

**NATIONAL POLICY ON THE PREVENTION
AND MANAGEMENT OF INFECTION POST
TRANS RECTAL ULTRASOUND (TRUS)
GUIDED PROSTATE BIOPSY**

DISCLAIMER

This policy represents the view of the NCCP, which was arrived at after careful consideration of the evidence available. The expectation of the NCCP is that healthcare professionals will use clinical judgement, medical and nursing knowledge in applying the principles and recommendations contained in this document. Recommendations may not be appropriate in all circumstances. Therefore nothing in this policy shall override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient in consultation with the patient and/or carer. Therapeutic options should be discussed with a clinical microbiologist or infectious disease physician on a case-by-case basis as necessary.

1. INTRODUCTION	1
1.1 SCOPE OF THIS POLICY	1
1.2 TARGET AUDIENCE	1
1.3 BACKGROUND	1
1.4 AIMS OF THE NATIONAL POLICY	2
1.5 METHODOLOGY AND LITERATURE REVIEW	3
1.6 PROCEDURE FOR UPDATE OF THE POLICY	4
2. SUMMARY OF RESULTS OF NCCP SURVEY	5
3. PREVENTION OF INFECTIOUS COMPLICATIONS PRE TRUS-GUIDED PROSTATE BIOPSIES	8
3.1 ANTIMICROBIAL RESISTANCE SCREENING OF PATIENTS PRE TRUS-GUIDED PROSTATE BIOPSY	8
3.2 ANTIMICROBIAL PROPHYLAXIS PRE TRUS-GUIDED PROSTATE BIOPSY	11
3.3 ADJUNCTIVE MEASURES TO ANTIMICROBIAL PROPHYLAXIS	14
3.4 INFECTION PREVENTION AND CONTROL CONSIDERATIONS	15
4. MANAGEMENT OF INFECTIOUS COMPLICATIONS IN PATIENTS POST TRUS	17
4.1 SURVEILLANCE OF INFECTION POST BIOPSY	17
4.2 MONITORING ADVERSE EVENTS AND ANTIMICROBIAL RESISTANCE (AMR) SURVEILLANCE POST TRUS-GUIDED PROSTATE BIOPSY	20
4.2.1 GOVERNANCE WITHIN THE PROSTATE CANCER LEADS NETWORK	20
4.2.2 KEY PERFORMANCE INDICATORS (KPI) FOR NCCP PROSTATE BIOPSY CENTRES	21
4.3 MANAGEMENT OF PATIENTS WHO PRESENT WITH INFECTIOUS COMPLICATIONS	21
4.3.1 PATIENT INFORMATION	22
4.3.2 PRINCIPLES OF CARE POST TRUS-GUIDED PROSTATE BIOPSY	22
4.3.3 MANAGEMENT OF PATIENTS WITH SUSPECTED/CONFIRMED TRUS-GUIDED PROSTATE BIOPSY RELATED SEPSIS ...	23
 APPENDICES	
APPENDIX 1: NCCP NATIONAL PROSTATE BIOPSY INFECTION PROJECT BOARD	25
APPENDIX 2: LITERATURE REVIEW -METHODOLOGY	26
APPENDIX 3: DETAILS OF CONSULTATION PROCESS 3 RD TO 27 TH FEBRUARY 2014	29
APPENDIX 4: SUGGESTED PATIENT OR GP QUESTIONNAIRE (PRE TRUS-GUIDED PROSTATE BIOPSY)	31
APPENDIX 5: HELICS SURVEILLANCE DEFINITIONS FOR URINARY TRACT INFECTION AND BLOODSTREAM INFECTION	32
APPENDIX 6: DRAFT NCCP PATIENT BOOKLET: HAVING A TRUS PROSTATE BIOPSY: WHAT YOU SHOULD KNOW	33
 REFERENCES:	34
GLOSSARY:	37
ABBREVIATIONS:	38

1. INTRODUCTION

1.1 SCOPE OF THIS POLICY

Cancer, its prevention, diagnosis and treatment are a major challenge for our society. Each year approximately 30,000 Irish people develop cancer and 8,500 die of the disease (www.ncri.ie). The second National Cancer Strategy 'A Strategy for Cancer Control in Ireland, 2006' advised that Ireland needed a comprehensive cancer control policy programme.¹ Cancer control aims to prevent cancer, cure cancer, and increase survival and quality of life for those who develop cancer, by converting the knowledge gained through research, surveillance and outcome evaluation into strategies and actions.

Prostate cancer diagnostic clinics (rapid access clinics) were created by the National Cancer Control Program (NCCP), and facilitate men and their doctors in the diagnosis of early prostate cancer. Infections following transrectal ultrasound (TRUS)-guided prostate biopsies are reportedly increasing in incidence, specifically those due to antimicrobial resistant bacteria. It is the responsibility of the NCCP and its operational committee, the Prostate Cancer Leads Network, to ensure that Irish men are not exposed to undue risk or harm. The prevention and monitoring of infections following TRUS-guided prostate biopsy as outlined in this policy is mandatory in all diagnostic clinics within the responsibility of the NCCP, and we would encourage all diagnostic clinics in Ireland to operate to similar standards.

1.2 TARGET AUDIENCE

This national policy is relevant to all multi-disciplinary prostate cancer teams within the eight NCCP designated cancer centres.

1.3 BACKGROUND

A transrectal ultrasound (TRUS) is an ultrasound technique that is used to view a man's prostate and surrounding tissues. The ultrasound transducer (probe) sends sound waves through the wall of the rectum into the prostate gland, which is located directly in front of the rectum. TRUS may also be called prostate sonogram or endorectal ultrasound.

Infectious complications following TRUS-guided prostate biopsy are well-described.² Puncture of the rectal wall with the potential for transfer of pathogens from the rectum into the sterile prostate gland or surrounding tissue during TRUS-guided prostate biopsy appears to be the principal mechanism leading to infection. This is supported by high reported rates of bacteraemia (16%–75%) and bacteriuria (36%–53%) immediately post procedure in the absence of prophylactic antibiotics and that most infections manifest clinically within three days of the biopsy.² A variety of infectious complications have been reported following TRUS-guided prostate biopsy including: urinary tract infection (UTI), prostatitis, blood stream infection (BSI), and severe sepsis. The incidence of infectious complications has been reported to be increasing. The incidence of UTI is reported as between 2 – 6%, with 30%–50% of these patients having accompanying BSI. Severe sepsis has been

reported in 0.1%–2.2% of patients. One recent study reported that among post–TRUS-guided prostate biopsy patients hospitalised with *Escherichia coli* bloodstream infection, 25% had severe sepsis requiring intensive care unit (ICU) admission.²

However, it is thought that the true incidence of infectious complications related to the procedure is underestimated, as the literature usually concentrates on hospitalised patients rather than the less severe complications that are managed in primary care. A recent European study reported that 4.2% of patients had a fever in the two weeks post-procedure, whereas only 0.8% were hospitalised.²

The commonest pathogen implicated in post–TRUS-guided prostate biopsy sepsis is *E. coli*, accounting for approximately 75%–90% of infectious complications. Over recent years antimicrobial-resistant *E. coli* has been increasingly described, most commonly displaying fluoroquinolone resistance and/or production of an extended spectrum β -lactamase (ESBL) or carbapenemase (CRE).

Patient-specific risk factors associated with an increased risk of infection following TRUS-guided prostate biopsy include underlying medical co morbidities, particularly diabetes mellitus, recent hospitalisation, untreated asymptomatic bacteriuria, history of prostatitis or UTI, presence of bladder stones, prostate size and the presence of long term urethral catheters.^{2,3} Procedural factors including the number of cores taken during the biopsy procedure have been associated with post biopsy infection in some studies, though not in others. Risk factors for infection with antimicrobial-resistant bacteria following TRUS-guided prostate biopsy that have been described include: history of previous fluoroquinolone exposure in the last three to twelve months, history of prior infection with antibiotic resistant *Enterobacteriaceae* (e.g., quinolone resistance, ESBL, CRE), travel to areas with a high prevalence of resistant pathogens such as ESBL producing *E. coli*, history of previous TRUS-guided prostate biopsy or implantation of fiducial markers within the last year, the patient is a healthcare worker and immunosuppression.

1.4 AIMS OF THE NATIONAL POLICY

1. To summarise the findings of the national survey of the eight designated NCCP prostate cancer centres and also the Mercy Hospital, Cork and Adelaide, Meath and National Children's Hospital (Tallaght), Dublin.
2. To provide recommendations for the prevention of infection following TRUS-guided prostate biopsy. This is to include advice on the optimum antimicrobial prophylaxis strategy.
3. To provide recommendations for the surveillance of infection following TRUS-guided prostate biopsy.
4. To provide recommendations for the management of patients presenting with infection related to TRUS-guided prostate biopsy.

The National Standards for Safer Better Healthcare provide a strategic approach to improving safety, quality and reliability in our health services.⁴ The following are the elements of an infection

prevention and management programme for NCCP rapid access prostate biopsy clinics to ensure that patient care is reliable, designed to keep patients safe and of high quality in line with the National Standards.

PATIENT-CENTRED CARE

- Prevention and management of infection post TRUS-guided prostate biopsy is a key priority for all healthcare staff.
- Patient information on infectious complications following TRUS-guided prostate biopsy.
- Governance and reporting systems to provide assurance.
- Implementation of the National Standards in Infection Prevention and Control.⁵

EFFECTIVE CARE

Systems and controls in place to:

- Monitor outcomes in terms of infectious complications following TRUS-guided prostate biopsy.
- Monitor compliance with National standards relevant to this area.
- Analyse and learn from infectious complications when they occur. Dissemination of learning and institution of controls to prevent recurrence.

