NORTH CAROLINA STATE HEALTH COORDINATING COUNCIL

PETITION TO ELIMINATE THE PROPOSED NEED DETERMINATION FOR TWO LITHOTRIPTORS FROM THE DRAFT 2024 STATE MEDICAL FACILITIES PLAN
JULY 26, 2023

Petitioners:

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Statement of the Requested Change:

Petitioners PSC, Stone Institute, and HealthTronics (collectively, "Petitioners") are each long-time, existing providers of mobile lithotripsy services in North Carolina. They represent five of the seven mobile lithotripsy providers in North Carolina, accounting for about 85% of the lithotripsy procedures performed in North Carolina. *See* Exhibit 1. Combined, Petitioners represent 181 practicing urologists. Petitioners respectfully request that the State Health Coordinating Council ("SHCC") eliminate the proposed need determination for two new

lithotripsy units from the Draft 2024 State Medical Facilities Plan ("SMFP"). *See* Table 15D-3 of the Draft 2024 SMFP, p. 335, attached as Exhibit 1. Instead, Petitioners respectfully suggest that the SHCC consider appointing a workgroup to analyze lithotripsy use rates and trends, which may inform future need determinations. All areas of North Carolina, including rural communities, have access to mobile lithotripsy now. Given its mobile nature, the service can be easily adapted to meet future needs, as long as there are urologists in the area to provide the service.

Lithotripsy in General

Kidney stones (also known as renal calculi, nephrolithiasis or urolithiasis) are made of minerals and salts that form inside the kidneys. Diet, excess body weight, certain medical conditions, as well as certain supplements and medications, are all potential causes of kidney stones. Elimination of the stones from the body can be very painful. Some stones will pass on their own, but others may require specific treatments.[1]

Lithotripsy treats kidney stones by pulverizing them using extracorporeal shock waves ("ESW"). As set forth in Chapter 15D of the Draft 2024 SMFP, "[a] technician places an emitter in contact with the patient's abdomen to focus the shock waves on the stone. The shock waves then shatter the stone, which can be expelled in the urine. Extracorporeal shock wave lithotripsy (ESWL) is the non-invasive procedure to which this section pertains." *See* Exhibit 1[2].

Shock wave lithotripsy ("SWL") is one of the preferred treatments for small to medium sized stones. Its advantages include a high success rate; it is non-invasive; it involves minimal post-procedure discomfort; and can often be scheduled quickly.[3]

SWL was first performed on a patient in 1980.[4] In the United States, the first SWL treatment was performed as an experimental clinical procedure at the Shands Hospital at the University of Florida in August, 1984. The U.S. Food and Drug Administration ("FDA") approved SWL for routine use in December, 1984.[5] Lithotripsy has been performed in North Carolina since 1985.[6]

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[1] https://www.mayoclinic.org/diseases-conditions/kidney-stones/symptoms-causes/syc-20355755. (accessed 6/9/23).

[2] Today, the preferred terminology is shock wave lithotripsy ("SWL"). *See, e.g.,* https://www.kidney.org/atoz/content/kidneystones_shockwave#what-shock-wave-lithotripsy (accessed 6/9/23).

[3] https://urology.wustl.edu/patient-care/kidney-stones/surgery-for-kidney-stones/ (accessed 6/7/23).

[4] Chaussy, C.G. (2018). The History of Shockwave Lithotripsy. In: Patel, S., Moran, M., Nakada, S. (eds) The History of Technologic Advancements in Urology. Springer, Cham. https://doi.org/10.1007/978-3-319-61691-9_11 (attached as Exhibit 2). The Chaussy article traces the beginnings of lithotripsy to its early days in aviation technology and studies performed in Germany by Dornier, an aerospace manufacturer.

[5] C. Williams, J. Kaude, R. Newman, J. Peterson, and W. Thomas, *Extracorporeal Shock-Wave Lithotripsy: Long-Term Complications,* American Journal of Radiology, 150:311-315, Feb. 1988. (attached as Exhibit 3)

[6] https://issuu.com/wfirm/docs/history-of-urologyv2 (accessed 6/7/23).

In addition to lithotripsy, there are a number of treatment options. These treatment options include[7]:

1. Medications, such as alpha blockers, allopurinol, potassium citrate and thiazide diuretics, to aid in the passing of stones and the medical management of stones[8];
2. Ureteroscopy ("URS") is a minimally invasive outpatient procedure in which a urologist inserts a small scope with a camera on its tip into the patient's ureter or kidney to look for stones. If the stone is small, it may be snared with a basket device and removed whole from the ureter. If the stone is large, or if the diameter of the ureter is narrow, the stone will need to be fragmented, which is usually accomplished with a laser. Once the stone is broken into tiny pieces, these pieces are removed. Similar to SWL, ureteroscopy works best on small to medium sized stones;[9]
3. Percutaneous nephrolithotomy (also called PCNL or tunnel surgery) is used to treat larger or more complex stones or a large number of smaller stones in the kidney. This procedure requires a small incision in the flank and is performed on an inpatient basis;[10]
4. Laparoscopic and robotic-assisted surgery may be appropriate for patients with large or complex stones;[11] and
5. Open surgery, a more invasive surgical procedure used to directly access the stone. Though rarely used, open surgery may be an option for patients with very large stones or stones that cannot be resolved through other treatments.[12]

Reasons for the Proposed Change:

Petitioners have filed this petition because there has been a steady decline in lithotripsy utilization in North Carolina. There is sufficient available lithotripsy capacity in all areas of North Carolina, including rural communities.

There are currently eight providers of lithotripsy in North Carolina, using thirteen mobile lithotriptors and one fixed lithotriptor. Petitioners own eleven of the thirteen mobile units serving North Carolina. The mobile units serve host sites throughout North Carolina, including urban and rural communities. Some of the mobile units also serve host sites in Virginia. The fixed unit is located at Mission Hospital in Asheville. The SMFP defines the service area for lithotriptors as statewide. *See* Exhibit 1, Table 15D-1. All areas of North Carolina, including rural

[7] *See, e.g.*, https://www.health.harvard.edu/blog/kidney-stones-what-are-your-treatment-options-2019071817350. (accessed 6/7/23); https://www.mayoclinic.org/diseases-conditions/kidney-stones/diagnosis-treatment/drc-20355759. (accessed 6/7/23).
[8] https://nyulangone.org/conditions/kidney-stones/treatments/medications-dietary-changes-for-kidney-stones. (accessed 6/9/23).
[9] https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/ureteroscopy. (accessed 6/7/23).
[10] https://urology.wustl.edu/patient-care/kidney-stones/surgery-for-kidney-stones/. (accessed 6/7/23).
[11] https://www.uptodate.com/contents/kidney-stones-in-adults-surgical-management-of-kidney-and-ureteral-stones. (accessed 6/7/23).
[12] https://www.webmd.com/kidney-stones/surgery-for-kidney-stone (accessed 6/7/23).

communities, have access to mobile lithotripsy. Given its mobile nature, the service can be easily adapted for future needs, as long as there are urologists available to provide the service.

SMFP need determinations for lithotriptors are relatively rare, with the last such need determination appearing in the 2016 SMFP. *See* Exhibit 4. To the best of petitioners' knowledge, since the time lithotripsy first appeared in the 1997 SMFP, there has never been a need for two lithotriptors in a single year's SMFP.

The need methodology for lithotripsy first appeared in the 1998 SMFP and has essentially remained the same since then. Then, as now, the annual incidence of urinary stone disease is deemed to be 16 per 10,000 population. *See* Exhibits 1 and 5. Although the methodology describes the capacity of a lithotriptor as 1,500 cases, the methodology does not consider utilization of existing machines. Rather, the methodology is based on population, a use rate of 16 per 10,000 and a further assumption that 90% of kidney stones can be treated by SWL.

Lithotripsy is the only technology that is regulated by an SMFP need methodology that does not consider utilization.[13]

For the reasons explained below, no additional lithotriptors are needed in North Carolina and the draft need determination should be removed for 2024. Instead, Petitioners respectfully suggest that the SHCC consider appointing a workgroup to study lithotripsy utilization in North Carolina. This may provide guidance for future need determinations.

1. SMFP Data for Lithotripsy

The following chart illustrates lithotripsy utilization in the 2017-draft 2024 SMFPs[14]:

SMFP Year	Number of Lithotripsy Providers	Number of Lithotriptors	Total Number of Procedures	Number of Procedures per Lithotriptor
2017	8	14	10,019	716
2018	8	14	9,529	681
2019	8	15[15]	9,253	617
2020	8	15	8,710	581
2021	8	15	8,952	597
2022	8	14[16]	7,268	519
2023	8	14	7,310	522

[13] While the data indicates the need methodology should be updated to better reflect more recent trends, Petitioners are not challenging the need methodology in this summer petition. These facts are provided for context.

[14] Petitioners chose 2017 as the starting point because the last need determination for lithotripsy was in the 2016 SMFP. The SMFP contains data from two years prior, so the data in the 2017 SMFP is from 2015. Data from the draft 2024 SMFP is from 2022.

[15] The increase is attributable to PSC's implementation of an additional lithotriptor as a result of the need determination in the 2016 SMFP.

[16] The decrease in lithotriptors is due to Catawba Valley Medical Center giving up one of its two mobile units.

SMFP Year	Number of Lithotripsy Providers	Number of Lithotriptors	Total Number of Procedures	Number of Procedures per Lithotriptor
2024 (draft)	8	14	7,926	566

Source: 2017 SMFP-draft 2024 SMFP

According to the SMFP data, the number of procedures reported over this time period has declined by 26.4%. The number of procedures per lithotriptor has declined by 26.5%.

2. North Carolina Population Data

To align population data with SMFP data, Petitioners consulted population data for July 1, 2015 and July 1, 2022. This corresponds to data in the 2017 SMFP and the draft 2024 SMFP. As of July 1, 2015, the population of North Carolina in 2015 was 10,042,802[17]. As of July 1, 2022, the population was 10,698,973.[18] This is an increase of 6.5%.

3. What the Data Reveals

Despite strong growth in North Carolina's population, there has been a marked decrease in lithotripsy utilization. Comparing 2017 SMFP data (2015 data) to draft 2024 SMFP data (2022 data) shows an overall decrease of 2,093 procedures. The steepest decline occurred in the 2022 SMFP (2020 data), with a decrease of 1,684 procedures from the 2021 SMFP (2019 data). Undoubtedly, COVID-19 played a role in this decrease, but as the data shows, utilization has been on a downward trend for several years before COVID-19. Between the 2017 SMFP (2015 data) and the 2021 SMFP (2019 data), the number of procedures declined by 1,067 or 11.9%. While post-COVID-19 procedure volume is slowly climbing, it is still quite low compared to pre-COVID volumes. For example, the draft 2024 SMFP (2022 data) shows that procedure volume is down by 1,026 procedures, compared to data in the 2021 SMFP (2019 data).

Additionally, the number of procedures per lithotriptor has also been on a downward trend for many years. Even in the 2017 SMFP, when procedures were at their highest level in this data set, the number of procedures per lithotriptor was 716, which is less than half of what the SMFP defines as capacity (1,500 cases), and also well below 1,000 cases, which the SMFP defines as full utilization for projecting need. In the draft 2024 SMFP, the number of cases per lithotriptor is only 566. While some machines are busier than others, the overall picture is one of significant excess capacity. *See* Exhibit 1.

Finally, a significant portion of the existing capacity is used to serve patients in Virginia. If the Virginia procedures are removed from the total, the excess capacity in North Carolina becomes even greater, as shown in the table below.

[17] https://www.census.gov/newsroom/archives/2015-pr/cb15-215.html (accessed 6/7/23).
[18] https://www.census.gov/quickfacts/NC (accessed 6/7/23).

SMFP Year	Total Procedures	Number of Procedures performed in VA	Percent performed in VA
2017[19]	10,019	938	9.4%
2018[20]	9,529	936	9.8%
2019[21]	9,253	1,026	11.1%
2020[22]	8,710	1,036	12%
2021[23]	8,952	827	9.2%
2022	7,268	515	7.1%
2023	7,310	761	10.4%
2024 (draft)	7,926	1,188	15%

Source: 2017 SMFP-draft 2024 SMFP

4. What Does the Future Hold for Lithotripsy in North Carolina?

North Carolina's declining trend in lithotripsy utilization is not expected to change in the foreseeable future due to a variety of factors. These factors include a shortage of urologists, prevalence of other treatments for kidney stones such as URS, and a possible preference that younger urologists have for URS over SWL. Each of these contributing factors is discussed below.

1. A shortage of urologists

Urologists are required for lithotripsy. Unfortunately, there is a shortage of urologists in the United States, and this shortage is projected to worsen over time. Ten years ago, the UNC School of Medicine released a study predicting that the number of urologists in the United States would fall by 29% in 2025. *See* Exhibit 6. Congressman Greg Murphy from North Carolina's Third District, a practicing urologist, has spoken about the shortage of urologists and the difficulties that hospitals and medical practices have recruiting urologists, including in North Carolina.[24]

[19] In the 2017 SMFP, two providers reported 258 procedures in South Carolina. The South Carolina procedures are included in the total.
[20] In the 2019 SMFP, two providers reported 233 procedures in South Carolina. The South Carolina procedures are included in the total.
[21] In the 2019 SMFP, two providers reported 162 procedures in South Carolina. The South Carolina procedures are included in the total.
[22] In the 2020 SMFP, two providers reported 87 procedures in South Carolina. The South Carolina procedures are included in the total.
[23] In the 2021 SMFP, one provider reported 1 procedure in South Carolina. The South Carolina procedure is included in the total. The 2022 and 2023 SMFP do not show any procedures in South Carolina.
[24] See https://grandroundsinurology.com/congressman-greg-murphy-md-on-the-urologist-shortage/ (accessed 6/8/23).

The American Urological Association ("AUA") identifies addressing the urologic workforce as a priority. *See* Exhibit 7, *Our Priority: Address the Urologic Workforce*. While there are many strategies to address the workforce shortage, none of these strategies is a "quick fix" for a long-term, systemic problem. For example, while the CARES Act provided funding to increase the number of residency slots, training physicians take years and it will take years to grow the supply of urologists. A 2021 white paper by Merritt Hawkins, a physician search and consulting firm, observed that new urologists comprise less than 2% of U.S. residency graduates each year. See Exhibit 8, *Urology: Supply, Demand and Recruiting Trends*, p. 3. Further, as discussed below, if residents are not trained in SWL, they may be less likely to use SWL once they enter practice.

A 2022 paper published by *AUA News* observed:

> According to the 2020 American Urological Association Census, there are 13,352 practicing urologists in the United States, an increase from 11,703 in 2014, when the first AUA Census was conducted. The urologist-to-population ratio has also increased from 3.70 per 100,000 in 2014 to 4.07 in 2020. However, despite this increase 62% of counties in the United States currently have no practicing urologists, and the majority of urologists, approximately 90%, practice in a metropolitan area compared to just 0.4% practicing in rural areas.
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> Though the increased number of practicing urologists has positive implications, the demographic makeup of the workforce presents concerns for a future shortage in the field. Specifically, a considerable and increasing proportion of practicing urologists are over 65 years of age, increasing from 23% of urologists over the age of 65 in 2014 to 30% in 2020. Furthermore, the percent of practicing urologists under the age of 34 years has decreased from 7.2% in 2014 to 5.4% in 2020. In combination with increased demand from an aging population, an aging workforce is cause for concern as the number of postgraduate training positions may not be enough to replace a rising number of retiring surgeons.

See Exhibit 9, *The Urology Workforce in the 21st Century: Trends and Predictions,* May 1, 2022.

The Journal of the American Medical Association ("JAMA") Network published a study in November 2021, *Projected US Urology Workforce per Capita 2020-2060*. The study employed two models, a continued growth model and a stagnant growth model. The continued growth model assumed 13.8% more urologists joining practice every five years. The stagnant growth model assumed no growth in the number of urologists joining practice. The authors of the study reported:

> In 2019 there were 13,044 urologists (11,758 men [90.1%]; 1,286 women [9.9%]; median age range, 55 to 59 years) with 3.99 urologists per 100,000 persons and 311 new urologists entering the workforce. In a continued

> growth model, 2030 will have the lowest number of urologists per capita of 3.3 urologists per 100,000 persons, and recovery to baseline will occur by 2050. There are 23.8 urologists per 100,000 persons aged 65 and older in 2020, which decreases to 15.8 urologists per 100,000 persons aged 65 years and older in 2035 and never recovers to its baseline level by 2060. In a stagnant growth model, there will be a continued decrease of urologists per capita with 3.1 urologists per 100,000 persons by 2060. There is a continued decrease in per capita urologists at each time point, with 13.1 urologists per 100,000 persons aged 65 years and older by 2060.
>
> With the impending urology workforce shortage, there will be an exaggerated shortage of total urologists per persons aged 65 years and older in both models. This projection highlights the need for structural changes and advocacy to maximize the available urology workforce.

See Exhibit 10, p. 1.

The study further observed:

> Our analysis demonstrates that prior efforts to increase the urology workforce have been insufficient, with problems escalating in the decades to come. Specifically, despite an additional 14 accredited urology residency programs between 2013 and 2018, our current supply of practicing urologists of 13,044 is still far short of the 14,400 urologists projected necessary to meet the demand for urological services. Our projections demonstrate that the disparity will worsen in the coming decades even with continued growth of 13.8% graduating urologists every 5 years. Because of the number of retiring urologists, the number of urologists per capita will not reach baseline 2020 levels until 2050. Without additional growth of training positions, the workforce shortage will become even more severe, with a continued decline in urologists per capita through 2060. We provided these 2 alternate models for workforce projections, understanding that the actual urology workforce will most likely fall between these 2 projections. Regardless, our field must be prepared to face a growing shortage of physicians for the next 40 years, and possibly beyond.

See Exhibit 10, pp. 5-6.

The elderly population will feel the effects of this shortage most directly. According to the Urology Fact Sheet from the National Ambulatory Medical Care Survey, approximately 53% of

urology office visits are by patients age 65 and older.[25] According to the US Census, as of July 1, 2022, 17.4% of North Carolina's population is age 65 or older.[26] The North Carolina Office of State Budget and Management ("NCOSBM") data indicates that by 2029, one in five North Carolinians will be at least 65 years old, and by 2031 there will be more older adults than children.[27]

Kidney stone prevalence increases with age. According to one study conducted from 2007-2016, the highest prevalence of kidney stones was found in men older than 80 years.[28] *See* Exhibit 11, p. 29.

Urologists treat many other conditions besides kidney stone disease, and they perform many other services besides lithotripsy. Depending on the physician, lithotripsy may be a very small percentage of a urologist's daily or weekly practice, or perhaps not even a part of the physician's practice, as the trend in urology is toward increasing sub specialization.[29] While the SHCC is not able to address the shortage of urologists, the SHCC does have the power to control excess capacity in lithotripsy. Adding two additional lithotriptors to a state that is already experiencing excess capacity and a shortage of urologists is not sound planning or policy.

2. Increase in URS

While North Carolina's need methodology does not assume that every patient with kidney stones is an appropriate candidate for lithotripsy, the methodology does assume that lithotripsy is appropriate in 90% of cases of urinary stone disease. *See* Exhibit 1. This assumption has been in existence since the 1998 SMFP. *See* Exhibit 5. Petitioners do not challenge the assumption or the methodology in this petition, but note the assumption may not reflect trends over the last 25 years in the treatment of kidney stone disease. Stated differently, the fact that 90% of cases *could* be treated by SWL does not mean that 90% of cases *are* treated by SWL.

