Case Report Form CovidSurg-Cancer-Prostate

NB: Complete this additional CRF only for patients that have prostate cancer.

CovidSurg

NIHR Global Health Research Unit on Global Surgery

Patient **REDCap ID:**_____

Cancer-specific information

Prostate Specific Antigen (ng/ml) at presentation:_____

Primary Gleason score: 3 | 4 | 5

Secondary Gleason score: 3 | 4 | 5

Was Prostate MRI performed? ☐ Yes ☐ No

Would MRI have been performed in the pre-COVID-19 era?
☐ Yes ☐ No

Date of Prostate MRI: __/__/____

Radiological T3/T4 stage
☐ Suspected T3a (suspected capsular involvement)
☐ Unequivocal T3a (clear radiological evidence of capsular involvement)
☐ T3b or T4 (seminal vesicle involvement)

Pre-operative plan for nerve-sparing
☐ No recommendation available ☐ Bilateral nerve sparing
☐ Unilateral nerve sparing ☐ Non-nerve sparing

Management

Was an updated prostate MRI obtained prior to surgery?
☐ Yes ☐ No

Date of new pre-operative MRI: __/__/____

Re-imaged radiological T-stage prior to surgery
T1 | T2 | T3 | T4 | Unknown

Re-imaged T3/T4 prior to surgery
☐ Suspected T3a (suspected capsular involvement)
☐ Unequivocal T3a (clear radiological evidence of capsular involvement)
☐ T3b or T4 (seminal vesicle involvement)

Re-imaged radiological N-stage prior to surgery
N0 | N1 | N2 | Unknown

Re-imaged radiological M-stage prior to surgery
M0 | M1 | Unknown

Pre-operative plan for nerve-sparing
☐ No recommendation available ☐ Bilateral nerve sparing
☐ Unilateral nerve sparing ☐ Non-nerve sparing

Which neoadjuvant therapy was used?
☐ Bicalutamide 50mg OD ☐ Bicalutamide 150mg OD
☐ LHRH agonist (eg. Goserelin). ☐ LHRH agonist (eg. Degarelix)

Was a pelvic lymph node dissection performed?
☐ Extended ☐ Standard ☐ Not performed

Console time (minutes): _____

Blood loss (millimetres):_____

Surgeon level of training
☐ Consultant performed
☐ Trainee, with consultant supervising
☐ Trainee, not supervised by consultant

Pathological T-stage 3/4
T3a | T3b | T4

Change in treatment strategy
☐ Remain of active surveillance ☐ Long-term hormone treatment
☐ Radiotherapy ☐ Other:_____

Re-imaged T3/4
☐ Suspected T3a (suspected capsular involvement)
☐ Unequivocal T3a (clear radiological evidence of capsular involvement)
☐ T3b or T4 (seminal vesicle involvement)

Prostate specific antigen level 3-months after date of operation. Any PSA level between 2-4 months postoperatively permissible
☐ Available ☐ Unavailable :_____

Prostate specific antigen level 3-months after date of study entry. For non-operated patients, any PSA level between 2-4 months postoperatively is allowed
☐ Available ☐ Unavailable :_____

Do you have permission to extend follow-up for prostate cancer patients to 12-months from the date of study entry? ☐ Yes ☐ No

12-month follow-up

Did the patient go on to have an operation related to their tumour between 3 and 12 months after study entry? ☐ Yes ☐ No

Was an update prostate MRI obtained prior to surgery? ☐ Yes ☐ No

Date of new pre-operative MRI: __/__/____

Re-imaged radiological T-stage prior to surgery
T1 | T2 | T3 | T4 | Unknown

Re-imaged T3/T4 prior to surgery
☐ Suspected T3a (suspected capsular involvement)
☐ Unequivocal T3a (clear radiological evidence of capsular involvement)
☐ T3b or T4 (seminal vesicle involvement)

Re-imaged radiological N-stage prior to surgery
N0 | N1 | N2 | Unknown

Re-imaged radiological M-stage prior to surgery
M0 | M1 | Unknown

Pre-operative plan for nerve-sparing
☐ No recommendation available ☐ Bilateral nerve sparing
☐ Unilateral nerve sparing ☐ Non-nerve sparing

Did any change in this operated patient's treatment occur as a result of the COVID-19 pandemic? In comparison to care in the pre-COVID-19 era. Select all that apply
☐ No change to care – no neoadjuvant therapy
☐ No change to care – underwent neoadjuvant therapy equivalent to that indicated in pre-COVID-19 era
☐ Delay to definitive surgery
☐ More rapid time to definitive surgery
☐ Change in choice of operation
☐ Operation in an alternative hospital (eg. Designated COVID-free)
☐ Interventional radiology procedure performed before surgery where this would not typically have been indicated
☐ Underwent neoadjuvant therapy given, not typically indicated
☐ No neoadjuvant therapy given, typically indicated
☐ Underwent longer/more intensive course of neoadjuvant therapy than typically indicated
☐ Underwent shorter/less intensive course of neoadjuvant therapy than typically indicated
☐ Underwent adjuvant therapy, not typically indicated
☐ No adjuvant therapy, typically indicated
☐ Other:_____