SAFE CARE

- Implementation of this policy.
- Audit and assessment of policy compliance.

BETTER HEALTH AND WELL BEING

- Healthcare staff and patient education regarding the prevention and management of infectious complications following TRUS-guided prostate biopsy.

1.5 METHODOLOGY AND LITERATURE REVIEW

The NCCP Prostate Biopsy Infection Project Board was convened to review current national practices associated with TRUS-guided prostate biopsy. This is in light of recent reported increases in TRUS-guided prostate biopsy associated infection and increasing antimicrobial resistance.^{2,3,6} To inform this process and to assist with devising a national policy, the project board performed a national survey of the designated NCCP centres in Ireland performing this procedure (Section 2). Currently, there is no national standardised surveillance programme for surveillance of infections following TRUS-guided prostate biopsy or agreed national policy for the prevention and management of infection following TRUS-guided prostate biopsy.

The project board first met in May 2013. Membership is outlined in Appendix 1. The agreed terms of reference for the group were:

1. To conduct an online survey of the eight designated NCCP prostate cancer centres, Mercy Hospital, Cork and Adelaide, Meath and National Children's Hospital (Tallaght), Dublin to determine current national practice in relation to the prevention and management of infection following TRUS-guided prostate biopsy.
2. To conduct a literature search for the clinical questions raised by the board as outlined in Appendix 2.
3. To draft and agree a national prostate biopsy surveillance form and protocol, and circulate to relevant stakeholders for their review and feedback.
4. To present the findings of the national survey at the NCCP Prostate Cancer Quality and Audit Forum meeting in Dublin Castle on the 8th November 2013.

The consultation exercise, which is summarised in Appendix 3, involved the active soliciting of feedback from professional groups. Submissions made during the consultation process were discussed at the group's final meeting in February 2014 and incorporated as appropriate into the final policy.

1.6 PROCEDURE FOR UPDATE OF THE POLICY

This policy will be reviewed in September 2014, after one year of collation of post-TRUS-guided prostate biopsy infection data by the NCCP (as outlined in Sections 4.1 – 4.3).

2. SUMMARY OF RESULTS OF NCCP SURVEY

Ten centres were invited to complete an on-line electronic survey which was conducted in May 2013. These comprised the eight designated NCCP prostate cancer centres, in addition to the Mercy University Hospital, Cork and the Adelaide, and Meath and National Children's Hospital (Tallaght), Dublin. Completed surveys were returned from all centres. All centres surveyed reported that TRUS-guided prostate biopsies were carried out on-site and four centres also performed transperineal prostate biopsies.

Five centres performed TRUS-guided prostate biopsies in the interventional radiology department, three in a rapid access prostate clinic (RAPC) facility and two centres in the urology outpatient department. In 2011, eight centres carried out 3,466 prostate biopsies, in 2012 nine centres carried out 3,771 prostate biopsies and up to May 2013, seven centres had carried out 2,338 prostate biopsies.

In relation to routine antimicrobial prophylaxis, all centres used an oral fluoroquinolone, either ciprofloxacin or ofloxacin. Five centres reported using a second agent in combination with a fluoroquinolone, such as IV gentamicin, IV amikacin and PO or PR metronidazole. Antimicrobial prophylaxis dosing schedules varied from single dose (n=2), 24 hours (n=4), 48 hours (n=1), 72 hours (n=2) to five days (n=1). Dosing of ciprofloxacin varied with either 500mg or 750mg prescribed.

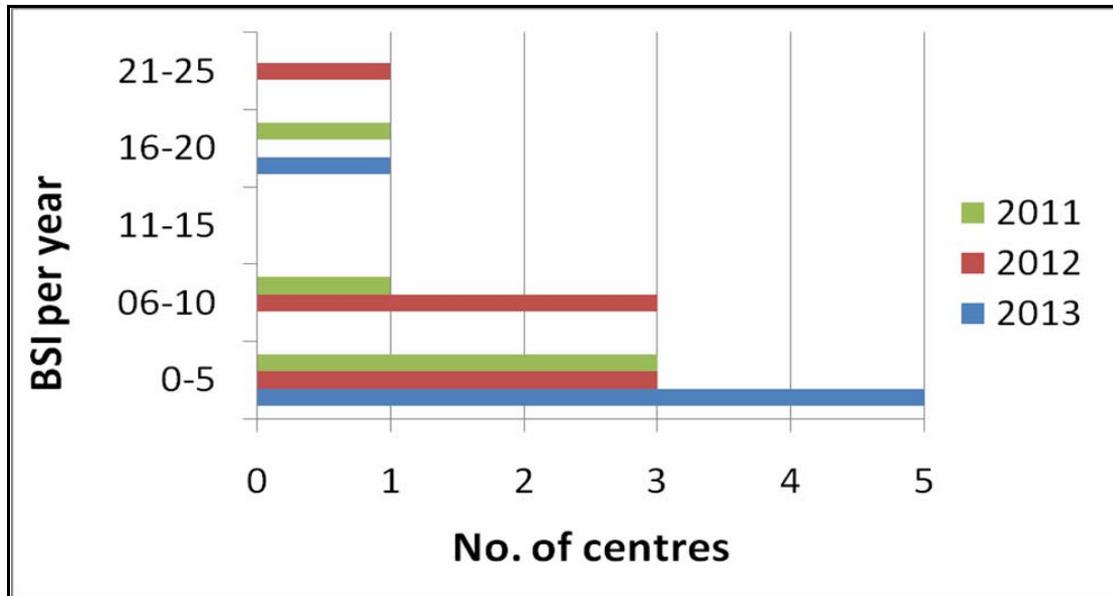
Three centres used a formal risk assessment tool to assess patients for potential colonisation with antimicrobial resistant organisms and adjusted antimicrobial prophylaxis accordingly. In these centres all patients were asked about a history of colonisation/infection with an antimicrobial resistant organism and immunocompromise. Other risk factors assessed included, previous antimicrobial use and specifically previous fluoroquinolone use (n=2), previous urological procedures (n=2), history of sepsis/infection following TRUS-guided prostate biopsy (n= 1), and indwelling material, abnormality of the renal tract, diabetes mellitus, age and/or recent hospitalisation (n=1).

Pre-procedure screening for carriage of resistant *Enterobacteriaceae* did not occur routinely. A single centre reported an ongoing pilot study of screening for the presence of ESBL producing *Enterobacteriaceae* using rectal swabs.

The majority of centres surveyed (n=7) reported having a programme in place for the surveillance of infection following TRUS-guided prostate biopsy, although the methodology used varied between centres. Patient follow-up occurred by phone (n=5) or at clinic (n=7). Five centres used a combination of methods.

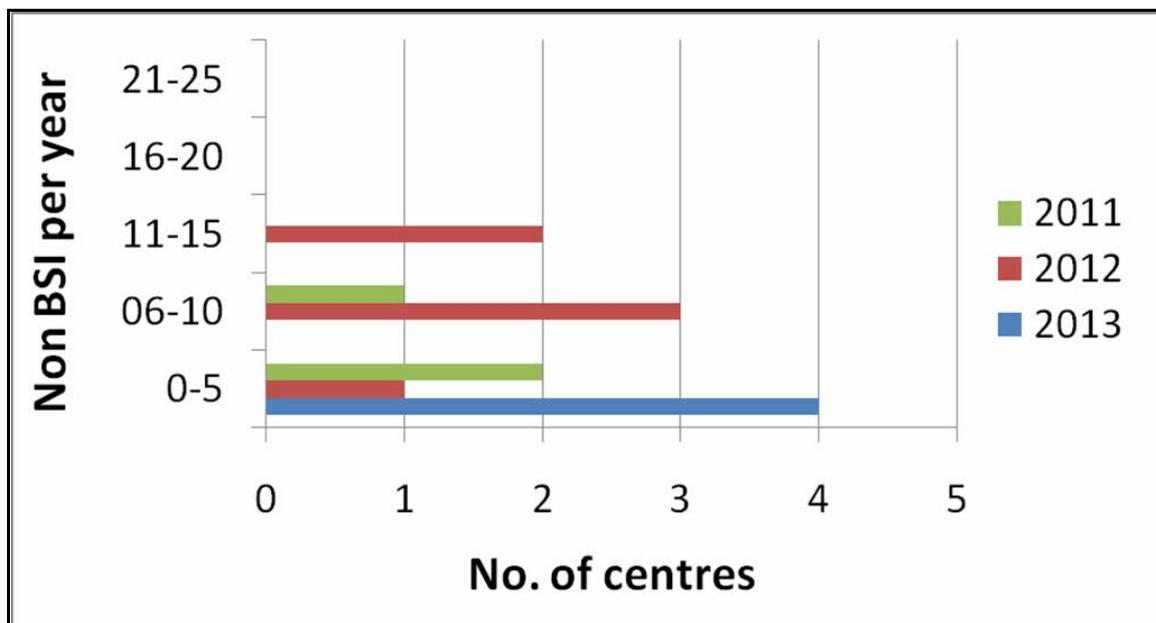
Figures 1 and 2 summarise submitted data for the estimated annual number of post TRUS-guided biopsy infections encountered at each centre, stratified into BSI and infections other than BSI (UTI, prostatitis, epididymitis and spinal abscess).