In February 2023, the Journal of Endourology published a study, *Ureteroscopy and Shock Wave Lithotripsy Trends from 2012 to 2019 Within the US Medicare Dataset: Sharp Growth in Ureteroscopy Utilization*. *See* Exhibit 12. Using the public Medicare Physician & Other Practitioners database (https://data.cms.gov), the study determined case numbers of SWL and URS from 2012 to 2019. The study found:

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[25] The data reported on the Urology Fact Sheet is from 2015-2016. The CDC's website states that the Fact Sheet was updated on 7/21/21. *See* https://www.cdc.gov/nchs/ahcd/factsheets.htm (accessed 7/3/23).
[26] https://www.census.gov/quickfacts/NC (accessed 6/8/23).
[27] https://www.osbm.nc.gov/blog/2022/12/30/ncs-population-reach-140-million-2050#:~:text=By%202029%2C%20one%20in%20five,compared%20to%2035%20in%202000). (accessed 6/8/23)
[28] See Chewcharat A., Curhan G. Trends in the prevalence of kidney stones in the United States from 2007 to 2016. Urolithiasis. 2020;49:27–39. doi: 10.1007/s00240-020-01210-w. [PubMed] [CrossRef] [Google Scholar]
[29] https://www.urologytimes.com/view/subspecialization-trends-whos-doing-what-and-where (accessed 7/13/23).

> In 2012, urologists performed 41,135 SWL procedures versus 21,184 URS. URS overtook SWL in 2017 and by 2019 was the dominant modality (60,063 URS *vs* 43,635 SWL). Between 2012 and 2019, total URS cases annually increased by 5700 . . . while the number of SWL cases peaked in 2015 and has since declined on average -1.6% per year . . ., while the number of urologists performing URS steadily rose from 1147 in 2012 to 2089 in 2019, reflecting an additional 246 urologists (21%/year) performing URS annually. The caseload of high-volume stone urologists showed similar trends with average URS cases increasing by 2.9/year/urologist . . . and average SWL cases declining by 0.9/year/urologist. URS utilization has increased dramatically and outpaced SWL utilization from 2012 to 2019 within the Medicare population. URS was increasingly used by both the general urologist population and high-volume stone urologists while SWL utilization has begun to decline.

Exhibit 12, p. 219.

The study goes on to describe some of the factors driving the increase in URS:

> Potential factors contributing to the increased utilization of URS are the constantly improving ureteroscope and laser capabilities, residency and endourology fellowship training that emphasizes management with URS over SWL, and the development of single-use ureteroscopes that may improve the attractiveness of URS for lower volume providers.

Exhibit 12, p. 222.

There are, of course, variations by region and practice preferences. While Petitioners are not aware of any study focusing on North Carolina's use of SWL compared to URS, the declining utilization of SWL as shown in the SMFP data tends to support the conclusion that other therapies, such as URS, are increasingly being used to treat kidney stones in North Carolina.

3. Lack of Residency Training in SWL

Effective July 1, 2019, the Accreditation Council for Graduate Medical Education ("ACGME"), the organization that oversees medical residency and fellowship programs in the United States,[30] revised its program requirements for graduate medical education in urology. ACGME removed the requirement that clinical facilities must contain state-of-the-art equipment to perform SWL. *See* Exhibit 13, p. 9.[31] Although urology residents were once required to log a minimum number

[30] *See* https://www.acgme.org/about/overview/. (accessed 7/3/23).

[31] The 2022 ACGME Program Requirements for Graduate Medical Education in Urology make no reference to lithotripsy. *See* Exhibit 14, p. 6.

of 10 lithotripsy procedures in their case logs, ACGME has deleted lithotripsy from case logs. *Compare* Exhibits 15 and 16 (2012 ACGME case logs and 2022 ACGME case logs). Interestingly, ACGME has increased the minimum number of ureteroscopy cases from 60 to 90. *Compare* Exhibits 15 and 16.

Petitioners understand that at least some of the urology residency programs in North Carolina offer training in SWL,[32] but not all urologists practicing in North Carolina were trained in North Carolina. While there is nothing to preclude any residency training program from offering training in SWL, the fact that it is no longer required by ACGME suggests residents may be less likely to have exposure to SWL, especially if they were trained outside of North Carolina. This in turn may influence how they treat kidney stones when they enter practice.

Even before ACGME removed its SWL requirements from urology residency programs, residents were becoming increasingly exposed to endoscopic treatments. According to a 2013 article in *Urology Times*, *Ureteroscopy vs. Shock Wave Lithotripsy: Advances Spell Positive Future for Both*, Stephen Y. Nakada, MD, professor and chairman of urology at the University of Wisconsin, Madison, stated:

> We're in an endoscopic epoch of urology. In training programs now, urologists are being exposed to endoscopic surgical approaches much earlier than they were years ago. Flexible ureteroscopy has gone from being commonly performed at the chief resident level to being commonly performed at the junior resident level. The residents have much more robust experience with endoscopic surgery in the course of their training program, at least in the United States, such that as they finish, they oftentimes have performed more ureteroscopic stone cases than they have shock wave lithotripsy procedures.
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> As a result, they have already passed that learning curve and they're very facile with the required surgical techniques. It's a true trend, and it makes sense given how our training programs have evolved with regard to endoscopic surgery.

See Exhibit 17, p. 3. While Petitioners are not aware of any definitive study showing that younger urologists prefer URS over SWL for the treatment of kidney stones, the ACGME information, Dr. Nakada's experience, and the declining number of lithotripsy procedures in North Carolina provide at least some support for the proposition that younger urologists may increasingly rely on URS for the treatment of kidney stones.

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[32] See, e.g., https://school.wakehealth.edu/education-and-training/residencies-and-fellowships/endourology-robotic-surgery-fellowship/curriculum (accessed 7/3/23). *See also* https://surgery.duke.edu/education-and-training/fellowship-programs/endourology-metabolic-stone-disease-laparoscopic-and-robotic-surgery-fellowship/program-structure (describing urology fellowship program) (accessed 7/3/23).

Statement of the Adverse Effects on the Providers or Consumers of Health Services that are Likely to Ensue if the Change is not Made:

If the need determination is not eliminated, the State of North Carolina will be in the unusual position of encouraging excess capacity in healthcare, which is directly contrary to the purpose of the SMFP. Patients are harmed because money that should be spent on addressing real and urgent problems, including recruiting and retaining health professionals in urban and rural areas, will be diverted to creating excess capacity. The estimated cost of a new mobile lithotriptor and a trailer is about $2 million.

Statement of Alternatives to the Proposed Change that Were Considered and Found not Feasible:

Petitioners considered two alternatives: 1) leaving the proposed need determination as is; and 2) petitioning to reduce the need to one lithotriptor. Neither alternative is feasible. For the reasons stated in this petition, there is no need for any additional lithotriptors in North Carolina, and this situation is not expected to change anytime soon. Accordingly, Petitioners determined that the best course of action is to file a petition seeking to eliminate the need determination in its entirety.

Evidence that the Proposed Change Would Not Result in Unnecessary Duplication of Health Resources in the Area:

This petition is intended to prevent, not create, unnecessary duplication of health resources in North Carolina. As demonstrated above, North Carolina has significant excess lithotripsy capacity now. There is no reason to think that this excess capacity will end in the foreseeable future, so there is no reason to add to the excess capacity. Approving this petition eliminates unnecessary duplication of health resources.

Evidence that the Requested Change is Consistent with the Three Basic Principles Governing the Development of the SMFP: Safety and Quality, Access and Value:

This petition is grounded in the three basic principles of safety and quality, access and value. North Carolina residents have access to lithotripsy if their physician determines that is the best option to treat their kidney stones. There is significant excess capacity now, which can be used to accommodate even more patients who need and can benefit from SWL. Since most lithotriptors in North Carolina are mobile and the service area is statewide, barriers to access are not due to lack of access to machines; rather, barriers may exist due to a lack of urologists. As the Draft 2024 SMFP (Exhibit 1) shows, there is access to mobile lithotripsy now throughout North Carolina, including in rural communities. Given its mobile nature, the service can be easily adapted to meet future needs. Adding two more lithotriptors will not solve the inherent problem of a shortage of urologists, increase the likelihood that more urologists in residency will receive training in SWL, or cause urologists to choose lithotripsy over URS or other methods of treatment.

Conclusion

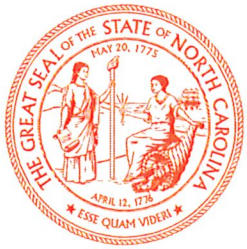
As owners of mobile lithotriptors, Petitioners are advocates for lithotripsy and are proud of its long history of safe and effective care. Petitioners are committed to providing high quality, local access for lithotripsy services. Petitioners have each invested millions of dollars over many years purchasing state-of-the-art technology to treat stone disease. When utilization of the existing lithotriptors indicates that additional capacity is needed, Petitioners would certainly support a future need determination, but that time has not yet arrived. While this petition is not the vehicle to propose changes in the need methodology, it is apparent that the methodology should be changed to reflect current trends. One option is to consider utilization of existing machines, which is currently not considered. Recognizing the SHCC may not wish to make any changes now, the SHCC may wish to consider appointing a workgroup to study lithotripsy data and trends more closely, with the goal of changing the methodology. For now, however, Petitioners respectfully request that the SHCC eliminate the proposed need determination for two additional lithotriptors in the Draft 2024 SMFP.

Petitioners appreciate the SHCC and DHSR Planning Staff's attention and would be pleased to answer any questions that SHCC members or staff may have.

STATE HEALTH COORDINATING COUNCIL

2024

PROPOSED STATE MEDICAL FACILITIES PLAN



NC DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Division of Health Service Regulation

D. LITHOTRIPTORS

Introduction

A ***lithotriptor***, according to G.S. § 131E-176(14i), means "extra-corporeal shockwave technology used to treat persons with kidney stones and gallstones." Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. A technician places an emitter in contact with the patient's abdomen to focus the shock waves on the stone. The shock waves then shatter the stone, which can be expelled in the urine. Extracorporeal shock wave lithotripsy (ESWL) is the non-invasive procedure to which this section pertains.

Data Sources

In addition to the standard data sources listed in the introduction to this chapter, this methodology also obtains the July 1 projected population data from the North Carolina Office of State Budget and Management for the current SMFP publication year, which is two years beyond the current reporting year.

Definition

A lithotriptor's service area is statewide. A ***statewide*** service area is defined as a planning area that encompasses the entire state when determining need. For mobile equipment, the definition does not imply that a CON applicant is required to project that it will provide mobile services in a certain number of counties, health service areas (HSA), or regions. Similarly, once developed, the equipment does not have to serve a certain number of counties, HSAs, or regions.

Assumptions of the Methodology

1. The incidence of urinary stone disease forms the basis of the methodology. The annual incidence of urinary stone disease is approximately 16 per 10,000 population. Lithotripsy is not an appropriate treatment for all cases of urinary stone disease. It has been estimated that lithotripsy is appropriate for 85% to 90% of kidney stone patients, when surgery is indicated.[1] Therefore, the need determination methodology assumes that lithotripsy is appropriate in 90% of cases of urinary stone disease.

2. The annual treatment capacity of a lithotriptor is 1,500 cases. The methodology considers 67% (or 1,000 cases) to be full utilization for purposes of projecting need.

Application of the Methodology

Step 1: Divide the July 1 estimated state population by 10,000 and multiply the result by 16, which yields the estimated incidence of urinary stone disease per 10,000 population.

Step 2: Multiply the result from Step 1 by 90% to calculate the number of patients in the state who have the potential to be treated by lithotripsy in one year.

Step 3: Divide the result of Step 2 by 1,000 and round to the nearest whole number to calculate the low range of the annual treatment capacity of a lithotriptor. A remainder of 0.50 or greater rounds to the next highest whole number; a remainder of less than 0.50 rounds to the next lowest whole number.

Step 4: Sum the number of existing lithotriptors in the state *(Table 15D-1)*, the number of CON-approved lithotriptors under development, and the number of lithotriptors available pursuant to need determinations pending review or appeal.

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[1] Pahiri, J.J. & Razack, A.A. (2001) "Chapter 9: Nephrolithiasis." In *Clinical Manual of Urology*, 3rd edition, by Philip M. Hanno, Alan J. Wein, & S. Bruce Malkowicz. New York: McGraw-Hill.

Step 5: Subtract the result of Step 4 from the result of Step 3 to calculate the number of additional lithotriptors needed in the state *(Table 15D-2)*.

Unless otherwise specified by the methodology, calculations do not use rounded values. However, fractional values are rounded automatically when displayed.

Table 15D-1: Mobile and Fixed Lithotripsy Providers and Locations Served

MOBILE LITHOTRIPSY

Provider	Machines	Area Generally Served	Facility	Location	State	Number of Procedures
Carolina Lithotripsy	2	Eastern NC	Carolina East Medical Center	New Bern	NC	85
			Carteret General Hospital	Morehead City	NC	31
			Duke Raleigh Hospital	Raleigh	NC	8
			FirstHealth Moore Regional Hospital	Pinehurst	NC	201
			Halifax Regional Medical Center	Roanoke Rapids	NC	22
			Highsmith Rainey Specialty Hospital	Fayetteville	NC	32
			Johnston Medical Center	Smithfield	NC	40
			Lenoir Memorial Hospital	Kinston	NC	16
			New Hanover Regional Med Center	Wilmington	NC	80
			Novant Health (Brunswick Medical Center)	Bolivia	NC	35
			Rex Surgery Center of Cary	Cary	NC	82
			Scotland Memorial Hospital	Laurinburg	NC	76
			Vidant (Beaufort Hospital)	Washington	NC	4
			Vidant (Pitt Medical Center)	Greenville	NC	177
			WakeMed (Raleigh Campus)	Raleigh	NC	70
			Wayne Memorial Hospital	Goldsboro	NC	47
			Wilson Medical Center	Wilson	NC	10
Total Procedures						**1,016**
Average Procedures per Lithotriptor						**508**
Catawba Valley Medical Center	1	Western and Central NC	Catawba Valley Medical Center	Hickory	NC	194
Total Procedures						**194**
Average Procedures per Lithotriptor						**194**

MOBILE LITHOTRIPSY						
Provider	**Machines**	**Area Generally Served**	**Facility**	**Location**	**State**	**Number of Procedures**
Fayetteville Lithotriptors - SC II	1	Western NC	Advent Healthcare (Park Ridge Hospital)	Hendersonville	NC	78
			Frye Regional Medical Center	Hickory	NC	19
			Harris Regional Medical Center	Sylva	NC	23
			Haywood Regional Medical Center	Clyde	NC	61
			Margaret Pardee Hospital	Hendersonville	NC	69
			Mission Hospital McDowell	Marion	NC	1
			Rutherford Regional Medical Center	Rutherfordton	NC	28
			St. Luke's Hospital	Columbus	NC	11
Total Procedures						**290**
Average Procedures per Lithotriptor						**290**
Fayetteville Lithotriptors - VA I	1	Eastern NC	The Outer Banks Hospital	Nags Head	NC	1
			Vidant Chowan Hospital	Edenton	NC	18
		Other Locations	Bon Secours Mercy Petersburg	Petersburg	VA	21
			Mary Immaculate Hospital	Newport News	VA	53
			Mary Washington Hospital	Fredericksburg	VA	198
			Riverside Doctors Surgical	Williamsburg	VA	3
			Southside Community Hospital	Farmville	VA	22
			Spotsylvania Regional Medical Center	Fredericksburg	VA	3
			Strafford Regional Hospital	Stafford	VA	13
Total Procedures						**332**
Average Procedures per Lithotriptor						**332**

MOBILE LITHOTRIPSY						
Provider	**Machines**	**Area Generally Served**	**Facility**	**Location**	**State**	**Number of Procedures**
Piedmont Stone Center	5	Western and Central NC	Appalachain Regional Healthcare System (Watauga Medical Center)	Boone	NC	133
			Ashe Memorial Hospital	Jefferson	NC	3
			Atrium Health Wake Forest Baptist (High Point Medical Center)	High Point	NC	344
			Atrium Health Wake Forest Baptist (Lexington Medical Center)	Lexington	NC	133
			Atrium Health Wake Forest Baptist (Wilkes Medical Center)	North Wilkesboro	NC	59
			Caldwell UNC Health Care	Lenoir	NC	72
			Cone Health (Alamance Regional Medical Center)	Burlington	NC	122
			Cone Health (Annie Penn Hospital)	Reidsville	NC	65
			Cone Health (Wesley Long Hospital)	Greensboro	NC	308
			Davis Regional Medical Center	Statesville	NC	20
			Hugh Chatham Memorial Hospital	Elkin	NC	122
			Iredell Memorial Hospital	Statesville	NC	125
			Maria Parham Health	Henderson	NC	25
			Northern Regional Hospital	Mount Airy	NC	24
			Novant Health (Forsyth Medical Center)	Winston-Salem	NC	100
			Novant Health (Rowan Medical Center)	Salisbury	NC	107
			Novant Health (Thomasville Medical Center)	Thomasville	NC	21
			Piedmont Stone Center, PLLC	Winston-Salem	NC	726
			Randolph Hospital	Asheboro	NC	81
			Salisbury VA Health Care System	Salisbury	NC	34
			UNC Health (Blue Ridge Healthcare Hospital-Valdese)	Valdese	NC	119
			UNC Health (Blue Ridge-Morganton)	Morganton	NC	49
			Wake Forest Baptist Medical Center	Winston-Salem	NC	20
		Other Locations	Carilion New River Valley Medical Center	Christiansburg	VA	110
			Centra Health Lynchburg General Hospital	Lynchburg	VA	227
			Piedmont Day Surgery Center	Danville	VA	32
			Sentara Martha Jefferson Hospital	Charlottesville	VA	218
			Sovah Health-Martinsville	Lynchburg	VA	220
			Twin County Regional Healthcare	Galax	VA	68
Total Procedures						**3,687**
Average Procedures per Lithotriptor						**737**

MOBILE LITHOTRIPSY						
Provider	**Machines**	**Area Generally Served**	**Facility**	**Location**	**State**	**Number of Procedures**
Stone Institute of the Carolinas	2	Western and Central NC	Atrium Health (Cabarrus)	Concord	NC	149
			Atrium Health (Carolinas Medical Center)	Charlotte	NC	21
			Atrium Health (Huntersville)	Huntersville	NC	108
			Atrium Health (Matthews Medical Center)	Charlotte	NC	131
			Atrium Health (Mercy)	Charlotte	NC	41
			Atrium Health (Mint Hill Medical Center)	Mint Hill	NC	20
			Atrium Health (Pineville)	Charlotte	NC	142
			Atrium Health (Union)	Monroe	NC	162
			Atrium Health (University)	Charlotte	NC	119
			Cleveland Regional Medical Center	Shelby	NC	139
			Gaston Memorial Hospital	Gastonia	NC	294
			Lake Norman Regional Medical Center	Mooresville	NC	195
			Lincoln Medical Center	Lincolnton	NC	2
			Novant Health Presbyterian Medical Center	Charlotte	NC	96
Total Procedures						**1,619**
Average Procedures per Lithotriptor						**810**
Provider	**Machines**	**Area Generally Served**	**Facility**	**Location**	**State**	**Number of Procedures**
Triangle Lithotripsy Corporation	1	East Central NC	Durham Ambulatory Surgery Center	Durham	NC	53
			Nash Day	Rocky Mount	NC	18
			North Carolina Specialty Hospital	Durham	NC	62
			Rex Hospital	Raleigh	NC	285
			Sampson Regional	Sampson	NC	4
			Wake Medical	Raleigh	NC	201
			Wayne Memorial Hospital	Goldsboro	NC	46
Total Procedures						**669**
Average Procedures per Lithotriptor						**669**

FIXED LITHOTRIPSY

Provider	**Machines**	**Area Generally Served**	**Facility**	**Location**	**State**	**Number of Procedures**
Mission Hospital	1		Mission Hospital	Asheville	NC	119
Total Procedures						**119**
Average Procedures per Lithotriptor						**119**

Table 15D-2: Mobile and Fixed Lithotripsy

Total Procedures Reported	Units Reported	Average Procedures Per Unit
7,926	14	566

Table 15D-3: Lithotriptor Need Determination*

(Proposed for Certificate of Need Review Commencing in 2024)

Service Area	Lithotriptor Need Determination	Certificate of Need Application Deadline**	Certificate of Need Beginning Review Date
Statewide	2	To be determined	To be determined
It is determined that there is no need anywhere else in the state and no other reviews are scheduled.			

