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Short Report

# Introduction of surgical site surveillance post transrectal ultrasound (TRUS) guided prostate biopsy and the impact on infection rates

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#### SUMMARY

**Background:** Transrectal ultrasound (TRUS)-guided prostate biopsy is associated with infection rates between 0.3 % and 3.2%. Infectious complications include urinary tract infection, prostatitis, bacteraemia and sepsis. Surgical site surveillance in this patient cohort is becoming increasingly important given global increases in antimicrobial resistance.

*Methods:* Surgical site surveillance for patients undergoing TRUS biopsies was introduced in our hospital in 2017. All patients had a risk assessment form completed to assess for carriage or risk of carriage of multi-drug resistant organisms. An intense analysis was completed on any patient who developed an infection post-TRUS biopsy. Data was fed back on a quarterly basis to a multi-disciplinary working group. Members of this group include a Consultant Microbiologist, Infection Prevention and Control Nurse, Consultant Urologist, Antimicrobial Pharmacists and Clinical Nurse Ward Managers.

**Results:** 784 TRUS-guided biopsy of the prostate procedures were performed between January 1 st 2017 and the end of the third quarter, 2021. The rate of infection post-TRUS was 2.7% in 2017, 3.4% in 2018 and 3.2% in 2019. This improved to 0% in 2020 and 0.8% in the first three quarters of 2021.

**Conclusions:** Several interventions were introduced resulting in a sustained reduction in infection rates in this cohort. These include changing the choice of surgical antibiotic prophylaxis, improvement in the timing of antibiotic prophylaxis and scheduling of other urology procedures. The introduction of surgical site surveillance and multi-disciplinary input has demonstrated a reduction in infection rates post TRUS biopsy.

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# Introduction

\* Corresponding author. Tel.: +61 459 233 282. *E-mail address:* cianlen@gmail.com (C. Lenihan). Prostate cancer has the second-highest incidence of cancer amongst males globally as well as being the fifth leading cause of cancer mortality [1]. This, as well as a persistently

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upward trend of new cases diagnosed annually, has led to a growing need for accurate and safe methods of diagnosis [2]. The gold standard for diagnosis of prostate carcinoma is histological assessment obtained by transrectal ultrasoundguided (TRUS) systematic core needle biopsy [3]. While this diagnostic method is accurate, it is an invasive procedure that does not come without risk. This article will focus on the infectious complications of the procedure, which include; urinary tract infection, prostatitis, bacteraemia and sepsis.

There is a paucity of guidelines with regards to accepted rates of infectious complications post-TRUS-guided biopsy of the prostate. However, the current literature suggests that infection rates between 0.3% and 3.2% are to be expected [4]. It should be noted that this figure can vary enormously, with the American Urological Association quoting an expected post-procedure infection rate of between 5-7% [5].

Given such potential for infectious complications, several methods have been proposed to minimize this risk to the utmost extent possible. Proposed methods of proven effect in the literature include; augmented and targeted prophylaxis, the use of transperineal biopsy, and the use of povidone-iodine [6-8].

The Bon Secours Hospital, Cork, Ireland, is a large private hospital that performs both acute and elective urological procedures. Drawing on evidence-based methods from the available literature, national guidance, and using proven methods of reducing surgical site infection from other procedures, several new interventions were introduced at our site to help tackle the problem of infectious complications post-TRUSguided-biopsy of the prostate [9].

#### Methods

This descriptive, prospective cross-sectional study examined all patients who underwent a TRUS-guided biopsy of the prostate within our facility from 1st January 2017 to the conclusion of the third guarter of 2021. All patients undergoing a TRUS-guided biopsy of the prostate in the Bon Secours hospital have a surveillance form completed that is then returned to the Infection Prevention and Control Department. Data collected included patient demographics, antibiotic prophylaxis and timing, and if they had another procedure within 72 hours of the TRUS-guided biopsy. Any patient that is readmitted to the hospital within 30 days of the procedure is reviewed to examine if the patient was readmitted with a surgical site infection (SSI). An intense analysis report is completed on any patient who develops an infection post-TRUS-guided biopsy. Infections are classified as bloodstream infection, urinary tract infection or sepsis response without positive blood cultures. A surveillance report is generated on a quarterly basis. Surveillance data and the intense analysis report are fed back on a quarterly basis to a multi-disciplinary working group. Members of this group include a Consultant Microbiologist, Infection Prevention and Control Nurse, Consultant Urologist, Antimicrobial Pharmacists and Clinical Nurse Ward Managers.

