Management and Screening of Primary Vesicoureteral Reflux in Children: AUA Guideline

Revised, 2010

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VUR Guideline Summary

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Introduction

In 1997, the American Urological Association (AUA) published the Guideline on the *Management of Primary Vesicoureteral Reflux in Children.*[1] Since that time there has been an expanding body of literature involving not only the evaluation and the management of vesicoureteral reflux (VUR) but also the role of screening in its management. For this reason, the AUA appointed a Panel of experts to update the 1997 document and elected to expand its scope to include guidelines for the screening of siblings of children with vesicoureteral reflux (VUR) and of neonates/infants with prenatally diagnosed hydronephrosis. A literature search, review of the evidence, and data extraction from the relevant clinical studies and case series were performed. Extracted data underwent meta-analysis to determine the outcomes related to five topics: 1) management of children over one year of age with VUR; 2) evaluation and management of infants with VUR; 3) management of children with VUR and Bladder and Bowel Dysfunction (BBD); 4) screening of siblings and offspring of patients with VUR; and 5) screening of neonates and infants with prenatal hydronephrosis. This document summarizes the guideline statements derived from a meta-analysis. Additional chapters (1-5) provide a detailed summary of each of these topics.

From the evidence and expert opinion, the Panel drafted guideline statements. According to AUA nomenclature, these statements are graded with respect to the degree of flexibility in application. A "standard" is the most rigid treatment policy. A "recommendation" has significantly less rigidity and an "option" the least. These terms are defined as follows:

1. **Standard**: A guideline statement is a standard if (1) the health outcomes of the alternative interventions are sufficiently well-known to permit meaningful decisions and

(2) there is virtual unanimity among panel members about which intervention is preferred.

2. **Recommendation**: A guideline statement is a recommendation if (1) the health outcomes of the alternative interventions are sufficiently well-known to permit meaningful decisions and (2) an appreciable, but not unanimous majority of the panel members agrees on which intervention is preferred.
3. **Option**: A guideline statement is an option if (1) the health outcomes of the interventions are not sufficiently well-known to permit meaningful decisions or (2) preferences are unknown or equivocal.

Although the development of a clinical guideline is often limited by the availability of quality data, which is notably true with respect to the VUR literature, recommendations can be based on general principles developed from a formal meta-analysis as well as experience and clinical judgment. These guidelines for management of VUR were based upon risk assessment, considering the probability for spontaneous resolution versus perceived risk for recurrent urinary tract infection (UTI) and renal injury. In the absence of incontrovertible evidence of the advantage of one approach over another, the Panel has elected to include only three Standards in this document. Statements that have been designated as Recommendations are those for which the Panel determined there was sufficient evidence, even if not consistently of the highest quality or proven to the preferred degree of rigor, to advocate for a particular clinical approach. Statements designated as Options are those for which the Panel determined there was evidence of relatively equal strength and quality supporting more than one approach, with any approach being acceptable and justifiable. In the absence of definitive evidence, stronger guidelines cannot

appropriately be made and the final decisions regarding clinical care reside with the physician and family.

Initial Evaluation of the Child with VUR

General evaluation

Standard: VUR and urinary tract infections may detrimentally affect the overall health and renal function in affected children. Therefore, on initial presentation the child with VUR should undergo a careful general medical evaluation including measurement of height, weight, blood pressure and serum creatinine if bilateral renal abnormalities are found.

[Based on Panel consensus]

Recommendation: Urinalysis for proteinuria and bacteriuria is recommended. If the urinalysis indicates infection, a urine culture and sensitivity is recommended.

[Based on Panel consensus]

Option: A baseline serum creatinine may be obtained to establish an estimate of glomerular filtration rate (GFR) for future reference.

[Based on Panel consensus]

Imaging procedures

Recommendation: Because VUR and urinary tract infection may affect renal structure and function, performing renal ultrasound to assess the upper urinary tract is recommended.

[Based on Panel consensus]

Option: DMSA (technetium-99m-labeled dimercaptosuccinic acid) renal imaging can be obtained to assess the status of the kidneys for scarring and function.

[Based on review of the data and Panel consensus]

DMSA (technetium-99m-labeled dimercaptosuccinic acid) renal imaging can provide information regarding the degree of existing renal cortical abnormalities that may affect decision-making. In addition, DMSA imaging can serve as a baseline for future comparison. Although such information may be of use in management of any patient with VUR, those most likely to have scarring include patients with VUR grades III–V, younger children, those with an abnormal renal ultrasound study, and those with recurrent febrile UTIs.

Assessment of voiding patterns

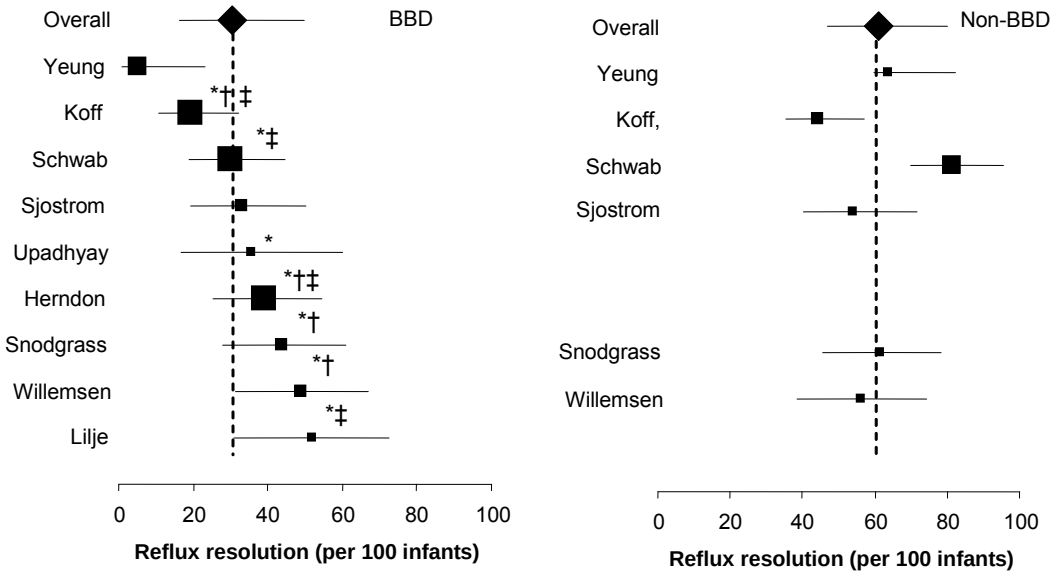
Bladder/bowel dysfunction (BBD), dysfunctional voiding, dysfunctional elimination syndrome and dysfunctional lower urinary tract symptoms refer to a common but poorly characterized complex of symptoms typically including urinary incontinence, dysuria, urinary tract infections (UTI), urinary frequency or infrequent voiding, and constipation. BBD is used to describe children with abnormal lower urinary tract symptoms of storage and/or emptying which include

lower urinary tract conditions such as overactive bladder and urge incontinence, voiding postponement, underactive bladder, and voiding dysfunction, and may also include abnormal bowel patterns including constipation and encopresis.

The appropriate approach to the management of the child with VUR and BBD has not been defined, yet the child with this combination of conditions may be at greater risk of renal injury due to infection. The presence of untreated BBD can be shown to affect several aspects of VUR. The incidence of breakthrough UTI in children on continuous antibiotic prophylaxis (see below) is greater in those with BBD than in those without BBD. In children receiving CAP, resolution rates were 31% for those with BBD and 61% for those without BBD (Figure 1).

Figure 1. Forest plots of reflux resolution among children receiving continuous antibiotic prophylaxis

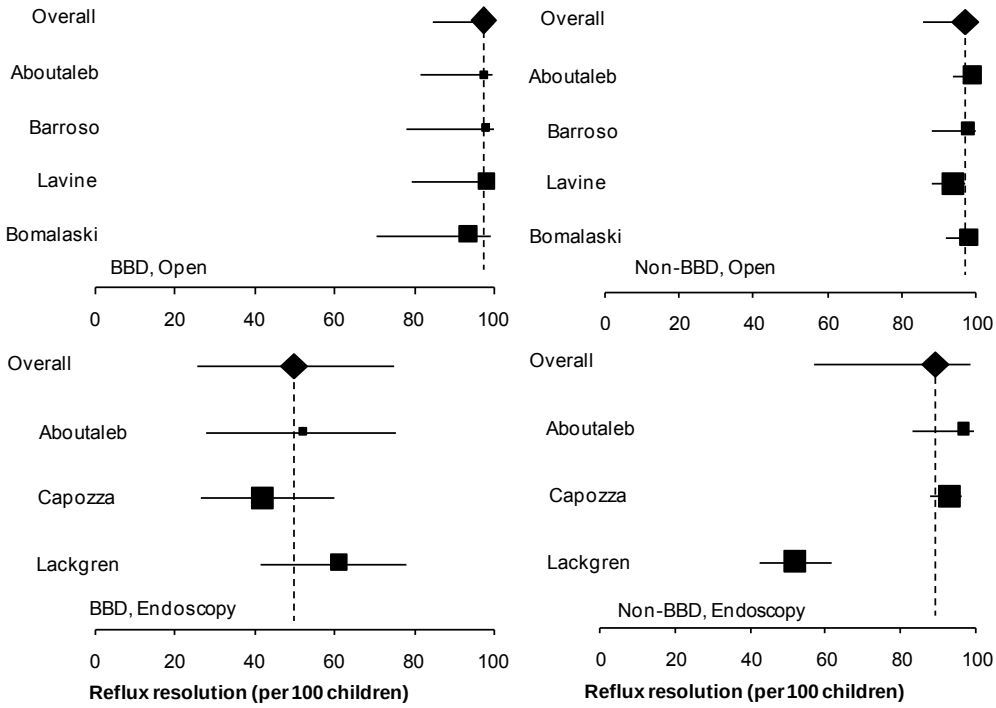
(Concurrent/prior use of: *bladder training, †anticholinergics, ‡stool softeners)



In children treated with endoscopic surgery, resolution rates at initial follow-up were 50% for those with BBD and 89% for those without BBD (Figure 2). For children treated with open

surgery, the presence of BBD did not appear to alter surgical resolution rates, which were 97% in both groups (Figure 2).