* Any person can apply for a CON to meet the need, not just the health service facility or facilities that generated the need.

** Application deadlines are absolute, pursuant to 10A NCAC 14C.0202(2). The filing deadline is 5:00 p.m. on the application deadline date.

The History of Shockwave Lithotripsy

Christian G. Chaussy

Abstract

With a prevalence of 2-3 % urolithiasis is one of the most common diseases. Currently there is no causal therapy against the forming of stones. Until 35 years ago, when the first patient was treated with extracorporeal shockwaves and kidney stones were reduced to a size which permitted the fragments to be passed naturally, it required a surgical intervention for the removal of stones. It needed a total of 7 years experimental work and development until it was possible to treat the first patient on February 7, 1980 with Extracorporeal Shockwave Lithotripsy (ESWL) It is this event that should reform the treatment of urolithiasis in the years to come. After three years of clinical studies the method was applied internationally. Originating from Germany in the years 1984/1986, following the introduction of the extra-corporeal Shockwave lithotripter HM3, the legendary bathtub, the method of a non-invasive therapy became accepted worldwide. After further studies in the USA the method was FDA approved in 1984.Over 1 million annual treatments worldwide still prove the efficiency of Extracorporeal Shock Wave Lithotripsy.

The Beginning

In aviation hypersonic flight in rain was presenting a considerable challenge for the resilience of the airplane structure. The rain drops created a shockwave which did not only destroy the material at the point of impact, but also caused damages on the interior of the material. Further research under laboratory conditions to try and explain the phenomena was conducted.

To research this collision high velocity projectiles were fired from a light-gas gun onto a

target thereby creating shockwaves [Fig. 1a, b] The impact of shockwaves on living tissue was of equal interest to the military. At the end of the 60s research was conducted at Dornier in collaboration with the Institute of Applied Physics and Electrical Engineering of the University Saarbrücken to, amongst others, determine the reciprocity of shockwaves on organic tissue. In the course of this research it was discovered that shockwaves caused no visible injuries when passing through muscle tissue, fat tissue or fascia. Exception were bordering areas with high acoustic impendences. It was this project that gave rise to the idea to destroy kidney stones inside the body using shockwaves.

In 1971 at the symposium of the German Physical Society first results were presented in which shockwaves, created using high velocity water drops and using a water filled, closed tube as waveguide, were able to destroy kidney stones. (20)

The idea was further pursued using a light-gas gun and firing projectiles with a velocity of up to 5 km/s on a metal target, which was connected to an open water recipient.

The shockwaves produced in the target enter the water recipient, in which a stone had been placed. Depending on the form of the target a straight or focused shockwave hit the stone. With a straight wave only small cracks were produced, however with the focused wave substantial fragmentation of the stone was achieved. [Fig. 1c]

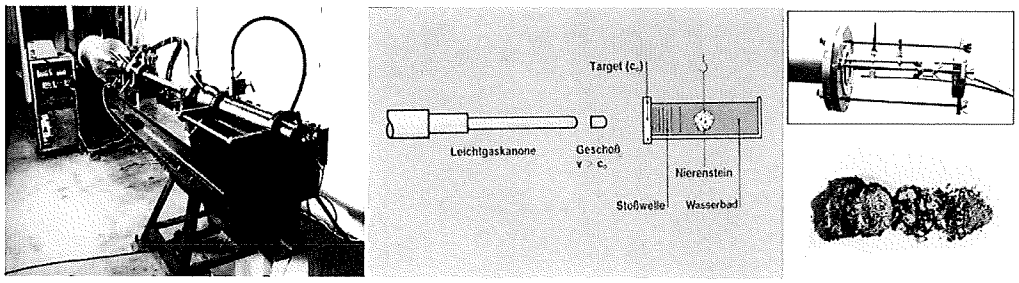
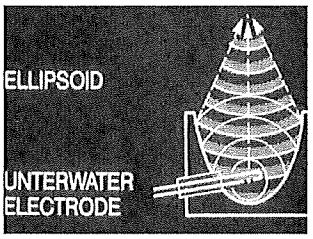


Figure1.(a) Light Gas Gun (b) Scheme of Lithotripsy. (c) Target and destructed Kidneystone

It had thus far been unknown to use shockwaves for therapeutic purposes. Substantial

experimental and theoretical studies conducted by an interdisciplinary workgroup, consisting of members of the Department of Urology University Munich, the Institute of Surgical Research and Dornier, were therefore required prior to a clinical application. These studies started in January 1974.(1,3,6,14,15,16,17) The substantial funding for this project, at the time considered as extremely high risk, came from the German Ministry of Research and Technology. Today a similar project would probably no longer receive public funding, thus such innovation would be impossible.

(a) 

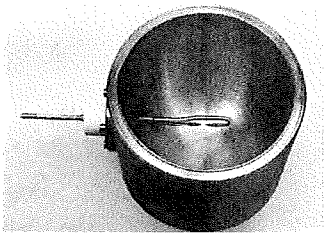
(b) 

Figure 2. (a) Principle of Lithotripsy with underwater spark. (b) Ellipsoid with Electrode

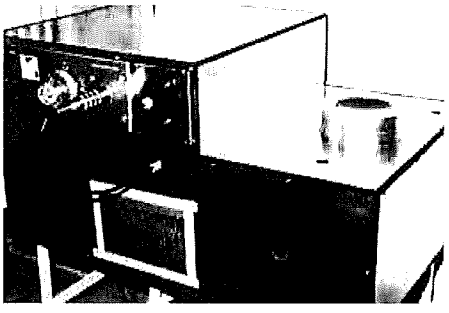
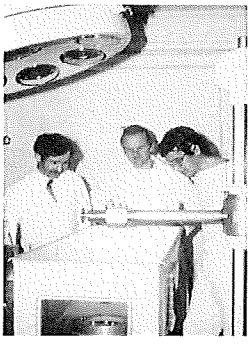
(a) 
(b) 

Figure 3. (a) First experimental device for in-vitro and in-vivo studies (b) Inspektion of a experimental device for larger animals (C. Chaussy, F Eisenberger und B. Forssmann – right to left)

The costly physical trials could only be justified if there was a likelihood that the shockwave would not prove to damage organs. For this reason the laboratory apparatus in the starting phase of the project was constructed for tests on vital structures .[Fig. 2+3] The medical trials conducted were structured in two segments, in-vitro and in-vivo trials. The in-vitro experiments were aimed at determining if the delicate erythrozytes would be destroyed and if consequences on the proliferal processes were to be expected. The impact of the shockwave on abdominal- and thorakal organs in a small animal were tested during the in-vivo experiments.

In a free standing water bath probes with a standardized volume of 10ml dog blood were adjusted into the focal point and the impact of the exposition to up to 4 shockwaves at 20kV was studied. Increasing with the number of shockwaves was the concentration of serum haemoglobin to a level of 400mg/100ml. The increase seemed not to be relevant in comparison to the total blood volume of the animal. Later in a dog, despite a twentyfold shockwave exposure, no increase in the concentration of serum hemoglobin could be found.

The impact of the shockwave on the proliferative processes in a mixed lymphocyte model were compared to untreated cell cultures in the same way. The reactivity of the exposed lymphocytes did not differ to that of the untreated control group. A change in the stimulation capacity was not found.

For the in-vivo trials the test facility had to be modified. Instead of the water bath a bench was used, with which the shockwave could directly be coupled with the trial animal using a membrane. Using spacers the distance between the membrane and focal point was altered and allowed for the shockwave to act in a certain depth from the skin's surface.

Narcotized rats were fixed to the bench and the thoracic and abdominal area randomly

treated with ultrasound at 20kV. Single shockwave exposure in the thoracic region caused massive lung trauma resulting in the deaths of the animals. This had not been entirely unexpected as the lung possesses other acoustic impedances as muscle or fat. These injuries were prevented by insulating the lung with air-filled materials which stopped the shockwave entering this part of the body. The animals survived ultrasound treatment of the abdominal area with 10 shockwaves without any clinical side effects. Histological tests conducted 24 hours and 14 days after the treatment showed neither macroscopic nor microscopic pathological changes. (9)

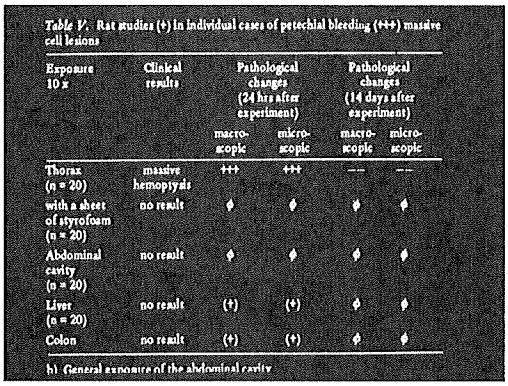


Table V: Rat studies (+) in individual cases of petechial bleeding (+++) massive cell lesions

Exposure 10 x	Clinical results	Pathological changes (24 hrs after experiment)		Pathological changes (14 days after experiment)	
		macro-scopic	micro-scopic	macro-scopic	micro-scopic
Thorax (n = 20)	massive hemoptysis	+++	+++	--	--
with a sheet of styrofoam (n = 20)	no result	∅	∅	∅	∅
Abdominal cavity (n = 20)	no result	∅	∅	∅	∅
Liver (n = 20)	no result	(+)	(+)	∅	∅
Colon	no result	(+)	(+)	∅	∅

b) General exposure of the abdominal cavity

Table 1: Results of un-targeted Shockwave exposition in vivo.

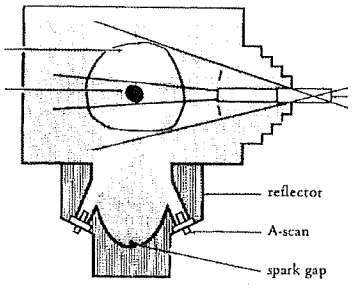
Further trials focused specifically on the influence of shockwave exposure on the liver and intestine. The respective organs were eventerated, brought into focus and after successful exposure repositioned. After two exposures the intestine showed petechial bleeding. Massive haemorrhages or lesions of the intestinal wall never occurred. The liver also showed petechial bleeding. After 14 days no pathological alterations could be found on either organ.

[Tab.1].

Localisation and Stone Model

While the concretions during in-vitro testing in the water bath could be placed into the object's focal point by sight, an accurate and reliable tracing for inside the animal had to be found. The idea of using ultrasound for the positioning was fascinating. The expansion of ultrasound and shockwaves adhere to the same physical laws.

[Fig. 4 a, b]

(a) 

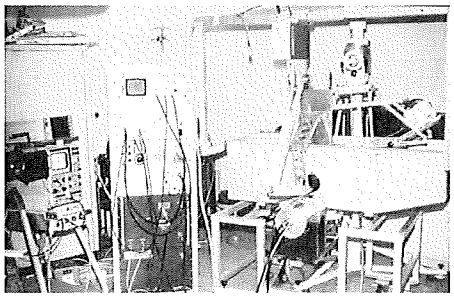
(b) 
(c) 

Figure 4. (a) Integration of Ultrasound Scanners (b) Experimental lithotripter with integrated Ultrasound Scanners (c) Transverse Sonogram after Stone implantation

During in- vivo experiments an unambiguous localization only succeeded in exceptions, if the concretion could be located close to the skin surface. A reproducible localization for specific experimental trials or a clinical application did not appear useful.

The emerging ultrasound diagnostic with compound scanners in the B-san mode seemed promising for additional information and to reliably locate the stone. Therefore, a B-Scan was integrated, where the pictures were recorded using a fluoroscope. However this method, combined with the A-Scan, did not provide a reliable localization due to the many artefacts. A change of the apparatus to a system of greyscales did not significantly improve the stone identification as the stone shadow, essential to identifying the stone, was generally superimposed by artefacts. [Fig. 4c]

It proved difficult to find a test subject for the extracorporeal destruction of kidney stones with symptoms comparable to those of a human patient, especially as kidney stones only seldom occur in animals. All attempts using special long term-diets as well as the implantation of exogenous materials, which showed no similarities to a human kidney stone, delivered only unsatisfactory results. Nevertheless, in order to research the treatment of human lithiasis it was completely indispensable to have a simple, reproducible model for large animals.

Initially the idea of injecting liquid resin into the renal calix, which would harden under the influence of body temperature and uric liquid, was pursued. Using acryl acetate the lining of kidney duct system with a renal pelvis calculus was successful. [Fig 5a] As these artificial stones did not possess the physical characteristics of a natural kidney stone the destruction into small fragments was not possible.

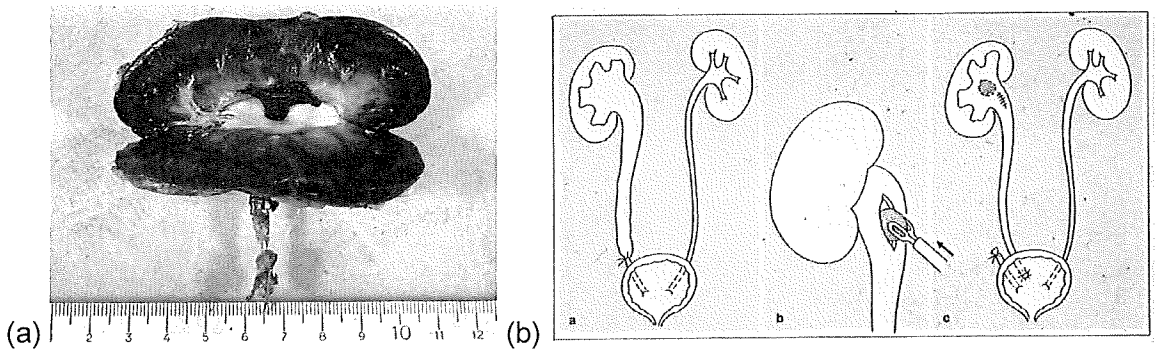


Figure 5. (a) Implanted artificial acrylacetate stone (b) Experimental procedure for the implantation of human kidneystones in dogs

It was therefore decided to implant freshly obtained human kidney stones in the kidney duct system of a dog. Primarily due to size discrepancies between the renal pelvis and the kidney stone, intra-operational technical difficulties in connection with complications in the post-operational course, the initial attempts of implanting sufficiently large kidney stones

did not yield the expected results.

A solution to these problems could be achieved by the following procedure:

Dogs did receive an abdominal section under sterile conditions and the right ureter was ligated prevesically. The research animals did later receive a fine median abdominal section and were implanted with a contrast giving human kidney stone with a diameter of between 1- 2 cm. Afterwards the ureter was re-implanted into the bladder. Following surgery the discharge of urine and the position of the stones was checked in intervals of 8 days using IVP. The intervention did not cause changes in the kidney duct system. The medical requirements for systematic testing of the method in a reproducible animal model were found. [Fig. 5b] (2, 13)

Despite the ongoing problems of reliable ultrasound tracing the animal testing commenced. In the first step the effects of shockwave exposure on the right kidney were tested in a series of 20 non-stone carrying dogs. Up to 10 high energy shockwaves were applied in a grid on the kidney. 48 hours after the exposure a section was conducted and tissue samples taken from kidney, liver, spleen, pancreas, duodenum, colon, lungs, ribs and spinal column and tested for shockwaves induced side effects. No macroscopic alterations were found in any of the exposed organs. In some cases slight bleeding was recorded in the lower right pulmonary lobe, but none of these cases induced a haematothorax. Histological studies of these organs showed no pathological changes.

Due to the difficulties in locating the stones using ultrasound, the destruction was only possible in isolated cases. [Fig. 6] Nevertheless, these were of major importance for the continuation of the project, as the project sponsor had intended to discontinue the subsidies. It proved that extracorporeal shock wave lithotripsy is generally possible and with the first stone destruction the project sponsor could be convinced to authorize further

grants.

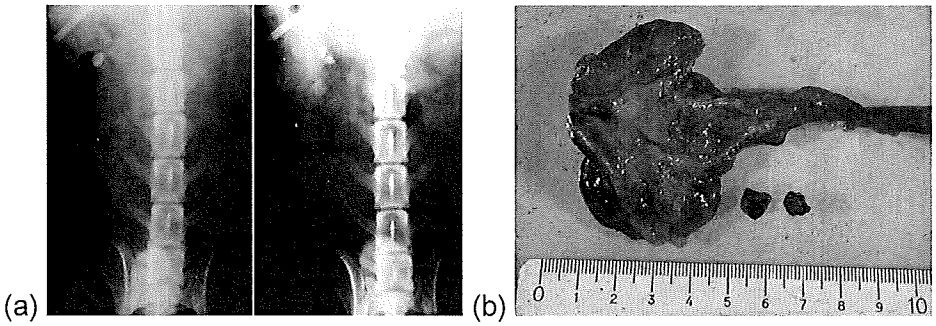


Figure 6. First in-vivo stone destruction (a) X-ray pre and post shockwave exposure (b) Section specimen

Localisation with X-Rays

To circumvent the deficiencies of ultrasound tracing, the possibility of integrating x-rays into a shockwave apparatus, as a technique to obtain images was considered,

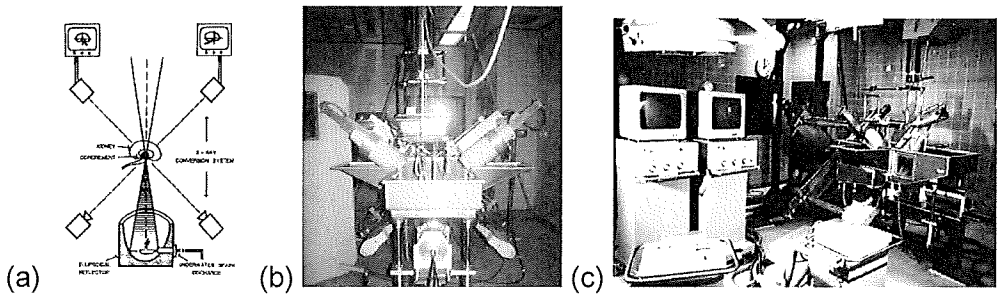


Figure 7. Lithotripter for animal experiments. (a) and (b) Principle of X-ray localisation (c) Total view of the experimental setup

An image intensifier and two conventional tubes of x-ray C-arches were integrated in a shock wave apparatus in a way that the central beams would cut the shock wave focal

point at an angle of 40° with regards to the ellipsoid axis.[Fig.7]

Both systems could be rotated around the focal point vertically to the central beams. This should enable to move the stone shadow out of a bone cover for better identification. X-ray tube and image intensifier could be moved along the central beams to find the best distance for an optimal image.