The choice of surgical antibiotic prophylaxis (SAP) for this procedure has changed throughout the last number of years, in keeping with national guidance, and forms a key component of this study [9]. Prior to 2016, a triple prophylactic antibiotic approach, comprising of metronidazole, gentamicin and ciprofloxacin was used. Ciprofloxacin was also continued for seven days following the procedure. From 2017-2019, patients



Figure 1. Timeline of events and subsequent interventions within the study period. SAP; Surgical Antibiotic Prophylaxis, EUA; European Association of Urology, PGD; Patient Group Directive.

at increased risk of, or with known prior colonisation of multidrug-resistant organisms (MDRO) received both ciprofloxacin and gentamicin prior to the procedure. Patients without these risk factors or known colonisation received ciprofloxacin alone. In 2018 and 2019 the Food and Drug Administration (FDA) and European Medicine Agency (EMA) issued warnings concerning the use of fluoroquinolone antibiotics, citing increasing concerns of side-effects such as neuropsychiatric toxicity, long-term disability and aortic dissections and aneurysms [10]. In response to this, the European Association of Urology (EAU) in June 2019 issued a statement recommending against the use of fluoroquinolones for prevention of infection in TRUS-guided biopsy of the prostate. [11]. In line with these recommendations and using data obtained from the surveillance program, in 2019, the use of ciprofloxacin for pre-procedure prophylaxis in our hospital was suspended, and gentamicin was used as the sole agent for prophylaxis. As a result of surveillance, as well as stringent quarterly analysis of all patients who undergo TRUS-guided biopsy of the prostate in our hospital, it was guickly noted that there had been a large increase in post-procedure infection rates in the last quarter of 2019. This appeared to align with the recent change in antibiotic prophylaxis choice. Guided by this data, an informed decision was made that as of 2020, all patients undergoing this procedure would receive both gentamicin and ciprofloxacin prophylaxis. One dose of ciprofloxacin is given 1-2 hours pre-procedure, and one final dose is given 12 hours after the first. A single dose of gentamicin is given within 60 minutes of the procedure. This remains in effect at present. A copy of the three compulsory pre-procedural forms utilised in 2017, 2019 and 2020 can be found in Supplementary Material files 1, 2 and 3 respectively.

As well as the changes to antibiotic prophylaxis outlined above, a number of further interventions were made. These changes consisted of; a multidisciplinary evaluation of the process to improve the timing of antibiotic prophylaxis, including the development of flow charts for the ward, deferral of TRU-CUT procedures to greater than one week post TRUS-guided biopsy, and a patient group directive (PGD) was developed to enable nurses to dispense a second dose of ciprofloxacin to patients to take post-discharge, with the aim of improving medication adherence. TRU-CUT is another type of prostate biopsy that is performed in order to obtain targeted samples of a palpable nodule in the prostate. Surveillance and analysis of patients undergoing TRUS-guided biopsies continued, and the data was then analysed and fed back to see what impact, if any, the new measures had borne on the rate of infective complications.

A timeline of the events is outline in Figure 1 below:

### Results

784 TRUS-guided biopsy of the prostate procedures were performed between January 1<sup>st</sup> 2017 and the end of the third quarter, 2021. There were 18 associated infections recorded during this time, an overall infection rate of 2.3%. As previously stated, there are currently no national figures with which to compare this figure, however international data suggests rates of between 0.3-3.2% [4]. From the beginning of January 1<sup>st</sup> 2020 to the end of the third quarter 2021, however, there were 228 procedures performed in our hospital, with 1 associated infection – an overall infection rate of 0.43%. This is compared

to a previous overall infection rate of 3% from 2017 to 2019 (17 associated infections from 556 procedures).

Of the 18 TRUS associated infections reported since 2017, 5 were bloodstream infections (0.6% of all procedures) 8 were urinary tract infections (1% of all procedures), and 5 were considered to have a septic response without positive blood cultures (0.6% of all procedures). These results are highlighted below.