Figure 2: Forest plots of reflux resolution in children undergoing intervention with curative intent (open surgery or endoscopic)



Standard: Symptoms indicative of bladder/bowel dysfunction should be sought in the initial evaluation, including urinary frequency and urgency, prolonged voiding intervals, daytime wetting, perineal/penile pain, holding maneuvers (posturing to prevent wetting), and constipation/encopresis.

[Based on Panel consensus]

Family and patient education

Standard: Family and patient education regarding VUR should include a discussion of the rationale for treating VUR, the potential consequences of untreated VUR, the equivalency of certain treatment approaches, assessment of likely adherence with the care plan, determination of parental concerns and accommodation of parental preferences when treatment choices offer a similar risk-benefit balance.

[Based on Panel consensus]

Initial Management of the Child with VUR

The goals of management of the child with VUR are to 1) prevent recurring febrile UTIs; 2) prevent renal injury; and 3) minimize the morbidity of treatment and follow-up. Separate guidelines are provided for management of VUR for the child less than one year of age and for the child over one year.

It should be noted that several recent publications have questioned the efficacy of continuous antibiotic prophylaxis (CAP) in reducing recurrent UTI and by extension the importance of identifying VUR following urinary tract infection (UTI).[2-5] Until recently, management of VUR without CAP was considered a deviation from standard care, limiting the available data to address questions concerning VUR health risks or the use of CAP. Future studies may identify patient subgroups most likely to benefit from VUR identification and treatment.

The child with VUR less than one year of age

Recommendation: Continuous antibiotic prophylaxis is recommended for the child less than one year of age with VUR with a history of a febrile urinary tract infection. This approach is based on the greater morbidity from recurrent urinary tract infections found in this population.

[Based on review of the data and Panel consensus]

Recommendation: In the absence of a history of febrile urinary tract infections, continuous antibiotic prophylaxis is recommended for the child less than one year of age with VUR grades III–V who is identified through screening.

[Based on review of the data and Panel consensus]

Option: In the absence of a history of febrile urinary tract infections, the child less than one year of age with VUR grades I–II who is identified through screening may be offered continuous antibiotic prophylaxis.

[Based on review of the data and Panel consensus]

Option: Circumcision of the infant male with VUR may be considered based on an increased risk of urinary tract infections in boys who are not circumcised compared to those who are circumcised. Although there are insufficient data to evaluate the degree of this increased risk and its duration, parents need to be made aware of this association to permit informed decision-making.

[Based on review of the data and Panel consensus]

The child with UTI and VUR more than one year of age

Guidelines for management of VUR in the child more than one year of age are somewhat different from those for the child less than one year of age, reflecting several contributing elements that influence clinical outcomes. These include the greater likelihood of BBD, the lower probability of spontaneous resolution of VUR, lower risk of acute morbidity from febrile UTI and the greater ability of the child to verbally complain of symptoms to indicate acute infection. The management decision should be made with recognition of the clinical context, including the presence of BBD, patient age, VUR grade, the presence of scarring, and parental preferences. Given the individuality of each patient and their parental preferences, there can be no uniform guidelines of management.

Recommendation: If clinical evidence of bladder/bowl dysfunction is present (see "Initial evaluation of the child with VUR" above) treatment of bladder/bowel dysfunction is indicated, preferably before any surgical intervention for VUR is undertaken.

There are insufficient data to recommend a specific treatment regimen for bladder/bowel dysfunction, but possible treatment options include behavioral therapy (see Glossary for description), biofeedback (appropriate for children more than age five), anticholinergic medications, alpha blockers, and treatment of constipation. Monitoring the response to bladder/bowel dysfunction treatment is recommended to determine whether treatment should be maintained or modified.

[Based on Panel consensus]

Recommendation: Continuous antibiotic prophylaxis is recommended for the child with bladder/bowel dysfunction and VUR due to the increased risk of urinary tract infection while bladder/bowel dysfunction is present and being treated (Table 1).

[Based on review of the data and Panel consensus]

Option: Continuous antibiotic prophylaxis may be considered for the child over one year of age with a history of urinary tract infections and VUR in the absence of bladder/bowel dysfunction (Table 1).

[Based on review of the data and Panel consensus]

Option: Observational management without continuous antibiotic prophylaxis, with prompt initiation of antibiotic therapy for urinary tract infections, may be considered for the child with VUR in the absence of bladder/bowel dysfunction, recurrent febrile urinary tract infections, or renal cortical abnormalities (Table 1). While this approach is currently under investigation and therefore no firm recommendation can be made, preliminary data suggest that some groups of patients with VUR may do as well with this approach as with continuous antibiotic prophylaxis.

[Based on review of the data and Panel consensus]

Table 1. Treatment of the child with VUR and UTI over one year of age.

	CAP	*Observation*
No BBD, recurrent febrile UTI, renal cortical abnormalities	*option*	*option*
BBD, recurrent febrile UTI, OR renal cortical abnormalities	*recommended*	*not recommended*

Option: Surgical intervention for VUR, including both open and endoscopic methods, may be used. Prospective randomized, controlled trials have shown a reduction in the occurrence of febrile urinary tract infections in patients who have undergone open surgical correction of VUR as compared to those receiving continuous antibiotic prophylaxis.

[Based on review of the data and Panel consensus]

Follow-up Management of the Child with VUR

Ongoing monitoring of a child's overall health is necessary. Specific testing related to VUR will depend on the clinical situation and any factors described below that might indicate the potential for ongoing or progressive renal injury. These guidelines apply to all children, irrespective of age.

General follow-up

Recommendation: General evaluation, including monitoring of blood pressure, height, and weight is recommended annually.

[Based on Panel consensus]

Recommendation: Urinalysis for proteinuria and bacteriuria is indicated annually, including a urine culture and sensitivity if the urinalysis is suggestive of infection.

[Based on Panel consensus]

Imaging – cystography and ultrasonography

Recommendation: Ultrasonography is recommended every 12 months to monitor renal growth and any parenchymal scarring. Voiding cystography (radionuclide cystogram or low-dose fluoroscopy, when available) is recommended between 12 and 24 months with longer intervals between follow-up studies in patients in whom evidence supports lower rates of spontaneous resolution (i.e. those with higher grades of VUR [grades III-V], bladder/bowel dysfunction, and older age). If an observational approach is being used, follow-up cystography becomes an option.

[Based on review of the data and Panel consensus]

Option: Follow-up cystography may be done after one year of age in patients with VUR grades I–II; these patients tend to have a high rate of spontaneous resolution and boys have a low risk of recurrent urinary tract infection.

[Based on review of the data and Panel consensus]

Option: A single normal voiding cystogram (i.e. no evidence of VUR) may serve to establish resolution. The clinical significance of grade I VUR, and the need for ongoing evaluation is undefined.

[Based on review of the data and Panel consensus]

Imaging - DMSA

Recommendation: DMSA imaging is recommended when a renal ultrasound is abnormal, when there is a greater concern for scarring (i.e. breakthrough urinary tract infection [BT-UTI; see Glossary for description], grade III-V VUR), or if there is an elevated serum creatinine.

[Based on review of the data and Panel consensus]

Option: DMSA may be considered for follow-up of children with VUR to detect new renal scarring, especially after a febrile urinary tract infection.

[Based on review of the data and Panel consensus]

Interventions for the Child with Breakthrough UTI (BT-UTI)

When a febrile breakthrough UTI (BT-UTI) occurs in a child with VUR receiving CAP, consideration of alternative interventions is recommended. The occurrence of a febrile BT-UTI indicates a failure of therapy and raises the concern for renal injury. The clinical manifestations of BT-UTI may not be classic, particularly in the younger child in whom systemic symptoms may predominate. The specific alternative therapy should be determined based upon the individual risks to the patient, which include clinical factors such as reflux grade, degree of scarring and BBD. Therapy with curative intent, including open surgery, offers protection against febrile UTI,

but is obviously associated with morbidity; less morbid approaches, such as endoscopic injection therapy, may have lesser success in VUR resolution. In the absence of new renal cortical abnormalities, a change in the antibiotic used for prophylaxis may be effective. In any event, the occurrence of BT-UTI should signal the need for a re-evaluation of the efficacy of the ongoing treatment plan for the child.

Recommendation: If symptomatic breakthrough urinary tract infection occurs (manifest by fever, dysuria, frequency, failure to thrive, or poor feeding), a change in therapy is recommended. If symptomatic breakthrough urinary tract infection occurs, the clinical scenario will guide the choice of treatment alternatives; this includes VUR grade, degree of renal scarring, if any, and evidence of abnormal voiding patterns (bladder/bowel dysfunction) that might contribute to urinary tract infection, as well as parental preferences. [Based on Panel consensus]

Recommendation: It is recommended that patients receiving continuous antibiotic prophylaxis with a febrile breakthrough urinary tract infection be considered for open surgical ureteral reimplantation or endoscopic injection of bulking agents for intervention with curative intent.

[Based on Panel consensus]

Option: In patients receiving continuous antibiotic prophylaxis with a single febrile breakthrough urinary tract infection and no evidence of pre-existing or new renal cortical abnormalities, changing to an alternative antibiotic agent is an option prior to intervention with curative intent.

[Based on Panel consensus]

Recommendation: In patients not receiving continuous antibiotic prophylaxis who develop a febrile urinary tract infection, initiation of continuous antibiotic prophylaxis is recommended.

