



# Urological Surveillance and Medical Complications in the United States Adult Spina Bifida Population

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<b>OBJECTIVE</b>	To evaluate urologic follow-up and prevalence of medical complications among adult patients in the United States with myelomeningocele (MMC) who are Medicare beneficiaries.
<b>METHODS</b>	We performed a retrospective study using a 5% Medicare sample from 2007 to 2010. We defined acceptable minimum follow-up criteria as patients receiving all of the following: serum creatinine, upper urinary tract imaging, and a urologist evaluation within a 2-year period. We queried associated diagnoses and relevant complications using International Classification of Diseases, Ninth Revision codes, graded based on clinical impact. A regression model identified factors associated with evaluation completeness as well as with increased prevalence of medical complications.
<b>RESULTS</b>	We identified 825 patients with MMC, predominantly Caucasian (85.1%) and female (61.3%), with a mean age of $51.2 \pm 17.2$ years. Only 33.5% of the patients met the minimum acceptable follow-up criteria. Forty-four percent saw a urologist within the 2-year period. Most complications observed were mild, observed in 27.6% of patients. Moderate and severe complications were observed in 17.0% and 6.6% of patients, respectively. The most common complications were cystitis (16.4%), pressure ulcers (7.1%), chronic kidney disease (4.4%), and pyelonephritis (3.7%). Logistic regression indicated that younger age, male gender, and adequate follow-up were associated with increased prevalence of complications.
<b>CONCLUSION</b>	Despite high prevalence of complications in patients with MMC, most are not receiving the minimum recommended follow-up. The 33.5% of patients who received adequate surveillance were diagnosed with more complications, likely secondary to improved disease ascertainment. Prospective studies are needed to look at follow-up strategies and how these can improve outcomes for patients with MMC. UROLOGY 123: 287–292, 2019. © 2018 Elsevier Inc.

Before 1960, the survival rate for all forms of myelomeningocele (MMC) was 10%–12%. The development of ventriculoperitoneal shunts, antibiotic treatments for urinary tract infections, and subsequent advances in urinary diversion and catheterization techniques radically changed the once-dismal prognosis for children born with this condition,<sup>1</sup> in which survival now exceeds 85%. With decreases in the birth prevalence of MMC after the introduction of prenatal diagnosis and folate supplementation, there may actually be more adults currently living with MMC in the United States than there are children with MMC,<sup>2–4</sup> highlighting the importance of studying this population in its adulthood. Recent data from the Spina Bifida Association suggest that there

are more than 160,000 adult individuals with MMC living in the United States<sup>5</sup>. At present, there is no high-level evidence regarding adult urologic care for the patient with MMC that takes into consideration the heterogeneity of disease severity, and there are little data regarding their long-term urologic outcomes.<sup>3</sup> To date, we do not have published guidelines in the United States regarding surveillance for patients with MMC, but existing screening *recommendations* for patients with MMC entail a urologist visit with yearly renal ultrasonography to assess upper urinary tract anatomy, consideration of renal function assessment via laboratory testing, and possible urodynamic evaluation every 2 years to detect subclinical changes in bladder behavior.<sup>6</sup> These recommendations have been based on evidence stemming from overall guidelines for patients with neurogenic bladder and have been designed to address all patients with neurogenic lower urinary tract dysfunction, and not MMC specifically.<sup>7</sup> Our objective is to investigate how many patients with MMC within a retrospective sample actually received adequate surveillance, in line with available

**Financial Disclosure:** The authors declare that they have no relevant financial interests.

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Submitted: June 2, 2017, accepted (with revisions): August 29, 2017

recommendations. We hypothesize that many patients do not receive the minimum acceptable surveillance for their neurogenic lower urinary tract dysfunction (NLUTD). Our secondary objective is to identify the prevalence of specific medical complications that are related to NLUTD, and to single out those factors associated with increased prevalence of complications.

