

White Paper



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AUA Quality Improvement Summit 2014: Conference Proceedings on Infectious Complications of Transrectal Prostate Needle Biopsy

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ABSTRACT

Purpose: The AUA Quality Improvement Summit is a continuing AUA effort to provide education around issues related to quality improvement and patient safety. Due to the rapidly increasing rates of hospitalization following prostate needle biopsy, the Quality Improvement Summit's choice of Infectious Complications of Transrectal Prostate Needle Biopsy (TPNB) as a focus of this first conference is both timely and of considerable importance to patient safety.

Materials and Methods: The information presented at the AUA Quality Improvement Summit is largely unpublished data provided by the presenting physicians. Infection rates are predominantly self-reported with protocols specified by the physicians' home institutions. Beyond the identified speakers, the open forum of this summit allowed for input from a majority of the participants.

Results: Current hospitalization rates for TPNB infections vary widely from 0.5 to 6 percent. Antibiotic resistance of coliform organisms appears to be a major risk for these infectious complications. The prophylactic protocols used also vary widely amongst the represented institutions. Antibiotic resistance profiles show extreme regional variation, and as such, a prophylaxis antibiotic protocol should be based on the current local antibiogram in order to reduce infection rates. Opinions vary in relation to the specific antibiotics appropriate for an augmented antibiotic prophylaxis, in the use of rectal swab and pre-biopsy enema, povidine-iodine preparation of the rectal vault. Standardization of the transrectal antibiotic prophylaxis across practices has been proven to reduce the infectious complications rates.

Conclusions: Urologists should monitor the practice's prostate biopsy infection rates and consult the current local antibiogram. Physicians should query patients to assess whether or not they are high-risk for fecal carriage of resistant coliform organisms, an identified risk for a TPNB complication. Individuals at high-risk for resistant coliforms may be identified by recent antibiotic usage (within six months), foreign travel, and exposure to healthcare environments whether as an employee or patient. When a patient is deemed high-risk for resistant organisms prophylactic protocols might be intensified; a rectal swab might be considered, or the antibiotic coverage may be augmented.

INTRODUCTION

In On January 25, 2014, the American Urological Association (AUA) held its inaugural Quality Improvement Summit at AUA headquarters in Linthicum, Maryland. The summit was convened in a continuing effort on the part of AUA to provide quality improvement and patient safety training to AUA members. The Quality Improvement Summit addressed the timely topic of prostate needle biopsy complications, focusing primarily on the increasing number of post-biopsy infections. Under the direction of Summit Chair Dr. Timothy Averch, the discussion was organized into five main sections under the central theme of reducing complications associated with transrectal ultrasound-guided (TRUS) prostate biopsies. Each section included several presentations followed by group discussions involving both panel and audience members.

The topic of prostate needle biopsy was chosen for the inaugural summit due to its topical nature. In a 2010 article published in the *Journal of Urology*, Nam et al.¹ discussed a nearly 4 percent rise in 30-day admission rates due to infection following prostate needle biopsy. Since the publication of this study of over 75,000 Canadian patients, a number of other physicians have noticed similar rises in their own patient populations. Whether it is due to antibiotic resistance or prebiopsy preparation, this is a serious issue for patient safety. The risks of sepsis attendant with prostate biopsy may be greater than the benefits of early detection of prostate cancer, an indication that certain patients forego screening. Thus far, there is no consensus in support of specific quality improvement methods that will reduce post-biopsy complications.

As a quality improvement initiative, understanding the need for value-based medical practice, it is the goal of the AUA Quality Improvement Summit to bring together existing information and

translate it into practical use to benefit the patient. Currently, the suggested practices herein are based on expert opinion; future well-designed trials will be available to test protocols and outcomes measures aimed at the prevention of prostate needle biopsy complications.

**KEYNOTE SPEAKER—DR. KATE GOODRICH, CENTERS FOR MEDICARE &
MEDICAID SERVICES (CMS) CENTER FOR CLINICAL STANDARDS AND
QUALITY**

In recent years, CMS has turned its focus to a quality improvement strategy that concurrently pursues three aims: better care for individuals, better health for communities and populations, and affordable care. Under those aims are six goals: patient safety, patient and family engagement, communication and care coordination, effective prevention and treatment of disease, promotion of healthy living in communities, and creation of affordable healthcare through improvement.

Quality measurement is one means through which healthcare can be improved. While currently largely tied to payment incentives and patient-centered outcomes research, it is through the generation of comparative effectiveness that physician groups are able to learn from one another in order to improve quality in targeted areas, such as reduction of post-biopsy infection. It is CMS policy that measures should be patient-centered and outcome-oriented, whenever possible. The focus has been on developing measures that are meaningful both to patients and providers and removing those measures that are no longer appropriate. While it is no easy task to align measures across the country with every payer, there is recognition that this needs to take place.