[Based on Panel consensus]

Option: In patients not receiving continuous antibiotic prophylaxis who develop a non-febrile urinary tract infection, initiation of continuous antibiotic prophylaxis is an option in recognition of the fact that not all cases of pyelonephritis are associated with fever. [Based on Panel consensus]

Surgical treatment of VUR

When intervention with the intention to cure VUR is being considered, open and endoscopic surgical techniques are available with differences in morbidity and success. The resolution rate per 100 children was 98.1 for open surgery (95% CI: 95.1, 99.1) and 83.0 for endoscopic therapy (95% CI: 69.1, 91.4) after a single injection of bulking agent. Data and clinical experience demonstrating the durability of endoscopic therapy for VUR are limited. Post-operative UTIs can occur with either approach and adequate comparative data are lacking. The incidence of post-operative UTI is strongly associated with the incidence of pre-operative UTI, and to the presence of BBD. The number of adverse events following endoscopic or open surgery for VUR was low. The overall postoperative obstruction rate calculated from 28 articles was 0.4 (95% CI: 0.2, 1.2) per 100 children.

Option: Surgical intervention for VUR, including both open and endoscopic methods, may be used. Prospective randomized controlled trials have shown a reduction in the occurrence of febrile urinary tract infections in patients who have

undergone open surgical correction of VUR as compared to those receiving continuous antibiotic prophylaxis.

[Based on review of the data and Panel consensus]

Postoperative imaging for patients receiving definitive interventions

There were insufficient data to provide any specific recommendations with regard to the duration of follow-up following definitive interventions. The small but significant risk of post-procedural obstruction was the rationale for the follow-up standard.

Standard: Following open surgical or endoscopic procedures for VUR, a renal ultrasound should be obtained to assess for obstruction.

[Based on review of the data and Panel consensus]

Recommendation: Postoperative voiding cystography following endoscopic injection of bulking agents is recommended.

[Based on review of the data and Panel consensus]

Option: Postoperative cystography may be performed following open ureteral reimplantation.

[Based on review of the data and Panel consensus]

Follow-up Management Following Resolution of VUR

It is recommended that a plan be provided to the family/patient and the primary care physician regarding monitoring for the long-term potential issues related to VUR. This is of particular importance in patients with renal scarring prior to reflux resolution or in whom there is a recurrence of UTI after reflux resolution. While there are no data with which to assess a specific

follow-up program, the Panel's recommendations reflect the recognition that the long-term health impact of VUR and renal injury may be distant in time, difficult to accurately predict and subtle in clinical presentation. It is recognized that the incidence of serious health effects may be low, but increase with the length of follow-up. The presence of known renal injury is associated with higher risk of later effects. The recommendation for follow-up with somatic measures and blood pressure reflect routine recommended follow-up by the American Academy of Pediatrics.

Option: Following the resolution of VUR, either spontaneously or by surgical intervention and if both kidneys are normal by ultrasound or DMSA scanning, general evaluation, including monitoring of blood pressure, height, and weight, and urinalysis for protein and urinary tract infection, annually through adolescence is an option.

[Based on Panel consensus]

Recommendation: Following the resolution of VUR, either spontaneously or by surgical intervention, general evaluation, including monitoring of blood pressure, height, and weight, and urinalysis for protein and urinary tract infection, is recommended annually through adolescence if either kidney is abnormal by ultrasound or DMSA scanning.

[Based on Panel consensus]

Recommendation: With the occurrence of a febrile urinary tract infection following resolution or surgical treatment of VUR, evaluation for bladder/bowel dysfunction or recurrent VUR is recommended.

[Based on Panel consensus]

Recommendation: It is recommended that the long-term concerns of hypertension (particularly during pregnancy), renal functional loss, recurrent urinary tract infection, and familial VUR in the child's siblings and offspring be discussed with the family and communicated to the child at an appropriate age.

[Based on Panel consensus]

Screening for VUR in Siblings and Neonates with Prenatal Hydronephrosis

The prevalence of VUR is approximately 27% in siblings of children with VUR (see Chapter 5, table 1). The screening methods to detect VUR include voiding cystourethrogram (VCUG) or radionuclide cystography. Some practitioners use renal ultrasonography to screen for renal abnormalities as a selection criterion for voiding cystography. The goal of screening for VUR in siblings or neonates with prenatally detected hydronephrosis is to identify clinically unapparent VUR in order to initiate preventative therapy, usually CAP. However, the value of CAP in preventing febrile UTI and renal damage in VUR is unproven. Therefore, recommendations for screening are limited by the uncertainty of any potential benefit gained by identifying VUR. Identification of VUR may be of some benefit by increasing the awareness of parents and health providers to the potentially increased risk of pyelonephritis and renal scarring.

Sibling screening

Recommendation: In siblings of children with VUR, a voiding cystourethrogram or radionuclide cystogram is recommended if there is evidence of renal cortical abnormalities or renal size asymmetry on ultrasound or if there is a history of urinary tract infection in the sibling who has not been tested.

[Based on Panel consensus]

Option: Given that the value of identifying and treating VUR is unproven, an observational approach without screening for VUR may be taken for siblings of children with VUR, with prompt treatment of any acute urinary tract infection and subsequent evaluation for VUR.

[Based on Panel consensus]

Option: **Sibling screening of older children who are toilet trained may be offered, although the value of identification of VUR is undefined.**

[Based on Panel consensus]

Option: Ultrasound screening of the kidneys in the sibling of a child with VUR may be performed to identify significant renal scarring and to focus attention on the presence and potential further risk of VUR.

[Based on Panel consensus]

Option: Screening offspring of patients with VUR can be considered as similar to screening of siblings.

[Based on Panel consensus]

Screening in the neonate with a history of prenatal hydronephrosis

The presence of VUR in neonates with a history of prenatal hydronephrosis can be confirmed by performing a VCUG or radionuclide cystography. Based on the outcomes analysis (see Chapter

5), the incidence of VUR in neonates with prenatal hydronephrosis is approximately 16%. Females with a prenatal diagnosis of PNH had a significantly higher ($p = 0.022$), incidence of VUR compared to male infants. The distribution of VUR grade in neonates was similar to that of children who presented later in life; VUR grade was found to be grade III or greater in two thirds of patients, with renal abnormalities occurring in nearly 50% of those with grades IV-V. These considerations suggest that those with prenatal hydronephrosis are a group at increased risk for VUR and subsequent sequelae. The recommendation for VCUG in children with the Society for Fetal Urology (SFU) grade 3 and 4 hydronephrosis is based on the potential for bladder outlet obstruction being present as well as the risk of VUR.

Recommendation: Voiding cystourethrogram is recommended for children with high-grade ((Society of Fetal Urology grade 3 and 4) hydronephrosis, hydroureter or an abnormal bladder on ultrasound (late-term prenatal or postnatal), or who develop a urinary tract infection on observation.

[Based on review of the data and Panel consensus]

Option: **An observational approach without screening for VUR, with prompt treatment of any urinary tract infection, may be taken for children with prenatally detected hydronephrosis ((Society of Fetal Urology grade 1 or 2), given the unproven value of identifying and treating VUR. It is also considered an option to perform a** voiding cystourethrogram **in these patients to screen for VUR.**

[Based on Panel consensus]

Summary and Conclusions

This Guideline does not offer a simple formula for the care of children with VUR since the data were not sufficient to permit development of strict "standards of care" in many instances. However, certain findings from this meta-analysis can be used to guide the management of VUR. In particular, it was determined that VUR significantly increases the risk of developing renal scarring in the setting of acute pyelonephritis, with an odds ratio of 2.8 per patient and 3.7 per renal unit. Also, while resolution of VUR will reduce the incidence of febrile UTI, the overall incidence of UTI may remain unchanged.

Recent studies have demonstrated that CAP has not been proven to reduce the incidence of febrile UTI in children with VUR.[2-5] These results have challenged the core of current expectant therapy of VUR, yet the general applicability of these new findings remains uncertain. Very careful review of the strengths and limitations of these studies must be considered before broadly accepting this approach. However, these data do suggest that an observational approach to VUR with antibiotic therapy initiated on diagnosis of an acute UTI may be an option in selected children.

The following provides a summary of the findings of the meta-analysis and relevant guideline statements. See Clinical Chapters 1–5 for the supporting data and a more complete discussion of each of these topics.

Management of VUR in the child over one year of age with no BBD

On detection of VUR in the child over one year of age, it is recommended that the child be evaluated for evidence of renal disease and for symptoms suggestive of BBD. Children with higher grades of VUR (i.e. grades III to V) are at greater risk of having renal cortical abnormalities. DMSA scanning can be useful in identifying those with preexisting abnormalities. If CAP is used, reassessment of VUR by cystogram between 12 and 24 months after the prior

cystogram is recommended to determine when therapy can be stopped. This analysis, as well as the 1997 Guideline[1], found that resolution rates are prolonged with higher grades of VUR. It is recommended, but not mandated, that BT-UTI prompt consideration of a change in approach, which might include varying the antibiotic used for CAP. Therapy with the intention to cure, including open or endoscopic surgery, is recommended for recurrent infections, new renal abnormalities determined by DMSA scanning, and parental preference.

Endoscopic injection therapy for VUR is an option in the treatment of VUR. Success rates for open surgery are 98%, with few complications, compared to rates of 83% for endoscopic surgery; however, the higher success rates for open surgery are offset by the greater expense and the need for in-patient hospitalization. Postoperative UTIs can occur with either treatment, but are more likely to occur in patients with a prior history of frequent UTIs. Following surgery, an ultrasound to confirm absence of obstruction is a standard of care. While an infrequent occurrence, urinary obstruction may be "clinically silent" and have severe consequences that could be readily corrected. Cystography is a recommendation after endoscopic surgery and an option after open surgery. Following reflux resolution (surgically or spontaneously) it is recommended that a planned follow-up, including assessment for infection, renal abnormalities, and overall health, be continued through adolescence.

Management of the infant under one year of age with VUR

Infants under one year of age may not show clinical evidence of pyelonephritis as clearly as older children and they may have a greater risk of infection-related morbidity. It is therefore recommended that CAP be used in these children until more definitive studies suggest otherwise. Reflux resolution occurs in about 50% of these children within 24 months.