Further in-vitro tests with low pressure amplitudes of approximately 30 MPa were conducted to define a threshold for the destruction of stones. The capacity of the surge generator was reduced from 2 KF to 20nF, 40 nF and 60nF. Using these generators and 50-300 shockwaves in one second intervals, the stones could be decomposed into finer particles as had so far been possible with one, strong shockwave,[Fig. 8]

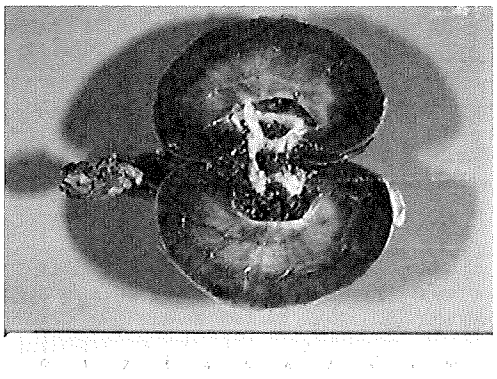


Figure 8. Prepared dissection of a stone bearing dog kidney immediately after shockwave exposure

A total of 17 dogs implanted with kidney stones were included in the trial series. During and after the trials no impairments caused by shockwave exposure were found. 13 of the animals were stone-free after spontaneously passing the particles. In 11 of these animals, this was achieved after a single shock wave exposure. The remaining 3 animals received additional treatment 14 days later to further crush larger particles still remaining in the

renal pelvis. Following the repeated shock wave exposure 2 further animals were stone-free after 14 days. In 4 animals complete stone passage could not be achieved. [Fig.9]

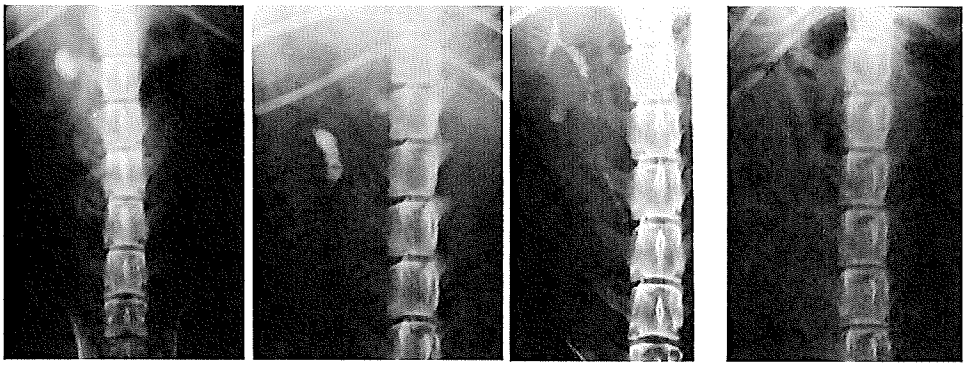


Figure 9. Monitoring of an experimental shockwave exposure (dog) a) before, immediately, one day after and two weeks after lithotripsy

Blood samples for laboratory testing were taken from each of the animals prior to and after the shockwave exposure as well as 1 and 2 weeks later. None of the tested parameters showed any salience to the initial values. To assess the possible shockwave effects on the kidney functions split isotope studies on 6 of the animals, prior to, 4 and 14 days after shockwave exposure were performed with ^{99m}Tc- DMSA. (4,12,18)

The HM1 – The first clinical lithotripter

The results obtained from the animal experiments justified a transfer of the method into clinical use. The design of the pre-clinical prototype was adapted in size in relation to the patient.

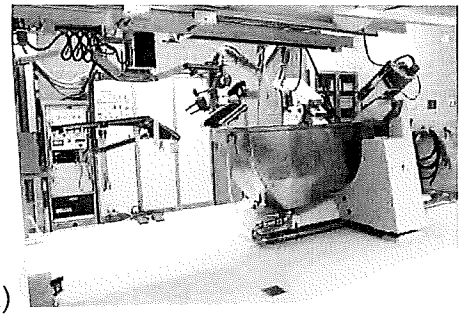
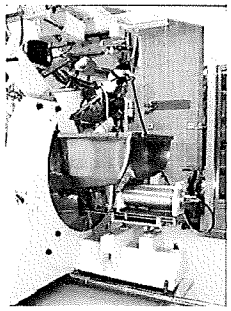
(a)  (b) 

Figure 10. (a) Total view of shockwave lithotripter (HM 1) (b) Detailed view of the shock wave generator underneath the bath tub

In a type of "training program" tracking tests were conducted with volunteers, using the apparatus known as HM1 which was installed in the Institute for Surgical Research in October 1979, [Fig.10] to determine the positioning and to practice the treatment process. This initiated some necessary changes on the device; due to the buoyancy during the lowering into the water bath and the adjusting of the stone into focus with an anaesthetised patient a firm fixation was not given. Once the patient stretcher had been equipped with a harness system and changes had been made to the motion axis a reliable localization became possible.

The first, and the following patients were chosen following a strict selection process. Based on the experience gained from the animal testing, it was decided that the stone in the renal pelvis should be no larger than a cherry. Unobstructed conditions for passages in the urinary tract and the exclusion of an infection in the urinary tract were prerequisites for the passage of the stone particles.

Prerequisite for a fine-grained disintegration was the reliable localization achieved by a high radiographic contrast of the stone. To avoid unexpected complications and to ensure the assessment of possible side effects of a shockwave therapy - though not caused by the shockwave - patients with internal risk factors were not accepted . Based on the requirement parameters for inclusion and exclusion which essentially still apply today were defined.

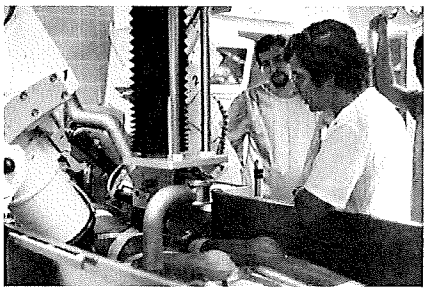


Figure 11. Patient, C. Chaussy and Anaesthesist in one of the first treatments

The first treatment took place on February 7th, 1980. Intubation anaesthesia was used in this and 13 other cases. [Fig. 11] However, soon after it was discovered that the, for the patient less strenuous peridural anaesthesia was sufficient. The narcotized patient was harnessed to the stretcher and placed into the water bath using the patient positioning device. The method tracking and adjusting the stone into the shockwave focal point was identical to the procedure during animal testing. [Fig. 12]

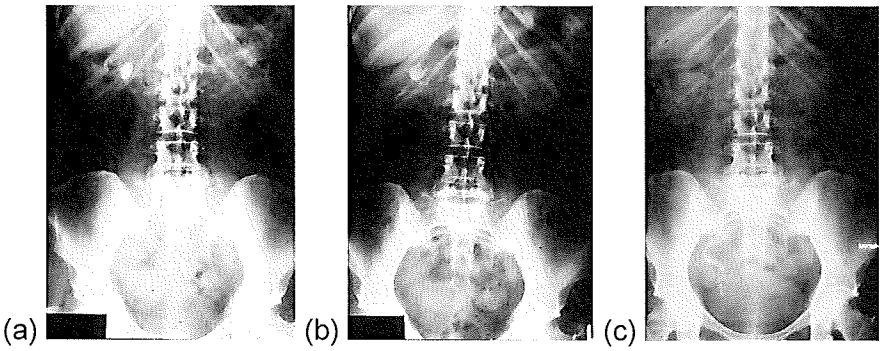
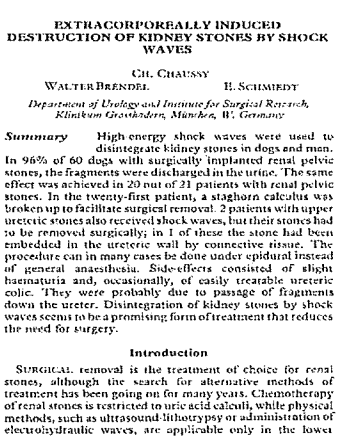


Figure 12. Patient X-ray follow-up (a) before (b) immediately after Shock wave exposure (c) Steinstrasse in distal ureter

To avoid premature breaking of the stone the shockwave was initially applied with low energy. In intervals of 50 to 100 shockwave releases the progress of the disintegration was checked. Towards the end of the disintegration process die energy of the shockwave was increased to better shatter larger fragments still remaining. Depending on the size of the stone a total of 500 to 1500 shockwaves were applied. At the beginning the time necessary for application was approximately 90 minutes, caused by repeated changes of the underwater electrode. The treatment time was reduced to 30 – 45 minutes after various technical improvements caused an increase in the electrode's life cycle.
In some cases extrasystoles caused by shockwaves could be observed during shockwave exposure, a phenomena which could to this day not fully be explained. By releasing a shockwave triggered by the ECG immediately after the R-Wave this interaction with the conduction system was avoided

Until Mai 1982 a total of 221 extracorporeal shockwave lithotripsies, or "ESWL" as it should become known, were conducted on 206 patients.15 patients had to receive a second ESWL to become stone-free. 39% of the patients had already received surgery once or twice on the same kidney before. The majority of the stones, 75%, were located in the renal pelvis. Following the first positive experience the method could be extended to renal calyx in 23% of the cases.



EXTRACORPOREALLY INDUCED DESTRUCTION OF KIDNEY STONES BY SHOCK WAVES

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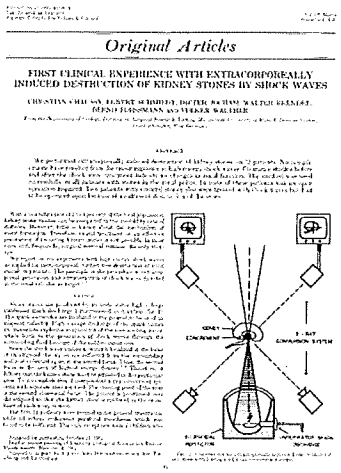
Summary High energy shock waves were used to disintegrate kidney stones in dogs and men. In 96% of 60 dogs with surgically implanted renal pelvic stones, the fragments were discharged in the urine. The same effect was achieved in 20 out of 21 patients with renal pelvic stones. In the twenty-first patient, a staghorn calculus was broken up to facilitate surgical removal. 2 patients with upper ureteric stones also received shock waves, but their stones had to be removed surgically; in 1 of these the stone had been embedded in the ureteric wall by connective tissue. The procedure can in many cases be done under epidural instead of general anaesthesia. Side-effects consisted of slight haematuria and, occasionally, of easily treatable ureteric colic. They were probably due to passage of fragments down the ureter. Disintegration of kidney stones by shock waves seems to be a promising form of treatment that reduces the need for surgery.

Introduction

SURGICAL removal is the treatment of choice for renal stones, although the search for alternative methods of treatment has been going on for many years. Chemotherapy of renal stones is restricted to uric acid calculi, while physical methods, such as ultrasound-lithotrypsy or administration of electrohydraulic waves, are applicable only in the lower

(a)



Original Articles

FIRST CLINICAL EXPERIENCE WITH EXTRACORPOREALLY INDUCED DESTRUCTION OF KIDNEY STONES BY SHOCK WAVES

(b)

Figure 13. (a) Publication of the first clinical results in The Lancet 1980;2: 1265-1268. (b) Publication of first clinical experience in J Urol 1982;127: 417-20.

Furthermore 4 high ureter stones were treated, two of them impacted stones, which nevertheless had to be removed surgically after shockwave exposure. Despite fine fragmentation the particles could not be passed as they were bound into an organic matrix, comparable to a sack. The particles of the other two stones were passed after just a few days. The stones consisted to 90% of calcium oxalate, 5% magnesiumamoniumphospate and the remaining 5% of different chemical components

including uric acid and a cysteine stone.

Further examinations up to one year after ESWL showed no anomalies in the laboratory parameters compared to the base line. Also no significant difference in the renal function studies was found. As early as end of 1980 results from the first 21 patients were published (5) and in 1982 the clinical study was published as well (7,8). [Fig. 13]

1981

The installation of the HM2 in Munich required a space allocation plan. The investment of 2,1 Mio. DM (in 1981 US $ 855000) was only possible with the help of the Bavarian insurance companies and the committee for home dialysis (Kuratorium für Heimdialyse = KfH). Without their dedication the project would not have been possible at all. (4,12)

1982

On May 20, 1982 the first Lithotripsy center was launched in Munich under the supervision of Ch. Chaussy at the Department of Urology (E.Schmiedt), University of Munich. With this set up fast and further clinical evaluation of the extension of indications was possible. The treatment of staghorn stones by fractionated shock wave exposition in multiple sessions, of infected stones under antibiotic pre-treatment and of multiple stones was possible. Also high risk patients were accepted. Furthermore PNCL, which was initially regarded as competition, was introduced as auxiliary procedure to ESWL . After these successful extensions of indications for ESWL operative indications for stone removal were limited to 10 – 15 % of stone patients. (4,10,11)

1983

The data and success of ESWL sparked an enormous interest in Germany and worldwide. In 1983 the 2nd Lithotripsy Center was opened in Stuttgart (F. Eisenberger). (21)
A FDA study, necessary for approval of ESWL in the USA, was planned at 6 centers. In spite of the great interest displayed by radiologists, it was possible to keep the procedure in the hands of urologists; main reason was that all principal investigators had to be trained in Munich and the Munich urologists refused to train radiologists.

1984

The first device in the US was installed in February in Indianapolis (D. Newman, J. Lingeman); another 5 clinics followed. The US FDA study was monitored by G. Drach. Due to the method's success, the PMA was already granted for general marketing in December. This fast decision was mainly due to the acceptance of the data from the clinical study conducted by the Munich Urology clinic which played a significant role because the results of the USA study were not published until 2 years later (19)

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Extracorporeal Shock-Wave Lithotripsy: Long-Term Complications

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Robert C. Newman[2]
John C. Peterson[3]
William C. Thomas[3]

Of 148 patients who had extracorporeal shock-wave lithotripsy (ESWL) for renal lithiasis in 1984, 21 (14%) returned after 17–21 months for renal function tests (21 patients) and blood pressure determination (20 patients). Quantitative radionuclide renography showed a statistically significant ($p = .048$) decrease in the percentage of effective renal plasma flow (ERPF) to the treated kidney. Two of these patients had developed hypertension requiring treatment but became normotensive when given medication. In the other patients there was a statistically significant increase in both systolic ($p = .0002$) and diastolic ($p = .015$) blood pressures. Information about blood pressure was also obtained from an additional 71 (48%) of the 148 patients; of the total 91 patients (61%) in whom blood pressures were obtained, seven (8%) had developed sufficiently severe hypertension to require treatment beginning within 21 months after ESWL.

Side effects of ESWL for renal lithiasis include hemorrhage, edema, and acute tubular necrosis of the kidney. This form of renal trauma is associated with an immediate decrease in renal function of the treated kidney, and this decrease may be permanent. ESWL is also associated with the onset of hypertension, which may occur immediately or be delayed by several weeks or months. Although the pathogenesis remains unknown, hypertension is an important complication of ESWL in about 8% of patients.

Extracorporeal shock-wave lithotripsy (ESWL) for renal stone disease [1] was first performed at the Shands Hospital of the University of Florida on August 15, 1984, as an experimental clinical procedure. By December 19, 1984, the date on which the United States Federal Drug Administration (FDA) approved the procedure for routine use, we had treated 148 patients. Early in our experience with this new technique, we encountered the abrupt onset of hypertension immediately after ESWL in a patient who also had a perirenal hematoma and a marked decrease in the percentage of effective renal plasma flow (ERPF) to the treated kidney. This experience prompted a prospective study of renal function and morphology immediately after ESWL [2]. Quantitative radionuclide renography disclosed reduced renal function (a decrease in ERPF of more than 5 percentage units) in 10 (30%) of 33 of the treated kidneys, and MR imaging disclosed evidence of renal trauma (edema or hemorrhage) in 24 (63%) of 38 of these treated kidneys. A retrospective review of the medical records of the first 79 patients in this experimental group disclosed that three patients (4%) had developed sustained hypertension immediately after ESWL that required antihypertensive medication [3]. These observations led us to ask four questions: (1) Is a decrease in renal function after ESWL permanent or is it only temporary? (2) Is the hypertension that occurs immediately after ESWL temporary, or will it persist? (3) Because renal trauma may induce hypertension after a delay of weeks or months, what is the long-term prevalence of hypertension? (4) Is there a causal relationship between decreased renal function and hypertension after ESWL?

When permission was obtained from the FDA to perform ESWL on an experimental basis, it was stipulated that all patients should be examined 3 months after

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0361–803X/88/1502–0311

treatment to determine the efficacy of the procedure and to discover possible complications. Unfortunately, there was poor compliance with this requirement and in the first report of the United States cooperative study [4], 3-month follow-up data were available in only 37% (926/2501) of the patients. For these reasons, we initiated a concerted effort in 1986 to have the first 148 patients treated here under the FDA experimental protocol return to the hospital for evaluation. We report the long-term effects of ESWL on renal function as determined by renography and the prevalence of hypertension occurring after ESWL in this group of patients.

Materials and Methods

A letter was sent to all 148 patients asking them to return to the hospital for an abdominal radiograph, quantitative radionuclide renography, and blood pressure measurement. Of these 148 patients, only 21 (14%) returned for the tests 17–21 months after ESWL. The mean age of these 21 patients was 51 years (range, 28–68 years); nine were women and 12 men. The mean number of shocks per treatment was 1400 (range, 800–2000), and the kilovoltage used ranged from 18 to 24 kV. After these 21 patients had been tested, we were able to obtain follow-up information in an additional 71 patients (48%) either from the referring physicians or from clinical notes made by other physicians at this institution after the ESWL therapy.

Quantitative Radionuclide Renography

We used the comprehensive radionuclide renal function test of Dubovsky et al. [5] and Kontzen et al. [6] in which 300–500 μCi (11.1–18.5 MBq) of ^{131}I-orthoiodohippurate (Hippuran) are administered intravenously 30 min after oral ingestion of 500 ml water. Images were obtained with an Ohio Nuclear Series 100 scintillation camera (Solon, OH) interfaced with an MDS computer (Ann Arbor, MI). Total ERPF was calculated from the formula of Tauxe et al. [7], and the percentage of ERPF for each kidney was obtained from the 1–2 min interval after injection of the radionuclide.

Blood Pressure

Pre-ESWL values were obtained from the medical records in which systolic and diastolic blood pressures were measured in the hospital at 6-hr intervals before ESWL. The average number of measurements was 5.6 (range, 2–15). The mean value of the pre-ESWL blood pressures was compared with post-ESWL follow-up values obtained during the return visit at which time the blood pressure was measured at least three times and the lowest value recorded. An increased systolic blood pressure was considered to be ≥150 mm Hg; an increased diastolic blood pressure, ≥95 mm Hg.