In the fourth quarter of 2019 alone, directly after switching our choice of surgical antibiotic prophylaxis as outlined in the Methods section to single-agent gentamicin, there were 3 TRUS associated infections from 32 procedures. This represented an infection rate of 9.4% and prompted a further change in antibiotic choice as well as the remaining interventions outlined in this surveillance bundle. The implemented changes from January 1<sup>st</sup> 2020, led to a statistically significant reduction in infection rates. The rate of infection was 0.43% with dual antibiotic prophylaxis and our other outlined interventions, versus 9.4% with gentamicin alone (P=0.0063) (Table I).

All patients have a risk assessment form completed to assess for carriage or risk of carriage of MDRO on admission. Since 2016, all patients are screened for extended-spectrum beta-lactamases (ESBL) and carbapenemase-producing Enterobacteriaceae (CPE) on the day of the procedure. If a patient had a history of an MDRO or a recent positive urinary culture they were given appropriate prophylaxis. Since its commencement, 1031 patients undergoing the procedure have been screened for ESBL and CPE. 38 (4%) of these patients screened positive for ESBL, with none screening positive for CPE. These results are highlighted in Table II. Patients are swabbed on the day of admission prior to the procedure. As outlined in Supplementary Files 1, 2 and 3, tailored prophylaxis is given as appropriate based on risk factors for MDROs. The results of screening, while not available at the time of procedure, are used should a patient develop an infection. At this point the screening results are available and are utilised to ensure the patient is commenced on the appropriate antibiotic (Table III).

The table below outlines the number of infections resulting from gentamicin-resistant, ciprofloxacin-resistant, and ESBL positive isolates. It is noted that only one infection over the last four years was as a result of an ESBL positive isolate.

Attempts to improve the timing of antibiotic prophylaxis had mixed results. Interventions included educational sessions by antimicrobial pharmacists, introduction of flow charts and improved communication between the ward and interventional radiology. Flow charts were developed for the ward to emphasise the importance of timely antibiotic prophylaxis, as well as clearly defining the appropriate choice of antibiotic. Wards were considered to be compliant with hospital guidelines for antibiotic prophylaxis when ciprofloxacin was administered between 1-2 hours and gentamicin within 1 hour of the commencement of the procedure.

Ciprofloxacin was administered within the correct timeframe 73% of the time in 2020 and 62% of the time in the first three quarters of 2021. This was a reduction from a compliance rate of 81% in 2019. It is possible that this reduction in compliance was as a result of the COVID-19 pandemic, which saw changes in hospital activity, resulting in patients for TRUSguided prostate biopsy being admitted to different wards and units of the hospital. The reduced level of familiarity of staff in these units with the procedure may have contributed to the lower levels of compliance with timing. Compliance with the timing of gentamicin administration however saw a noticeable

#### Table I

Number of biopsies performed with categorisation of associated infections

	2017	2018	2019	2020	Qtr1	Qtr2	Qtr 3	2021	2017-
					2021	2021	2021		2021
Total # of TRUS biopsies procedures	220	178	158	109	39	42	38	119	784
No. Of TRUS associated infections	6	6	5	0	0	0	1	1	18
Overall TRUS infection rate(%)	2.7	3.4	3.2	0.0%	0.0	0.0	2.6	0.8	2.3%
TRUS associated BSI numbers	1	1	3	0	0	0	0	0	5
TRUS associated BSI rate (%)	0.5	0.6	1.9	0.0%	0.0	0.0	0.0	0.0	0.6%
TRUS associated UTI numbers	3	4	1	0	0	0	0	0	8
TRUS associated UTI rate (%)	1.4	2.2	0.6	0.0%	0.0	0.0	0.0	0.0	1%
TRUS associated Sepsis response ( neg cultures) numbers	2	1	1	0	0	0	1	1	5
TRUS associated Sepsis response ( neg cultures) rate	0.9	0.6	0.6	0.0%	0.0	0.0	2.6	0.8	0.6%

**Legend**: BSI; Bloodstream infection. Defined as one positive blood culture for a recognised pathogen or two positive cultures for a common skin contaminant with signs/symptoms associated with sepsis. UTI; Urinary tract infection. Defined as having urinary tract associated symptoms and a positive urine microbiology culture report. Sepsis (neg cultures); a clinically septic response believed to be secondary to the procedure, without positive blood cultures.