FIG 1: NUMBER OF BLOODSTREAM INFECTION (BSI) BY NUMBER OF CENTRES (N=10) 2011-2013*



**Up to June 2013*

FIG 2: NUMBER OF NON BLOODSTREAM INFECTIONS (BSI) REPORTED POST BIOPSY BY NUMBER OF CENTRES (N=10) 2011-2013*



**Up to June 2013*

Seven centres (70%) reported having a formal protocol for the management of patients presenting with infection following TRUS-guided prostate biopsy, whilst three centres do not currently have a formal protocol. The empiric antimicrobial treatment guidelines varied between centres with a formal protocol. Four centres recommended meropenem (with concurrent gentamicin in one centre). Use of co- amoxiclav with concurrent gentamicin (n=1) or use of single agent piperacillin/tazobactam (n=1) was also reported. Empiric use of ciprofloxacin or amikacin was not reported by any centre. A number of centres (n=4) recommended discussion of empiric antimicrobial therapy with a clinical microbiologist or infectious diseases physician.

3. PREVENTION OF INFECTIOUS COMPLICATIONS PRE TRUS-GUIDED PROSTATE BIOPSIES

TRUS-guided prostate biopsy is a widely performed day-case procedure to facilitate prostate biopsy where the patient is suspected of having prostate cancer. The procedure is generally safe, although it can be uncomfortable and has some side effects including bleeding and urinary infection. A small number of men (1-2%) will experience a serious infection or become septic after a TRUS-guided prostate biopsy and require hospital admission.

TRUS-guided prostate biopsy is 70-90% accurate in determining the presence of a clinically significant prostate cancer. Some cancers will be missed, hence the occasional need for a repeat biopsy. A repeat biopsy may also be required if the PSA remains elevated despite a previously normal biopsy. Repeating TRUS-guided prostate biopsy increases the risk of sepsis. Performing a prostate biopsy by the transperineal route is rarely associated with infection, and may be the preferred approach where the risk of sepsis is high. In addition, the transperineal route allows for additional sampling of the prostate, improving diagnostic accuracy.

KEY POINT

The NCCP has published guidelines to assist doctors in deciding who should be referred for TRUS-guided prostate biopsy.⁷ Patients are encouraged to discuss the risks of TRUS-guided prostate biopsy with their GP/urologist and should only proceed where the likely benefit exceeds the possible risks of the procedure (i.e. the benefit of diagnosing a life threatening prostate cancer at an early stage when it may be cured would likely exceed the risks and inconvenience of prostate biopsy).

3.1 ANTIMICROBIAL RESISTANCE SCREENING OF PATIENTS PRE TRUS-GUIDED PROSTATE BIOPSY

KEY POINTS

- **Patients with a history of colonisation/infection or with risk factors for carbapenem resistant *Enterobacteriaceae* (CRE) should be screened in advance with a rectal swab for CRE carriage and not listed for TRUS-guided prostate biopsy pending CRE screening results.**
 - **Indications for CRE screening are outlined at www.hpsc.ie.**
 - **If the results of CRE screening are positive, it is recommended that the multi-disciplinary team discuss the optimal strategy for performing the prostate biopsy safely in this patient (e.g., consideration of a transperineal biopsy approach). This is because of the potential consequences of CRE infection for the patient.**
- **For all other patients antimicrobial prophylaxis options should be stratified according to the patient's risk factors for possible rectal carriage of antimicrobial resistant**

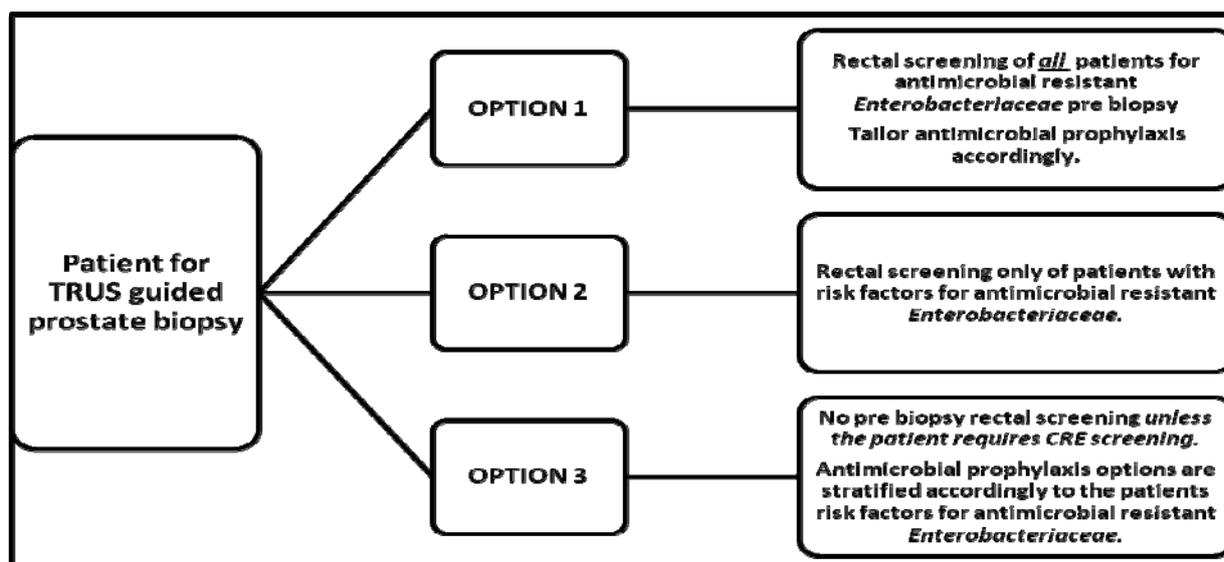
Enterobacteriaceae. Details of antimicrobial risk factors should be sought by the urologist when reviewed at the hospital appointment (Appendix 4).

- Risk factors may include but are not limited to:
 - History of fluoroquinolone use in the previous six months.
 - Patient is a healthcare worker.
 - Previous sepsis/infection following TRUS-guided prostate biopsy.
 - History of antimicrobial resistant *Enterobacteriaceae* colonisation/infection (e.g., ESBL, fluoroquinolone and/or aminoglycoside resistance).
 - Other risk factors as per local policy.

RATIONALE

The project board considered the three options as outlined in Figure 3 for the management of patients pre-TRUS-guided prostate biopsy.

FIG 3: OPTIONS CONSIDERED BY THE NCCP PROSTATE INFECTION BOARD



Two options (1 and 2 in Figure 3 above) included consideration of pre-biopsy screening for rectal carriage of antimicrobial resistant *Enterobacteriaceae* to direct antimicrobial prophylaxis. This approach could certainly be justified in light of increasing reports of antimicrobial resistance in *Enterobacteriaceae* spp. in Ireland and increasing local and international reports of post TRUS-guided prostate biopsy infectious complications due to antimicrobial resistant organisms (specifically fluoroquinolone resistant *Enterobacteriaceae*).^{2,3} The clear advantage of pre biopsy screening (either option 1 or 2), is that this approach may detect patients who are colonised with antimicrobial resistant *Enterobacteriaceae* in advance, so that antimicrobial prophylaxis can be tailored for each patient accordingly. However, in the context of the existing national care pathways of the NCCP rapid access

prostate clinics, a decision to recommend a national pre-TRUS-guided prostate biopsy screening programme would need careful consideration of the following factors:

- The need for the NCCP to obtain accurate standardised information on the true incidence of infectious complications post TRUS-guided prostate biopsy in NCCP rapid access prostate clinics as outlined in this policy (including infections due to antimicrobial resistant *Enterobacteriaceae*). This information would be an important element on which to base an assessment of the requirement for a national pre biopsy screening programme.
- Thereafter, an economic evaluation of the costs associated with a national antimicrobial resistant screening programme pre TRUS-guided prostate biopsy in NCCP centres would be required. This would include consideration of the logistics of screening (screening in primary vs. secondary care etc.), transport and laboratory costs (requirement for specialist screening media, laboratory scientist and clinical microbiologist time etc.) and the potential need to redesign the national rapid access process, to ensure that where rectal screening swabs are indicated to detect carriers of antimicrobial resistant *Enterobacteriaceae*, that there is sufficient time allowed to ensure that results are back in time before the patients TRUS-guided prostate biopsy. Other logistical issues that would need to be considered would include the need to ensure that antimicrobial prophylaxis choice is tailored to the individual patient's screening results. Antimicrobial allergies and co-morbidities (e.g., renal impairment), would need to be taken into consideration, input from a clinical microbiologist would be required for each case. There is also a need to coordinate the antimicrobial prophylaxis plan ahead of the clinic visit, as the patient may have to take oral antimicrobials up to two hours ahead of the procedure and in some cases IV access may be required to administer IV antimicrobials.
- At present, it is unclear what the optimal specimen type and laboratory protocol is for screening of carriage of resistant *Enterobacteriaceae* though most studies evaluate rectal swabs or faeces specimens. The sensitivity of rectal screening with respect to detection of antimicrobial resistant *Enterobacteriaceae* remains unclear. Additionally, some patients may carry resistant *Enterobacteriaceae* at low levels, which may lead to a false-negative screening test results.

With respect to screening all patients in advance of TRUS-guided prostate biopsy for antimicrobial resistant *Enterobacteriaceae* (option 1), while individual studies indicate its usefulness in their institutions,^{8,9} at present, this approach is not recommended in international guidelines.⁶ Others recommend that each urologist weigh the need for a prostate biopsy in relation to risk, assess the individual risk factors including the risk of harboring antimicrobial resistant bacteria (i.e. ESBL, fluoroquinolone resistance) and consider the need for a rectal screen before the procedure.¹⁰ A pilot project of routine rectal screening for carriage of ESBL-producing *Enterobacteriaceae* pre-biopsy is currently ongoing in one of the Irish centres surveyed. A large prospective, non randomised trial evaluating the efficacy of directed antimicrobial prophylaxis prior to TRUS-guided prostate biopsy,

compared with ciprofloxacin prophylaxis, is currently recruiting.¹¹ There is a need however, for further studies to evaluate the clinical utility and cost-effectiveness of pre-biopsy screening for carriage of resistant *Enterobacteriaceae* in targeting antimicrobial prophylaxis.