Statistical Analysis

The Student paired t-test and the Pearson correlation were used for the analyses.

Results

Comparison of Renal Function Before and After ESWL

Twenty-one patients had renography after ESWL for comparison with their pretreatment test (Table 1). The total ERPF

TABLE 1: Correlation of Renal Function and Hypertension Before and After ESWL

Age	Gender	Shocks	Effective Renal Plasma Flow (ml/min)							Blood Pressure (mm Hg)					
			Pre-ESWL			Post-ESWL			Change in %	Pre-ESWL		Post-ESWL		Change in Systolic	Change in Diastolic
			Both Kidneys	Treated Kidney	% Treated Kidney	Both Kidneys	Treated Kidney	% Treated Kidney		Systolic	Diastolic	Systolic	Diastolic		
54	F	800	610	340	56	670	340	51	−5	104	73	150	90	+46	+17
33	M	950	685	300	44	655	355	54	+10	106	72	124	78	+18	+6
55	F	2000	515	210	41	525	220	42	+1	126	86	160	94	+34	+8
62	M	1600	510	255	50	510	230	45	−5	145	89	142	80	−3	−9
68	F	1600	160	60	37	95	10	9	−28	122	76	160	100	+38	+24
37	M	1000	765	445	58	690	395	57	−1	112	72	120	80	+8	+8
45	F	800	380	135	35	355	120	33	−2	100	59	112	74	+12	+15
50	F	1600	505	240	48	525	225	43	−5	135	81	160	78	+25	−3
64	F	2000	645	350	54	675	270	40	−14	120	72	156	90	+36	+18
55	F	900	540	270	50	535	290	54	+4	115	85	Normotensive on medication			
39	M	1600	650	265	44	515	230	45	+1	117	75	126	80	+9	+5
63	F	1600	155	70	45	485	225	46	+1	115	79	130	80	+15	+1
39	M	1600	585	315	54	510	215	42	−12	147	94	Normotensive on medication			
59	M	1600	485	295	61	540	340	63	+2	118	83	120	80	+2	−3
64	M	1400	400	170	43	425	150	35	−8	132	82	150	84	+18	+2
35	M	1600	680	340	50	720	355	49	−1	119	83	120	76	+1	−7
48	M	1600	415	260	63	590	220	46	−17	136	82	150	90	+14	+8
28	M	1200	520	265	51	815	385	47	−4	139	74	Not taken after ESWL			
62	M	1100	595	310	52	530	260	49	−3	122	79	130	80	+8	+1
53	M	1000	605	325	54	540	275	51	−3	132	85	130	84	−2	−1
56	F	1700	475	235	49	415	235	56	+7	125	66	140	90	+15	+24
Mean 51		1400	520	260	50	540	255	46		123	78	138	84		
SD ±12		±380	±150	±90	±7	±150	±90	±11		±13	±8	±16	±7		

Note.—ESWL = extracorporeal shock-wave lithotripsy.

to both kidneys increased slightly but not significantly from a mean of 520 ml/min before ESWL to 540 ml/min after ESWL. There was a slight but also insignificant decrease in the ERPF of the treated kidney from a mean of 260 ml/min before ESWL to a mean of 255 ml/min after ESWL. However, the percentage of total ERPF to the treated kidney declined from a mean of 50% before ESWL to a mean of 46% after ESWL, and this decrease was statistically significant ($p = .048$). In addition, the ERPF to the treated kidney decreased by more than 5% in 24% (5/21) of patients.

Comparison of Blood Pressures Before and After ESWL

At the time of post-ESWL renography, blood pressures were recorded in 20 of 21 patients (Table 1). Five patients were taking hydrochlorothiazide before ESWL and recorded no change in medication at the follow-up examination. Two of 20 patients had developed hypertension after ESWL but became normotensive when given medication. The mean systolic blood pressure of the remaining 18 patients increased from 123 mm Hg before ESWL to 138 mm Hg after ESWL, and this increase was statistically significant ($p = .0002$); the mean diastolic blood pressure increased from 78 mm Hg before ESWL to 84 mm Hg after ESWL, and this increase was also statistically significant ($p = .015$). One of these 18 patients was found to have sustained hypertension, and antihypertensive medication was started.

In addition to these 20 patients, we obtained information about blood pressure from the medical records or from the referring physicians in an additional 71 patients. Four (6%) of these 71 patients had developed hypertension after ESWL for which medication was administered, thus yielding an overall prevalence of hypertension in seven (8%) of 91 patients. Of these seven patients, the onset of hypertension requiring treatment was detected immediately after ESWL in three instances, at 6–8 weeks in two instances, and between 6 and 12 months in two instances.

Correlation Between Renal Function Changes and Blood Pressure Changes

A definite trend indicated a correlation between decreasing percentage of ERPF to the treated kidney with increasing systolic and diastolic blood pressure in the 18 patients in whom all measurements were available, but the correlation was not significant in this small series ($p = .12$ for the correlation with systolic blood pressure and $p = .22$ for diastolic blood pressure). However, when we compared the change in the percentage of ERPF to the treated kidney with the absolute blood pressure, we noted a more impressive relationship (Fig. 1). With one exception, all patients with a change in the percentage of ERPF to the treated kidney in the range between −3% and +10% were normotensive. Conversely, with two exceptions, all patients with a change in the percentage of ERPF between −4% and −28% either were hypertensive (systolic ≥ 150 mm Hg and/or diastolic ≥ 95 mm Hg) or had become hypertensive after ESWL and were normotensive when given medication. Although not definitive, these results suggest a long-term correlation between decreased renal function of the treated kidney and hypertension in patients treated with ESWL.

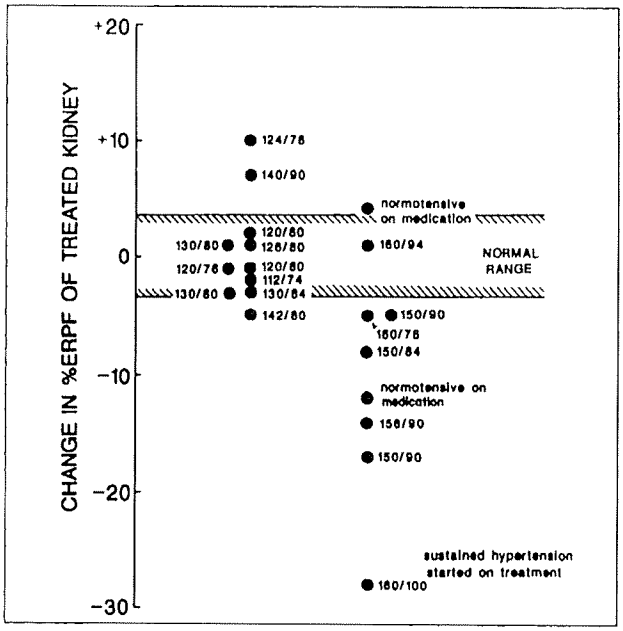

Fig. 1.—Correlation of change in percentage of effective renal plasma flow (ERPF) of treated kidney with blood pressure at 17–21 months after extracorporeal shock-wave lithotripsy (ESWL). Left column shows normotensive patients (systolic blood pressure <150 mm Hg; diastolic blood pressure <95 mm Hg). Right column shows hypertensive patients (systolic blood pressure ≥150 mm Hg and/or diastolic blood pressure ≥95 mm Hg) or patients who had become hypertensive after ESWL and were normotensive on medication.

Discussion

The United States cooperative study of ESWL required a radionuclide renogram before and 3 months after ESWL. The renogram could be performed either with ^{131}I-orthoiodohippuric acid, an agent that is used to measure ERPF, or with ^{99m}Tc-DTPA, which is used to measure glomerular filtration rate (GFR). In either case, the intention was to obtain a quantitative estimate of renal clearance. Because renal clearance of GFR agents is about 20% of renal clearance of ERPF agents, the cooperative study report [4] cited only the change in total renal clearance 3 months after ESWL. Total renal clearances were recorded for 494 patients, of which 241 were decreased, five were unchanged, and 248 were increased. When individual changes were measured, a statistically significant increase of total renal clearance was found. These 3-month post-ESWL results agree well with our 18-month post-ESWL results in which 10 of 21 patients had decreased total ERPF, one of 21 had the same total ERPF, and 10 of 21 had increased total ERPF. Mean total ERPF also increased slightly, but this change did not reach significance.

After unilateral nephrectomy, the remaining kidney may undergo compensatory hypertrophy and an increase in ERPF [8]. Decreased ERPF to a kidney resulting from renal trauma caused by ESWL can probably be compensated for by an increased ERPF to a healthy untreated kidney. For this rea-

son, the measurement of total renal clearance will not detect the presence of an adverse effect of ESWL on a treated kidney unless the untreated kidney is unable to respond. A compensatory increase in ERPF to the untreated healthy kidney may result in an increase in total ERPF to an amount greater than the pre-ESWL value, as was noted in the cooperative study [4] and also in the present report. For this reason the absolute value of the ERPF to the treated kidney, which is obtained by multiplying the percentage of ERPF to the treated kidney by the total ERPF, may not change significantly. The assessment of a change in renal function after ESWL is therefore incomplete without determination of the differential renal function of the treated kidney. Future studies of the acute and long-term effects of ESWL on renal function should always include an analysis of the relative function of the treated kidney.

The normal range of percentage of ERPF to a single kidney in a two-kidney healthy patient is 45–55% [9]. Our range of 35–63% in treated kidneys before ESWL was considerably larger than this, presumably because of the presence of stones and frequently some obstruction. The reproducibility of the percentage of ERPF to a single kidney in a two-kidney patient is ±3% (Dubovsky EV, personal communication). That is, if the percentage of ERPF to a single kidney is 45%, a repeat measurement will be between 42% and 48%. Thus a decrease in the percentage of ERPF to a single kidney from 45% pre-ESWL to 35% post-ESWL would be more than three times the change expected from the error of measurement. In our earlier study of renal function immediately after ESWL [2], we found a significant ($p = .025$) decrease in the percentage of function of the treated kidney when ERPF was measured. We also found that 30% of patients (10/33) had an abnormal decrease in the percentage of ERPF to the treated kidney of more than 5%. These findings have been confirmed by Bomanji et al. [10] who measured GFR in 42 patients immediately after ESWL. They found a significant ($p = .01$) decrease in the percentage function of the treated kidney, and 21% of patients (9/42) had an abnormal decrease in renal function of the treated kidney of 8% or more. When we used either our criterion of abnormality (a decrease of 6% or more) or the criterion of Bomanji et al. (a decrease of 8% or more) [10], we found that 24% of patients had an abnormal decrease in renal function of the treated kidney at 17–21 months. The fact that ESWL may result in a significant decrease in the percentage of ERPF to the treated kidney, both acutely and at 17–21 months, suggests that the decrease in renal function caused by ESWL may be permanent. In none of our 21 patients was there evidence of unrecognized ureteral obstruction as a possible cause of the decreased renal function of the treated kidney.

Peterson and Finlayson [3] reported a 4% (three of 79 patients) frequency of sustained hypertension occurring immediately after ESWL. The data in the present report indicate that sustained hypertension, either occurring immediately after ESWL or developing several months later, may be permanent. The overall frequency of hypertension requiring treatment in our patients was 8% (7/91). This frequency is in close agreement with the recent report of Lingeman and Kulb [11] who found that 24 (8%) of 295 patients required pharmacologic intervention for hypertension that had developed during the 1-year period after ESWL. Beyond the age of about 45 years (in both men and women), systolic blood pressure rises at an average rate of 0.5–1.0 mm Hg/year until the seventh decade [12]. All of the patients with sustained hypertension listed in this report and in the report of Lingeman and Kulb [11] developed hypertension either immediately after ESWL or within 1 year after ESWL, thus exceeding any age-related increase in blood pressure. The combined results of the two series, composed of nearly 400 patients, indicate that clinically significant hypertension arising from renal trauma caused by ESWL is likely to occur in about 8% of patients.

ESWL has been described as a well-engineered, highly selective application of brute force [13]. After a few hundred shocks, macroscopic hematuria caused by intrarenal hemorrhage occurs in virtually all patients [1, 2], and this hemorrhage may be serious in patients who have a tendency to bleed [14, 15]. Although the originators of the procedure recorded a very low frequency (0.6%) of subcapsular hematoma [1], a prospective study with MR imaging revealed a much higher frequency (29%) of subcapsular, perirenal, and/or intraparenchymal hemorrhage [2]. The difference in the rate of occurrence of renal hemorrhage may be attributed to the much less sensitive sonographic technique used by Chaussy et al. [1]. The high frequency of hemorrhage that we documented with MR has been confirmed by three recent studies in which CT [16, 17] and MR [18] were used for evaluation of kidneys treated with ESWL. Experiments with dogs have confirmed that the clinically observed MR and CT abnormalities are caused by renal and subcapsular hemorrhages, frequently associated with small vein thromboses, interstitial edema, and acute tubular necrosis [19–22].

External mechanical trauma is known to result in interstitial edema and extravasation of urine and blood into the interstitial space [23]. These same effects caused by ESWL explain the enlargement of the kidney seen on excretory urography, MR, and CT [2, 16–18, 24], as well as the total and partial parenchymal obstructive patterns seen in renography and the renal edema and hemorrhages seen on MR [2].

We have not yet found the cause of the long-term decrease in the percentage of ERPF to the treated kidney. The partial and total parenchymal obstructive patterns observed by renography immediately after ESWL, and attributed to acute tubular necrosis and edema caused by hemorrhage, were not seen in our patients 17–21 months after ESWL, thus indicating the resolution of these two processes. All but one of 21 patients had a normal excretory phase of the renogram curve of the treated kidney, indicating the absence of mechanical obstruction due to persistent or recurrent stones. The one patient in whom the percentage of ERPF was reduced to a very low value had no stone but a small atrophic kidney. Possibly renal fibrosis, which has been observed in canine kidneys 30 days after ESWL [22], may be responsible for the long-term decrease in the percentage of ERPF to treated kidneys.

Peterson and Finlayson [3] suggested that renal trauma caused by ESWL may cause hypertension as the result of a

perirenal hematoma via the well-known Page kidney effect (trauma → perirenal hemorrhage → fibrosis → compression of renal parenchyma → increased interstitial pressure → decreased renal perfusion → renin release → generation of angiotensin II → hypertension). In a review of 29 cases of Page kidney [25], a history of trauma could be elicited in 78%, and the interval between the trauma and the discovery of hypertension varied widely from 24 hr to 12 years but generally was less than 1 year. Of the seven patients in the present report who developed sustained hypertension after ESWL, three had MR immediately after ESWL and all three of these patients had perirenal or subcapsular hemorrhage. In the immediate post-ESWL period, decreased renal plasma flow may be reasonably attributed to increased interstitial pressure caused by perirenal or intrarenal hemorrhage and the resultant edema. Up to 18 months after ESWL, decreased renal plasma flow may result either from increased interstitial pressure possibly caused by fibrosis due to intrarenal hemorrhage or by fibrosis due to pressure from a perirenal fibrotic process.

Our study of the long-term effects of ESWL on renal function and blood pressure is weakened by the small number of patients and by the absence of any control data, such as the long-term effects on renal function and blood pressure in patients with comparable renal lithiasis treated by other techniques (e.g., percutaneous lithotripsy or surgical lithotomy). Also, the late renal changes and hypertension may not have been due to the trauma of ESWL but to some other process unrelated to renal lithiasis, such as unilateral renal artery stenosis. These alternative explanations can only be adequately addressed by a prospective study with appropriate controls. The observations in this report together with those of Lingeman and Kulb [11] strongly support the need for such a prospective study. Because hypertension induced by renal trauma may be delayed and is often asymptomatic, urologists and other physicians performing ESWL should be alerted to the fact that hypertension is a potentially important complication of the procedure. Our experience shows that blood pressure should be measured periodically for at least 1 year after ESWL.

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The reader's attention is directed to the Commentary on this article, which appears on the following pages.

2016

STATE HEALTH COORDINATING COUNCIL

STATE MEDICAL FACILITIES PLAN

DHSR
N.C. Division of Health Service Regulation

North Carolina Department of Health and Human Services

LITHOTRIPSY

Introduction
Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. Extracorporeal lithotripsy is lithotripsy that occurs outside the body. Extracorporeal shock wave lithotripsy (ESWL) is the non-invasive procedure with which this section will concern itself.

A lithotripter is a device that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient's abdomen and the shock waves are focused on the stone, which is shattered by the force.

A lithotripter's service area is the lithotripter planning area in which the lithotripter is located. The lithotripter planning area is the entire state.

Lithotripter Utilization
Lithotripter utilization can be reasonably estimated by the incidence of urinary stone disease. Urinary stone disease, or urolithiasis, is a disease in which urinary tract stones or calculi are formed. The annual incidence of urinary stone disease is approximately 16 per 10,000 population[1]. Not all cases of urinary stone disease would be appropriately treated by lithotripsy. It has been estimated that 85 to 90 percent of kidney stone patients, when surgery is indicated, can be treated successfully by ESWL treatment. The annual treatment capacity of a lithotripter has been estimated to be 1,000 to 1,500 cases.

The number of lithotripsy procedures reported in North Carolina for the period of 2013-2014 was 10,459 procedures. There were 14 lithotripsy units operated by eight providers. Procedures were provided by a fixed unit at one facility, and by 13 mobile units operated by seven providers. Given the 14 lithotripsy units, the average number of procedures per lithotripter for the 2013-2014 fiscal year is 747.

Access
Due to the mobility of lithotripter services, and the subsequent number of sites from which the service is provided, it may be concluded that geographic access is available to the maximum economically feasible extent.

Lithotripsy Need Determination Methodology
North Carolina uses a methodology based on the incidence of urinary stone disease. The need is linked to the estimate of urinary stone disease cases and is based on the assumption that 90 percent could be treated by ESWL.

The standard methodology used for determining need for lithotripters is calculated as follows:

Step 1: Divide the July 1, 2016 estimated population of the state, available from the North Carolina Office of State Budget and Management, by 10,000 and multiply the result by 16, which is the estimated incidence of urinary stone disease per 10,000 population.

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[1] Pahiri, J.J. & Razack, A.A. (2001) "Chapter 9: Nephrolithiasis". In Clinical Manual of Urology, by Philip M. Hanno, Alan J. Wein, S. Bruce Malkowicz. McGraw-Hill Professional Publisher.

Step 2: Multiply the result from Step 1 by 90 percent to get the number of patients in the state who have the potential to be treated by lithotripsy in one year.

Step 3: Divide the result of Step 2 by 1,000, which is the low range of the annual treatment capacity of a lithotripter, and round to the nearest whole number.

Step 4: Sum the number of existing lithotripters in the state, lithotripters not yet operational but for which a certificate of need has been awarded, and lithotripter need determinations from previous years for which a certificate of need has yet to be awarded.

Step 5: Subtract the result of Step 4 from the result of Step 3 to calculate the number of additional lithotripters needed in the state.

Lithotripsy Services in North Carolina

There are eight providers that offer lithotripsy services in North Carolina. On the following pages, Table 9A and Table 9B provide information on the number of procedures as well as the location of the facilities served by these eight providers.