## METHODS

We performed a retrospective, cross-sectional evaluation of a 5% sample of Medicare administrative data from 2007 to 2010. Medicare is a federal system of health insurance for people over 65 years of age and for many younger patients who may qualify for coverage if they have permanent disabilities, such as MMC. The minimum adequate surveillance threshold was adapted from the existing Paralyzed Veterans of America screening recommendation,<sup>8</sup> which recommends the minimum adequate surveillance to be serum creatinine, upper urinary tract imaging, and a urologist visit within a 2-year period. These guidelines are not specific for adult patients with MMC, but were used because no equivalent screening recommendations currently exist for this population. Patients were considered to have “adequate and complete surveillance” if they received all 3 study components within the 24-month period, “some surveillance” if they received 1 or 2 studies during the period, and “no surveillance” if none of the 3 components were encountered during the 24-month period. Provider identification numbers were used to identify the urologist visit. The additional components (serum creatinine and imaging data) were obtained using current procedural technology codes entered during the study period. The studies that were included in the category of upper tract imaging were the following: renal or abdominal ultrasound, intravenous pyelogram, abdominal computed tomography (CT) scan, magnetic resonance imaging, nuclear medicine renal scan, or a voiding cystourethrogram. Other common urologic diagnostic studies, including urinalysis, urine cytology, cystoscopy, urodynamics, and urine cultures, were also tabulated but not included as fulfilling the screening evaluation criteria.

Patient demographic variables collected included age, gender, race or ethnicity, and region of residence based on zip code. Distance of patient travel to a referral center was calculated using the patient's zip code and the location of the hospital based on information provided by the American Hospital Association Guide.<sup>9</sup> Distance of travel was included as a variable with the hypothesis that increased distance of travel for specialized care may be associated with decreased access to adequate surveillance.

NLUTD-associated complications and diagnosis of MMC were collected using the International Classification of Diseases, Ninth Revision codes (Fig. 1). The complications encountered that were associated to NLUTD and thus relevant to our study included urinary tract infections, catheter-associated complications, pressure ulcers, implanted urologic device complications, renal failure,

uroolithiasis, vesicoureteral reflux, hydronephrosis, fistula, and urothelial malignancy (Fig. 1). Patients included had at least 24 months of follow-up data.

We graded complications based on their clinical implications. Mild complications were defined as those that warranted only outpatient treatment. Moderate complications were those that required minor surgery, admission for treatment, or had the potential to result in upper tract deterioration. Severe complications were any complications that were life-threatening or required major surgery. Chronic complications, such as chronic renal failure, were excluded if they were diagnosed at any time before the 2-year study period.

Multivariate logistic regression was used to identify associations with complications. We included the following variables: age, gender, race, travel distance to referral center, and geographic location of residence. Variables were selected for the multivariable model a priori. They were first tested in a univariate fashion and subsequently winsorized to 95%.

## RESULTS

Eight hundred twenty-five patients with MMC were identified as having 2 years of data and were included in the analysis. Women comprised 61.3% of the sample, and the mean age of the entire group was  $51.2 \pm 17.7$  years. Most patients were Caucasian (85.1%). Of the entire cohort, 42 patients (5.0%) received no screening studies over the 2-year period, 507 patients (61.5%) received some but not all screening, and 276 (33.5%) received all 3 screening evaluations required for “adequate and complete surveillance” (33.5%). Patients traveled a mean of  $25.4 \pm 15.2$  miles to receive care from a urologist or a rehabilitation center with Urology or Physical Medicine and Rehabilitation services. Table 1 demonstrates demographic variables for patients receiving all categories of surveillance.

Forty-four percent of patients (N = 365) saw a urologist during the 2-year period and 54.9% had some form of upper tract evaluation, and most of these upper tract imaging studies were CT scans (345 patients, 41.6% of entire cohort) followed by abdominal ultrasound (39.8% of patients). Ninety percent of the population had a serum creatinine laboratory test performed during the study. Other urologic investigations that were performed in this population, but were not considered part of annual screening, included urinalysis in 79.4%, urine culture in 57.5%, and cystoscopy in 13.4% (Table 2).

Twenty-seven percent of all patients (N = 229) had a minor complication during their 2-year follow-up, with most of these being acute or recurrent cystitis (16.4% prevalence over the 24-month period). Moderate complications were observed in 141 patients (17.1%), with the most common being chronic kidney disease (4.4%). There was a lower prevalence of severe complications, occurring in 54 patients (6.6%). Table 3 highlights the breakdown for complications by severity. Our multivariate model indicated that male gender, younger age, and receiving some or all the NLUTD-recommended screening were associated with greater prevalence of complications. Patient distance of travel to their treating physician (urologist or Physical Medicine and Rehabilitation specialist) did not affect the rate of complications. Comorbidity indices were not available for most

Spina bifida occulta	756.17
Meningocele/myelomeningocele/spina bifida	741 (with additional subcategories 0-3 for location of defect)
Spina bifida without hydrocephalus	741.9

CPT-4 codes for diagnostic test:

<b>Serum creatinine</b>	80048, 80050, 80053, 80069
<b>Upper tract imaging:</b>	
Intravenous urogram	74400, 74410, 74415
Ultrasound abdomen	76700, 76705, 76770, 76775
Cystogram/fluoroscopic UDS	74430, 74450
Voiding cystourethrogram	74455, 78740
CT abdomen	74150, 74160, 74170
MRI abdomen	74181, 74182, 74183, 74185
Nuclear renal scan	78700, 78701, 78704, 78707, 78708, 78709, 78725
<b>Other investigations:</b>	
Urinalysis	81000, 81001, 81002, 81003, 81005, 81007, 8101, 81020, 81025, 8105, 81099
Urodynamics	51725, 51726, 51741, 51772, 51784, 51785, 51795, 51797
Urine culture	87086, 87088
Urine cytology	88104, 88106, 88107, 88108, 88112, 88160, 88161, 88162
Cystoscopy	52000, 52204, 52260, 52265, 52285,
Post void residual	51798, 78730
24 hour urine	82570, 84156
Serum PSA	84153

ICD-9 Codes for complications:

<b>Mild:</b>	
Acute cystitis	595.0
Infection and inflammation reaction due to indwelling urinary catheter	996.64
Inflammation of prostate	601
*Pressure ulcers low back, hip, buttock	707.03-05
*Unspecified stage	707.20, 707.25
*Stage 1	707.21
*Stage 2	707.22
Urethral false passage	599.4
<b>Moderate:</b>	
Infection of kidney	590
Acute pyelonephritis	590.1x
Renal and perinephric abscess	590.2
Other not specified infection of kidney	590.8x
Unspecified infection of kidney	590.9
Urethral abscess	597.0
Orchitis and epididymitis	604
*Traumatic urethral stricture	598.1
*Post operative urethral stricture	598.2
*Other specified causes of urethral stricture	598.8
*Unspecified cause urethral stricture	598.9
*Urethral fistula	599.1
*Urethral diverticulum	599.2
*Mechanical complication of GU device- due to urethral catheter	996.31
*Mechanical complication of GU device- unspecified device	996.30
*Other complications of device - due to GU implant	996.76
*Chronic kidney disease	585
Calculus of kidney and ureter	592
Bladder stone	594
*Vesicoureteral reflux (VUR)	593.7
*VUR unspecified or no nephropathy	593.70
*VUR with reflux nephropathy, unilateral	593.71
*VUR with reflux nephropathy bilateral	593.72
*VUR with reflux nephropathy, NOS	593.73
*Other: including adhesion of ureter, ureterocele	593.89
*Hydronephrosis	591
*Hydroureter	593.5
*Pressure ulcers low back, hip, buttock Stage 3	707.23
<b>Severe:</b>	
Infection due to other internal GU device, implant	996.65
Septicemia	038
Rupture of bladder, non traumatic	596.6
*Vesical fistula (urethrovesical, vesicocutaneous, vesicoperineal)	596.2
*Bladder cancer	188.X, 233.7
<b>Other diagnoses not include in model:</b>	
*Prostate cancer	185

\* Chronic conditions excluded if they occurred in prior two year period

**Figure 1.** International Classification of Diseases, Ninth Revision (ICD-9) and current procedural technology (CPT-4) codes for myelomeningocele-associated diagnoses and diagnostic tests.

**Table 1.** Degree of surveillance received by demographic criteria

	Spina Bifida			Total (n = 825)	Stats
	None (n = 42)	Some Surveillance (n = 507)	Complete Bladder Surveillance (n = 276)		
Age (mean)	49.4 ± 15.7	52.8 ± 18.2	48.5 ± 17.7	51.2 ± 17.7	ANOVA P = .0042
Sex:					Chi-square P = .0051
Male	20 (6.3%)	174 (54.6%)	125 (39.1%)	319 (38.7%)	
Female	22 (4.4%)	333 (65.8%)	151 (29.8%)	506 (61.3%)	
Race or ethnicity					Chi-square P = .13
White	33 (4.7%)	424 (60.4%)	245 (34.9%)	702 (85.1%)	
Black	3 (4.7%)	44 (68.8%)	17 (26.6%)	64 (7.8%)	
Other	6 (10.2%)	39 (66.1%)	14 (23.7%)	59 (7.2%)	
Average distance of travel to referral center	46.6 ± 38.4	23.5 ± 30.6	26.2 ± 28.7	25.4 ± 15.2	ANOVA P = .18
Region:					Chi-square P = 0.43
Midwest	11 (5.4%)	121 (59.6%)	71 (35.0%)	203 (24.6%)	
Northeast	9 (5.9%)	84 (54.9%)	60 (39.2%)	153 (18.6%)	
South	16 (4.7%)	214 (62.9%)	110 (32.4%)	340 (41.2%)	
West	6 (4.7%)	88 (68.2%)	35 (27.1%)	129 (15.6%)	
Year of diagnosis:					Chi-square P = .0049
2007	22 (4.1%)	319 (59.0%)	200 (37.0%)	541 (65.6%)	
2008	20 (7.0%)	188 (66.2%)	76 (26.8%)	284 (34.4%)	