Management of the child with VUR and BBD

Evidence supports the importance of BBD in the natural history and clinical outcomes of VUR; the presence of BBD has been shown to reduce the rates of reflux resolution and increase the incidence of UTI in patients managed with CAP, to reduce the cure rate of endoscopic therapy, and to increase the incidence of UTI after definitive reflux cure. It is therefore recommended that all children be evaluated for possible BBD based on clinical history. Although treatment regimens vary and there are no data supporting one approach over another, the Panel recommends treatment of BBD in the child with VUR as an integral part of reflux management.

Screening the siblings and offspring of patients with VUR

The incidence of reflux in siblings of children with VUR is 27% and the incidence decreases with the age of the sibling. The incidence of renal cortical abnormalities depends on whether the sibling has a history of UTI. The incidence of reflux in the offspring of a patient with VUR is 35.7% (see Chapter 4). It is considered an option and not a recommendation to screen for VUR in siblings and offspring due to the fact that the health benefit of identifying VUR in these patients has not been proven. It is recommended that this information be shared with the family in order to permit an informed decision with the recognition that identifying and managing the VUR may or may not be a benefit to that child.

Screening infants with a history of prenatally detected hydronephrosis for VUR

Infants with prenatally detected hydronephrosis have an incidence of VUR of 16.2% that is not predicted by the grade of hydronephrosis (see Chapter 5, figure 1); therefore, hydronephrosis grade cannot be used to select infants at risk for VUR. This analysis found no significant difference in incidence between sexes. The incidence of renal cortical abnormalities is much greater for children with grades III-V VUR. Again, there has been no demonstration of any health

benefit of screening for and identifying VUR in these infants. It is therefore a recommendation that families be informed of the potential risk and permitted to participate in the decision-making.

Conclusions

It is becoming increasingly evident that identification of a child's individual risk factors should be taken into consideration when managing VUR. In recognizing that BBD is a major factor in UTI occurrence, reflux persistence and surgical outcomes, clinical management of BBD is a priority. Similarly, we can be more comfortable with a less intensive intervention in the child with a low risk of renal injury, i.e., those with no prior infections, healthy kidneys, normal voiding and a low-grade of VUR. This does not imply that observation is better, although it is a more appropriate option than previously considered. The clinician who is looking for a "recipe" to manage all children with VUR will be disappointed in this Guideline, but such a "cookbook" approach is what has produced much of the current confusion in the management of VUR. The evolution of VUR management will be guided by better selection of patients for different levels of therapy, a better understanding of the interaction of contributing factors such as BBD and the renal response to infection in VUR management, as well as incorporating family choices in care when medical options are not clearly different. Research efforts need to be intensified to develop a scientific basis for the selection of therapies; in addition, improvements in the VUR literature are needed to permit ongoing review and assessment of our progress.

Conflict of Interest Disclosures

All panel members completed Conflict of Interest disclosures. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

Scientific Study or Trial: Jack S. Elder, QMed Scandinavia (U); **Meeting Participant or Lecturer:** Billy Arant, Novartis (C); **Other:** Jack S. Elder, FSC Laboratories (U); **Investment Interest:** Antoine E. Khoury, Covalon (U), Interface Biologics (U)

AUA Guideline for Management and Screening of Primary Vesicoureteral Reflux in Children

The supporting systematic literature review and the drafting of this document were conducted by the Pediatric Vesicoureteral Reflux Clinical Guidelines Panel (the Panel) created in 2006 by the American Urological Association Education and Research, Inc. (AUA). The Practice Guidelines Committee (PGC) of the AUA selected the Panel chair and vice chair, who in turn appointed the additional Panel members with specific expertise in this disease. The mission of the Panel was to develop either analysis- or consensus-based recommendations, depending on the type of evidence available and Panel processes, to support optimal clinical practices in the management and screening of primary vesicoureteral reflux in children.

This document was submitted to approximately 75 urologists and other health care professionals for peer review. After revision of the document based upon the peer review comments, the guideline was submitted to and approved by the PGC and the Board of Directors of the AUA. Funding of the Panel and of the PGC was provided by the AUA, although Panel members received no remuneration for their work. Each member of the PGC and of the Panel furnished a current conflict of interest disclosure to the AUA.

This document provides guidance only and does not establish a fixed set of rules or define the legal standard of care. As medical knowledge expands and technology advances, the guidelines may change. Today they represent not an absolute mandate but rather current proposals or recommendations for treatment under the specific conditions described. For all these reasons, the Guidelines do not preempt physician judgment in individual cases. Also, treating physicians must take into account variations in resources, and in patient tolerances, needs and preferences.

Conformance with the recommendations reflected in this document cannot guarantee a successful outcome.

This document may also include information or recommendations about certain drug uses ('off label') that are not approved by the Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines are not intended to provide legal advice about use and misuse of these substances.

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Appendix 1: Members of the 1997 Vesicoureteral Reflux Guideline panel

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Appendix 2: Members of the 2010 Vesicoureteral Reflux Guideline panel

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Appendix A3: Article Status Report
Vesicoureteral Reflux Panel

Citations Retrieved	Number of articles	Date range
Initial Literature search- October 2005	1,501	12/1994-12/2005
March 2006	207	1/1965-12/1994
References selected from Elder paper	6	8/2005
October 2006	98	12/2005-9/2006
References from Hollowell VUR2520	6	11/2006
Peter's JPU Rev	1	12/2006
October-December 2006	28	10/2006-12/2006
Methodologist added articles missed in search	3	10/2005-6/2006
July 2008	367	9/2006-7/2008
August 2008	32	
Total Citations Retrieved & Reviewed	**2,249**	

Articles Reviewed and Selected for Extraction by Panel		% Citations Retrieved
Initial Literature search- October 2005	291	12.9%
March 2006	29	1.3%
References selected from Elder paper	0	0.0%
October 2006	14	0.6%
References from Hollowell VUR2520	0	0.0%
Peter's JPU Rev	1	0.0%
October-December 2006	10	0.4%
Methodologist added articles missed in search	3	0.1%
July 2008	0	0.0%
August 2008	0	0.0%
Total Articles selected for Extraction	**348**	**15.5%**

Extraction Status as of February 5, 2007		% Extracted	% Citations Retrieved
Total Data Entered	348	**100.0%**	**15.5%**
Accepted	186	53.4%	8.3%
Rejected	162	46.6%	7.2%
Total Extracted to date	**348**	**100.0%**	**15.5%**
% Complete	**100.0%**		

Reasons for Rejection	Occurrences
No relevant outcomes or complications data	41
Cannot adequately separate stages	11
Cannot interpret data to fit extraction form	12
Insufficient treatment efficacy follow-up (must be ? 3 months)	3
Doesn't deal with treatment:	20
Basic Science	1
Epidemiology	8
Other	
Other reason for exclusion: specify:	66
	162

Characteristics of Accepted Articles

Study Design	Articles
Medical record review	51
Case Series/Report	36
Controlled trial	10
Review/policy	1
Case-control study	0
Cohort Study	46
Meta-analysis	0
Data base or surveillance	0
Letter: Ref.	0
Opinion or testimony	0
Other: spec.	2
NOT IDENTIFIED	42
	188

VUR – Topics 1, 2 3, and 5

Cover Sheets

Citation: «Authors», «Title», «Journal», «Year», «Date», «Volume», «A_Pages»

Extractor A: «Extractor1_Initials» Date: _____

Extractor B: «Extractor2_Initials» Date: _____

Reconciliation Date: _____

_____ ACCEPTED and Extracted

___ Insufficient treatment efficacy follow-up
Complications data only extracted

___ IRS group

___ Needs Panel Review

_____ REJECTED and not Extracted

Article REJECTED due to (check all that apply):
___ No relevant outcomes or complications data
___ Cannot adequately separate stages
___ Cannot interpret data to fit extraction form
___ Insufficient treatment efficacy follow-up (must be ≥ 3 months)
___ Doesn't deal with treatment:
___ Basic Science ___ Epidemiology ___ Other
___ Other reason for exclusion:
specify: _____

___ Duplicate, of Ref # _____ if known

1. Study Design
_____ Medical record review
_____ Case Series/Report
_____ Controlled trial
_____ Review/policy
_____ Case-control study
_____ Cohort Study
_____ Meta-analysis
_____ Data base or surveillance
_____ Letter: Ref._____
_____ Opinion or testimony
_____ Other: spec._____

Study Features (check all that apply)
___ Retrospective
___ Prospective
___ Randomized
___ Patient blinded
___ Provider blinded
___ Outcome evaluator blinded
___ Cross-over

2. Are there particular difficulties with this study that make it less useful for our purposes (include study flaws and items that cause the study interventions or population not to match our needs)?

___ Serious design flaws (specify_____)
___ Randomization failure
___ Confounders present
___ Selection bias
___ Patient population not relevant
___ Incomplete or biased statistics/data
___ Blinding failure or insufficient
___ Compliance problems (intensity)
___ Cross-over problems
___ Atypical intervention
Other: (describe)

3. Are there other data or points in this article that would be relevant that are not covered elsewhere?

VUR – Topics 1, 2 3, and 5

Cover Sheets

4. Study: Total patients enrolled: _____ (N)
Country: _____ ___ Check if multi-center/location
Study dates: _____ through _____ (leave blank if not specified)

5. Inclusion/Exclusion Criteria
a. Mark with an I (inclusion) or with an E (exclusion) all the following that apply.

____ bacteriuria	____ posterior urethral valves	____ other: _____
____ bladder outlet obstruction	____ prenatal hydronephrosis	____ other: _____
____ bladder wall thickening	____ spina bifida	____ other: _____
____ dilated ureters	____ scarring present	____ other: _____
____ duplicated system	____ scarring absent	____ other: _____
____ exstrophy episodes/complex	____ unexplained fever	____ other: _____
____ history of UTI	____ ureteroceles	____ other: _____
____ multicystic dysplastic kidney	____ voiding pattern (normal)	____ other: _____
____ neurogenic bladder	____ voiding pattern (dysfunctional)	____ none specified

6. Group Definitions:
Define in the table below the groups for which you are going to collect outcome information. For each group you indicate in the table you will need to fill out a set of pages 4-6. Indicate a NS (none specified) or multiple whenever levels of a factor are not specified or aggregated.