The board agreed that at present, in the absence of standardised Irish post TRUS-guided prostate biopsy infection surveillance data for NCCP centres and the absence of an international consensus on pre biopsy screening, that there was not enough evidence available on which to base a recommendation for a national pre biopsy antimicrobial resistance screening programme. This will clearly need to be reviewed as new evidence emerges. The board agreed that individual centres that are evaluating pre biopsy screening should continue with this process and that their data would be reviewed in one year's time in addition to the first year of NCCP post TRUS-guided prostate biopsy infection surveillance data. The decision on pre biopsy antimicrobial resistance screening will be then updated as appropriate. An economic analysis will be required at this stage to evaluate the cost benefit of this approach.

The only exception to the recommendation on pre biopsy antimicrobial resistance screening is for CRE screening. The board agreed that as the consequences of CRE infection post biopsy can present a management challenge (i.e., there are few antimicrobial choices available for CRE infection – none of which are first line antimicrobials), that patients with risk factors for CRE (as outlined by the HPSC at www.hpsc.ie), and patients with a past history of CRE colonisation/infection should have a rectal swab taken for CRE carriage, in advance of being scheduled for the TRUS-guided prostate biopsy. These patients should not be listed for TRUS-guided prostate biopsy until the results have been reviewed. If the results of CRE screening are positive, it is recommended that the multi-disciplinary team discuss the optimal strategy for performing the prostate biopsy safely in this patient (e.g., transperineal biopsy approach). This is because of the potential consequences of CRE infection for the patient.

For all other patients who do not meet HPSC criteria for CRE screening, the antimicrobial prophylaxis for TRUS-guided prostate biopsy should be chosen based on the patients' risk factors for potential colonisation with antimicrobial resistant *Enterobacteriaceae* as outlined in Table 1 and Figure 4.

3.2 ANTIMICROBIAL PROPHYLAXIS PRE TRUS-GUIDED PROSTATE BIOPSY

KEY POINTS

- **Antimicrobial prophylaxis is recommended for all patients undergoing TRUS-guided prostate biopsy.¹²**
 - **Figure 4 outlines the recommended approach. Refer to Table 1 for timing of antimicrobials pre biopsy.**
- **As outlined previously in this policy, patients with a history of colonisation/infection or with risk factors for CRE should be screened in advance with a rectal swab for CRE**

carriage and not listed for TRUS-guided prostate biopsy pending CRE screening results. If the results of CRE screening are positive, it is recommended that the multi-disciplinary team (MDT) discuss the optimal strategy for performing the prostate biopsy safely in this patient.

- Thereafter there are two recommended options (2a and 2b in Figure 4 below):
 - Oral ciprofloxacin 750mg as a one drug antimicrobial prophylaxis regimen for patients *without* risk factors for colonisation with resistant *Enterobacteriaceae*.^{10, 12} Patients with risk factors for antimicrobial resistant *Enterobacteriaceae* (other than CRE) should be given a two drug antimicrobial prophylaxis regimen. A combination of ciprofloxacin and an aminoglycoside is recommended (unless the patient has a history of previous microbiology results indicating resistance to fluoroquinolones and/or aminoglycosides, in which case the prophylaxis choice should be discussed with the local clinical microbiologist).^{13,14}

OR
 - Local MDT review of recent post TRUS-guided prostate biopsy infection surveillance data is used to inform the appropriate antimicrobial prophylaxis regimen for that centre. The choice of empirical antimicrobial prophylaxis should take local/regional antimicrobial resistance rates into consideration in addition to the pharmacokinetic and pharmacodynamic characteristics of the chosen antimicrobial.
- Before prescribing antimicrobial prophylaxis, it is important to document if the patient has an antimicrobial allergy and calculate the Creatinine Clearance (CrCl) for adjustment of dosing/therapy in renal impairment.

RATIONALE

Most data supports the use of fluoroquinolones for antimicrobial prophylaxis pre TRUS-guided prostate biopsy based on analysis in the highest number of studies and patients.¹⁵ Ciprofloxacin is reported as superior to ofloxacin.¹⁶ Ciprofloxacin has a broad spectrum of activity against intestinal flora and high prostatic tissue concentrations after oral administration.¹⁷ The higher oral dose (750mg) is selected to optimise the duration that drug concentration is above the minimal inhibitory concentration (MIC) of the likely causative pathogen.¹⁸

There is no conclusive data to support either the use of long-course (3 days) over short (1 day) regimens or multiple over single dose schedules.^{2,15} Prophylaxis should begin at least 60 minutes prior to the biopsy procedure and should be discontinued within 24 hours.¹²

FIG 4: ANTIMICROBIAL PROPHYLAXIS PRE TRUS-GUIDED PROSTATE BIOPSY

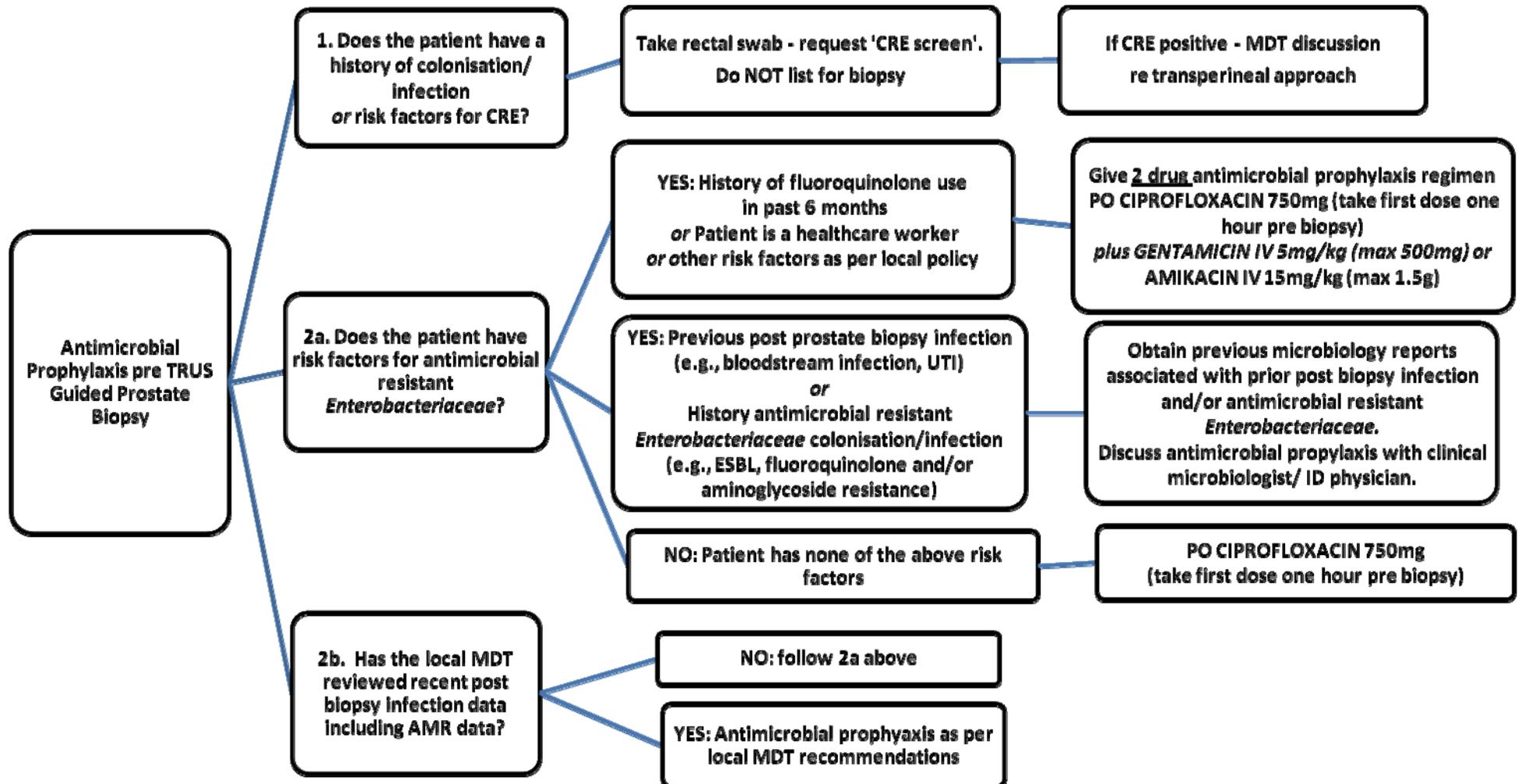


Table 1: Empiric Antimicrobial Prophylaxis for patients undergoing TRUS-guided prostate biopsy 12,14,15,18,19					
Drug	Route	Does if normal function	Adjust in renal impairment	How long before biopsy?	Duration
Ciprofloxacin	PO	750mg	none	1 hour	one further dose 12 hours post-biopsy
‡ Gentamicin	IV	5mg/kg (max 500 mg)	*use alternative if CrCl <30ml/min	30 minutes [§]	single dose
‡ Amikacin	IV	15mg/kg (max 1.5g)	*use alternative if CrCl <30ml/min	30 minutes [§]	single dose

‡Consult local policy for details of administration of intravenous gentamicin or amikacin.