**Table 2.** Frequency distribution of annual urologic investigations

	Spina Bifida		Total (n = 825)
	2007 (n = 545)	2008 (n = 284)	
Screening			
Urologist visit	264 (48.4%)	101 (35.6%)	365 (44.0%)
Cr	499 (91.6%)	247 (87.0%)	746 (90.0%)
Upper tract:			
US abdomen	246 (45.1%)	84 (29.6%)	330 (39.8%)
IVP	8 (1.5%)	1 (0.35%)	9 (1.1%)
Nuclear renal scan	24 (4.4%)	8 (2.8%)	32 (3.9%)
CT abdomen	242 (44.4%)	103 (36.3%)	345 (41.6%)
MRI abdomen	20 (3.7%)	6 (2.1%)	26 (3.1%)
Cystogram	22 (4.0%)	3 (1.1%)	25 (3.0%)
VCUG	12 (2.2%)	3 (1.1%)	15 (1.8%)
Any upper tract evaluation			455 (54.9%)
% of patients who received "adequate surveillance"	200 (24.4%)	76 (9.2%)	276 (33.5%)
Other possible investigations			
UDS	63 (11.6%)	20 (7.0%)	83 (10.0%)
Urinalysis	444 (81.5%)	214 (75.4%)	658 (79.4%)
Urine culture	336 (61.7%)	141 (49.7%)	477 (57.5%)
Urine cytology	45 (8.3%)	19 (6.7%)	64 (7.7%)
Cystoscopy	83 (15.2%)	28 (9.9%)	111 (13.4%)
PVR	59 (10.8%)	27 (9.5%)	86 (10.4%)
24-hour urine	129 (23.7%)	50 (17.6%)	179 (21.6%)
PSA (male = 319)	62 (%)	27 (%)	89

CT, computed tomography; MRI, magnetic resonance imaging; PSA, prostate-specific antigen; PVR, post void residual; UDS, urodynamic studies; US, ultrasound; VCUG, voiding cystourethrogram.

patients, and as such these variables were not included in the final model to preserve sample size.

## DISCUSSION

Most patients with MMC in the cross-sectional sample did not undergo the complete minimum acceptable evaluations. Only 33.4% of the population identified in this study underwent the predetermined minimum

surveillance criteria during the identified 24-month period. Based on published surveys of treating urologists, most providers prioritize careful surveillance of these patients, in an effort to preserve their renal function and to avoid long-term complications as these patients transition into adulthood.<sup>6,10-13</sup> The results of our study demonstrate, however, that although most urologists may agree that lifelong surveillance is needed, only a small percentage of patients are receiving adequate follow-up. Only

**Table 3.** Percent of patients with spina bifida complications

	2007 (N = 541)	2008 (N = 284)	Total (N = 825)
<b>Mild:</b>			
Acute or recurrent cystitis	17.6%	13.5%	16.4%
Inflammation because of catheter	1.9%	0.56%	1.5%
Prostatitis	0.23%	—	0.16%
Pressure ulcers stage I or II	8.7%	3.1%	7.1%
Urethral false passage	—	—	—
Total patients with mild complications	176 (32.5%)	53 (18.7%)	229 (27.8%)
<b>Moderate:</b>			
Infection of kidney	4.1%	2.8%	3.7%
Orchitis	0.34%	0.28%	0.32%
Urethral complication	0.56%	0.56%	0.56%
Complication because of device	0.68%	—	0.48%
Chronic kidney disease	4.6%	3.6%	4.4%
Acute renal failure	0.68%	0.56%	0.65%
Kidney stone	2.8%	3.6%	3.1%
Vesicoureteric reflux	0.34%	0.28%	0.32%
Hydronephrosis	4.0%	2.2%	3.5%
Stage III pressure ulcer	2.3%	2.0%	2.2%
Total patients with moderate complications	102 (18.9%)	39 (13.7%)	141 (17.1%)
<b>Severe:</b>			
Infection because of internal GU device, implant, graft	1.0%	0.28%	0.81%
Rupture of bladder, non traumatic	0.23%	—	0.16%
Vesical fistula	0.23%	—	0.16%
Bladder cancer	3.3%	0.84%	2.6%
Pressure ulcers stage IV	49 (9.1%)	5 (1.76%)	54 (6.55%)
Total patients with severe			