- **Group ID**: start in 1 and use decimal points to indicate groups related by stratifying variables. For example 1.1 for outcomes in subgroup with VUR grade 1, 1.2 for individuals with VUR grade 2 and so on.
- Indicate whether the group has outcome for individuals from **Topic** 1 (high grade VUR), 2 (DES), 3 (3-6 no DES) or 5 (hydronephrosis).
- Indicate for which type of **Units** (ureters **U**, patients **P**, both **B**) are outcomes.
- Indicate the **VUR grade** of the units for which outcomes are reported in this group.
- Indicate the treatment (**Rx type**) class from prophylactic antibiotic, prophylactic antibiotic and bladder hygiene, observation management, open surgery, endoscopic injection, other. Please use this classification for the sake of consistency throughout the extractions.
- Indicate the **Time** at which outcomes are being reported. For different times generate different groups.
- Use the **Comment/Definition** column to include any detail related to the row item that you consider important for the group you created and for which you will extract outcome data, or which will help you to easily identify it in subsequent pages.

Group ID	Topic No	Units	VUR Grade	Rx type	Time	Other factor(s)	Comments/Definition

7. Comments:

8. Total time completing this extraction: _____ minutes.

VUR – Topics 1, 2, 3, and 5

Group Characteristics

9. Group Characteristics

Patients: N = _____ **Renal units: N=** _____

Age: Mean: _____ Median: _____ Std. Dev:_____ Min: _____ Max: _____ (Age at start of intervention if provided)

Age 1: _____ _____ (n or %) Age 2: _____ _____ (n or %) Age 3: _____ _____ (n or %) (fill all that apply)

Sex: Male: N ____ or % _____ Female: N ____ or % _____ (fill number "N" or percentage "%" as it applies)

10. Baseline Conditions

	Patients			Renal Units/Ureters			
VUR Severity	**Some**	**%**	**Num**	**Some**	**%**	**Num**	**Comments/Definition**
Grade I							
Grade II							
Grade III							
Grade IV							
Grade V							
Grade (other):							
Presentation	**Some**	**%**	**Num**	**Some**	**%**	**Num**	**Comments/Definition**
UTI							
PNDx							
Hydronephrosis							
Laterality	**Some**	**%**	**Num**	**Some**	**%**	**Num**	**Comments/Definition**
Unilateral							
Bilateral							
Not specified							
Elimination Dysfunction	**Some**	**%**	**Num**	**Some**	**%**	**Num**	**Comments/Definition**
Present							
Absent							
Not specified							
Renal Function	**Some**	**%**	**Num**	**Some**	**%**	**Num**	**Comments/Definition**
Scarring present							
Hypertension							
Loss							
Renal length	Level _____ Number at level _____ % at level _____						
Creatinine clearance	Level _____ Number at level _____ % at level _____						

11. Comments on Group Characteristics

VUR – Topics 1, 2, 3, and 5

Group Treatment Characteristics

12. Treatments

- Fill in the **Check** column if row item is evaluated in manuscript, even if no specific or discernable number is provided.
- Use either the percent **(%)** column or the **Num** column to indicate the percent and/or number of patients and/or renal units evaluated.
- Use the **Comment/Definition** column to include any detail related to the row item that you consider important and that is not addressed by the table format.

Treatment number in a sequence: (0 – not known, 1 – first rx, 2 – second rx, 3 – third rx, and so forth)

Same intervention (eg. Endoscopic injection): _____ Different intervention (eg. Antibiotic, then surgery): _____

A. Medical

	Patients			
Intervention	**Some**	**%**	**Num**	**Comments/Definition**
Continuous prophylaxis				
Intermittent prophylaxis				
Agent	TMX ____ NF ____ PCN/Cef ____ TR ____ SUL ____ Other _____ NS ____			
Anticholinergic	Ditropan ____ Other _____ NS ____			
Other management	Biofeedback ____ Time voiding ____ Other _____			

B. Watchful waiting (no antibiotics)

	Patients			
Intervention	**Some**	**%**	**Num**	**Comments/Definition**
Observation				
Monitoring frequency (months)	Mean: _____ Median: _____ Std. Dev: _____ Min: _____ Max: _____			

C. Surgery

	Patients			Renal Units/Ureters			
	Some	**%**	**Num**	**Some**	**%**	**Num**	**Comments/Definition**
Open							
Modality	Politano-Leadbetter ____ Glenn-Anderson ____ Cohen T-T ____ Lich-Gregoir ____ Gil-Vernet ____						
Modality	Detrusorrhaphy ____ Vesicostomy ____ Other _____ Not stated ____						
Endoscopic	**Some**	**%**	**Num**	**Some**	**%**	**Num**	**Comments/Definition**
Initial ____ Delayed ____							
Agent	Dextranomer-HG (Deflux) ____ Polydimethylsiloxane (Macroplastique) ____						
Volume injected (ml or cc)	Mean: _____ Median: _____ Std. Dev: _____ Min: _____ Max: _____						

13. Follow-up Duration (mo): Mean: _____ Median: _____ Std. Dev: _____ Min: _____ Max: _____

14. Comments

VUR – Topics 1, 2, 3, and 5

Group Outcomes

15. Outcomes **Resolution data is:** **A. Actual** **B. Actuarial/life table** **C. Kaplan-Meier** (circle one)

			Patients			Renal Units/Ureters		
Outcome measure	**Time Months**	**%**	**X Num**	**Y Den**	**%**	**X Num**	**Y Den**	**Comments/Definition of Success/Failure**
Resolution								
Reduced grade								
Worsened								
UTI Febrile								
UTI Cystitis								
UTI not specified								
Somatic growth impairment								
Renal scarring (new)								
Renal scarring (overall)								
Hypertension (new)								
Hypertension (overall)								
Renal functional loss (new)								
Renal functional loss (overall)								
Post-operative catheter								

Measure	**Mean**	**Median**	**Std. Dev**	**Min**	**Max**
Catheter duration (days)					
Inpatient mean hospital stay (days)					
Outpatient mean hospital stay (hours)					

16. Complications (peri-operative and during follow-Up)

			Patients			Renal Units/Ureters		
Side effects	**Time Months**	**%**	**X Num**	**Y Den**	**%**	**X Num**	**Y Den**	**Comments/Definition**
None								
Allergic reaction								
Hematologic								
New VUR, Contralateral								
Obstruction/hydronephrosis, requires no REOP								
Obstruction/hydronephrosis, requires REOP								
Obstruction/hydronephrosis, none detailed								
Not stated								

17. Relationship of scarring to bacteriuria, if known for this particular group: (enter the number of patients in each box)

	New or Progressive Scarring			New or Progressive Scarring	
	Y	N		Y	N
Bacteriuria since Rx - present			Bacteriuria since Rx - absent		

18. Comments (regarding this group only)

VUR Screening in Perinatal Hydronephrosis

Cover Sheets

Citation: «Authors», «Title». «Journal», «Date», «A_Pages»

Extractor A: __«Extractor1_Initials»_____ Date: _____

Extractor B: ___«Extractor2_Initials»_____ Date: _____

Reconciliation Date: _____

_____ ACCEPTED and Extracted

___ Insufficient screening/follow-up

___ Needs Panel Review

_____ REJECTED and not Extracted

Article REJECTED due to (check all that apply):
___ No relevant outcomes data
___ Cannot adequately separate stages
___ Cannot interpret data to fit extraction form
___ Insufficient follow-up (must be ≥ 6 months)
___ Doesn't deal with screening:
___ Basic Science ___ Epidemiology ___ Other
___ Other reason for exclusion:
specify: _____
___ Duplicate, of Ref # _____ if known

1. Study Design

____ Case Series/Report
____ Controlled trial
____ Review/policy
____ Case-control study
____ Cohort Study
____ Meta-analysis
____ Data base or surveillance
____ Letter: Ref._____
____ Opinion or testimony
____ Other: spec._____

Study Features (check all that apply)
___ Retrospective
___ Prospective
___ Randomized
___ Patient blinded
___ Provider blinded
___ Outcome evaluator blinded
___ Cross-over

2. Are there particular difficulties with this study that make it less useful for our purposes (include study flaws and items that cause the study interventions or population not to match our needs)?

___ Serious design flaws (specify_____)
___ Randomization failure
___ Confounders present
___ Selection bias
___ Patient population not relevant
___ Incomplete or biased statistics/data
___ Blinding failure or insufficient
___ Compliance problems (intensity)
___ Cross-over problems
___ Atypical intervention
Other: (describe)

3. Are there other data or points in this article that would be relevant that are not covered elsewhere?

VUR Screening in Perinatal Hydronephrosis

Cover Sheets

4. Study: Total Patients enrolled: _____ (N)

Country: _____ ___ Check if multi-center/location

Study Dates: _____ through _____ (leave blank if not specified)

5. Inclusion/Exclusion Criteria

- Mark with an I (inclusion) or with an E (exclusion) all the following that apply.

____ bacteriuria	____ exstrophy episodes	____ spina bifida
____ bladder outlet obstruction	____ history of UTI	____ unexplained fever
____ bladder wall thickening	____ multicystic dysplastic kidney	____ ureteroceles
____ dilated ureters	____ posterior urethral valves	____ other_____
____ duplicated system	____ prenatal hydronephrosis	____ none specified

6. General Patient Sample Characteristics

Renal units: N= _____

Patients age: Mean: _____ Median: _____ Std. Dev:_____ Min: _____ Max: _____

Sex distribution: Male: N _____ or % _____ Female: N ____ or % _____ (fill number "N" or percentage "%" as it applies)

7. Standard Used for Diagnosis

a) VUR: ____ Intl. Classification System ____ other _____ _____ none specified

b) Hydronephrosis: ____ Soc. for Fetal Urology Scale ____ other _____ _____ none specified

8. Diagnosis of Hydronephrosis

a) Pre-natal: _____ 2nd trimester _____ 3rd trimester _____ no time specified _____ none specified

b) At birth: _____ ≤ 3 months _____ other _____ _____ none specified

c) AP diameter threshold (mm) _____

9. Definitions

____ (%) abnormal differential uptake by DMSA Creatinine clearance calculation:_____

10. Comments

11. Total time completing this extraction: _____ minutes.

VUR Screening in Perinatal Hydronephrosis

Definitions of Groups with Outcomes

12. Screening regimen groups

Define in the table below the groups for which you are going to collect outcome information. For each group you indicate in the table you will need to fill out a page 4.