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Carolina Lithotripsy, LTD, 2014 Litho Place, Fayetteville, NC 28304-

Machines 2; #1137 (11/15/2000); #01179 (12/15/2011)

Areas Generally Served: Eastern North Carolina

Facility and Location	*Procedures*
CarolinaEast Medical Center, New Bern, NC	103
Carteret General Hospital, Morehead City, NC	53
Columbus Regional Healthcare System, Whiteville, NC	12
Duke Raleigh Hospital, Raleigh, NC	10
FirstHealth Moore Regional Hospital, Pinehurst, NC	162
FirstHealth Richmond Memorial Hospital, Rockingham, NC	25
Halifax Regional Medical Center, Roanoke Rapids, NC	30
Highsmith-Rainey Specialty Hospital, Fayetteville, NC	177
Johnston Health, Smithfield, NC	81
Lenoir Memorial Hospital, Kinston, NC	21
New Hanover Regional Medical Center, Wilmington, NC	201
Novant Health Brunswick Medical Center, Supply, NC	12
Onslow Memorial Hospital, Jacksonville, NC	4
Rex Hospital, Raleigh, NC	125
Southeastern Regional Medical Center, Lumberton, NC	73
Vidant Beaufort Hospital, Washington, NC	28
Vidant Medical Center, Greenville, NC	138
WakeMed, Raleigh, NC	50
Wayne Memorial Hospital, Goldsboro, NC	17
Wilson Medical Center, Wilson, NC	38
Total Procedures:	**1,360**
Average Number of Procedures per Lithotripter:	**680**

Provider: Catawba Valley Medical Center, 810 Fairgrove Church Road, SE, Hickory, NC 28602-

Machines 2; #1355 (11/2010); TC-2051 (03/2001)

Areas Generally Served: Western and Central North Carolina

Facility and Location	*Procedures*
Carolinas HealthCare System- Blue Ridge, Morganton, NC	39
Catawba Valley Medical Center, Hickory, NC	321
Rutherford Regional Medical Center, Rutherfordton, NC	68
Scotland Memorial Hospital, Laurinburg, NC	135
Total Procedures:	**563**
Average Number of Procedures per Lithotripter:	**282**

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Fayetteville Lithotripters Limited Partnership-South Carolina II, 9825 Spectrum Drive, Bldg 3, Austin, TX 78717-

Machines 1; SID OR-197 (01/17/2011)

Areas Generally Served: Western North Carolina and South Carolina

Facility and Location	*Procedures*
Charles George VA Medical Ctr, Asheville, NC	25
Harris Regional Hospital, Sylva, NC	118
Haywood Regional Medical Center, Clyde, NC	112
Margaret R Pardee Memorial Hospital, Hendersonville, NC	93
Park Ridge Health, Hendersonville, NC	60
St. Luke's Hospital, Columbus, NC	7
The McDowell Hospital, Marion, NC	32
Transylvania Regional Hospital, Brevard, NC	46
Oconee Medical Center, Seneca, SC	100
Total Procedures:	**593**
Average Number of Procedures per Lithotripter:	**593**

Provider: Fayetteville Lithotripters Limited Partnership-Virginia I, 9825 Spectrum Drive, Bldg 3, Austin, TX 78717-

Machines 1; SID OR-519 (11/9/2013) replaced SID 1147

Areas Generally Served: Eastern North Carolina and Virginia

Facility and Location	*Procedures*
Sentara Albemarle Medical Center, Elizabeth City, NC	24
The Outer Banks Hospital, Nags Head, NC	17
Vidant Chowan Hospital, Edenton, NC	51
Harborview Medical Center, Suffolk, VA	20
Louise Obici Memorial Hospital, Suffolk, VA	2
Mary Immaculate Hospital, Newport News, VA	157
Maryview Medical Center, Portsmouth, VA	8
Riverside Tappahannock Hospital, Tappahannock, VA	9
Riverside Walter Reed Hospital, Newport News, VA	4
Southside Community Hospital, Farmville, VA	19
Spotsylvania Regional Medical Center, Fredricksburg, VA	1
Total Procedures:	**312**
Average Number of Procedures per Lithotripter:	**312**

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Piedmont Stone Center, PLLC, 1907 S Hawthorne Road, Winston-Salem, NC 27103-

Machines 4; 01138 (03/26/2002); 01175 (04/10/2003); 01171 (04/24/2003); 1925 (12/26/2006)

Areas Generally Served: Western and Central North Carolina and Virginia

Facility and Location	*Procedures*
Carolinas HealthCare System-Blue Ridge, Valdese,	94
Davis Regional Medical Center, Statesville,	45
High Point Regional Health System, High Point,	498
Hugh Chatham Memorial Hospital, Elkin,	182
Iredell Memorial Hospital, Statesville,	144
Lexington Medical Center, Lexington,	64
Maria Parham Medical Center, Henderson,	60
Morehead Memorial Hospital, Eden,	172
Northern Hospital of Surry County, Mount Airy,	50
Novant Health Forsyth Medical Center, Winston-Salem,	116
Novant Health Rowan Medical Center, Salisbury,	213
Novant Health Thomasville Medical Center, Thomasville,	41
Randolph Hospital, Asheboro,	115
Wake Forest Baptist Medical Center, Winston-Salem,	103
Watauga Medical Center, Boone,	144
Wesley Long Hospital, Greensboro,	326
Wilkes Regional Medical Center, North Wilkesboro,	75
Alamance Regional Medical Center, Burlington, NC	186
Annie Penn Hospital, Reidsville, NC	14
Piedmont Stone Center, Winston-Salem, NC	799
Yadkin Valley Community Hospital, Yadkinville, NC	9
Lynchburg General Hospital, Lynchburg, VA	254
Martha Jefferson Hospital, Charlottesville, VA	204
Memorial Hospital of Martinsville, Martinsville, VA	110
Montgomery Regional Hospital, Blacksburg, VA	131
Piedmont Day Surgery Center, Danville, VA	43
Twin County Regional Hospital, Galax, VA	74
Total Procedures:	**4,266**
Average Number of Procedures per Lithotripter:	**1,067**

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Stone Institute of the Carolinas, LLC, 215 S Main Street, Suite 201, Davidson, NC 28036-

Machines 2; 2053 (10/2006); 1048 & 01384 (01/2001)

Areas Generally Served: Western and Central North Carolina

Facility and Location	*Procedures*
Carolinas HealthCare System-Lincoln, Lincolnton, NC	60
Carolinas Medical Center, Charlotte, NC	153
Carolinas Medical Center-Huntersville, Charlotte, NC	72
Carolinas Medical Center-Northeast, Concord, NC	220
Carolinas Medical Center-Pineville, Charlotte, NC	217
Carolinas Medical Center-Union, Monroe, NC	115
Carolinas Medical Center-University, Charlotte, NC	211
Caromont Regional Medical Center, Gastonia, NC	126
Cleveland Regional Medical Center, Shelby, NC	108
Lake Norman Regional Medical Center, Mooresville, NC	184
Novant Health Matthews Medical Center, Matthews, NC	197
Novant Health Presbyterian Medical Center, Charlotte, NC	87
Piedmont Medical Center, Rock Hill, SC	161
Surgery Center at Edgewater, Fort Mill, SC	34
Total Procedures:	**1,945**
Average Number of Procedures per Lithotripter:	**973**

Provider: Triangle Lithotripsy Corp, 7003 Chadwick Dr #321, Brentwood, TN 37027-

Machines 1; 10142940 (04/01/2010)

Areas Generally Served: East Central North Carolina

Facility and Location	*Procedures*
Central Carolina Hospital, Sanford, NC	126
Duke Regional Hospital, Durham, NC	28
Durham Ambulatory Surgical Center, Durham, NC	104
Nash General Hospital, Rocky Mount, NC	127
North Carolina Speciality, Durham, NC	13
Rex Hospital, Raleigh, NC	217
Rex Surgery Center, Cary, NC	168
Sampson Regional Medical Center, Clinton, NC	15
WakeMed, Raleigh, NC	253
Wayne Memorial Hospital, Goldsboro, NC	74
Total Procedures:	**1,125**
Average Number of Procedures per Lithotripter:	**1,125**

Total Mobile Procedures: **10,164**

Table 9B: Fixed Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Hospital License Renewal Application")

Provider: Mission Hospital, Inc./Mission, 509 Biltmore Ave., Asheville, NC 28801

Machines: 1 08/2000

Area Served:

Facility and Location	*Procedures*
WNC Stone Center, Asheville, NC	295
Total Number of Procedures:	**295**
Average Number of Procedures per Lithotripter:	295

Table 9C: Mobile and Fixed Lithotripsy

(Total Procedures/Units Reported)

Total Procedures Reported	Units Reported	Average Procedures Per Unit
10,459	14	747

Need Determination
Application of the standard methodology for the North Carolina 2016 State Medical Facilities Plan determined the need for one lithotripter as shown in Table 9D. There is no need anywhere else in the state and no other reviews are scheduled.

Table 9D: Lithotripter Need Determination

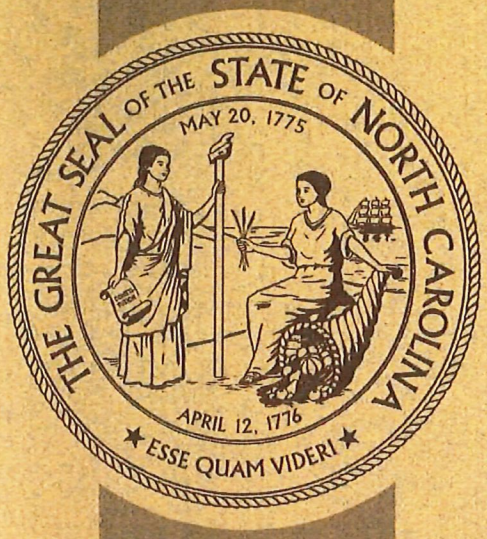
(Scheduled for Certificate of Need Review Commencing in 2016)

It is determined that the service areas listed in the table below need additional lithotripters as specified.

Lithotripters	Lithotripter Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
Statewide	1	June 15, 2016	July 1, 2016
It is determined that there is no need for additional lithotripters anywhere else in the state and no other reviews are scheduled.			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).



The 1998 State Medical Facilities Plan

North Carolina State Health Coordinating Council
Medical Facilities Planning Section
Division of Facility Services
NC Department of Health and Human Services

Lithotripsy

Introduction

Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. Extracorporeal lithotripsy is lithotripsy that occurs outside the body. Extracorporeal shock wave lithotripsy (ESWL) is the non-invasive procedure that this section will concern itself with.

A lithotripter is a device that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient's abdomen and the shock waves are focused on the stone which is shattered by the force.

Lithotripter Utilization

Lithotripter utilization can be reasonably estimated by the the incidence of urinary stone disease. Urinary stone disease or urolithiasis is a disease in which urinary tract stones or calculi are formed. The annual incidence of urinary stone disease or urolithiasis is approximately 16 per 10,000 population. The annual incidence would translate into 11,357 urinary stone disease cases per year in North Carolina based on the estimated population of the state on July 1, 1995.

Not all cases of urinary stone disease would be appropriately treated by lithotripsy; thus, the cases that could be treated by this technology would be less than the 11, 357 cases that occur annually. It has been estimated that 85% to 90% of kidney stone patients, when surgery is indicated, can be treated successfully by ESWL treatment. The above estimate translates to 10,221 cases based on 90% that could be treated by ESWL; thus, approximately 10,000 patients have the potential to be treated by lithotripsy per year.

The annual treatment capacity of a lithoripter has been estimated at between 1,000 and 1,500 cases.

North Carolina Utilization

The number of lithotripsy procedures reported in North Carolina for the period of 1995-96 was 5,194 procedures with one provider report missing. There were 14 lithotripsy units operated by 10 providers.

Procedures were provided by fixed units at three hospitals, and by 11 mobile units operated by 7 providers. The average number of procedures per lithotripter per year is 371.

Access

Because of the mobility of lithotripter services, and the subsequent number of sites from which the service is provided, it may be concluded that geographic access is available to the maximum economically feasible extent.

Other States' Need Determination Methodologies

In the December, 1992 State of Tennessee's Health Guidelines for Growth, the methodology for determining need for extracorporeal shock wave lithotripsy services (ESWL) was the following:

ESWL Need = 1 ESWL Unit per 1,000,000 Population
The need shall be based upon the 1995 population projected four (4) years forward.

If North Carolina used the above methodology and projected population to July,1999, the need for lithotripters would be a maximum of 8 lithotripters providing service in the state.

In the 1992-1995 Kentucky State Health Plan, the methodology was stated as follows:

No additional renal ESWLs shall be approved, unless every existing renal ESWL in the state performed at least 1,000 procedures in the previous year. One thousand procedures represents 50 percent utilization of 50 weeks of operation at 40 hours per week allowing an average of one hour per procedure.

If North Carolina used the above methodology, the need for lithotripters would be held to the present number of 14 lithotripters providing service in the state. In North Carolina there are 13 lithotripters that do not meet the threshold of 1,000 procedures per year.

North Carolina's Need Determination Methodology

North Carolina uses a methodology based on the incidence of urinary stone disease. The need is linked to the above estimate of 11,357 cases and based on the assumption that 90% could be treated by ESWL; thus, approximately 11,000 patients in the state have the potential to be treated by lithotripsy per year.

With an annual treatment capacity of a lithoripter being estimated at between 1,000 and 1,500 cases, the maximum number of lithotripters needed in the state would be 11, based on the 11,357 cases and 1,000 procedures per lithotripter.

Need Determination

There are 14 lithotripters in the state and the proposed methodology indicates a maximum need of 11 lithotripters in the state. As a result, it is determined that there is no need for additional lithotripters in the state.

Lithotripsy Services in North Carolina

The ten providers which offer lithotripsy services in North Carolina are listed in the following pages.

Providers of Mobile Lithotripsy for Year 1996

1. **Carolina Lithotripsy, Ltd.**
   2008 Litho Place
   Fayetteville, North Carolina 28304
   Number of Lithotripters: 2
   Dates of Purchase: 1989, 1992
   Approximate Purchase Price: $1.2 - $1.3 million
   Number of Entities Provided Services: 25
   Total Number of Procedures Performed: 1,581

Area Served

Eastern North Carolina		# of Procedures
Hospitals:		
Sampson County Memorial Hospital, Inc.	Clinton	26
Cape Fear Valley Medical Center	Fayetteville	184
Columbia Brunswick Hospital	Supply	32
Wilson Memorial Hospital	Wilson	57
Wayne Memorial Hospital	Goldsboro	83
Pitt County Memorial Hospital	Greenville	147
Lenoir Memorial Hospital	Kinston	69
Carteret General Hospital	Morehead City	28
Southeastern General Hospital	Lumberton	119
Craven Regional Medical Center	New Bern	98
Moore Regional Hospital	Pinehurst	129
Raleigh Community Hospital	Raleigh	70
Franklin Regional Medical Center	Louisburg	1
Halifax Memorial Hospital, Inc.	Roanoke Rapids	23
Richmond Memorial Hospital	Rockingham	49
Johnston Memorial Hospital	Smithfield	48
Onslow Memorial Hospital	Jacksonville	13
Beaufort County Hospital	Washington	42
Columbus County Memorial Hospital	Whiteville	97
New Hanover Memorial	Wilmington	185
Heritage Hospital	Tarboro	22

Non-Hospitals:		
Blue Ridge Day Surgery	Raleigh	2
Fayetteville Ambulatory Surgical Center	Fayetteville	40
SurgeCenter of Wilson	Wilson	6
Jacksonville Surgery Center	Jacksonville	11
Total:		**1,581**
Average # of Procedures Per Lithotripter:		**791**

2. **Catawba Memorial Hospital**
810 Fairgrove Church Road
Hickory, NC 28602

Number of Lithotripters: 2
Dates of Purchase: 1990, 1991
Approximate Purchase Price: $1.56 million for a new one
$ .61 million for a used one
Number of Entities Provided Services: 8
Total Number of Procedures Performed: 560

Area Served

Western and Central North Carolina		**# of Procedures**
Hospitals:		
UNC Hospitals	Chapel Hill	68
Haywood County Hospital	Clyde	85
Scotland Memorial Hospital	Laurinburg	65
Catawba Memorial Hospital	Hickory	77
Frye Regional Medical Center	Hickory	92
The McDowell Hospital	Marion	69
Grace Hospital, Inc.	Morganton	49
Rutherford Hospital, Inc.	Rutherfordton	55
Total:		**560**
Average Number of Procedures Per Lithotripter:		**280**

3. **Fayetteville Lithotripters**
Limited Partnership -SC II
2008 Litho Place
Fayetteville, NC 28304

Number of Lithotripters: 1
Dates of Purchase:
Approximate Purchase Price:
Number of Entities Provided Services: 4
Total Number of Procedures Performed: 154

Area Served

Western North Carolina		# of Procedures
Hospitals:		
St. Luke's Hospital , Inc.	Columbus	11
Park Ridge Hospital	Fletcher	4
Margaret R. Pardee Memorial Hospital	Hendersonville	84
C. J. Harris Regional Hospital	Sylva	55
Total:		154
Average # of Procedures Per Lithotripter:		154

4. **Fayetteville Lithotripters**
Limited Partnership -Virginia I
2008 Litho Place
Fayetteville, NC 28304

Number of Lithotripters: 1
Dates of Purchase:
Approximate Purchase Price:
Number of Entities Provided Services: 1
Total Number of Procedures Performed: 47

Area Served

Eastern North Carolina		# of Procedures
Hospitals:		
Albemarle Hospital, Inc.	Elizabeth City	47
Total:		47
Average # of Procedures Per Lithotripter:		47

5. Piedmont Stone Center
Suite 103-104 3000 Bethesda Place
Winston-Salem, NC 27103

Number of Lithotriptors: 3
Dates of Purchase:
Approximate Purchase Price: $4.0 Million
Number of Entities Provided Services: 17
Total Number of Procedures Performed: 1679

Area Served

Western and Central North Carolina		# of Procedures
Hospitals:		
Randolph Hospital, Inc.	Asheboro	33
Franklin Regional Medical	Louisburg	4
Watauga Medical Center	Boone	121
Alamance Regional	Burlington	76
Morehead Memorial Hospital	Eden	46
The Moses H. Cone Memorial Hospital	Greensboro	269
High Point Regional Hospital	High Point	202
Wilkes Regional Medical Center	North Wilkesboro	31
Annie Penn Memorial Hospital	Reidsville	33
Rowan Memorial Hospital, Inc.	Salisbury	59
Columb. Davis Community Hospital	Statesville	104
Iredell Memorial Hospital	Statesville	58
Community General Hospital	Thomasville	2
Valdese General Hospital	Valdese	20
Maria Parham Hospital	Henderson	54
Alleghany Memorial	Sparta	52
Non-Hospitals:		
Piedmont Stone Center	Winston-Salem	515
Total:		**1,679**
Average # of Procedures Per Lithotripter:		**560**

6. **The Stone Institute**
Limited Partnership
1600 E. Fifth Street
Charlotte, NC 28204

Number of Lithotripters: 1
Dates of Purchase: 1991
Approximate Purchase Price: $2.0 Million
Number of Entities Provided Services: 8
Total Number of Procedures Performed:

Area Served

Western and Central North Carolina		**# of Procedures**
Hospitals:		
Stanley Memorial Hospital	Albemarle	
Presbyterian Speciality Hospital	Charlotte	
Cabarrus Memorial Hospital	Concord	
Gaston Memorial Hospital	Gastonia	
Lincoln County Hospital	Lincolnton	
Union Memorial Hospital	Monroe	
Lake Norman Regional Medical Center	Mooresville	
Cleveland Memorial Hospital, Inc.	Shelby	
Total:		**No Report**