one-third of patients met the minimum acceptable criteria for surveillance used in our study. However, these criteria would not meet an acceptability standard when contrasted to existing guidelines, which also recommend performing an initial urodynamics evaluation in this population for determination of urinary tract safety.<sup>14,15</sup> Previous reports confirm high levels of urologist noncompliance with recommendations specific to neurogenic bladder and NLUTD.<sup>16</sup> When considering that the surveillance recommendation used as the primary outcome in our review represents a below minimum accepted surveillance recommendation, it is likely that the percentage of patients receiving adequate screening is smaller than what we have reported here.

Currently, there are no standardized recommendations for what constitutes adequate surveillance specific to the adult MMC population, or what the follow-up surveillance schedule should be. If anything, the neurogenic bladder guidelines in existence, such as those of the European Association of Urology, are more intensive than that used in our study and are not intended specifically for the MMC population.<sup>17</sup> In addition, these guidelines categorize MMC as a neurogenic bladder diagnosis that is high risk for neurogenic bladder deterioration.<sup>18,19</sup>

Surveillance in this population can be quite variable. Different research groups have advocated for varying frequencies of follow-up visits, although most agree with the baseline physical examination, renal ultrasonography, and serum creatinine measurement.<sup>7,13,20,21</sup> Notwithstanding, serum creatinine offers limited utility as an estimate of

glomerular filtration rate in the MMC population, and other studies, such as cystatin C and total 24-hour urine creatinine, have been championed as more informative and definitive tests. As reported in our study, many patients underwent other evaluations during this time-frame, such as cystoscopy, urodynamic evaluation, urinalysis, and urine culture. This may be caused by 2 factors: first, the adult MMC population is heterogeneous, making a standardized follow-up protocol difficult given varying levels of NLUTD severity. In a systematic review of patients with MMC, Veenboer et al demonstrated the heterogeneity in neurogenic bladder states within this population: 58.4% of patients performed intermittent catheterization, 13.8% had normal voiding, 10.5% had urinary diversions, and 4.3% had an indwelling catheter.<sup>6</sup> Second, our study was a snapshot in time, preventing us from determining whether the studies were obtained as part of a diagnostic workup or for true screening. This emphasizes an important limitation of our study, and emphasizes the possibility that the population undergoing actual surveillance was even lower than the reported 33.4%. The high rate of CT scan utilization points to the possibility that these evaluations were performed for cause and not for screening.

In addition, the patient population in this study likely represents the most disabled patients, who are unable to work and who are candidates for Medicare based on their disability before the required age of 65 years. As such, the study is not reflective of the entire population of MMC adult patients, as it does not include the important, albeit

much smaller, group of MMC individuals with higher functionality. The study also does not include patients who receive state-administered insurance such as Medicaid and similarly funded programs.

As also noted in a previous analysis of surveillance in the spinal cord injury population, our study found that increased surveillance, male gender, and younger age were associated with a higher risk of complications.<sup>22</sup> An explanation for male gender being associated with more medical complications may be because of the increased bladder outlet resistance in the male patient with MMC compared with the less resistant bladder outlet in female patients with MMC. This may be impactful in patients with impaired compliance whose higher outlet resistance results in greater risk of upper tract deterioration.<sup>23,24</sup> These risk associations can also be because of the previously discussed endogeneity within the statistical model and the inability to distinguish between screening and diagnostic evaluations. The study is also limited to billing data, and does not report any patient-centered outcomes, which are incredibly important in tailoring the adult care for these patients.

We conclude that there is a high prevalence of medical complications in the adult MMC population. Our snapshot of this adult population also demonstrates that most patients are not receiving acceptable follow-up, according to our currently available recommendations for neurogenic lower urinary tract dysfunction. Guidelines specific to the MMC population are in development and may allow urologists to better track outcomes in this vulnerable population, as more of them reach adulthood than ever before.

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