- **Group ID**: start in 1 and use decimal points to indicate groups related by stratifying variables. For example 1.1 for females and 1.2 for males.
- If the group is defined by **sex** (male/female), otherwise write **NS** for none specified.
- Indicate the group **age** of the group, otherwise write **NS** for none specified.
- Indicate the **race** of the group if it is specified in the manuscript, otherwise write **NS** for none specified.
- Indicate the screening **Type** applied to the group: US (ultrasound), VCUG (voiding cystogram), DMSA (scintigraphy), other, none specified (NS).
- If there is a stratification in the manuscript for a factor not contemplated in the columns of the table and that you consider relevant for this screening topic use the **Other factor(s)** column to define the levels of that particular factor. In such case please use the **Comments/Definition** column to indicate what is the factor.
- Use the **Comment/Definition** column to include any detail related to the row item that you consider important for the group you created and for which you will extract outcome data.

Group ID	Sex	Race	Hydro grade	Type	Other factor(s)	Comments/Definition

13. Comments

VUR Screening in Perinatal Hydronephrosis

Group Characteristics/Outcomes

14. Group Characteristics

Group definition: _____ **Patients: N=** _____ or % _____ **Renal units: N**= _____ or % _____

Age (years)	Mean: _____ Median: _____ Std. Dev: _____ Std. Error: _____ Min: _____ Max: _____

15. Screening Regimen

Indicate in **Type** the imaging modality for this specific group, the time of the **first evaluation** for individuals in this group, the **frequency**, whether individuals where under **antibiotic** while being during screening/follow-up for screening, and the duration of such **follow-up**.

Type	First Eval	Freq.	Antibiotic	Comments/Definition

Follow-up time (months)	Mean: _____ Median: _____ Std. Dev: _____ Std. Error: _____ Min: _____ Max: _____

16. Outcomes

- Fill in the **Check** column if row item is evaluated in manuscript, even if no specific or discernable number is provided.
- Use either the percent **(%)** column or the **Num** column to indicate the percent and/or number of patients and/or ureteral units evaluated.
- Use the **Comment/Definition** column to include any detail related to the row item that you consider important and that is not addressed by the table format.
- For **Complications** please indicate the particular side effects of screening for which you are extracting outcomes.

VUR diagnosis data are: **A. Actual** **B. Actuarial/life tables** **C. Kaplan-Meier** (circle one)

	Patients				Ureters				
VUR	**Check**	**%**	**Num**	**Den**	**Check**	**%**	**Num**	**Den**	**Comments/Definition**
Grade I									
Grade II									
Grade III									
Grade IV									
Grade V									
Grade (multiple)									
No grade specified									
Unilateral									
Bilateral									
Breakthrough UTI									
Renal scarring									
Complications									

Creatinine clearance	Mean: _____ Median: _____ Std. Dev: _____ Std. Error: _____ Min: _____ Max: _____

17. Comments (regarding this group only)

29020 AAP parent page. Shopping-cart safety. Pediatrics. 2006 Aug; 118: e545-6

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21270 Abeysekara, C. K., Yasaratna, B. M., Abeyanunawardena, A. S. Long-term clinical follow up of children with primary vesicoureteric reflux. Indian Pediatr. 2006 Feb; 43: 150-4

10710 Abidari, J. M., Park, K. H., Kennedy, W. A., Shortliffe, L. D. Serial followup of the contralateral renal size in children with multicystic dysplastic kidney. J Urol. 2002 Oct; 168: 1821-5; discussion 1825

1530 Aboutaleb, H., Bolduc, S., Bagli, D. J., Khoury, A. E. Correlation of vesicoureteral reflux with degree of hydronephrosis and the impact of antireflux surgery. J Urol. 2003 Oct; 170: 1560-2; discussion 1562

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2250 articles listed

Appendix 7: VUR Definitions

UTI

- General term for a symptomatic infection of any part of the urinary tract including bladder, ureters and kidney. Symptoms may range from just dysuria (pain with urination) to fever, nausea and vomiting and even to sepsis (blood stream infection). Usually associated with pyuria (pus cells or white blood cells), bacteria in the urine, and growth of a micro-organism on culture.
- The clinical definition is usually qualified by providing an estimate of the concentration of bacteria in the urine, typically 100,000 bacteria (or colony-forming units) per milliliter. For a voided specimen, the convention is that greater than 10^5 organisms represent a UTI, but in some cases, fewer organisms can be an accurate representation of a clinical infection. This may depend upon how the specimen was obtained.
- RIVUR Definition (Randomized Intervention for Vesicoureteral Reflux in Children – (http://www.cscc.unc.edu/rivur/faq.php):):

III.A. Febrile UTI (fUTI)

fUTI requires the presence of (1) fever, (2) pyuria based on urinalysis, and (3) culture-proven infection with a single organism. Specifically, the study definition of fUTI requires:

I. Fever

- *Documented temperature of at least 100.4 °F or 38°C, measured anywhere on the body either at home or at doctor's office*

AND

II. Pyuria on urinalysis

- *>10 WBC/mm3 (uncentrifuged specimen) OR*
- *>5 WBC/hpf (centrifuged specimen), OR*
- *>1+ leukocyte esterase on dipstick*

AND

III. Culture proven infection with a single organism

- *>5 x 10^4 CFU/mL (catheterized or suprapubic aspiration urine specimen) OR*
- *>10^5 CFU/mL (clean voided specimen).*

III.B. Symptomatic Non-febrile UTI (SUTI)

SUTI requires the presence of (1) urinary tract symptoms, (2) pyuria on urinalysis, and (3) culture-proven infection with a single organism. Specifically, the study definition of SUTI requires:

I. Symptoms

- *Suprapubic, abdominal, or flank pain or tenderness, or urinary urgency, frequency, or hesitancy, or dysuria, or foul smelling urine, or in infants < 4 months old, failure to thrive, dehydration, or hypothermia*

AND

II. Pyuria on urinalysis

- *>10 WBC/mm3 (uncentrifuged specimen) OR*
- *>5 WBC/hpf (centrifuged specimen), OR*
- *>1+ leukocyte esterase on dipstick*

AND

III. Culture proven infection with a single organism

- *>5 x 10^4 CFU/mL (catheterized or suprapubic aspiration urine specimen) OR*
- *>10^5 CFU/mL (clean voided specimen).*

Febrile UTI (fUTI)

- UTI with fever as well as possible other symptoms including dysuria, urgency and frequency, flank pain, nausea and vomiting.

Pyelonephritis

- Strictly defined, this is a UTI with infection and inflammation of the tissue of the kidney as well as the renal pelvis. May be termed acute pyelonephritis to distinguish from chronic, which has other clinical implications.[1]

Clinical Pyelonephritis

- Usually means a UTI with fever and some localizing signs of kidney involvement. These can be flank pain, nausea or vomiting. Not all patients with pyelonephritis will have fever, particularly infants, and not all febrile UTIs represent pyelonephritis.

Radiological Pyelonephritis

- The strict definition of pyelonephritis includes the clinical signs with radiological confirmation by way of a radionuclide scan (usually DMSA) or by CT or MRI, demonstrating abnormal perfusion of the kidney tissue. US can demonstrate this with special techniques (Power Doppler) but this is infrequently used.

BT-UTI

- Break-through UTI represents an infection that has occurred while a patient is on preventive antibiotic therapy, usually termed continuous antibiotic prophylaxis (CAP). These can be with or without fever and other symptoms. Usually the causative organism is resistant to the antibiotic being used. If not, it can suggest that the medication is not being taken regularly.

Reflux Nephropathy

- Broadly defined, this is any abnormality of the kidney, typically demonstrated by DMSA scanning, that is associated with VUR. It may be typical pyelonephritic scarring, acquired renal injury due to infection, or it may be congenital reflux nephropathy. The latter term is used to define the renal abnormalities seen on DMSA scanning or pathologically that are usually associated with VUR detected in infancy with no apparent infection. It is presumed that these lesions are dysplasia. There is evidence to support this presumption, but there are few data in kidneys that do not have severe abnormality. The relationship of this dysplasia to VUR is uncertain

Bladder/Bowel Dysfunction (BBD)

(Dysfunctional Elimination Syndrome (DES))

- This is a very broad term for any clinical pattern of urinating and defecating that is not normal. Many terms are used to describe the various elements and clinical patterns that can occur within this general term, including overactive bladder, LUTS, constipation, urge syndrome, etc. The fundamental elements include both

bladder and bowel function, and have various underlying causes. Terminology is evolving, although a recent publication from the International Children's Continence Society (ICCS)[2] has laid out a structured nomenclature. Unfortunately, for the purposes of this guideline, the reporting in the literature was so variable, that we could not specifically determine voiding abnormalities that could be strictly correlated with the new nomenclature. The panel therefore chose to use the general term of BBD to encompass the wide range of abnormal bladder and bowel function.

- The clinical patterns usually produce incomplete bladder emptying, often under abnormally high pressure, with poor control and frequent wetting (although this is not universal). The relevance to VUR is important, as these patterns can produce a higher likelihood of developing a UTI, usually due to inadequate bladder emptying, as well as voiding patterns that produce high bladder pressures which may make reflux worse or to persist longer than it might otherwise. These patterns can be treated by a variety of methods, but there are too few data to make strong recommendations as to the best form for any one child.