Determining thresholds for good performance is challenging. Through the hospital value-based purchasing system, CMS is able to reward providers for achieving a particular benchmark as well as improvement. It is recognized that process measures do not always predict outcomes. In the case of prostate needle biopsy, infection rates will never hit zero percent, but improvements over time can be rewarded through the CMS reporting system.

It is the goal of CMS to reward providers who deliver better outcomes at lower costs through value-based practice. In order for this to happen, the clinical community needs to be actively engaged in developing measures and choosing measures to drive improvement. Physicians must work relentlessly to focus on patient harm and improve health outcomes through such forums as the AUA Quality Improvement Summit.

LITERATURE REVIEW/RISKS/WHITE PAPER—DR. CHRISTOPHER GONZALEZ, NORTHWESTERN UNIVERSITY

The AUA/Society of Urologic Nurses and Associates (SUNA) White Paper on the Incidence, Prevention and Treatment of Complication Related to Prostate Needle Biopsy² discusses the etiology, incidence, risk factors, prevention and management of the most common complications related to TRUS-guided prostate biopsy with a focus on infection, bleeding and urinary retention. Infection-related complications include bacteriuria, urinary tract infection (UTI), lower-urinary tract symptoms (LUTS), febrile UTI, bacteremia and sepsis. The number of men requiring hospitalization due to infectious complications ranges from 0.6 to 4.1 percent, which is a significant increase over the past ten years.¹ This is at least partially due to increasing quinolone resistance,

specifically quinolone-resistant *E. coli*. Data from Liss et al. study³ show that 22 percent of men tested prior to a prostate biopsy in 2011 were found to harbor quinolone resistant coliforms on rectal swab.

The appropriate prophylaxis course is dependent upon identifying patient risk factors. The most prominent risk factor is exposure to any form of antimicrobials within six months of the biopsy. Other contributing factors include hospital employment and recent international travel. Knowledge of the local antibiogram is also important in defining the prevalence of resistant coliform strains. While there is currently no standard topical preparation of the rectum prior to biopsy, all patients undergoing a TPNB require antimicrobials directed against common colonic flora according to the AUA Best Practice Policy Statement on Urologic Surgery Antimicrobial Prophylaxis and supported by randomized placebo controlled trials. Additionally, single dosing is as effective as three-day dosing, and a single dose is as acceptable as one-day dosing.⁴ Alternative antibiotic regimens should be considered if risk factors exist for infection complications. Infectious disease consultation may be considered on a case-by-case basis.

The antibiogram shows the current local results of a laboratory testing for the sensitivities of isolated bacterial strains to various antibiotics. Review of this document, which details antibiotic sensitivities for coliform organisms most commonly associated with prostate biopsy infectious complications, prior to antimicrobial prescription is an important practice. This will aid in the selection of an appropriate alternative regimen. For example, when infectious disease specialists advise against the use of certain antimicrobials, high resistance levels as seen on the local antibiogram may be extant.

RECTAL SWAB

LITERATURE—DR. CHRISTOPHER GONZALEZ, NORTHWESTERN UNIVERSITY

While swabbing for rectal culture and sensitivity has been proposed as a pre-procedural tool to assess rectal flora and gauge any potential antibiotic resistance, how well do rectal cultures correlate with subsequent urine or the blood cultures in the setting of a prostate biopsy infectious complication?

Antibiotic resistance in the rectal flora was first evaluated in England, wherein approximately 75 percent of the study group underwent rectal swab cultures.⁵ Antibiotic resistance in coliforms of the bowel flora was 0.2 percent to amikacin, 10.6 percent to ciprofloxacin and 13.3 percent to co-amoxiclav. Urinary and hematogenous isolates from seven of eight patients developing subsequent UTI or sepsis identified these resistant coliform bacteria. Based on the close correlation between antimicrobial sensitivity of the swab to the cultures of blood and urine, these authors concluded that all patients should receive a rectal swab. Targeted prophylaxis would be recommended for men shown to harbor resistant coliforms.

In a 2012 observational study,⁶ German researchers included 236 men given a peri-procedural questionnaire for identification of risk factors for resistance and a swab rectal culture. Quinolone resistant *E. coli* was found in 22 percent of the isolates. An identified risk factor was quinolone usage less than six months prior to the procedure. Of note, a recent prostate biopsy was not a risk factor. Of this patient population, three percent had infectious complications with six of seven resulting in sepsis.

Targeted prophylaxis may reduce the rates of infectious complications. In a case control study, Taylor et al. ⁷ performed targeted prophylaxis in 457 men based on the rectal swab and the local antibiogram. Of those patients who received targeted prophylaxis, none had infectious complications. A pre-biopsy rectal culture swab is associated with increased costs. However, the risks of prostate biopsy infectious complications are expected to rise as quinolone resistance in the rectal flora increases. The cost-effectiveness of rectal swabs and targeted prophylaxis still needs to be determined. To improve cost-efficiency, a pre-biopsy questionnaire might identify those patients considered high-risk for a prostate biopsy infectious complication. Utilization of rectal swab in that population with targeted prophylaxis as deemed necessary might minimize costs and decrease the rate of infectious complications. Other cost-neutral protocols to reduce infectious rates might include formalin disinfection of biopsy needles after use on the same patient. The use of fleet enemas prior to biopsy to reduce colony counts might be beneficial but is unproven.

