Ray – before surgery
- ☐ Clinical diagnosis/chest X-Ray – after surgery

<u>Pre-op investigations:</u>
Haemoglobin:_____g/L WCC:_____10^9/L CRP:_____mg/L

Pre-op x-ray:

- ☐ Not performed
- ☐ Yes- normal
- ☐ Yes- abnormal

Pre-op chest CT:

- ☐ Not performed
- ☐ Yes- normal
- ☐ Yes- consolidation
- ☐ Yes- ground glass opacity
- ☐ Yes- pulmonary infiltration
- ☐ Yes- other abnormality

<u>Management</u>

Time from admission to operation (pre-op delay)
<6 hrs | 6-23 hrs | 24-47 hrs | 48-71 hrs | 72+hrs

COVID-19 Treatment

Did patient receive NSAIDs? No | Yes before admission | After admission | Both

Patient received during index admission?

- ☐ Antibiotics
- ☐ Antivirals
- ☐ Quinine/derivative
- ☐ Corticosteroids
- ☐ IV Immunoglobulins
- ☐ Interferon
- ☐ IL-6 blocker

Antiviral (name & dose):_____
Corticosteroid (name & dose):_____

Renal dialysis during index admission?
No | Yes but not at 30 days after surgery
Yes and ongoing dialysis at 30 days after surgery

Pre-op respiratory support:

- ☐ None
- ☐ Low-flow O2
- ☐ High-flow O2
- ☐ Non-invasive ventilation
- ☐ Invasive vent
- ☐ ECMO

Post-op respiratory support:

- ☐ None
- ☐ Low-flow O2
- ☐ High-flow O2
- ☐ Non-invasive ventilation
- ☐ Invasive vent
- ☐ ECMO

Duration of post-op mechanical ventilation:
1-23h | 24-47h | 48-71h | 72-167h | 168h+