*If renal impairment (CrCl < 30ml/min) or contra-indication to aminoglycoside use, consult clinical microbiologist/infectious diseases physician for advice.

§Note, the timing of the end of the infusion should coincide with commencement of biopsy.

3.3 ADJUNCTIVE MEASURES TO ANTIMICROBIAL PROPHYLAXIS

Adjunct measures in preventing infections following TRUS-guided prostate biopsy that have been described include pre-biopsy rectal cleansing enemas and rectal disinfection with agents such as chlorhexidine or povidone-iodine.^{2,20,21} The rationale for enema use is to reduce the rectal microbial burden pre biopsy and lessen the bacterial inoculum introduced during the biopsy procedure. However, the efficacy in reducing post biopsy infections has yet to be confirmed and is not recommended in European guidelines. The American Urological Association advises 'physician discretion' in their use.² While rectal disinfection has been proposed as another potential adjunct to antimicrobial prophylaxis, data supporting its efficacy is limited.

3.4 INFECTION PREVENTION AND CONTROL CONSIDERATIONS

As with any invasive procedure, patients who undergo TRUS-guided prostate biopsies are at a risk of infectious complications.²⁰ While the use of antimicrobial prophylaxis in TRUS-guided prostate biopsy is effective in reducing infections, adherence to good infection prevention and control precautions are also necessary to ensure patient safety. Standard Precautions should be used at all times by all healthcare staff when caring for patients. Local infection prevention and control guidelines should be followed. It is important that the environment is suitably prepared and all required equipment is available and checked to be in working order before commencing the procedure. All staff should be familiar with their expected roles and responsibilities.²²

ROOM PREPARATION

A clinical room which is spacious enough for at least three people is required, and should be suitably furnished with equipment and flooring which can be decontaminated if there are any spillages of body fluids.²³ The standard equipment includes:

- Examination couch
- Curtains or screen to maintain privacy
- Ultrasound machine
- Ultrasound probe
- Linen skip
- Healthcare waste bins
- Sharps bin
- Hand wash basin

A clinical trolley should be prepared in advance with the following items:

- Biopsy gun and needles or single use device
- Long spinal needles (to administer anaesthetic)
- Condoms/sheaths (for ultrasound probe)
- Antimicrobials (if not previously given)
- Local anaesthetic
- Specimen pots
- Lubricating jelly
- Wipes/gauze
- Gloves
- Needle guide
- Alcohol hand rub

KEY POINTS

- **Hand hygiene:** Hand hygiene should be performed as outlined by the World Health Organisation.²⁴
- **Aseptic technique:** All set up, preparation and procedures should be carried out using Aseptic Non Touch Technique (ANTT).²⁵
- **Clean equipment:** Prepare the ultrasound machine and probe ensuring they are intact and clean before and after use. The probe is covered with a condom or probe cover and is decontaminated as per the manufacturer's recommendation before and after each patient.¹⁰ As well as decontaminating the rectal probe, the ultrasound machine should be wiped down following use.
- **Personal protective equipment (PPE):** wear gloves during activities that have a risk of contact with blood or body fluids. Remove gloves after task, discard and perform hand hygiene.²⁶
- **A system to record the decontamination process:** This should be in place as the rectal probe is a reusable medical device.²⁷
- **Lubricating gel:** It is preferable to use single use sachets of gel. If a tube is used, ensure tube is dated when opened and dispensed into a clean single-use disposable container avoiding any contamination of the tube.
- **Specimens:** Ensure that each biopsy sample is placed in the correct and accurately labelled sample container containing 0% neutral buffered formalin solution.
- **Waste management:** Ensure that waste including single use items and sharps are disposed of correctly into the appropriate waste stream i.e. healthcare risk waste or healthcare non-risk waste.²²
- **Patient education:** Re-iterate the possible complications of the TRUS-guided prostate biopsy to the patient and how they should be managed. The patient should be given a patient information leaflet, informing them of signs and symptoms of post biopsy infection and what action to take should this occur (Appendix 6).

4. MANAGEMENT OF INFECTIOUS COMPLICATIONS IN PATIENTS POST TRUS

4.1 SURVEILLANCE OF INFECTION POST BIOPSY

KEY POINTS

- **Active surveillance using standardised definitions of infection should be carried out for infectious complications following TRUS-guided prostate biopsy.**
- **The infectious complications which should be captured following TRUS-guided prostate biopsy are urinary tract infection (UTI) and bloodstream infection (BSI). It is recommended that the Hospitals in Europe Link for Infection Control Surveillance (HELICS) surveillance definitions of these two infections are used (Appendix 5).**
- **All suspected cases of post-prostate biopsy infection should be discussed at a local multi-disciplinary surveillance meeting at which the surveillance form, microbiology results and healthcare record are reviewed and the HELICS surveillance definitions are applied.²⁸**
- **A systems analysis should be performed by the multidisciplinary prostate biopsy team where a patient suffers a confirmed BSI following TRUS-guided prostate biopsy. This is to identify potential predisposing factors and identify areas for improvement.**
- **Each centre should report the rate of UTI and BSI (onset up to 15 days, following the biopsy) per 100 biopsies on a quarterly basis to the NCCP.**

RATIONALE

At the time of writing of this policy, there is no national collation of standardised infectious complications following TRUS-guided prostate biopsy in Ireland. However data from the EARS-net surveillance system which is collated by the HPSC has indicated that antimicrobial resistance in *Enterobacteriaceae* spp. has increased in recent years. As of quarter 4 2013, the proportion of patients with BSI caused by *E. coli* producing ESBLs was 10.4% and the proportion of BSI caused by multi-drug resistant (MDR) *E. coli* (displaying resistance to three or more antimicrobial classes) was 14.7%. (Source: HPSC).

Standardising the methodology for surveillance of infectious complications following TRUS-guided prostate biopsy will permit meaningful comparison of infection rates, analysis of outcomes and management of these potentially significant infections. The definitions and variables proposed herein are suitable for epidemiologic infection surveillance purposes and should never be used in the clinical decision making process.

It is recommended that active surveillance is carried out for infectious complications following TRUS-guided prostate biopsy. The rationale for this is that reliance on passive surveillance (i.e. identification of patients upon hospitalisation following the procedure) will fail to identify all post-procedure infectious complications, such as those who are managed in the community by the patient's GP or

those where the patient re-presents to a different hospital to that from where the original biopsy was performed. The infectious complications that should be systematically captured following TRUS-guided prostate biopsy are UTI and BSI. It is recommended that the HELICS surveillance definitions of these two infections are used as outlined in Appendix 5.²⁸

A standardised surveillance questionnaire should be completed for all patients following TRUS-guided prostate biopsy and a local database maintained with cognisance of data protection regulations. The timing for performing surveillance for post-prostate biopsy infection should be designed to optimise information reporting. If the interval between the biopsy and surveillance questionnaire is too short, the patient may subsequently develop an infection which will not be captured by the surveillance system and if the interval is too long, crucial information may be forgotten. The method for administering the questionnaire to the patient could be either a paper-based questionnaire, which could be posted to the patient and returned by post or completed at the return visit to clinic for biopsy results or alternatively via a telephone questionnaire administered at a defined interval post biopsy. The proposed questionnaire content is displayed in Table 2. A duplicate copy of the completed surveillance form should be filed in the healthcare record and a copy retained by the surveillance coordinator. All suspected cases of post-prostate biopsy infection should be discussed at a local multi-disciplinary surveillance meeting at which the surveillance form, microbiology results and healthcare record are reviewed and the HELICS surveillance definitions are applied.

Table 2: Patient Questionnaire	
Today's date	DDMMYY
Patient identifier	Healthcare record number
Date of prostate biopsy	DDMMYY
Developed symptoms of suspected infection within two weeks after prostate biopsy	
NO <input type="checkbox"/> – do not complete rest of form	YES <input type="checkbox"/> – <u>proceed to complete rest of form</u>
Date of symptom onset:	DDMMYY
Reported symptoms: (tick box) <input type="checkbox"/> Temperature >38 <input type="checkbox"/> Dysuria <input type="checkbox"/> Urgency <input type="checkbox"/> Frequency <input type="checkbox"/> Supra pubic tenderness <input type="checkbox"/> Haematuria <input type="checkbox"/> Rigors <input type="checkbox"/> Other symptom (describe)	Information/description
Action taken: (tick box) <input type="checkbox"/> Attended GP <input type="checkbox"/> Attended ED <input type="checkbox"/> Admitted to hospital	If ED/hospital admission – give name of hospital attended and date of discharge
Antimicrobial prescribed for infection treatment	
Urine dipstick result	
Microbiology results MSU – not sent, no growth, positive growth Blood cultures – not sent, no growth, positive growth	If positive growth, get copies of reports and attach to surveillance form
Pre-biopsy risk assessment complete	Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, print and attach to surveillance form
Biopsy number (1, 2, 3 etc):	
If biopsy number ≥ 2 – date of prior biopsy	DDMMYY
Prophylaxis prescribed for latest biopsy 1 Agent, dose, duration 2 Agent, dose, duration	
Patient confirms prophylaxis taken as prescribed	Yes <input type="checkbox"/> No <input type="checkbox"/>
MDT surveillance meeting decision Post prostate biopsy BSI Post prostate biopsy UTI Post prostate biopsy other infection type – specify No infection complication	

4.2 MONITORING ADVERSE EVENTS AND ANTIMICROBIAL RESISTANCE (AMR) SURVEILLANCE POST TRUS-GUIDED PROSTATE BIOPSY

The NCCP centres should capture the following information, review & discuss at local MDT meeting quarterly and return to the NCCP on a quarterly basis:

1. Number of prostate biopsies performed at the centre in the last six months.
2. Total number of infections confirmed.
 - Total number of HELICS BSI confirmed.
 - Total number of HELICS UTI confirmed.
3. Rate of BSI per 100 biopsies.
4. Rate of UTI per 100 biopsies.
5. % of infections (BSI and UTI) due to ciprofloxacin resistant isolates.
6. % of infections (BSI and UTI) due to gentamicin resistant isolates.
7. % of infections (BSI and UTI) due to ESBL positive isolates.
8. % patients colonized with CRE (either history of or results of prebiopsy screening).
9. % of CRE infections (BSI and UTI).