IMPLEMENTATION—DR. MICHAEL LISS, UNIVERSITY OF CALIFORNIA SAN DIEGO

Pre-biopsy antibiotic prophylaxis is meant to minimize infectious complications in a cost effective manner. If rectal cultures reduce prostate biopsy infectious complications in a cost effective manner, protocols must be developed that guide the urologists, the collaborating microbiology laboratories and the infectious disease consultants. The basis of any implementation is based on two factors: acceptability and adoption. Any physician, microbiology laboratory and infectious disease consultant staff acceptance of a change in practice must be shown to be warranted and appropriate in both clinical and laboratory practice.

Successful adoption of targeted antibiotic prophylaxis directed by rectal culture requires the participation of multiple individuals, including the patient (who might have to make an extra trip to the lab), microbiologists, infectious disease consultants and urology office staff. Microbiologic protocols will need to standardize the proper way to culture bacteria. Infectious disease specialists will advise on targeted prophylaxis and on the treatment of any subsequent infectious complication. While the rectal swab can be performed by the urologist or at a nursing visit usually two weeks prior to the biopsy, the optimum timing of the swab has not been determined.

Multiple audience members shared personal experiences concerning difficulties with the logistics of implementing rectal culture in their practice. Much of this difficulty is in the lack of acceptance and adoption of rectal swabs by microbiologists and infectious disease consultants, cost concerns, and in patient demographics who live distant from the procedural space or the microbiology laboratory. While selected groups have had great success with the implementation of rectal swabs in their practice, this has not been widely adopted. The protocols regarding identification of at-risk groups and, most importantly, of standardized microbiology practices remains under-developed.

ANTIBIOTIC CHOICES

GUIDELINES—DR. J. STUART WOLF, JR., UNIVERSITY OF MICHIGAN

The degree of benefit afforded by surgical prophylaxis is determined by three considerations: patient-related factors, which is the ability of the host to respond to bacterial invasion; procedural factors, which is the likelihood of bacterial invasion of the operative site; and the potential morbidity of infection. In terms of surgical wound classifications, a TPNB is considered contaminated and the use of antimicrobials as prophylaxis is mandated.

The duration of any periprocedural antimicrobial prophylaxis should extend throughout the period in which bacterial invasion is facilitated, i.e. during the time period in which an infection is likely to be established. With a TPNB, the site has a preexisting colonization or contamination. In such a contaminated field, prophylaxis literature would suggest a full course of antibiotics to sterilize the area and convert it to a clean operation site prior to the biopsy, or at least the suppression of the bacterial count to reduce the risk of infection subsequent to the procedure. Neither option is feasible in this case, as the rectum cannot be effectively sterilized or even reliably have reduction of contamination prior to a TPNB.

Various consensus-based recommendations on TPNB protocols have been published. In 2010, the Canadian Urological Association guidelines recommended that, “broad-based gram-negative antibiotic prophylaxis prior to biopsy, may be continued for two to three days. Many centers have moved towards shorter courses.”⁸ The European Association of Urology (EAU) guidelines on prostate cancer from 2013 recommended that, “oral or intravenous antibiotics are the state of the art treatment... quinolones are the drug of choice.”⁹ While National Comprehensive Cancer Network (NCCN) guidelines on prostate cancer discuss fluoroquinolone resistance but issue no recommendations about prophylaxis. After a thorough review of moderate to poor quality literature, the AUA has attempted to identify consensus based guidelines in the AUA Best Practice Policy Statement on Urologic Surgery Antimicrobial Prophylaxis, which was updated in 2014. According to this document, first line therapy was oral fluoroquinolones and first, second and third generation cephalosporins, which can be given intravenous (IV) or intramuscular (IM). There are changes for recommended prophylaxis for TPNB. Oral Trimethoprim-sulfamethoxazole is now allowed as a prophylactic agent, and when using IM/IV Aminoglycoside or Aztreonam as an alternative agent, Metronidazole or Clindamycin are no longer required. Additionally,

recommendations are for empiric therapy only. If the choice of antimicrobial is based upon results of a documented rectal swab culture, then culture-directed antimicrobials can be administered.^{4,5} With rapidly changing antibiotic resistance, professional society guidelines may lag in recommendations for specific antibiotic prophylaxis. Real-time data on antibiotic resistance is best obtained from current antibiograms in the local practice region.

Addendum: Subsequent to this conference, the CMS Surgical Care Improvement Project (SCIP) announced that it will allow the administration of targeted antimicrobials for prostate biopsy prophylaxis if the antimicrobial choice is based upon results of a documented rectal swab culture.