#### Table II

Frequency and results of pre-procedural screening for MDROs (multidrug-resistant organisms)

2016 to 2021 n=968	Frequency		No of Pos ESBL results in patients who were screened	% of patients screened positive ESBL	No of Pos CPE screens	% of patients screened positive CPE
Yes	991	96%	38	4%	0	0%
No	40	4%				
	1031	100%				

**Legend**: ESBL; Extended spectrum beta-lactamase, CPE; Carbapenemase-producing enterobacterales.

improvement, from 43% in 2019 to 66% in 2020 and 84% for the first three quarters of 2021. Procedures were developed between staff nurses on the day ward and nurses in the

interventional radiology department to ensure there were no unexpected delays in the department prior to the provision of gentamicin. As gentamicin was given relatively close to the

### Table III

Analysis of infections resulting from MDROs (multidrug-resistant organisms)

	2017	2018	2019	2020	Qtr1 2021	Qtr 2 2021	Qtr 3 2021	2021
Total # of TRUS biopsies procedures	220	178	158	109	39	42	38	119
No. Of TRUS associated SSI	6	6	5	0	0	0	1	1
No of infections (BSI and UTI) due to Gentamicin resistant isolates.	0	1	1	0	0	0	1	1
% of infections (BSI and UTI) due to Gentamicin resistant isolates.	0.0%	17%	20%	0%	0%	0	100%	100%
No of infections (BSI and UTI) due to ESBL positive isolates.	0	0	1	0	0	0	0	0
% of infections (BSI and UTI) due to ESBL positive isolates.	0.0%	0.0%	20%	0%	0%	0	0	0%
No of infections (BSI and UTI) due to Ciprofloxacin resistant isolates.	1	4	2	0	0	0	0	0
% of infections (BSI and UTI) due to Ciprofloxacin resistant isolates.	33%	66%	40%	0%	0%	0	0	0%

### Table IV

The effect of reduced number of TRU-CUT procedures on infection rates

	2017	2018	2019	2020	2021	Total 2017/2021
(A) All patients who had TRUS procedure	220	178	158	109	119	784
(A) Total no of TRUS SSI	6	6	5	0	1	18
(A) TRUS SSI rate	2.7%	3.4%	3.2%	0.0%	0.0%	2%
(B) Total number of TRUS patients who didn't have a TRU –CUT *	204	145	134	107	118	708
(B) Total number of SSI identified in patients who had a TRUS procedure but no TRU-CUT	4	2	3	0	0	9
(B) Rate of SSI (in Patients who had a TRUS but no TRU CUT)	2.1%	1.4%	2.2%	0.0%	0.0%	1%
(C) Total number of Patients who had a TRUS and a TRU-CUT procedure.	26	33	24	2	1	86
(C) Total number of SSI identified in patients who had a TRUS and a TRU-CUT procedure.	2	4	2	0	0	8
(C) Rate of SSI (in Patients who had a TRUS and TRU-CUT)	8%	12%	8%	0%	0%	9%

**Legend**: \* = A small number of these patients may have had a second urology procedure within 72 hours of their TRUS-guided biopsy, however none of the patients in this category had a TRU-CUT urological procedure – the targeted intervention.

procedure time, this had a positive impact on compliance. In contrast, oral ciprofloxacin is given 1-2 hours pre-incision and therefore any delays in the process or in the interventional radiology department can't be as easily allowed for and may have resulted in non-compliance with timing.

Higher infection rates were seen in patients who had a TRU-CUT procedure within 72 hours of a TRUS biopsy between 2017 and 2019 inclusive. Until January 2020, this procedure was performed within 72 hours of the initial TRUS biopsy. Prior to this, higher rates of infection were noted in patients who had a TRU-CUT procedure within 72 hours of a TRUS biopsy (Table IV). Since January 2020, there was a reduction in the number of TRU-CUT biopsies performed and the decision was made that if a patient was to require a TRU-CUT biopsy that they would have this procedure performed at least 1 week after the TRUS biopsy where possible. A significant reduction in infection rates was observed (Table IV).

As well as the above measures, a patient group direction (PGD) was performed to allow nurses to dispense the second dose of ciprofloxacin to patients to take post-discharge. By the time patients were discharged from hospital, and travelled home, they were experiencing difficulties in accessing their local pharmacy to obtain the second dose of ciprofloxacin. It was determined that by providing the patients with a take-home dose of ciprofloxacin, patients were less likely to have their second dose delayed or omitted. We believe this offered an opportunity to improve patients' medical compliance without compromising care.