Which neoadjuvant therapy was used?
☐ Bicalutamide 50mg OD ☐ Bicalutamide 150mg OD
☐ LHRH agonist (eg. Goserelin). ☐ LHRH agonist (eg. Degarelix)

Urgency of surgery: Immediate | Urgent | Expedited | Elective
Anaesthesia type: Local | Regional | General
Operation:_____

Was a pelvic lymph node dissection performed?
☐ Extended ☐ Standard ☐ Not performed

Operative approach
☐ Open ☐ Minimally-invasive ☐ Minimally-invasive converted to open

Minimally invasive surgery type
☐ Laparoscopic ☐ Robotic-assisted

Did this represent a change to your typically operative approach in the pre-COVID-19 era?
☐ No change to operative approach
☐ Yes, chose to avoid minimally invasive surgery related to COVID-19
☐ Yes, chose to avoid open surgery related to COVID-19

Console time (minutes): _____

Blood loss (millimetres):_____

Surgeon level of training
☐ Consultant performed ☐ Trainee, with consultant supervising
☐ Trainee, not supervised by consultant

Final surgical intent upon completion of the procedure
☐ Curative ☐ Palliative

Pathological T-stage
T1 | T2 | T3 | T4 | Unknown

Pathological M-stage
M0 | M1 | Unknown

Pathological N-stage
N0 | N1 | N2/3 | Unknown

Resection margin
R0 | R1 | R2 | Unknown

Prostate specific antigen level 3 months after date of operation. Any PSA level between 2-4 months postoperatively permissible
☐ Available ☐ Unavailable :_____

Patient still planned for curative surgery? 12 months after study entry**?** ☐ Yes ☐ No

Why was an operation for cancer not performed during the 3 month follow-up period for this patient? Select all that apply
☐ Patient choice to avoid surgery during COVID-19 pandemic
☐ MDT decision to delay surgery due to patient risk
☐ Ongoing neoadjuvant therapy
☐ No bed/critical care bed/OR/theatre space available
☐ Change of recommendation in society guidelines related to COVID-19
☐ 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: _____

Cause of death whilst waiting for surgery
☐ Related to COVID-19 infection. ☐ Unrelated to COVID-19 infection

Change in treatment strategy
☐ Remain on active surveillance ☐ Long-term hormone treatment
☐ Radiotherapy ☐ Other:_____

NB: Continued on next page

Did any change in this non-operated patient's treatment occur as a result of the COVID-19 pandemic? In comparison to care in the pre-COVID-19 era

☐ No change to care – cancelled for other reason
☐ Operation cancelled because of COVID-19
☐ Operation delayed because of COVID-19
☐ Change in definitive treatment strategy because of COVID-19
☐ IR procedure performed before or instead of surgery, not typically indicated
☐ Underwent neoadjuvant therapy, not typically indicated
☐ No neoadjuvant therapy given, typically indicated
☐ Underwent longer/more intensive course of neoadjuvant therapy than typically indicated
☐ Underwent shorter/less intensive course of neoadjuvant therapy than typically indicated
☐ Reduced access to staging procedures
☐ Reduced access to staging procedures
☐ Other:_____

Has restaging/reimaging of this patient's cancer been performed? ☐ Yes ☐ No

Estimated date of restaging/reimaging: __/__/____

Restaged clinical or radiological T-stage
T1 | T2 | T3 | T4 | Unknown

Re-imaged T3/4

☐ Suspected T3a (suspected capsular involvement)
☐ Unequivocal T3a (clear radiological evidence of capsular involvement)
☐ T3b or T4 (seminal vesicle involvement)

Restaged clinical or radiological N-stage
N0 | N1 | N2/3 | Unknown

Restaged clinical or radiological M-stage
M0 | M1 | Unknown

Prostate specific antigen level 6-months after date of study entry (ng/ml). For non-operated patients, any PSA level between 5-7 months postoperatively is allowed
☐ Available ☐ Unavailable :_____

Prostate specific antigen level 9-months after date of study entry. For non-operated, any PSA level between 8-10 months postoperatively is allowed
☐ Available ☐ Unavailable :_____

Prostate specific antigen level 12-months after date of study entry. For non-operated, any PSA level between 11-13 months postoperatively is allowed
☐ Available ☐ Unavailable :_____