"A WISER WAY TO WIN"—DR. RICHARD WATSON, HACKENSACK MEDICAL CENTER

Much of the overuse of antibiotics is due to insecurities regarding failure to treat on the part of the physician and patient. Hence, many healthcare providers are using antibiotics more frequently than needed, longer than needed, and in greater combinations than needed. One consequence of this has been a dramatic rise in the prevalence of resistant organisms, and increasing limits on antimicrobial agents appropriate for prophylaxis. There remains a lack of consensus on how best to identify appropriate prophylaxis and its duration.¹⁰

The current lack of evidence-based guidelines risks antibiotic overuse, and contrariwise, and it likely is increasing the risk of antibiogram restrictions on antibiotic choices for prophylaxis.

Encouraging the disbursement of guidelines and protocols can only help improve patient safety.

PROTOCOL REVIEW

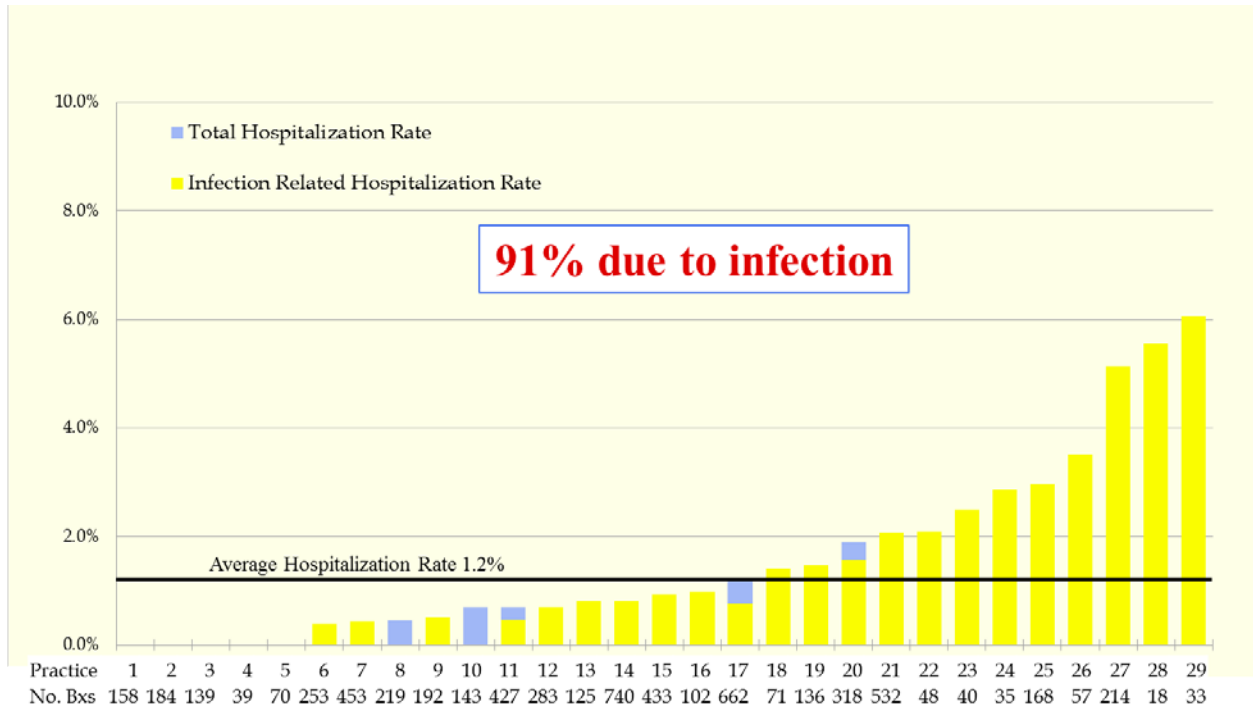
MICHIGAN UROLOGICAL SURGERY IMPROVEMENT COLLABORATIVE (MUSIC)–

DR. JAMES MONTIE, UNIVERSITY OF MICHIGAN

The goal of the Michigan Urologic Surgery Improvement Collaborative (MUSIC) is to make Michigan the best place in the country for prostate cancer care. As such, this collaborative is practice-based with clinical champions from each practice meeting three times per year to discuss gathered data and turn that data into action. One initiative is to make prostate biopsy safer and more efficient. The main outcome measure used is the 30-day hospitalization rate after prostate biopsy.

From March 2012 to December 2013, approximately 6,300 biopsies were present in the registry. The antibiotic prophylaxis by practice was compared to AUA practice guidelines, and culture data was obtained from any infection-related case. Overall, there was substantial variability: some practices having very low rates of hospitalization as opposed to others with average rates of 1.2 percent with an upper range of four to six percent. Ninety-one percent of those hospitalizations were due to infection. Of these 6,300 biopsies, 89 percent of the antibiotic regimens were AUA-compliant; 70 percent of the hospitalizations were associated with fluoroquinolone-resistant bacteria. These data demonstrated that the problem was not antibiotic noncompliance but antibiotic resistance despite compliance to an antibiotic protocol.