Average # of Procedures Per Lithotripter:

7. **Triangle Lithotripsy Corporation**
c/o American Diagnostic
7003 Chadwick Drive #321
Brentwood, TN 37027

Number of Lithotripters: 1
Dates of Purchase: 1990
Approximate Purchase Price: $1.7 - 1.9 Million
Number of Entities Provided Services: 6
Total Number of Procedures Performed: 698

Area Served

East Central North Carolina		**# of Procedures**
Hospitals:		
Western Wake Medical Center	Cary	43
Rex Hospital	Raleigh	203
Wake Medical Center	Raleigh	32
Central Carolina Hospital	Sanford	102
Nash Day Hospital	Rocky Mount	146
Non-Hospitals:		
Durham Ambulatory Surgery Center	Durham	172
Total:		**698**
Average # of Procedures Per Lithotripter:		**698**

1995 Providers of Fixed-Base (Hospital) Lithotripsy

1. **Duke-UNC Lithotripsy Center**
   Number of Lithotriptors: 1
   Date of Purchase: No review in 1995
   Approximate Purchase Price:
   Total Number of Procedures Performed:

Area Served

East Central North Carolina	# of Procedures
Total:	
Average # of Procedures Per Lithotripter:	New Service

2. **N. C. Baptist Hospitals, Inc.**
   300 S. Hawthorne Road
   Winston-Salem, NC 27103
   Number of Lithotriptors: 1
   Dates of Purchase: 8/15/85
   Approximate Purchase Price: $1.61 million
   Total Number of Procedures Performed: 107

Area Served

Western and Central North Carolina	# of Procedures
	107
Total:	**107**
Average # of Procedures Per Lithotripter:	**107**

3. **St. Joseph's Hospital**
   428 Biltmore Ave.
   Asheville, NC 28801
   Number of Lithotripters: 1
   Dates of Purchase: 04/1987
   Approximate Purchase Price: $1.1 million
   Total Number of Procedures Performed: 368

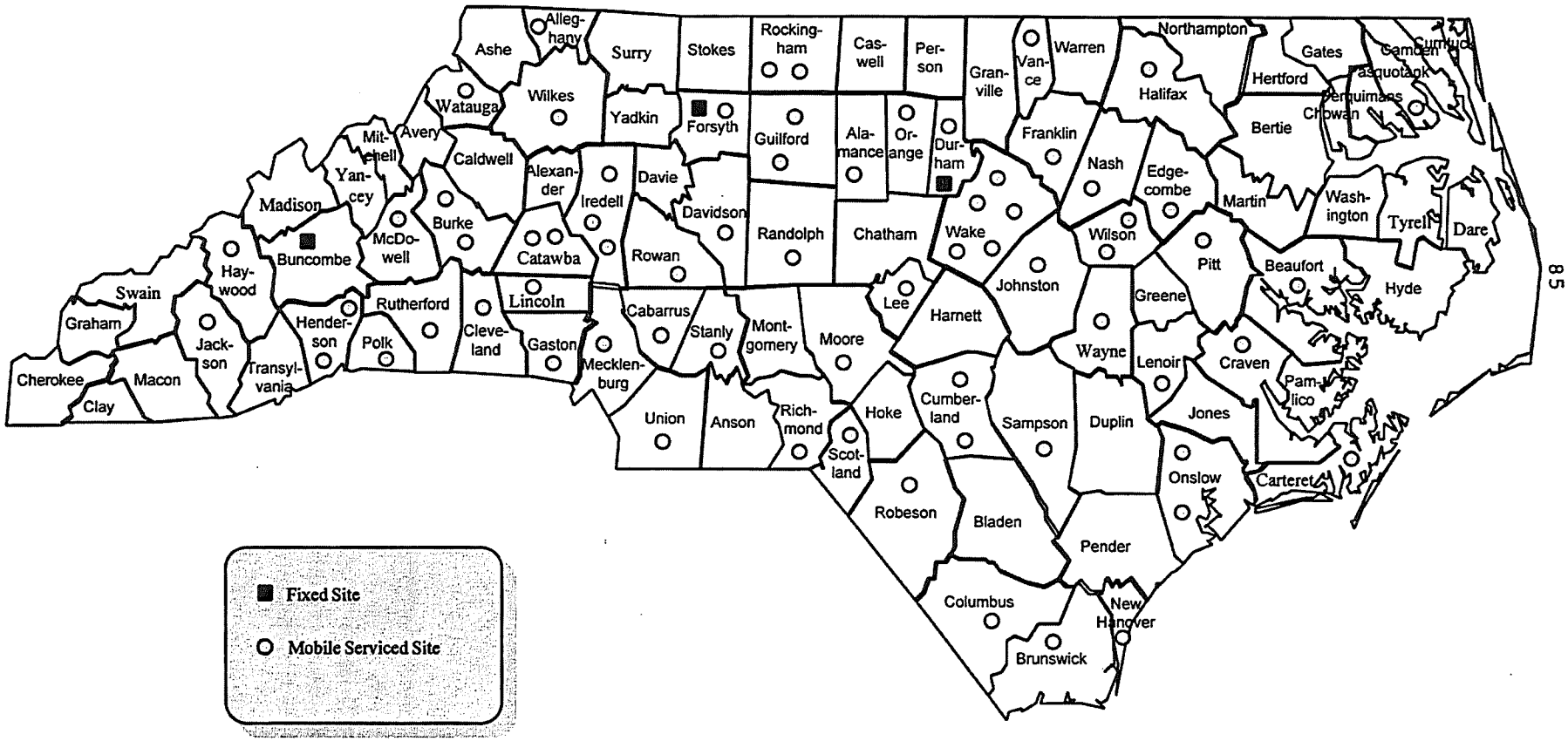
Area Served

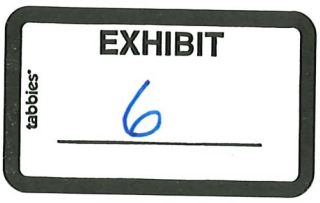
Western North Carolina	# of Procedures
	368
Total:	368
Average # of Procedures Per Lithotripter:	368

GRAND TOTALS

Number of Procedures:	5,194
Number of Lithotripters:	14
Average Number of Procedures Per Lithotripter:	371

Lithotripsy Service in North Carolina
May, 1997





UNC | SCHOOL OF MEDICINE
Urology

UNC releases study projecting future Urologist work force shortage

May 6, 2013

MAY 05, 2013 – Researchers are predicting that the number of urologists in the United States will fall sharply over the next 12 years, dropping by 29% by 2025 compared to 2009. The decline could boost mortality rates from several types of cancer and leave rural areas especially vulnerable to a shortage of urologic surgeons.

> "The demand is going to go up, and there aren't going to be enough of us," Raj S. Pruthi, MD, of the University of North Carolina at Chapel Hill

This will be good for existing urologists as they face greater demand for their services, Dr. Pruthi said. But in the big picture, he said, the urologist shortage threatens effective health care in the United States.

Dr. Pruthi and colleagues project a 29% decrease in the number of urologists from 2009-2025 and a 25% dip in full-time equivalent positions.

The study authors recalculated their projections to take into account possible increases in physicians due to proposals, such as federal legislation, to increase the number of doctors in the pipeline. But the projections barely changed.

What to do? Jed Ferguson, MD, a study co-author also from the University of North Carolina, said a variety of strategies are needed, including more funding for urologist training, increased use of non-physician providers, and more urology-related care by primary care providers.

Dr. Pruthi said the researchers will next try to adjust their projections to take into account the work habits of female urologists (whose numbers are on the rise) and young urologists from the millennial generation. Members of these groups tend to have different views about the work-life balance than other urologists, he said, and that can affect the amount of patient care that they're willing to take on.

More from Department of Urology

Kathryn Hacker Gessner, MD, PhD Receives Prestigious Pope Clinical Trainee Award

Urologists at UNC Perform Advanced "Fusion" Biopsies, Helping to Provide Enhanced Prostate Cancer Detection

Dr. Friedlander Selected as UNC IHQI Improvement Scholar

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Our Priority: Address the Urologic Workforce Shortage

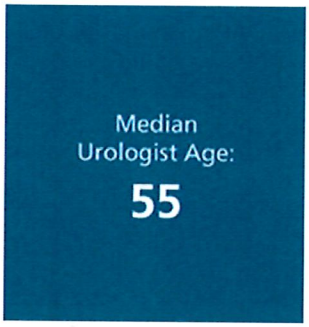
Why the Issue Matters

The United States is facing an overall shortage of physicians. Projections have shown that at least half of the shortage is among specialty medicine physicians such as urologists. In fact, over 60 percent of all U.S. counties have a practicing urologist, there have been significant declines in the number of urologists per capita, and the average age of a practicing urologist makes the specialty one of the oldest in the medical profession. While the number of specialty medicine physicians, such as urologists, is decreasing and the

average age is increasing, 53.8% of urology residents have more than $150,000 in student loan debt, and for 26.8% of them, the figure is $250,000 or more.

It is imperative that we work to address the workforce shortage in all urologic access practice environments, preserve access to appropriate and timely care, expand access to care with innovations including telemedicine, and advocate for increased graduate medical education (GME) funding and resources for urology positions.

Fast Facts



What the AUA is Doing

Coalition Activity

The AUA is an active member of the GME Advocacy Coalition, which is a group of hospital, physician, academic, and specialty stakeholder organizations that advocate on issue directly impacting the physician workforce and training.

Active Legislation

S. 4330, Specialty Physicians Advancing Rural Care Act – introduced by Sens. Jacky Rosen (D-NV) and Roger Wicker (R-MS) - would repay student loan debt for specialty physicians practicing in a rural setting:

- Payment of 1/6th of principal and interest paid annually for each year of full-time service in a practice in a rural setting
- Payment to $250,000 total
- Eligible loans include:
  - Any loan for education in specialty medicine
  - Any Federal Direct Stafford Loan
  - Federal Direct PLUS Loan
  - Federal Direct Unsubsidized Stafford Loan
  - Federal Direct Consolidation Loan

- Any Federal Perkins Loan
- Any other Federal loan as determined appropriate by the Secretary

Read the AUA's press release about H.R. 5924.

Take Action on this Bill

H.R. 2256 & S. 834, The Resident Physician Shortage Reduction Act – introduced in the House by Reps. Terri Sewell (D-AL-07), John Katko (R-NY-24), Thomas Suozzi (D-NY-03), and Rodney Davis (R-IL-13) and in the Senate by Sens. Bob Menendez (D-NJ), John Boozman (R-AR), and Chuck Schumer (D-NY) – would:

- Increase the number of GME residency slots by 14,000 over the next seven years;
- Direct half of the newly available positions to training in shortage specialties such as urology;
- Specify priorities for distributing the new slots (e.g., states with new medical schools); and
- Study the needs of the U.S. healthcare system to allocate residencies accordingly.

American Urological Association

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EXHIBIT
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8

Urology: Supply, Demand and Recruiting Trends

A resource provided by Merritt Hawkins, the nation's leading physician search and consulting firm and a company of AMN Healthcare (NYSE: AMN), the largest healthcare workforce solutions company in the United States.

MERRITT HAWKINS
an AMN Healthcare company

UROLOGY: SUPPLY, DEMAND AND RECRUITING TRENDS

INTRODUCTION

Merritt Hawkins, the nation's leading physician and advanced practitioner search and consulting firm, produces a series of surveys, white papers, speaking presentations and other resources intended to provide insight into various healthcare staffing and recruiting trends.

Topics for which Merritt Hawkins has provided data and analyses include physician compensation, physician practice metrics, physician practice plans and preferences, rural physician recruiting recommendations, physician retention strategies, physician visa requirements, and the economic impact of physicians, among a variety of others.

This white paper examines supply, demand and recruiting trends pertaining to urology.

DEVELOPMENT OF UROLOGY

The word "urology" is derived from the Greek ouron "urine" and logia "study of."

In ancient times, physicians used the general state of health of the entire body to judge a patient's condition, and did not attach much importance to uroscopy (the examination of urine). However, several ancient Greek writers described in a generally accurate manner afflictions of the urinary tract, laying particular importance on the color of the urine and on urinary sediment (European Museum of Urology. *History.uroweb.org/history-of-urology/*).

In the 16th and early 17th centuries the first attempts were made to replace uroscopy by chemical and physical methods. In the 18th century widespread interest in the chemistry of urine led to the discovery of both normal and pathological urine-constituents. Hermann Boerhaave (1688-1738), a Dutch botanist, chemist and physician was the first to isolate the chemical urea from urine, and he also invented a method to determine the specific gravity of urine.

It was not until the 19th century that the urinary tract could be inspected by technical means. The first attempts to make the urethra visible to the human eye go back to the Frankfurt physician Philipp Bozzini. Eventually, the invention of the cystoscope by Maximilian Nitze paved the way to modern urology.

CURRENT ROLE OF UROLOGY

Today, urology (also known as genitourinary surgery) is the branch of medicine focusing on surgical and medical diseases of the male and female urinary tract system and the male reproductive organs. Organs under the domain of urology include the kidneys, adrenal glands, ureters, urinary bladder, and the urethra, as well as the male reproductive organs, including the testes, epididymis, vas deferens, seminal vesicles, prostate and the penis.

According to Wikipedia:

> The urinary and reproductive tracts are closely linked, and disorders of one often affect the other. Thus a major spectrum of the conditions managed in urology exists under the domain of genitourinary disorders, and combines the management of medical (i.e., non-surgical) conditions, such as urinary-tract infections and benign prostatic hyperplasia, with the management of surgical conditions such as bladder or prostate cancer, kidney stones, congenital abnormalities, traumatic injury, and stress incontinence.

Current urological techniques include minimally invasive robotic and laparoscopic surgery, laser-assisted surgeries, and other scope-guided procedures. Urologists receive training in open and minimally invasive surgical techniques, employing real-time ultrasound guidance, fiber-optic endoscopic equipment, and various lasers in the treatment of multiple benign and malignant conditions. Urology is closely related to (and urologists often collaborate with the practitioners of) oncology, nephrology, gynecology, andrology, pediatric surgery, colorectal surgery, gastroenterology and endocrinology.

EDUCATION AND TRAINING

The path to becoming a urologist is a long and challenging one. A four-year college degree is required as well as the completion of four years of medical school. Medical school requires the completion of such classes as medical ethics, embryology, genetics, neuroscience and biochemistry. In the third and fourth year, students apply their classroom knowledge through clinical rotations.

Mandatory clinical rotations include internal medicine and psychiatry, and students also can choose elective rotations. Since urology is not usually one of the required rotations, students can choose it as an elective during their fourth year of medical school in order to get a better understanding of the field.

After graduating from medical school, students must complete a residency.

For more than 35 years, the American Urological Association (AUA) in conjunction with the Society of Academic Urologists has overseen the Urology Residency Match Program (a.k.a. Urology Match) for residency positions. Urology therefore is not part of the conventional national resident match. Annually, the Urology Residency Match consists of approximately 450 highly competitive applicants that apply for nearly 325 positions, of which virtually all are filled. The AUA has also expanded its services to fellowship matches, including pediatrics, urologic oncology, andrology, endourology and male reconstruction.

Urology is one of the most competitive and highly sought surgical specialties for physicians, with new urologists comprising less than 2% of United States residency graduates each year.

Urology residencies are a minimum of five years in length. Depending on the program, the time may be split by completing a two-year general surgery residency and three years focusing on urology training. For those who are interested in a subspecialty of urology, a one to three-year post-residency fellowship is also required. Once all educational and training requirements have been completed, physicians are eligible to take the exam to become board certified in urology.

UROLOGIC SUBSPECIALTIES

Upon successful completion of a residency program, many urologists choose to undergo further advanced training in a subspecialty area of expertise through a fellowship lasting an additional 12 to 36 months. Urology subspecialties may include:

- Urologic surgery
- Urologic oncology and urologic oncological surgery
- Endourology and endourologic surgery
- Urogynecology and urogynecologic surgery
- Reconstructive urologic surgery (a form of reconstructive surgery)
- Transplant urology (the field of transplant medicine and surgery concerned with transplantation of organs such as the kidneys, bladder tissue, ureters, and, recently, penises)
- Pediatric urology and pediatric urologic surgery (including adolescent urology, the treatment of premature or delayed puberty, and the treatment of congenital urological syndromes, malformations, and deformations)
- Robotic & laparoscopic surgery
- Female pelvic medicine and reconstructive surgery
- Male infertility/microsurgery/andrology
- Voiding disfunction

SCOPE OF PRACTICE

Urologists work in medical centers, clinics and private practice. Some urologists also conduct research on new treatments, procedures and medications for various urological conditions.

According to the 2019 American Association of Urology (AUA) Urology Census Report, practicing urologists see a median of 70 patients per week, or 3,640 patients per year. Approximately 53% of practicing urologists in the United States work in private practice (down from 60% in 2017), while 46% percent practice in institutional settings such as hospitals or academic medical centers (up from 40% in 2017), the AUA report indicates.

Urologists combine office-based consultations and patient management with surgery. Kidney stone patients comprise many of the patients of some urologists, and many urologists carve out a subspecialty interest.

A typical week for a general urologist is somewhere between two and four days in the office and then one and two OR days. Sometimes they will have a day consisting of office in the morning and then a two- to three-hour procedure in the afternoon.

When in the office, they may see a mix of new and returning patients and perform some office-based procedures, such as endoscopic checks of the bladder, vasectomies, or biopsies of the prostate under ultrasound.

According to Medscape's 2020 Urology Compensation Report, male urologists spend an average of 43 hours per week seeing patients and 15 hours a week on administrative/paperwork duties. Female urologists spend 38.9 hours a week seeing patients and 15 hours a week on paperwork/administrative duties.

Call duties in urology typically are relatively light. Most of the issues can be dealt with by emergency room physicians or with basic techniques known to other types of providers. When urologists do get called, the issue often can be dealt with over the phone, in contrast to other surgical specialties where physicians must perform operations in the middle of the night. Urology is a highly sought-after specialty in part because it offers a relatively controllable lifestyle.

A patient may be referred to a urologist for treatment of a range of conditions, including:

Urinary tract infections (UTIs): These often arise when bacteria migrate from the digestive tract to the urethra. Symptoms include abnormal urination, pain, incontinence, nausea, vomiting, fevers, and chills.

Incontinence: A malfunction in the urinary system can lead to involuntary loss of bladder control.

Male infertility: This can result from damage to the male reproductive tract and a variety of sperm disorders.

Kidney disease: Damage to the kidneys can lead to swelling in the hands and ankles, high blood pressure, and other symptoms.

Renal transplantation: A person may require kidney transplants following kidney failure.

Urologic oncology: Treatment of cancers that relate to the urological or male reproductive system, such as bladder cancer and prostate cancer.

Bladder prolapse: When the tissues and muscles of the pelvic floor are no longer able to support the organs in the pelvis, the organs can drop from their usual position.

Cancers: Of the bladder, kidneys, prostate gland, testicles, and any other cancer that affects the urinary system or, in men, the reproductive system.

Enlarged prostate: Benign prostatic hyperplasia (BPH) affects around 1 in 3 men over the age of 50 years. An overgrowth of cells in the prostate gland causes the urethra to constrict, leading to problems with urination.