#### **Discussion and recommendations**

Infection is the most troublesome complication encountered post-TRUS-guided biopsy of the prostate, and indeed the incidence of hospitalisation due to severe infections after this procedure appears to be increasing [12]. The need for frequent surveillance is emphasised in national guidelines [9]. This study highlights the importance of ongoing surveillance of such a procedure, with emphasis on the need for frequent analysis of infective complications. By having quarterly analysis of infection rates, we were able to intervene when a noticeable surge in infective complications became apparent in late 2019. Thus our first recommendation from this study is the necessity of surveillance for any procedure which carries a high risk of infective complications, with frequent analysis allowing for early intervention.

The importance of a multi-disciplinary team approach to optimising surgical procedures and reducing their infective complications cannot be understated. There was a significant reduction in infections since the beginning of 2020. It is difficult to identify the precise impact of each intervention. However, evidently, there were two significant changes that had a large bearing on infection rates. Firstly, the change from single agent gentamicin to dual-agent prophylaxis and also the deferral of TRU-CUT procedures to more than one week post-TRUS-guided biopsy with resultant decrease in the number of these procedures that were performed. Indeed, as previously outlined, augmented and targeted prophylaxis appears to have a substantial effect on rates of infection post-TRUSguided biopsy of the prostate in the available literature [6-8]. Why the change to single agent gentamicin led to an increase in infections when compared to dual prophylaxis is unclear. We hypothesise that this could potentially be due to gentamicin's relatively poorer penetration of the prostate when compared to ciprofloxacin. The deferral of TRU-CUT procedures to greater than one week post initial biopsy, as well as the overall decrease in the number of these procedures is likely to have decreased infection rates largely due to their being less procedural exposure, with data from 2017 through 2019 showing that patients who also underwent this procedure were at higher risk of developing infection.

Given the large impact, our surgical bundle appeared to have on infection rates, we also recommend the numerous other interventions that have been discussed in this study. Namely; methods to improve the timing of antibiotic prophylaxis, flow charts for the ward to streamline antibiotic choice, deferring other urological procedures where possible, and utilising patient group directives (PGD), are all practices which are cost-effective and relatively easy to implement.

# **Study limitations**

While a relatively large sample size has been obtained over the studied period (2017–2021), this analysis is limited by being based on results obtained from a single centre. Thus, the results achieved here may not be representative of other services, nationally or internationally. A longer surveillance period or prospective multi-centre study would be helpful in addressing this limitation.

Furthermore, as outlined above, the introduction of our surgical site surveillance bundle included numerous interventions (choice of surgical antibiotic prophylaxis, improvement in timing of prophylaxis and scheduling of other urology procedures) and therefore the exact influence of each intervention is difficult to determine. It is also noted that while there was a particularly high rate of SSI in the final quarter of 2019, the decision to change our SAP was made based on this relatively short data period.

A lack of data remains, both nationally and internationally, as to acceptable levels of infective complication post-TRUSguided biopsy of the prostate, and our study is limited by inferring our conclusions in this regard, from the broader literature. More research is needed in this area, and we hope that this study will add to the current literature on what rates of infection can be expected, even with best practice.

# Conclusions

Since surgical site surveillance post-TRUS-guided biopsy of the prostate was introduced in our hospital in 2017, we have demonstrated a reduction in infection rates. In addition to quarterly data feedback meetings, several changes were implemented during that time. The implemented changes discussed above have led to a reduction in SSI from an average of approximately 3% in the preceding 3 years to 0.43% in 2020 and the first three quarters of 2021.

# **CRediT** author statement

Cian Lenihan: Methodology, Writing — Original Draft, Writing — Review & Editing, Formal analysis, Visualisation, Validation, Project administration. Emma Daly: Conceptualisation, Formal Analysis, Project Administration. Margaret Bernard: Visualization, Data curation, Resources. Catriona Murphy: Visualization, Data curation, Resources. Sandra Lauhoff: Writing - Review & Editing, Data curation, Resources. Margaret Power: Writing - Review & Editing, Data curation, Resources. Dermot Lanigan: Resources, Investigation. Peter Ryan: Resources, Investigation. Olive Murphy: Conceptualisation, Supervision. Marianne Fraher: Conceptualisation, Supervision.

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## **Conflicts of interest**

The authors declare that there is no conflict of interest.

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### Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.infpip.2022.100247.

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