Figure 1: MUSIC Infection Rates



The collaborative devised a two-pronged action plan to lower infection rates. One option was to tailor antibiotics to high-risk patients through the use of a patient-specific rectal swab. The other option was to utilize prophylactic antibiotic for each patient based on the antibiotic resistance profiled from the local hospital antibiogram. Each practice was able to make its own choice based on consultation with infectious disease specialists and the logistics within the practice. The antibiogram-directed option was much easier to implement for the vast majority of practices. At the University of Michigan, the rectal swab was implemented, noting that the planning and preparation to make this change was significant and required collaboration with the microbiology lab, infectious disease, urologists, midlevel providers and the nursing staff. This patient-specific protocol based on rectal swab was implemented at University of Michigan in July 2013.

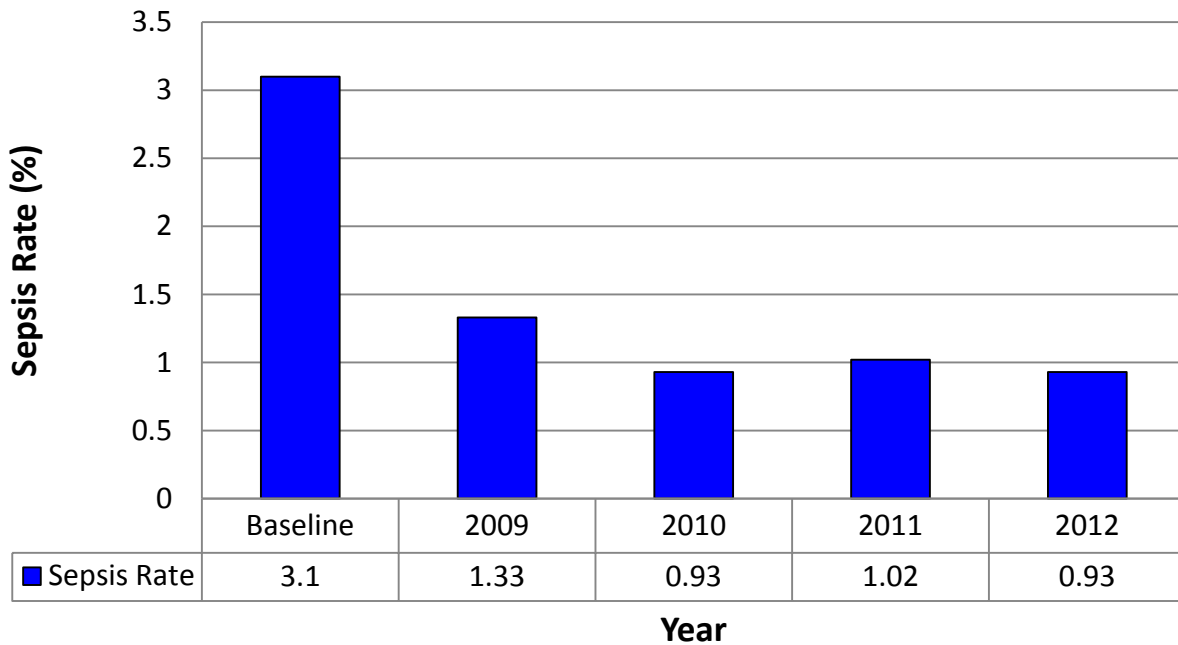
This strategy will be reevaluated as data are obtained over the next few years. If the patient-directed rectal swab approach shows significant risk reduction over historical controls and other Michigan

practice, then rectal swabs might be implemented more broadly. Alternatively, antibiogram-directed prophylaxis may prove as effective and at higher value to providers and patients. The MUSIC collaboration may allow additional risk factors may be examined and for augmented antibiotic protocol to be assessed.

ADVANCED UROLOGY CENTERS OF NEW YORK—DR. DEEPAK A. KAPOOR

Advanced Urology Centers of New York (AUCNY) is the largest urology group practice in the United States, with a large, diverse patient population concentrated in seven counties in the New York metropolitan area. As observed elsewhere, AUCNY found that post-biopsy infection rates were rising, reaching a peak of 3.1 percent in mid-2008; evaluation of the patient record revealed wide variation in prophylaxis regimens – even among physicians practicing in the same office. Utilizing antibiogram data from representative hospitals, AUCNY developed a protocol for regional prostate biopsy prophylaxis. The protocol involves giving all patients double antibiotic therapy. Any oral therapy should begin one to two days before the procedure and is to continue on the day of the procedure and for a minimum of two days after the procedure. Any parenteral antibiotic(s) should be given on the day of the procedure, one hour before it is performed. The antibiotics used for prophylaxis should be from two different classes of antibiotics and at least one of them should be bacteriocidal. All patients should perform an enema (at least a Fleet enema) on the morning of the procedure and consideration should be given to an enema the night before the procedure as well. In the first quarter following the implementation of this protocol, data showed that the sepsis rate was 1.67 percent. Annual sepsis rates are presented in Figure 2.