Infection data will be reviewed by the Prostate Leads network as outlined in Section 4.2.1 below. Each centre should have a process in place that enables results to be reviewed and investigated more urgently if there is an unexpected increase in infections over a short time period, or if there is evidence of infections being caused by a similar bacterial strain in multiple patients. These may indicate a common source outbreak that would need investigation. Statistical process control charts may assist in this regard. A systems analysis should be undertaken where a patient suffers a confirmed BSI following TRUS-guided prostate biopsy. A system analysis is a retrospective review undertaken in order to identify what, how and why it happened. In the case of BSI following TRUS-guided prostate biopsy, this process is to identify potentially preventable predisposing factors and prevent further recurrence or CDI in other patients/residents. The term 'system' analysis/investigation has replaced 'root cause' analysis/investigation as there is rarely one 'root cause' for any incident. The systems analysis process itself should be led by the consultant caring for the patient with the relevant clinical nurse manager, with the full support of the infection prevention and control team, risk management and patient safety and quality specialists.

4.2.1 GOVERNANCE WITHIN THE PROSTATE CANCER LEADS NETWORK

Operating Procedures: Individual hospitals will report quarterly to the NCCP. Agreed data to be reported is outlined above. The data manager within the NCCP will produce a report for the Prostate Leads Network. The data should be reviewed at the regular Leads Network meeting with the assistance of a Consultant Microbiologist who can advise on the data interpretation. It is the responsibility of the Leads Network to review the data and take whatever action is required in the

interest of patient safety. The Leads Network will report annually to the Board of the NCCP through issuing an annual TRUS Prostate biopsy infection report. Changing antimicrobial resistance patterns may require revisions of national antimicrobial prophylaxis regimens.

Troubleshooting: In the unlikely event of data not forthcoming from individual hospitals, the Chair of the Leads Network will contact the relevant department in the hospital and request the data by the end of the next quarter. This can subsequently be elevated to communication between the Director of the NCCP and the CEO of the hospital in question.

4.2.2 KEY PERFORMANCE INDICATORS (KPI) FOR NCCP PROSTATE BIOPSY CENTRES

LOCAL KPI

- Rate of UTI and BSI (onset up to 15 days from biopsy date) per 100 biopsies.
- Proportion of prostate biopsies where a risk assessment was completed on patients with confirmed BSI or UTI infection.
- Proportion of confirmed BSI with completed systems analysis.

NATIONAL KPI

- Each centre should report the rate of UTI and BSI (onset up to 15 days from biopsy date) per 100 biopsies on a quarterly basis to the NCCP.

4.3 MANAGEMENT OF PATIENTS WHO PRESENT WITH INFECTIOUS COMPLICATIONS

KEY POINTS

- All units performing TRUS-guided prostate biopsy should promote awareness of sepsis following TRUS-guided prostate biopsy within the hospital and in primary care. For example, regular educational sessions with staff in emergency, urology, out patients (OPD) and radiology departments and having clear accessible management guidelines for TRUS-guided prostate biopsy related sepsis displayed in the emergency, OPD and urology departments.
- Patients should be provided with clear *written* information before and after TRUS-guided prostate biopsy as outlined below (Appendix 6). Following their biopsy, patients should be given verbal and written instructions to inform them of the signs and symptoms of infection and how they need to respond. The written instructions should include details of the antimicrobial prophylactic agents used and the recommended management algorithm for the treatment of patients with potential infection post-TRUS-guided prostate biopsy.

- **The management of patients who present with infectious complications following TRUS-guided prostate biopsy is outlined in Figure 5. The main principle when selecting an appropriate empiric antimicrobial for treatment of suspected sepsis following TRUS-guided prostate biopsy is to select a different antimicrobial to that given as prophylaxis.**

4.3.1 PATIENT INFORMATION

Patients require information at several points of the patient journey. All patients should receive the information booklet *'Having your prostate checked: what you should know. A guide for men'*²⁹ produced by the NCCP, when they attend their GP and/or with their appointment letter, for the rapid access prostate clinic. This booklet gives an overview of what is involved in prostate assessment.

When it has been agreed that the patient requires a TRUS-guided prostate biopsy, the patient should receive an information leaflet about this procedure in advance. The NCCP has developed a patient booklet in this regard (Appendix 6). This booklet contains the following information;

- What a TRUS-guided prostate biopsy involves.
- Preparation for the biopsy, including which medications should be stopped prior to the biopsy.
- What to expect on the day of the TRUS-guided prostate biopsy.
- Potential complications.
- What action to take in the event of a complication.
- Relevant contact details of the medical and nursing team to contact in case of an emergency.
- When to expect the results of their biopsy.

On discharge following TRUS-guided prostate biopsy the patient should be given information for the GP or local ED in the case of an adverse event. The patient must be given time to discuss the information given and ask any questions.

4.3.2 PRINCIPLES OF CARE POST TRUS-GUIDED PROSTATE BIOPSY

All units performing TRUS-guided prostate biopsy should:

- Provide patients with a telephone contact number that they can call 24 hours a day in case of an emergency.
- Contact patients the next working day after the biopsy with a follow up phone call (this should be recorded in the patient's medical notes or electronic health record). This is to detect early post biopsy complications such as urinary retention or early infections.
- Promote awareness of TRUS-guided prostate biopsy related sepsis amongst referring institutions and GP practices and circulate local management guidelines.

4.3.3 MANAGEMENT OF PATIENTS WITH SUSPECTED/CONFIRMED TRUS-GUIDED PROSTATE BIOPSY RELATED SEPSIS

Where a patient develops signs or symptoms of infection following a TRUS-guided prostate biopsy, he should be advised to attend his GP, or if he becomes unwell outside of the usual GP clinic opening times, he should attend the Emergency Department (ED) of the hospital where the biopsy was performed or if this is not practical, his local ED and present the letter he was given after the prostate biopsy.

The management of patients who present with sepsis/infectious complications following TRUS-guided prostate biopsy is outlined in Figure 5. When the patient with potential infectious complications is reviewed, there are three considerations:

- (a) Does this patient require admission to hospital?
- (b) Is there a local infection (UTI) or are there signs of sepsis?
- (c) Are risk factors for antimicrobial resistant *Enterobacteriaceae* present?

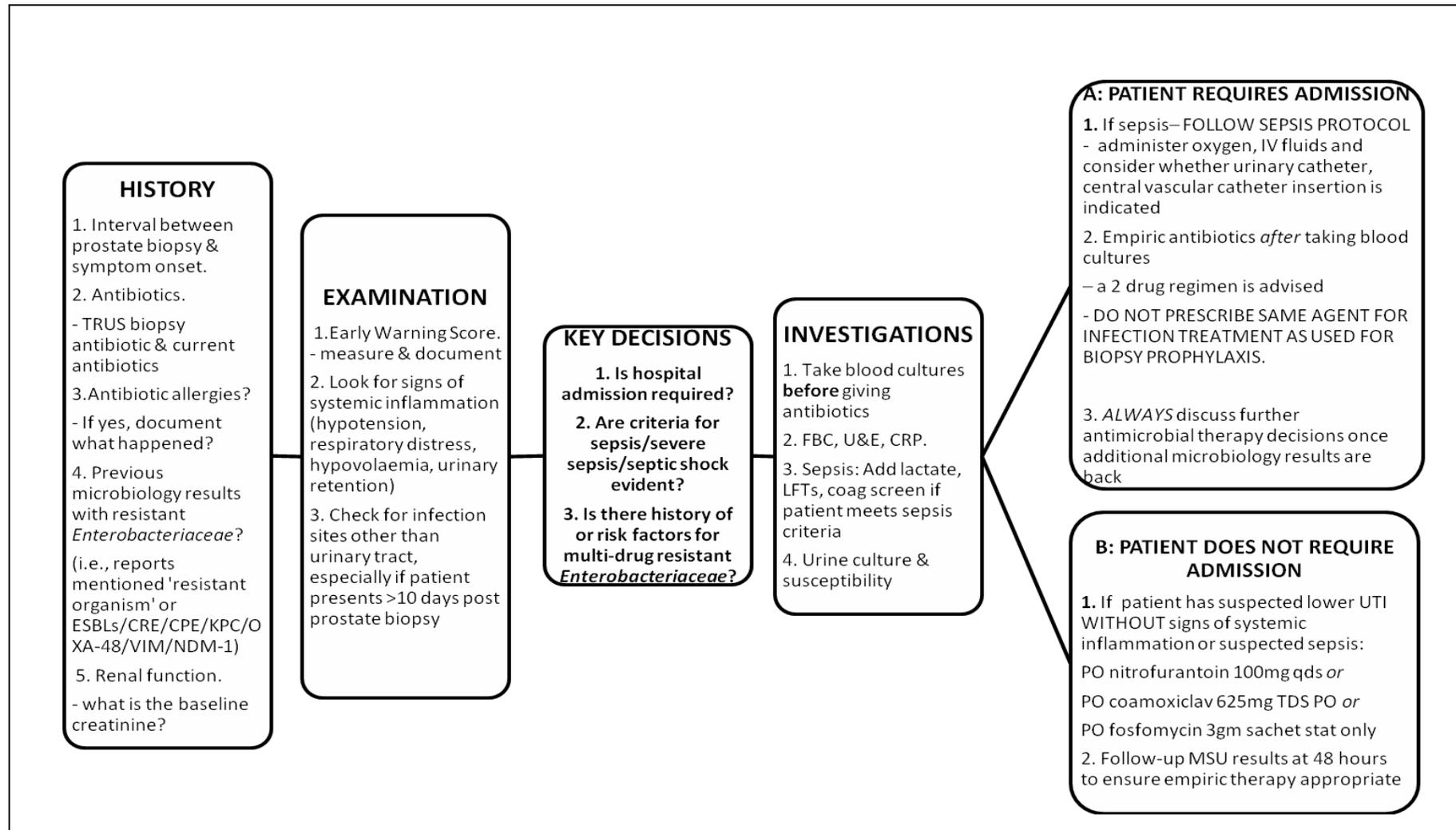
Clinical assessment should include:

- (a) Full history and physical examination.
- (b) Routine bloods, to include CRP. A serum lactate, liver function tests (LFT's) and coagulation screen should also be taken if sepsis is suspected.
- (c) Blood culture and mid stream urine (MSU) for culture prior to commencing antimicrobials.

Admission is required if the patient displays evidence of sepsis or is at risk for infection due to antimicrobial resistant *Enterobacteriaceae*, as oral antimicrobials are unlikely to be successful.

The main principle when selecting an appropriate empiric antimicrobial for treatment of suspected sepsis following TRUS-guided prostate biopsy is to select a different antimicrobial to that given as prophylaxis as antimicrobial resistance is likely.

FIGURE 5: THE MANAGEMENT OF PATIENTS WHO PRESENT WITH INFECTIOUS COMPLICATIONS POST TRUS-GUIDED PROSTATE BIOPSY



APPENDIX 1: NCCP NATIONAL PROSTATE BIOPSY INFECTION PROJECT BOARD

NCCP National Prostate Biopsy Infection Project Board		No. Meetings Attended
Mr. David Galvin, Co-Chair. National Prostate Cancer Lead, Consultant Urologist, St. Vincent's University Hospital and Mater Misericordiae University Hospital, Dublin.		6
Dr. Fidelma Fitzpatrick, Co-Chair. National Clinical Lead for HCAI & AMR Prevention. Consultant Microbiologist, Beaumont Hospital and HPSC, Dublin.		6
Ms. Emily Ahern	Antimicrobial Pharmacist, St. James's Hospital, Dublin and Representative of the Irish Antimicrobial Pharmacists Group.	3
Dr. Karen Burns	Consultant Microbiologist, HPSC & Beaumont Hospital.	4
Dr. Breida Boyle	Consultant Microbiologist, St. James's Hospital, Dublin.	1
Dr. Robert Cunney	Consultant Microbiologist HPSC and Temple Street Children's University Hospital, Dublin.	3
Dr. Carmel Cronin	Consultant Radiologist, Mater Misericordiae University Hospital, Dublin.	0
Mr. Garrett Durkan	Consultant Urologist, Galway University Hospital.	0
Ms. Kate Fitzpatrick	Urology Nurse Specialist, Beacon Hospital, Dublin and Chair European Association Urology Nursing. Representative of IAUN (Irish Association of Urology Nurses).	3
Dr. Margaret Hannan	Consultant Microbiologist, Mater Misericordiae University Hospital, Dublin.	3
Ms. Ann Higgins	Assistant Director of Nursing, Infection Prevention and Control, Mater Private Hospital; and representing the Infection Prevention Society.	1
Ms. Lenora Leonard	Infection Prevention and Control Nurse Specialist, Beacon Hospital, Dublin.	3
Ms. Catherine McGarvey	Prostate Cancer Nurse Specialist, Misericordiae University Hospital, Dublin.	5
Professor Philip Murphy	Consultant Microbiologist, Tallaght Hospital Joined group in August 2013	3
Ms. Eileen Nolan	Project Manager, NCCP	6
Dr. Cliodhna Ni Bhuachalla	Specialist Registrar Microbiology Moved to Australia in late 2013 and remained a contributor to this policy.	2
Mr. Kevin O'Regan	Consultant Radiologist, Cork University Hospital	1
Professor Tom Rogers	Consultant Microbiologist, St James's Hospital Joined group in August 2013	1
Librarians supporting the project:	Ms. Marie Carrigan, Librarian, St. Luke's Hospital Mr. Gethin White, Librarian, HSE	
Please note some members of the project board have not been members since the beginning, and this will be reflected in their attendances.		

APPENDIX 2: LITERATURE REVIEW - METHODOLOGY

NCCP GUIDANCE

- Aim to improve the quality of clinical care
- Are based on the best research evidence and expert consensus
- They prevent variation in practice
- Are developed using clear methods that are sound, transparent, consistent, and command the respect of stakeholders, including the Department of Health (DOH), and regulatory authorities such as the Health Information and Quality Authority (HIQA)

SUMMARY OF KEY POINTS

- Gaps in information are identified and clearly defined clinical questions are formulated
- The questions should be used as the basis for searching for the evidence
- A copy of the literature search should be included in the appendices of reports
- Information obtained from experts in the field, including expert opinion from those on the group, should also be documented
- The evidence should be appraised in terms of validity (truthfulness) and transferability to the Irish situations.
- Recommendations should be evidence-based, include clinical/research evidence, as well as expert opinion, population/patient values and cost

CLINICAL PICO (POPULATION, INTERVENTION, CONTROL, OUTCOME) QUESTIONS

PICO Clinical Questions	
Should patients who are undergoing prostate biopsy be screened before hand?	
Population (P)	Patients undergoing TRUS-guided prostate biopsy
Intervention (I)	Screening
Control (C)	Not Screening
Outcome (O)	Drug Resistance, Microbial Resistance
What are the optimum prophylactic antimicrobials for patients who are undergoing prostate biopsy?	
Population (P)	Patients undergoing TRUS-guided prostate biopsy
Intervention (I)	Appropriate Antimicrobial Prophylaxis
Control (C)	Inappropriate Antimicrobial Prophylaxis
Outcome (O)	Antimicrobial Prophylaxis/methods

PICO Clinical Questions (Continued)

What is the optimum surveillance for men undergoing prostate biopsies?

Population (P) Patients undergoing TRUS-guided prostate biopsy
Intervention (I)
Control (C)
Outcome (O) Optimum surveillance

How should patients who develop infection(s) post prostate biopsy be managed?

Population (P) Patients who have an infection post TRUS-guided prostate biopsy
Intervention (I)
Control (C)
Outcome (O) Optimum management of men with infection post TRUS-guided prostate biopsy

Should diabetes be a risk factor for colonisation with resistant organisms?

Population (P) Prostate cancer patients undergoing TRUS-guided prostate biopsy
Intervention (I) TRUS-guided prostate biopsy
Control (C) Diabetes or no diabetes
Outcome (O) Risk factor for colonisation with resistant organism

Should we include a patient's hospitalisation in any hospital abroad in the past 12 months or an Irish hospital reporting a CRE outbreak in the past 12 months as risk factors – If yes, should we recommend that such patients routinely have a rectal swab performed for carriage of CRE?

Population (P) Prostate cancer patients undergoing TRUS-guided prostate biopsy who have been in hospital with CRE within a year
Intervention (I) TRUS-guided prostate biopsy
Control (C)
Outcome (O) Higher risk of developing infection post TRUS-guided prostate biopsy

Is it cost effective to screen all patients for antibiotic resistant *Enterobacteriaceae* before they have a prostate Transrectal Ultrasound-Guided Biopsy (TRUS) guided prostate biopsy?

Population (P) Men having a TRUS-guided prostate biopsy
Intervention (I) Extended Spectrum Beta Lactamases (ESBL) screening
Control (C) not to screen for ESBL
Outcome (O) Cost Effectiveness of ESBL screening in reducing number with septicaemia post TRUS-guided prostate biopsy.

SAMPLE SEARCH STRATEGY

Q.3 what is the optimum post TRUS-guided prostate biopsy infection surveillance programme that should be in place in units performing TRUS-guided prostate biopsy?

Databases searched: Medline, Pubmed, Embase, Cochrane Library, and Google Scholar

Limits: Published in last 5 years, English language

Keywords used: Prostate Cancer, TRUS, TRUS-guided prostate biopsy, Transrectal ultrasound, Infection, Surveillance

MeSH headings used in Medline and Pubmed: Prostatic Neoplasm, Prostate/ultrasonography, Biopsy, Needle/*methods

APPENDIX 3: DETAILS OF CONSULTATION PROCESS 3RD TO 27TH FEBRUARY 2014

The draft national policy and a feedback form were sent to the following organisations for feedback. In addition a copy of the draft policy was placed on the NCCP website during the consultation period.