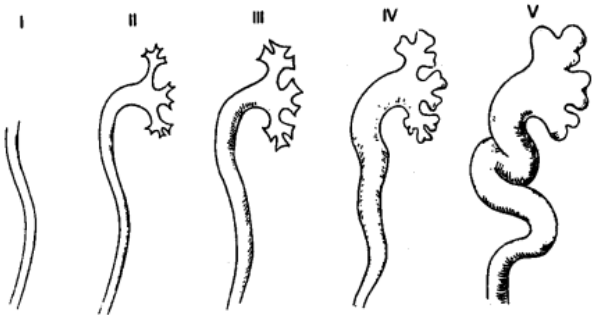
Therapies for BBD

- *Behavioral Therapy:* this approach includes regularizing voiding times, encouraging better relaxation and more complete emptying. This approach may be used in conjunction with other methods and is usually the foundation of an effective program of treatment.
- *Anticholinergic therapy*: this is a drug-based approach to patients with BBD having more aspects of urgency and frequency, rather than voiding postponement. The goal is to reduce the degree and frequency of urinary urgency, which is presumed to cause more pelvic floor contraction in an effort to prevent urinary incontinence. These medications are used temporarily, although often or months or even years, and should be used in coordination with a behavioral or biofeedback program.
- *Biofeedback:* this is a more complex treatment program that requires a dedicated staff and equipment. The goal is to teach the child what it feels like to relax their pelvic floor muscles to permit more effective voiding and to allow the child to train themselves to perform this while voiding.
- *Treatment of constipation:* this is usually a combination of increasing fluids, dietary modifications and occasional use of various laxatives and stool softeners.

Imaging for Reflux

VCUG

- The gold-standard for demonstrating the presence of VUR is the voiding cystourethrogram (VCUG). This is a radiological test that involves placing a catheter into the urethra of the child, filling the bladder with a radiological contrast agent that will show up on plain X-ray images or fluoroscopy. Back flow



GRADES OF REFLUX

of the contrast agent into the ureters and kidneys either during filling or voiding or both is indicative of VUR. VUR is graded from I to V, using the International Reflux Grading Scale. (Figure 1) This study also provides anatomic information regarding the bladder and urethra.

Figure 1: Reflux grading based on the International Scale[3].

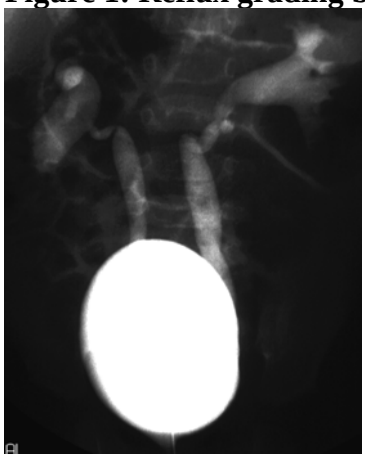


Figure 2: VCUG in a boy with bilateral Grade III VUR.

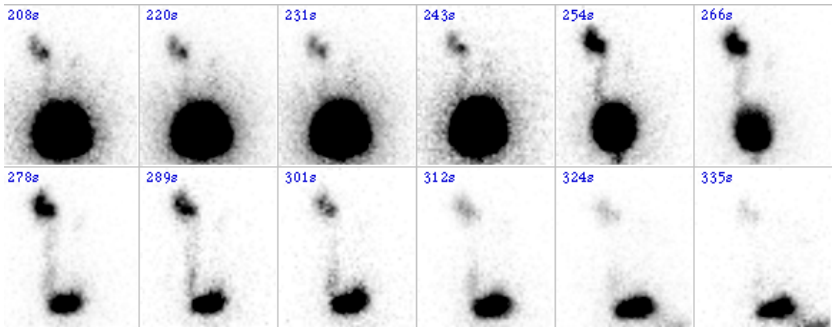


Figure 3: Radionuclide cystogram in child with left Grade III VUR and right Grade I. Continuous monitoring of filling and voiding may permit more sensitive detection of VUR.

An alternative is the radionuclide cystogram (RNC), which uses a radio-labeled liquid put into the bladder with a catheter. The location of the tracer is detected using a sensitive camera (gamma camera) that provides an image of the bladder and ureters/kidneys. It is more difficult to grade the reflux as precisely. This test requires slightly less radiation exposure than VCUG depending upon the type of fluoroscopy equipment available.

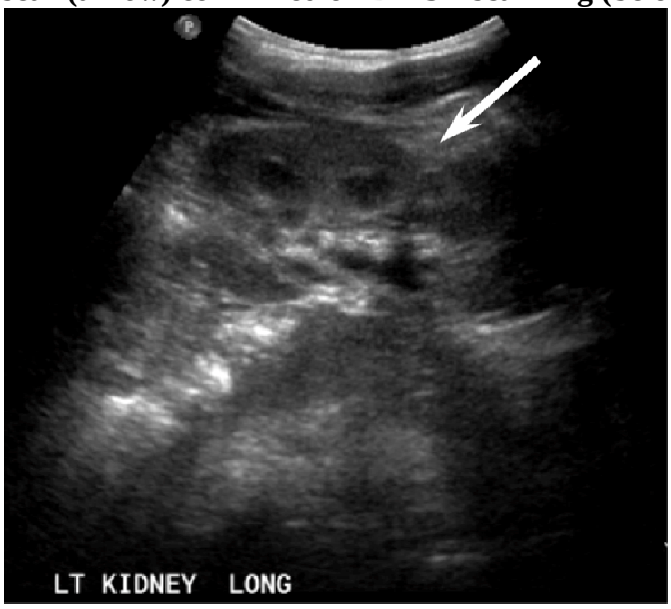
Either test requires catheterization and some centers use sedation for the testing. This can limit the test by inhibiting voiding in some children.

Ultrasound

- Ultrasound (also termed ultrasonography, sonography) imaging is performed using sound waves that are bounced off structures in the body to create an image. There is no radiation used and there are no proven adverse effects of ultrasonography. The images permit detailed examination of the kidneys and

bladder. They cannot determine function of a kidney directly, and are less sensitive to renal cortical abnormalities than DMSA scanning. Ultrasound is less expensive than DMSA scanning and may be adequate depending on the clinical situation.

Figure 4: Renal ultrasound of boy with left grade III VUR and a mid-renal scar (arrow) confirmed on DMSA scanning (below).



Attempts have been made to use ultrasound to detect VUR using materials instilled into the bladder, but these have not become widely used.

Radionuclide imaging: DMSA

- The gold-standard imaging test to detect renal cortical abnormalities is the DMSA scan using radio-labeled tracer injected into a vein. The tracer goes to the kidneys and using a sensitive camera (gamma camera), the relative function and structure of the kidney is determined. This test can identify areas of renal injury or abnormality, broadly termed renal cortical abnormalities in this report. These areas represent scarring caused by infection or abnormal areas of kidney from development. The cause of the latter areas is controversial, but is termed congenital reflux nephropathy.

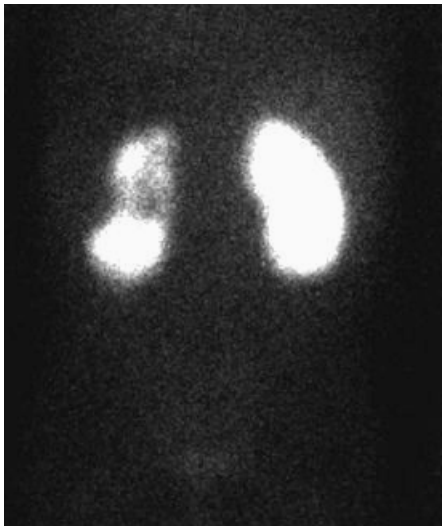


Figure 5: DMSA image of boy with Grade III VUR after infection with left renal cortical abnormalities. (Image is as if viewed from behind)

Therapies for Reflux

Observation

- An observational approach to managing reflux includes use of antibiotic treatment for acute UTIs. This may include surveillance cultures, but usually means treatment for symptomatic infections.

Continuous antibiotic prophylaxis (CAP)

- Managing VUR with daily antibiotic prophylaxis means using a low dose of an antibiotic agent in order to prevent UTIs that may cause acute pyelonephritis in the setting of VUR. The agents used are those that might otherwise be used in therapeutic doses for treatment of an infection. Usually CAP means once a day dosing of a single agent (trimethoprim-sulfamethoxazole is a single preparation but includes two drugs).

Curative interventions

- Interventions with the intent to cure the existing reflux include open surgical ureteral reimplantation, endoscopic injection of bulking agent into or under the ureter, and laparoscopic ureteral surgery.
    - *Open surgical anti-reflux operations*: Many operations have been described for the surgical cure of reflux with the most commonly used being the cross-trigonal or Cohen ureteral reimplantation (or ureteroneocystostomy), the Leadbetter-Politano reimplant, and the Lich-Gregoir or extravesical ureteral reimplantation or ureteroplasty (this operation is not strictly a reimplantation as the ureter is not separated from the bladder). Detailed descriptions of the procedures are available in general texts.[4] In general, these operations have very high success rates but require an incision and usually are managed with an in-patient hospital stay.
    - *Endoscopic anti-reflux procedures* are those in which a bulking agent is injected via cystoscopy under the ureter or into the ureteral wall to provide a more effective anti-reflux valve effect. Currently the only approved material in the USA is Deflux (Q-Med Scandinavia; now Oceana Therapeutics), which was introduced with FDA approval in 2001. Other materials that have been

used include Teflon paste, Macroplastique, Collagen, and numerous others; none of which are FDA approved. Reported success rates range widely as reported, but the procedure is appealing due to it being performed as an outpatient procedure with minimal morbidity.

- *Laparoscopic techniques* for anti-reflux surgery have been recently described that replicate the open procedures. There are very few reports and all reflect very early experience. The Panel considered these data too premature to permit useful comparisons with other methods.