Figure 2: AUCNY Post-Biopsy Sepsis Rate by Year



Physicians must recognize that bacterial resistance is constantly changing and must guard against cookie-cutter prophylaxis regimens. While guidelines may be developed to aid in antibiotic choice, the AUCNY experience demonstrates that that antibiotic resistance is not even regional—it is local. Constant monitoring of sepsis data and resistance patterns, as well as willingness to adopt evidence-based prostate biopsy protocols is essential to reducing the risk of infectious complications after prostate biopsy.

VIRGINIA UROLOGY—DR. MICHAEL FRANKS

Virginia Urology is an integrated group comprised of nearly 40 physicians serving the Richmond, Virginia metro area, where 2000 prostate biopsies are done yearly at two main ambulatory surgical centers. The Virginia Urology infrastructure and protocolized electronic medical record (EMR) system reduces much of the variance in terms of pre-biopsy protocol once a patient has decided on biopsy.

In 2007, the Virginia Urology Quality Assurance Program was developed to internally review prostate biopsy infection and post-biopsy sepsis rates, the goal being to reduce infection rates below one percent. At this time, quinolone resistance was becoming a significant issue, and the local antibiogram was used to guide prophylaxis choices. Beginning in 2010, after collaboration with infectious disease specialists, ciprofloxacin and cefdinir were orally before and after biopsy. The protocol also included an enema preparation of the rectum. Continued evaluation of the current antibiogram revealed a small increase in the percentage of multi-drug resistant organisms; however, the extended antibiotic coverage was effective with prostate biopsy infection rates remaining low, below 0.5 percent. Compliance with this standard protocol is being continually assessed. As Virginia Urology has been able to attain and maintain extremely low rates of infection, hospitalization, and sepsis rates using the current antibiogram, the benefit of targeted antibiotic prophylaxis based on rectal swab cultures is unknown.

Figure 3: Virginia Urology Infection Rates

TRUSP Post-op Infections							
Year	# Possible Infections	# Documented Infections	# Septic Cases	Total # Biopsies	Infection Rate (%)	VU Urine - E. coli Cipro %Sens	
2007	4	4	3	2514	0.16	73	
2008	17	7	2	2291	0.31	69	
2009	11	7	1	2339	0.30	70	
2010	4	4	2	2205	0.18	66	Cefdinir + Cipro
2011	11	11	4	2597	0.42	NA	incr eased MDRO, ESBL E. coli
2012	12	9	4	2143	0.42	64	
2013	11	5	2	1950	0.26	58	

CLEVELAND CLINIC—DR. J. STEPHEN JONES

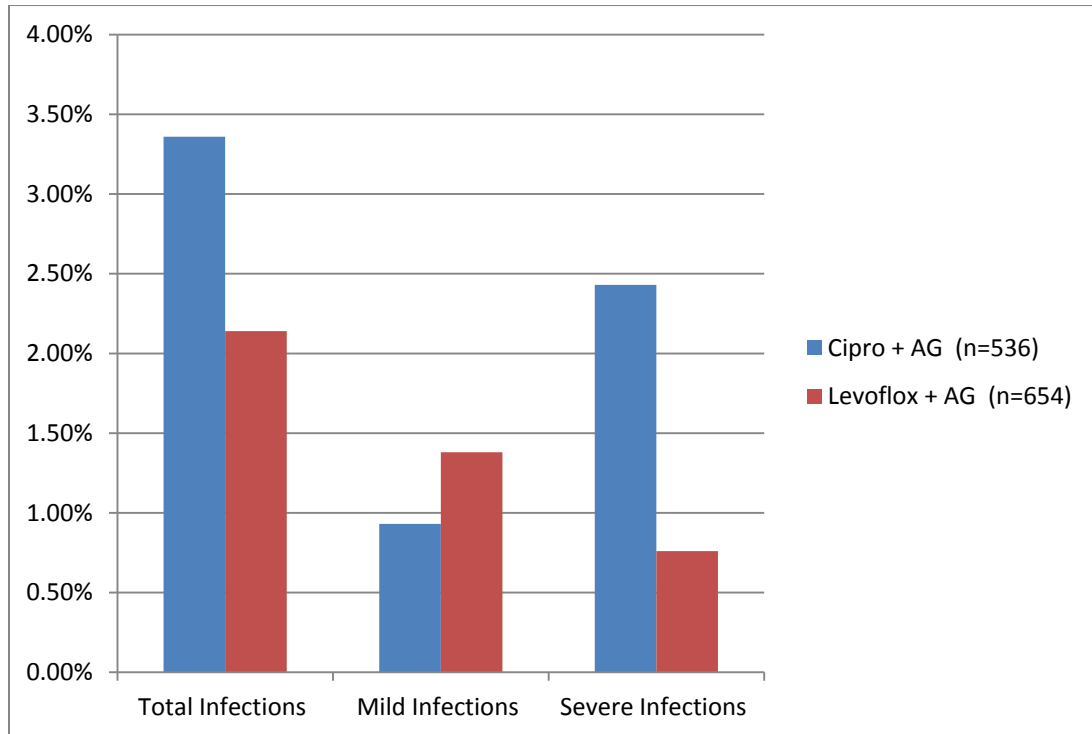
The physicians of Cleveland Clinic practice both at the main Cleveland Clinic campus as well as various family health and surgery centers in the community. The data presented on Cleveland Clinic are based on roughly 1,800 to 2,000 biopsies each year. Cleveland Clinic must follow SCIP measures, which at this time, align with AUA guidelines on Antibiotic Prophylaxis. Antibiotics are prescribed, but never for more than 24 hours unless there is another specifically identified indication for continuing the antibiotic. In the hospital setting, antibiotics must be given no more than one hour before the procedure in order to avoid a SCIP violation.