1. Irish Society of Clinical Microbiologists
2. Infection Prevention Society
3. Surveillance Scientists Association
4. IAPG - Irish Antimicrobial Pharmacists Group
5. Radiologists in the following hospitals that perform TRUS prostate biopsy (please note this list does not include all hospitals that perform TRUS e.g. private hospitals):
 - Beaumont Hospital
 - Cork University Hospital
 - Galway University Hospital
 - Mater University Hospital
 - Mercy Hospital, Cork
 - Mid-Western Regional Hospital
 - St. James's Hospital
 - St. Vincent's University Hospital
 - Tallaght Hospital
 - Waterford Regional Hospital
6. Irish Association of Emergency Medicine
7. Irish College of General Practitioners ICGP
8. NCCP CEO / Leads group
9. Ten centres that took part in the survey:
 - Beaumont Hospital
 - Cork University Hospital
 - Galway University Hospital
 - Mater University Hospital
 - Mercy Hospital, Cork
 - Mid-Western Regional Hospital
 - St. James's Hospital
 - St. Vincent's University Hospital
 - Tallaght Hospital
 - Waterford Regional Hospital
10. Irish Urology Nurses Association
11. Irish Society of Urology

The consultation period was for three weeks from 3rd February to 28th February 2014. We received feedback from the following:

- Dr. Deirdre Murray, Specialist in Public Health, NCCP
- Dr. Suzanne Corcoran, Consultant Microbiologist, Bon Secours Hospital, Glasnevin and Irish Society of Clinical Microbiologists
- Mr. David Mulvin, Consultant Urologist, St. Vincent's Hospital, D 4
- Mr. Frank O'Brien, Consultant Urologist, Cork University Hospital and Waterford Regional Hospital
- Ms. Ann Higgins, Chair Infection Prevention Society, and Project Board Member
- Professor Rogers, Consultant Microbiologist, St. James's Hospital and Project Board Member
- Dr. Geraldine Moloney, Clinical Research Fellow, Dept of Clinical Microbiology, Trinity College Dublin
- Professor Martin Cormican, Consultant Microbiologist, Galway University Hospital
- Professor Peter McCarthy, Consultant Radiologist, Galway University Hospital
- Dr Breida Boyle, Consultant Microbiologist, St. James's Hospital and Project Board Member

APPENDIX 4: SUGGESTED PATIENT QUESTIONNAIRE (PRE TRUS-GUIDED PROSTATE BIOPSY)

To help us choose the correct antibiotic prophylaxis regimen in order to reduce the risk of infection after your patient's biopsy, please complete the following;

1. Has your patient been prescribed a fluoroquinolone in the last 6 months (e.g. Ciprofloxacin, Ofloxacin)?
2. Has your patient previously had a TRUS biopsy? If so did your patient have an infection after the TRUS biopsy?
3. Has your patient been hospitalised abroad in the last year?
4. Is your patient a Healthcare worker?
5. Have previous microbiology results indicated that your patient has a history of ciprofloxacin resistant <i>Enterobacteriaceae</i> (e.g., <i>E. coli</i>), ESBL or other antibiotic resistant organism (please state which)?

APPENDIX 5: HELICS SURVEILLANCE DEFINITIONS FOR URINARY TRACT INFECTION AND BLOODSTREAM INFECTION

1.3 UTI: URINARY TRACT INFECTION

UTI-A: microbiologically confirmed symptomatic UTI

Patient has at least ONE of the following signs of symptoms with no other recognised cause: fever (>38°C), urgency, frequency, dysuria, or suprapubic tenderness **and** patient has a positive urine microbiology culture report. That is, $\geq 10^5$ microorganisms per ml of urine with no more than two species of microorganisms detected in the same urine sample.

UTI-B: not microbiologically confirmed symptomatic UTI

Patient has at least TWO of the following with no other recognised cause: fever (>38°C), urgency, frequency, dysuria, or suprapubic tenderness **and** at least ONE of the following:

- Positive dipstick for leukocyte esterase and/or nitrite
- Pyuria – White blood cells (WBC) or pus cells seen on urine specimen microscopy with ≥ 10 WBC/ml or ≥ 3 WBC/high-power field of unspun urine
- Organisms seen on Gram stain of unspun urine
- At least two urine cultures with repeated isolation of the same uropathogen (Gram-negative bacteria or *Staphylococcus saprophyticus*) with $\geq 10^2$ colonies/ml urine in non-voided specimens
- $\leq 10^5$ colonies/ml of a single uropathogen (Gram-negative bacteria or *S. saprophyticus*) in a patient being treated with effective antimicrobial agent for a urinary infection
- Clinician clinical diagnosis of a urinary tract infection
- Clinician institutes appropriate therapy for a urinary infection

Reporting instruction: For urinary tract infection, only fill in one subcategory (where more than one UTI definition is met by the patient, prioritise urinary tract infection as UTI-A>UTI-B).

1.6 BSI: BLOODSTREAM INFECTION

BSI: Laboratory-confirmed bloodstream infection

- ONE positive blood culture for a recognised pathogen (e.g., *Staphylococcus aureus*, *Escherichia coli*, *Candida albicans* etc.) [If any doubt regarding what constitutes a recognised pathogen, please discuss with microbiology]

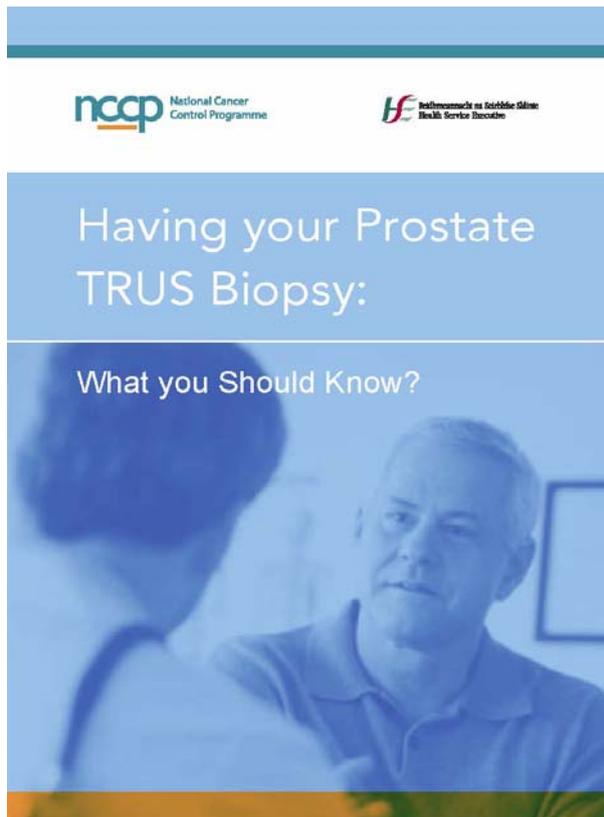
or

- Patient has at least ONE of the following signs or symptoms: fever (>38°C), chills or hypotension **and** TWO positive blood cultures for a common skin contaminant** (the same organism must have been isolated from two separate blood culture samples, usually taken within a 48 hour period).

**Skin contaminants = coagulase-negative staphylococci, *Micrococcus sp.*, *Propionibacterium acnes*, *Bacillus spp.*, *Corynebacterium spp.*

APPENDIX 6: NCCP PATIENT BOOKLET: HAVING A TRUS PROSTATE BIOPSY: WHAT YOU SHOULD KNOW

This booklet will be available on the NCCP webpage www.cancercontrol.hse.ie.



Contents

What should I know about having a prostate biopsy?	3
What is a prostate TRUS biopsy?	4
What should I do before my prostate biopsy?	6
What happens on the day of my prostate biopsy?	8
What happens at the hospital after my prostate biopsy?	10
What should I do after my biopsy?	11
What might I notice after my prostate biopsy?	11
When will I get the results?	14
Useful contacts	14
Questions to ask your doctor or nurse	16

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GLOSSARY:

Cockcroft-Gault equation: $\text{CrCl (ml/min)} = F [140 - \text{Age (yr)}] \times [\text{Weight (kg)}] / \text{Serum Creatinine } (\mu\text{mol/L})$
F=1.04 (female) or 1.23 (male)

Resistant *Enterobacteriaceae*: Resistance to ESBL (extended spectrum β lactams), fluoroquinolones and aminoglycosides

ABBREVIATIONS:

AMNCH	Adelaide Meath and National Children's Hospital
AMR	Antimicrobial Resistance
ANTT	Aseptic Non Touch Technique
AUA	American Urology Association
BSI	Blood Stream Infection
CRE	Carbapenem Resistant <i>Enterobacteriaceae</i>
CrCl	Creatinine Clearance
ESBL	Extended Spectrum β -lactamase
ED	Emergency Department
EU	European Union
GP	General Practitioner
HELICS	Hospitals in Europe Link for Infection Control Surveillance
HPSC	Health Protection Surveillance Centre
ICU	Intensive Care Unit
ID	Infectious Diseases
IM	Intramuscular
IV	Intravenous
KPI	Key Performance Indicators
LFT	Liver Function Test
MDT	Multi-disciplinary Team Meeting
MIC	Minimum Inhibitory Concentration
MSU	Mid Stream Urine
NCCP	National Cancer Control Programme
NHS	National Health Service
N/S	Not specified
OPD	Outpatient Department
PO	Per Oral
PPE	Personal Protective Equipment
PSA	Prostate Specific Antigen
PR	Per Rectum
RAPC	Rapid Access Prostate Clinic
TRUS	Transrectal Ultrasound
UTI	Urinary Tract Infection

National Cancer Control Programme
An Clár Náisiúnta Rialaithe Ailse
King's Inns House
200 Parnell St
Dublin 1

Tel: +353 (0)1 8287100
Fax: +353 (0)1 8287160
Email: info@cancercontrol.ie
Website: www.cancercontrol.hse.ie

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