Statistical analysis

Estimates

- Estimates for overall prevalence of VUR, renal damage, UTI and their stratification by available characteristics (grade, sex, pre-natal RPD/post-natal RPD/degree of HNP) were obtained using meta-analytic techniques. Aggregated estimates were obtained by using a linear mixed model under an empirical Bayes framework assuming a binomial distribution of the outcome. In these models, variables for adjustment/stratification were considered as fixed effects while the estimate for each study was assumed to vary from an overall value and characterized by a random effect presenting a normal distribution. The variance of this distribution was used to assess the degree of heterogeneity across studies estimates and the need to adjust for potential confounders at the study level. A variance term of the random effect significantly greater than zero was considered to signal heterogeneity. All estimates are provided with their 95% confidence interval (CI).
- Study level confounders considered as potential explanatory factors of heterogeneity if present were study design (retrospective, prospective), country where study took place categorized by regions (North America, Europe, Other), number of infants/renal units involved, year of publication. If heterogeneity was present and these factors tested, the selection of a particular model was determined by the Akaike's Information Criterion (AIC) of the model. A model with the smallest AIC among a series of nested models was selected, since that indicates a better model fit. These models were built using PROC NLMIXED in SAS v9.1 for Windows.
- Also, signs of publication bias were assessed using funnel plots for outcomes vs. the study sample size. If bias were present, then estimates across studies with smaller sample size should cluster to one side or the other of the overall estimate.

Definitions:

Linear mixed model

- A statistical model which includes both fixed and random effects. A fixed effect corresponds to a variable or characteristic for which all values of interest are included in the model. A random effect corresponds to a variable or characteristic for which a sample of the values of interest is included in the model. It is assumed that such sample is representative of the universe of values of interest.

Empirical Bayes framework

- A probabilistic approach in which the prior probabilities used in Bayes estimates are obtained from the data rather than being imputed (i.e., from prior knowledge or belief) as does the classical Bayes framework.

Epidemiological/statistical glossary

The following are brief descriptions of important study design concepts and characteristics that were employed in the execution of these guidelines. Examples for most of them are provided after each definition.

- *Case series:* study design in which a small number of individuals who share similar exposure(s), risk factor(s) and/or intervention(s) are described in detail. The main distinction of this design with other designs is precisely its more individual and descriptive approach rather than the analytical sample/group approach of the other designs.

- *Case-control study*: research design in which individuals are identified by their disease status/outcome (diseased=case, non-diseased=control), and followed-up back in time to determine their exposure to risk factors or intervention of interest. They are generally of a retrospective nature. Example: infants diagnosed with reflux (cases) are compared to healthy infants of similar age group, and information on potential risk factors for reflux is collected in both groups to determine the association of these risk factors to the incidence of reflux.

- *Cohort study*: research design in which individuals are selected from a general population by common characteristics of interest, usually the exposure(s), risk factor(s), or intervention(s) under examination. Although they generally are of a prospective nature, cohort studies can also be retrospective or cross-sectional (see below). Example: a group of children with low-grade reflux (the cohort) are closely followed-up for a period of three years to estimate the rate of spontaneous reflux resolution.

- *Controlled trial*: in this research design the experimenter has control over the exposure or intervention of interest. In this way (s)he can observe in the experimental units the potential effect(s) of subjecting them to the exposure or intervention. Example: a group of children with grade IV reflux are assigned to open surgery or endoscopic injection by the physician's recommendation in order to estimate the rate of reflux resolution.

- *Meta-analysis*: quantitative summarization of the existing knowledge (published and unpublished) regarding the effects in individuals of exposure(s), risk factor(s) or intervention(s) of interest in particular outcomes. Example: the overall reflux resolution rate for neonates.

- *Review: summ*arization of the existing knowledge (published and unpublished) regarding the effects in individuals of exposure(s), risk factor(s) or intervention(s) of interest. It does not necessarily imply the estimation of a quantitative summary measure.

- *Cross-sectional*: research design in which the status of the experimental subjects is determined at a single point in time, usually at the same time of the assessment of the exposure(s), risk factor(s) or application of the intervention(s). This design

allows the assessment of associations but not of a causal path. Example:. The prevalence of UTIs in a group of children is assessed from their medical charts. The children's age, sex, reflux and BBD status were also recorded. Associations between these variables and UTI were estimated.

- *Longitudinal study*: research design in which the experimental subjects are followed in time. Longitudinal studies can be of a prospective or retrospective nature, if the subjects are followed forward or backwards in time. However, more commonly, the longitudinal qualifier is left to design studies of a prospective nature. Example: the follow-up of children illustrated in the example of the cohort is prospective. If in addition, information on previous episodes of urinary infection were collected, that component would be retrospective.

- *Randomized study*: research design in which experimental subjects are assigned to a study group via a randomization process (i.e. governed by the laws of probability). Example: in the example of the controlled trial if the assignment to open or endoscopic surgery is done by the random draw of a number rather than by physician assignment, that would become a randomized study.

- *Cross-over*: research design in which all the experimental units are subjected to a number of interventions in sequence rather than to a unique intervention. Example: a group of toddlers with low-grade reflux are assigned to a sequence of two interventions, biofeedback and prophylactic antibiotics. One group is assigned to the sequence biofeedback and then antibiotic, the other group to the sequence antibiotic and then biofeedback.

- *Blinding*: process by which one or more actors -subject, researcher, outcome observer- of the research endeavor do not know the assignment of the experimental subjects to study groups. The main objective is to minimize certain types of biases. The easiest blinding is of subjects and outcome observers. Blinding researchers, especially in relation to surgery-related conditions is difficult to achieve. Example: a group of infants with low-grade reflux are recruited for a trial of a new antibiotic against UTI. Some infants are provided the new antibiotic while others the standard antibiotic. However, the patients/parents are unaware of the specific assignment.

- *Confounder*: variables or factors known or suspected to be associated with a subject status or condition and to the outcomes, and therefore are capable of modifying them. Example: age and reflux grades are confounders in reflux resolution.

- *Bias*: is a systematic error in the design, conduct or analysis of a study. There are several types of biases in epidemiology. The most common ones are:
    - *Selection bias*: experimental units are selected based on the knowledge of their characteristics, in particular those related to the condition, exposure or outcomes of interest.

- *Information bias*: use of different definitions of the measure(s) of interest, or quality and extent of the information is different for different experimental units.
- *Recall bias*: it occurs when individuals are interviewed regarding past events or exposures(s).
- *Publication bias*: when studies are submitted for publication or get published depending on the results they report.
- The greatest danger of bias is when it is differential. That is, when it occurs in different degree and/or direction among individuals or groups under study.

Ecological fallacy: is the bias introduced by an analysis performed at a more aggregated level in terms of the unit of analysis (for example the sample in a given study) but with inferences made at a lower level of analysis (the individual). The more patent expression of this bias is the one introduced by relationships made based on the marginal quantities of a 2x2 contingency table (i.e. the row and column totals) in the absence of the numbers in the inner cells of such table. (Can we provide a more basic description of this issue – it is important?)

Prevalence: measure of disease burden, which indicates the total number of existing cases presenting with a given disease or condition at a point or period in time among a population at risk for such disease or condition.

Incidence: measure of disease burden, which indicates the number of new cases of a given disease or condition occurring in a specified period of time.

p-value or statistical significance: indicates the likelihood of a statistic obtained from a sample to be as extreme as it should given the assumed distribution for such statistic.

Correlation: measures the linear association between two random variables. The most common measure of correlation is the Pearson correlation coefficient. A qualitative interpretation has been suggested to the strength of this association by Morton et al. (1996, p.92) as follows: negligible correlation for values below 0.2, weak between 0.2-0.5, moderate 0.5-0.8 and strong for values of 0.8 or greater.[5] The strength of the association (i.e. magnitude) should be differentiated from statistical significance (i.e. p-value).

Simpson's paradox: (also known as the reversal paradox or amalgamation paradox) A statistical paradox where the outcome rates of groups are reversed when combined. This is usually due to variation in the makeup of the groups and the presence of confounders that disproportionally affect one group over another.

Technical Appendix II – Estimates calculation

The following is an abbreviated technical description of the estimation process that takes place within the empirical Bayes approach. Within a Bayes framework, the estimation of parameters (i.e., mean of a distribution, odds ratio, etc.) is performed by the combination of information from the data and existing *prior* knowledge regarding the parameters of the distribution. The estimation is done based on the resulting or *posterior* distribution of the parameters. In the case where that prior knowledge is based on the data at hand too, the approach is termed empirical Bayes. Within this framework, the initial estimation of the prior distribution can be done parametrically or non-parametrically (assuming or not a particular distribution form). Following is an example of this process, adapted from Casella (1985).[6]

Assume that we observe *m* random variables (i.e. the mean age at reflux resolution) with a normal distribution with variable mean and same variance: $X_i \sim N(\theta_i, \sigma^2)$. In turn, the realizations (i.e. observed) of the variable mean (one per study) have an underlying distribution, normal too for simplicity but without loss of generality: $\theta_i \sim N(\mu, \tau^2)$.

The Bayes estimate for θ_i is given by the posterior mean which is in the case of a normal prior and normal data, the weighted average of the prior estimate of the mean (μ) and the sample estimate of the mean (X_i):

$$\theta_i^B(X_i) = [\sigma^2/(\sigma^2+\tau^2)]\mu + [\tau^2/(\sigma^2+\tau^2)]X_i$$

Notice how this weighted average is determined by the relative precision (variance) of the estimates for the prior (τ^2) and the sample (σ^2). If the precision of both the prior and the sample are similar, both components will have approximately half of the influence in determining the estimate.

The empirical Bayes estimate is obtained in a similar fashion with the only difference being that instead of assuming values for the mean and variance of the prior distribution, these parameters are estimated directly from the data:

$$\theta_i^{EB}(X_i) = \left[\frac{(p-3)\sigma^2}{\sum(X_i-\overline{X})^2}\right]\overline{X} + \left[1-\frac{(p-3)\sigma^2}{\sum(X_i-\overline{X})^2}\right]X_i$$

You can notice that the empirical Bayes estimate is also a weighted average, in this case of the overall mean and the individual data points. In the case that the variability of the sample values is large, the empirical Bayes will tend towards to overall mean. On the other hand when sample values exhibit small variability then the individual observations will prevail. Another important detail from the formulation above is that information from all the other samples is used to estimate each of the θ_i.

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