There was wide historical variability in the Cleveland Clinic prostate biopsy prophylaxis protocols ranging from a single oral periprocedural dose of ciprofloxacin without an enema to oral antibiotics

initiated the day prior and an enema. Informal polling of the audience revealed that enemas are not typically included in many office protocols. Dr. Jones commented that an enema is just as likely to pull stool into the rectum as to clear it. The Cleveland data did not demonstrate that use of an enema impacted the infectious complication rate; however, there was a statistically significant difference in rates of hematuria and hematospermia, higher in patients undergoing enema preparation.

In December 2010, as part of a quality initiative, patients undergoing a prostate needle biopsy were given a single dose of 500 mg of oral ciprofloxacin and subsequently queried about signs or symptoms of infection. The infectious rate was over 10 percent; not all respondents were cultured, most had not been hospitalized. The protocol was revised and standardized to include the concurrent use of IM gentamicin 1mg/kg with the single dose of ciprofloxacin. Almost all practitioners discontinued multi-day dosing. Following this change, the audience was again informally polled, and it was noted that the infection rate fell to approximately 2.5 percent. In an effort to further reduce infection rate, ceftriaxone was added to the regimen reducing the infection rate to approximately 1.4 percent. The current procedure is orally administration of 750mg levofloxacin and IM administration of 2mg/kg gentamicin. Infection rates are currently two percent.

Figure 4: Gentamicin+Levofloxacin 750 v. Gentamicin+Ciprofloxacin 500



The use of ciprofloxacin plus aminoglycoside to levofloxacin plus aminoglycoside was not associated with a statistically significant difference in mild infection rates. However, there was a statistically significant improvement in terms of severe infections. While gentamicin sensitivity for coliform organisms remains high, there is concern that if gentamicin is prescribed, will resistance eventually be created?

Colony-count reduction to reduce prostate biopsy infectious complications: Dr. Jay Raman of Pennsylvania State University shared his experience with a similar augmented approach and found that at his institution, the infection rate was not curbed by adding a dose of 2mg/kg IM or IV gentamicin. In 2012 the protocol at Dr. Raman's institution was changed to prescribe oral ciprofloxacin and use a Povidone-iodine rectal preparation. After approximately one year, infection rates fell from four to one percent. Rectal cultures were taken both before and after biopsy, and it was found that patients presenting at the time of biopsy have about 210,000 bacteria

in the rectal vault, but following Povidone-iodine preparation, there is a 97 percent reduction. The hypothesis is that while all of the ciprofloxacin-resistant bugs are not being caught, there is a reduction in the overall counts, thereby reducing the translocation of bacteria during the biopsy. Povidine-iodine preparation of the rectum to reduce prostate biopsy infectious complications: Dr. Gary Fialk of Reston, Virginia, practices in a community setting and also shared his experience with Povidone-iodine preparation. Dr. Fialk uses a commercially available Povidone-iodine gel as a lubricant and topical antimicrobial. Anecdotally, Dr. Fialk has not seen any adverse reactions and noted that infection rates are low.

QUALITY MEASURE DISCUSSION—DR. TIMOTHY AVERCH, UNIVERSITY OF PITTSBURGH; AND DR. CHRISTOPHER TESSIER, MANCHESTER UROLOGY ASSOCIATES

Quality indicators are commonly measured within three frameworks¹¹. There are structural measures, process measures, and outcome measures. More easily determined, urology process measures figure prominently in the Physician Quality Reporting System (PQRS); however, moving forward, the focus will shift to outcome measures. This measure is more difficult; there are limited outcome data on the natural history of most diseases. Prevention and cure, the perfect outcomes, are worthy goals, but unattainable in population-based systems. Hence, a less than perfect outcome measure may correlate but does not equate with a problem with quality of care.

The identification of appropriate outcome measures related to prostate biopsy infectious complications must incorporate variables over time and locale, yet be achievable and ultimately lead to actionable improvements in the quality of care. Consider: should the acceptable post-

biopsy sepsis rate be one percent? Is this uniformly achievable given increasing antibiotic resistance over time and locale? While process measures establish evidence-based standard protocols, do these process measures lead to a maximal reduction in prostate biopsy infections, the ideal outcome measure?

In developing the Science and Quality division, the AUA understands that a feedback loop is necessary to successfully implement quality changes. Evidence-based guidelines produce measures of quality that produce evaluative data which further inform the evidence base of the guideline. This feedback loop is critical to improving urologic care.

The overall consensus at this summit is that a process measure for prostate needle biopsy protocols would lack a specific mandate of a particular antibiotic or an outcome measure of an acceptable infection rate. However, an appropriate process measure may be useful to report infection rates. Given the seriousness of these complications, all urologists should be monitoring their practice’s infection rates and utilizing the local antibiogram to determine the antibiotic choice. Alternatively, a measure might direct a conversation with a patient to assess whether or not he is high-risk for antibiotic resistant fecal carriage.

Table 1: Summit Recommendations	
Recommendation 1	Establish TPNB protocols; evaluate and report infection rates quarterly
Recommendation 2	Consult the local antibiogram prior to prescription of antibiotics
Recommendation 3	Identify potential patients at high-risk for resistant coliforms: recent antibiotic use, international travel, and previous biopsy
Recommendation 4	Consider rectal swab or augmented antibiotics for high-risk patients

In conclusion, the AUA Quality Improvement Summit participants agreed that the TPNB infectious complications are a serious problem. Risk reduction is critical in allowing for a safe risk-benefit ratio for prostate cancer screening efforts in the appropriate patient groups. Moreover,

periprocedural prophylaxis will change as emerging resistance continues, as evidence-based clinical research determines best practice protocols for periprocedural preparation. Risk reduction is a regional issue as antibiograms recommended as the basis for prophylaxis have substantial regional variation. The protocols should be constantly reassessed and modified based on emerging data.

FUTURE DIRECTIONS

While this summit provided valuable input on prostate needle biopsy protocols, it also revealed the severe lack of published literature to aid in prostate needle biopsy prophylaxis decision making. The recommendations provided in this document must be considered expert opinion. Physicians are encouraged to periodically review infection rates and work closely with infectious disease and microbiology colleagues to develop prophylaxis protocols to minimize the chance of biopsy-related infection, and enhance the safety of a TPNB. The AUA will continue to monitor important clinical issues alerting members to newly available literature and recommendations on this and other subjects via these Conference summits, AUA white papers, AUA guidelines and *AUA News* and other communications vehicles.

¹ Nam RK, Saskin R, Lee Y et al: Increasing hospital admission rates for urological complications after transrectal ultrasound guided prostate biopsy. *J Urol* 210; **183**: 963.

² Gonzalez CM, Averch T, Boyd LA et al: AUA/SUNA White paper on the incidence, prevention and treatment of complications related to prostate needle biopsy. American Urological Association 2012.

³ Liss MA, Chang A, Santos R et al: Prevalence and significance of fluoroquinolone resistant *Escherichia coli* in patients undergoing transrectal ultrasound guided prostate needle biopsy. *J Urol* 2011; **185**: 1283.

⁴ Wolf JS Jr., Bennett CJ, Dmochowski RR et al: Best practice policy statement on urologic surgery antimicrobial prophylaxis. *J Urol* 2008; **179**: 1379.

⁵ Batura D, Rao GG and Nielsen PB: Prevalence of antimicrobial resistance in intestinal flora of patients undergoing prostatic biopsy: implications for prophylaxis and treatment of infections after biopsy. *BJU Int* 2010; **106**: 1017.

⁶ Steensels D, Slabbaert K, De Wever L et al: Fluoroquinolone-resistant E. coli in intestinal flora of patients undergoing transrectal ultrasound-guided prostate biopsy—should we reassess our practices for antibiotic prophylaxis? *Clin Microbiol Infect* 2012; **18**: 575.

⁷ Taylor AK, Zemower TR, Nadler RB et al: Targeted antimicrobial prophylaxis using rectal swab cultures in men undergoing transrectal ultrasound guided prostate biopsy is associated with reduced incidence of postoperative infectious complications and cost of care. *J Urol* 2012; **187**: 1275.

⁸ El-Hakim, A and Moussa S: CUA guidelines on prostate biopsy methodology. *Can Urol Assoc J* 2010; **4**: 89.

⁹ Heidenreich, A Bastian PJ, Bellmunt J et al: Guidelines on prostate cancer. *European Association of Urology* 2012.

¹⁰ Watson RA: Combating Infections after Prostate Biopsy: a wiser way to win. *AUA NEWS* (September) 2012; 17(9):16 <http://www.nxtbook.com/tristar/aua/news-september2012/index.php#/16>

¹¹ Avis Donabedian, in 1966 at University of Michigan developed this eponymous model for examining healthcare quality within these three parameters. It remains one of the most widely used constructs for evaluating healthcare services.