Erectile dysfunction: The penis is unable to attain sufficient rigidity to fully participate in sexual intercourse.

Peyronie's disease: A fibrous layer of scar tissue develops beneath the skin of the penis.

Interstitial cystitis or painful bladder syndrome: A chronic inflammatory bladder condition can produce discomfort ranging from mild to severe.

Kidney and ureteral stones: Small, hard deposits made from mineral and acid salts form in the kidneys but can pass through into the ureters.

Prostatitis: Infection or inflamation of the prostate can cause painful urination or ejaculation.

Undescended testes, or cryptorchidism: Normally, the testicles form inside the abdomen of a fetus and descend into the scrotum before birth. If one or both does not descend, sperm production can be impaired, and there is a risk of complications.

Urethral stricture: Scarring of the urethra can narrow or block the path of urine flowing from the bladder.

Pediatric urology: This includes the treatment of urological problems in children that are too complex for non-specialized pediatricians.

UROLOGY SUPPLY AND DEMAND TRENDS

Urology is one of a variety of specialties for which there is a rising demand in the U.S. and a limited supply (for more information on this topic, see Merritt Hawkins' white paper *Physician Supply Considerations: The Emerging Shortage of Specialists*).

In its June, 2020 report, the Association of American Medical Colleges (AAMC) projected a shortage of up to 139,000 physicians nationally by 2033. This will include a shortage of up to 55,000 primary care physicians, but an even larger shortage of up to 85,000 specialists (*The Complexities of Physician Supply and Demand: Projections From 2018 to 2033. Association of American Medical Colleges. June, 2020*).

In general, these shortages will be driven by demographic trends; in particular, the aging of the patient population and the aging of the physician workforce. A recent American Urologic Association (AUA) survey reported that 52% of practicing urologists are 55 years of age or older, while nearly 30% are 65 or older.

This suggests that perhaps half of the urologic workforce will retire from active practice within the next decade. Compounding the "graying" of urologists is a maldistribution of urologists. The same AUA survey verified that 72% of United States counties have either one or no urologist (*The State of the Urology Workforce and Practice in the U.S. American Urological Association. 2017*).

According to the Healthcare Resource and Services Administration's (HRSA) 2016 *Regional Projections of Supply and Demand for Surgical Subspecialty Practitioners*, there will be a deficit of 3,630 urologists by 2025.

The chart below indicates the current composition of urologists in full-time, active patient care roles:

UROLOGY SPECIALTY DEMOGRAPHICS		
Total	11,119	
In full-time, active patient care	9,094	
Board Certified	7,902	87% of those in active patient care
International medical graduates	1,079	12%
Administrative/teaching	118	1%
Last year residents	303	3%
Female	784	9%
Male	8,310	91%
45 or older	6,976	77%
55 or older	8,410	52%

Source: American Medical Association Physician Master File

As these numbers indicate, comparatively few urologists are international medical graduates (IMGs) – 12% compared to approximately 25% of all physicians. In addition, comparatively few are female – 9% compared to approximately 35% of all physicians. Most notably, urologists are among the oldest specialists on average (see chart below).

SPECIALTIES	PERCENT OF PHYSICIANS 55 OR OLDER
Pulmonology	73%
Psychiatry	60%
Cardiology (Non-Inv.)	54%
Orthopedic Surgery	52%
Urology	52%

SPECIALTIES	PERCENT OF PHYSICIANS 55 OR OLDER
Ophthalmology	48%
General Surgery	48%
Gastroenterology	45%
Anesthesiology	44%

Source: American Medical Association Physician Master File

Practice patterns change as urologists age. The AUA reports that urologists who continue to practice beyond age 65 see fewer patients than their under 65-year-old colleagues. Specifically, using 100 patient visits per week as a gauge of high office volume, only 8.2% of urologists over 65 see that threshold compared to 24.3% and 22.2% of urologists in the 55 to 64 and 45 to 54 age groups, respectively (*When Are Doctors Too Old to Practice? Wall Street Journal. July 25, 2017. L. Lagnado*). The aging of the urologist workforce therefore represents a loss of FTEs even before older urologists retire because they see fewer patients as they age.

DEMOGRAPHIC DESTINY

A large portion of urologic practice revolves around providing care for older patients. Following is an excerpt from a February 14, 2018 article published by Harvard Medical School that puts this challenge into perspective:

> Concurrent with the aging of practicing urologists will be the aging of the American population. In 2010, 13% of the population was aged 65 or older, by 2030 this will increase to 19%. Complicating the challenges of caring for an aging population is the fact that the elderly require more urologic care. According to CDC data, in 2010, 51% of all urologic visits were in patients over the age of 65. CDC data further show that in the 45- to 64-year-old group, there is an average of 8 urologic visits per 100 patient years. This increases to 22 visits per 100 patient years in the 65- to 74-year-old group and to 30 visits per 100 patient years in the 75-year-old and above group. (Addressing the Urology Shortage. Kevin Laughlin, M.D. Harvard Medical School. February 14, 2018.)

Over 10,000 Baby Boomers turn 65 in the U.S. every day, a fact that is driving demand for urologists and many other types of specialists steadily upward. Meanwhile, the supply of new urologists remains limited, with just over 300 completing their training and joining the workforce each year. As referenced in the AUA study cited above, this is not enough to supply urologists to many areas of the country in the ratios in which they are needed (see chart below).

SUGGESTED RATIO OF UROLOGISTS REQUIRED PER 100,000 PEOPLE	
Richard Cooper, M.D./University of Pennsylvania	3.4
Solucient	2.9
Hicks & Glenn	2.9
Graduate Medical Education National Advisory Committee (GMENAC)	3.2

The likelihood that additional urologists will be trained, and the number of new entrants increased, is limited due to the 1997 cap Congress placed on funding for physician graduate medical education. The cap was lifted in 2020 as a provision of the Covid-19 relief bill, but funding was only added for 1,000 additional residencies across all specialties. Many of these will likely be reserved for primary care and very few for urology.

EFFECT OF FEMALE AND YOUNGER UROLOGISTS

Urology has traditionally been a specialty dominated by male physicians. While it continues to be a male-dominated field, there are signs of change. Today, some urology training programs have more female than male residents. It is forecasted that the number of female urologists will increase from 7% in 2015 to 18.6% in 2035 (*Addressing the Urology Shortage. Kevin Laughlin, M.D. Harvard Medical School. February 14, 2018*). Among current urologists 45 or younger, 22% are female.

While this is will bring more diversity to the urology workforce, it may have the effect of reducing overall FTEs. In the *2018 Survey of America's Physicians* conducted by Merritt Hawkins on behalf of The Physicians Foundation, female physicians reported seeing 12% fewer patients than male physicians.

Recent urology graduates have undergone their training during the era when residency schedules have been restricted to 80 work hours per week. Many of them have expressed a greater interest in work-life balance. Although it may be attributable to multiple factors, the 2017 AUA Census reports that urologists under the age of 45 see fewer patients per week than any other age group, including urologists over 65 (*The State of the Urology Workforce and Practice in the U.S. American Urological Association. 2017*). This trend may also reduce total FTEs in the specialty.

A PERSISTING MALDISTRIBUTION OF UROLOGISTS

The AUA report cited above indicates that 72% of U.S. counties have one or no urologist. In some cases, this is understandable, as physician-to-population ratios indicate one urologist requires a base of about 30,000 patients and some smaller communities simply do not have the population to support a urologist. However, many other smaller communities could support a urologist but may be unable to find one.

Compounding the problem is the fact that younger urologists and female urologists are less likely to settle in rural areas. Approximately 7% of urologists under age 45 practice outside metropolitan areas compared to 9–14% of urologists in other age groups, according to the AUA. Because women urologists are also less likely to practice in rural areas, the urologist maldistribution is likely to become more intense in future years.

USE OF PAs AND NPs BY UROLOGISTS

Given these shortages, it is likely that more urology services will be provided by advanced practice professionals (APPs) such as physician assistants (PAs) and nurse practitioners (NPs).

APPs can see both new and return patients and can be trained to perform straightforward office-based procedures. They can also assist by managing inpatients and seeing consults.

The percentage of urologists who work in their primary practice with at least one advanced practice provider, including physician assistants or nurse practitioners, significantly increased from 62.7% in 2015 to 71.4% in 2019, according to the AUA.

THE EFFECT OF COVID-19 AND TELEHEALTH

For much of 2020, the Covid-19 pandemic suppressed utilization of non-virus-related treatments and procedures. This will likely create a backlog of work for urologists and many other types of specialists as the Covid-19 crisis is resolved.

The pandemic has greatly increased utilization of telemedicine across a variety of specialties and is likely to do so in urology. While less than 12% of practicing urologists were using telemedicine prior to the pandemic, according to the AUA, that number may be higher now, particularly as a means of conducting office visits.

Evolving technology also has the potential to increase urologist productivity and thereby expand FTEs. New, minimally invasive

therapies for benign prostatic hyperplasia, including Rezum, which employs water vapor therapy to induce prostatic tissue necrosis, as well as Urolift, which utilizes stainless steel brackets to widen the prostatic urethra, are showing promise as alternatives to traditional transurethral resection of the prostate.

MERRITT HAWKINS RECRUITING ENGAGEMENTS

Urology currently ranks 14th on Merritt Hawkins' list of most requested physician search engagements. However, it may be more revealing to note where urology ranks in terms of "absolute demand." In calculating "absolute demand" for physicians in various specialties, Merritt Hawkins considers number of search engagements for the specialty relative to the number of physicians in that specialty (i.e., job openings versus physicians available to fill them). In terms of absolute demand, urology ranks fourth among Merritt Hawkins' search engagements (see below):

MERRITT HAWKINS TOP SEARCH ENGAGEMENTS BY "ABSOLUTE DEMAND"
1. Hematology/Oncology
2. Radiology
3. Psychiatry
4. Urology
5. Cardiology
6. Family Medicine
7. Gastroenterology

Source: Merritt Hawkins 2020 Review of Physician and Advanced Practitioner Recruiting Incentives.

Given the supply and demand dynamics outlined above, we expect urology to be a high demand specialty, and a challenging specialty to fill, for the foreseeable future.

COMPENSATION IN UROLOGY

In its annual *Review of Physician and Advanced Practitioner Recruiting Incentives*, Merritt Hawkins tracks the starting salaries, signing bonuses and other incentives offered by our clients when recruiting physicians in various specialties. Below are low, average and high starting salaries for urologists as cited in the 2020 Review:

LOW	MEDIUM	HIGH
$300,000	$477,000	$625,000

Various sources track compensation/average income for urologists and other physicians. Data from some of these sources are

cited below:

SOURCE	AVERAGE
Sullivan Cotter	$497,595
Merritt Hawkins	$477,000
Medical Group Management Association	$475,377
American Medical Group Association	$469, 755
Integrated Health Strategies	$465,202
ECG Management	$449,605
Medscape	$417,000

It should be noted that Merritt Hawkins' data differs from other sources cited above in that we report starting salaries offered to urologists, rather than total pre-tax annual compensation. In general, Merritt Hawkins averages are usually lower than those of other sources, though our urology numbers are higher, underscoring the current strong demand for these physicians.

PRODUCTION INCENTIVES

The majority of urologist contracts Merritt Hawkins sees feature an incentive/production bonus allowing the physician to earn above the base salary offer. The *2020 Medscape Physician Compensation Report* indicates the average incentive bonus earned by urologists is $64,000. As a measure of urologist productivity, Statista indicates average work RVUs for urologists is 7,669, based on 2016 data.

UROLOGY RECRUITING RECOMMENDATIONS

As demand for urologists increases, so will the difficulty of recruiting these specialists. Hospitals, medical groups and other healthcare facilities that are seeking urologists should prepare to commit the required effort, flexibility, responsiveness and resources required to be successful in today's challenging market.

As when recruiting other types of physicians, when recruiting urologists it is important to structure the offer to be as appealing as possible to the widest number of potential candidates. Hospitals, medical groups and other facilities cannot control where they are located, or the lifestyle, educational and other amenities offered in their areas. However, they can control the quality of the practice being offered.

What urology candidates find appealing in a practice will vary, but there are some common denominators, including:

- Accessibility to a robot
- 4-4.5 day work week
- Call being no more than 1:4, if possible
- PA and NP support
- 2 days of dedicated OR time
- Ancillaries such as lithotripsy
- Efficient OR patient scheduling, admission and discharge
- Physician-friendly electronic health records (EHR)
- Covid-19 safety protocols/PPE availability
- Minimum possible paperwork duties, maximum patient consultation/OR time
- Ability to pursue a subspecialty
- Schedule flexibility
- Competitive compensation
- Fair, understandable productivity structure

Where compensation is concerned, it is important to come to the market with a competitive opportunity rather than coming in low and hoping to negotiate from there. Most urologist candidates are scheduling multiple interviews and virtually all of them are receiving extremely competitive offers. They often are not of the mindset that they need to engage in back and forth negotiations, because in many cases they already have offers that meet the majority of their requirements. What is considered competitive in urology compensation is a moving

target and cannot necessarily be determined based on data that is one or two years old.

Compensation offers in urology will vary from position to position and from region to region. A competitive offer for a new resident coming out of training in 2021 or 2022 can range anywhere from $400,000 to $525,000. For urologists with a track record of experience, offers may vary from $500,000 to $650,000.

It is important to be flexible and creative with the compensation package/incentives, including, when appropriate, such elements as:

- Residency stipends
- Student loan repayment
- Sign-on bonus, retention bonus
- Accelerated partnership track

Flexibility also is required when it comes to considering candidate parameters. Be open to international medical graduates and candidates of all ages if they display the competence, training and patient rapport you are seeking. As was referenced above, the majority of urologists are 55 or older, but the appropriate candidate may not be one of a particular age, he or she may simply be a physician with the requisite skills who wants to practice in your community.

CONCLUSION

As with all difficult searches, it is important in urology searches to be flexible, creative, and committed to quick turnarounds, accommodating the schedules of candidates, responding with information as needed, and making an offer as soon as an appropriate candidate is found. Know the market, know what is needed to be successful, and execute the search with the maximum amount of commitment and efficiency as possible.

ABOUT MERRITT HAWKINS

Established in 1987, Merritt Hawkins is the leading physician search and consulting firm in the United States and is a company of AMN Healthcare (NYSE: AMN), the largest healthcare workforce solutions organization in the nation. Merritt Hawkins' provides physician and advanced practitioner recruiting services to hospitals, medical groups, community health centers, telehealth providers and many other types of entities nationwide.

The thought leader in our industry, Merritt Hawkins produces a series of surveys, white papers, books, and speaking presentations internally and also produces research and thought leadership for third parties. Organizations for which Merritt Hawkins has completed research and analysis projects include **The Physicians Foundation, the Indian Health Service, Trinity University, the American Academy of Physician Assistants, the Association of Academic Surgical Administrators, The Maryland Medical Society, and the North Texas Regional Extension Center.**

This is one in a series of Merritt Hawkins' white papers examining a variety of topics directly or indirectly affecting the recruitment and retention of physicians and advanced practice professionals, including physician assistants (PAs) and nurse practitioner (NPs).

Additional Merritt Hawkins' white papers include:

- Physician Supply Considerations: The Emerging Shortage of Medical Specialists

- Physician Emotional Intelligence: Going Beyond "A-Type" Personalities
- Ten Keys to Enhancing Physician/Hospital Relations: A Guide for Hospital Leaders
- Rural Physician Recruiting Challenges and Solutions
- Psychiatry: "The Silent Shortage"
- NPs and PAs: Supply, Distribution, and Scope of Practice Considerations
- Supply, Demand and Recruiting Trends in Family Medicine
- Supply, Demand and Recruiting Trends in Internal Medicine
- The Economic Impact of Physicians
- International Physicians and Immigration Requirements: An FAQ
- The Growing Use and Recruitment of Hospitalists
- Staffing and Recruiting Considerations in Emergency Medicine

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The Urology Workforce in the 21st Century: Trends and Predictions

By: Christine Campisi, MS; Justin Loloi, MD; Amanda North, MD | Posted on: 01 May 2022

Print

According to the 2020 American Urological Association Census, there are 13,352 practicing urologists in the United States, an increase from 11,703 in 2014, when the first AUA Census was conducted.[1] The urologist-to-population ratio has also increased from 3.70 per 100,000 in 2014 to 4.07 in 2020. However, despite this increase 62% of counties in the United States currently have no practicing urologists, and the majority of urologists, approximately 90%, practice in a metropolitan area compared to just 0.4% practicing in rural areas.

Though the increased number of practicing urologists has positive implications, the demographic makeup of the workforce presents concerns for a future shortage in the field. Specifically, a considerable and increasing proportion of practicing urologists are over 65 years of age, increasing from 23% of urologists over the age of 65 in 2014 to 30% in 2020. Furthermore, the percent of practicing urologists under the age of 34 years has decreased from 7.2% in 2014 to 5.4% in 2020. In combination with increased demand from an aging population, an aging workforce is cause for concern as the number of postgraduate training positions may not be enough to replace a rising number of retiring surgeons.

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Projected US Urology Workforce per Capita, 2020-2060

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Abstract

IMPORTANCE Projections to 2035 have demonstrated concern regarding a worsening urology workforce shortage.

OBJECTIVE To project the size and demographic characteristics of the urology workforce per capita into 2060 and to anticipate the timing and degree of the impending urology workforce shortage.

DESIGN, SETTING, AND PARTICIPANTS This population-based cross-sectional study used the 2019 American Urological Association Annual Census data and the Accreditation Council for Graduate Medical Education's Data Resource Book from 2007 to 2018. The cohort included practicing urologists in 2019. US Census data were used to approximate the projected US population. Data analysis was performed from June 2020 to March 2021.

EXPOSURES Continued growth stock and flow model of 13.8% and stagnant growth model of 0% increase of the incoming urology workforce with cohort projection per projected US population.

MAIN OUTCOMES AND MEASURES The primary outcome was urology workforce projection per the population aged 65 years and older. Urology workforce projections per capita and demographic characteristics of the urology workforce up to 2060 were calculated under guided assumptions with 2 stock and flow models.

RESULTS In 2019, there were 13 044 urologists (11 758 men [90.1.%]; 1286 women [9.9%]; median age range, 55-59 years), with 3.99 urologists per 100 000 persons and 311 new urologists entering the workforce. In a continued growth model, 2030 will have the lowest number of urologists per capita of 3.3 urologists per 100 000 persons, and recovery to baseline will occur by 2050. There are 23.8 urologists per 100 000 persons aged 65 years and older in 2020, which decreases to 15.8 urologists per 100 000 persons aged 65 years and older in 2035 and never recovers to its baseline level by 2060. In a stagnant growth model, there will be a continued decrease of urologists per capita to 3.1 urologists per 100 000 persons by 2060. There is a continued decrease in per capita urologists at each time point, with 13.1 urologists per 100 000 persons aged 65 years and older by 2060.

CONCLUSIONS AND RELEVANCE With the impending urology workforce shortage, there will be an exaggerated shortage of total urologists per persons aged 65 years and older in both models. This projection highlights the need for structural changes and advocacy to maximize the available urology workforce.

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Key Points

Question What are the projected size and demographic characteristics of the urology workforce per capita in the US through 2060?

Findings In this cross-sectional study, 2 stock and flow models of continued (13.8%) and stagnant (0%) growth of the urology workforce based on the American Urological Association Annual Census data in 2019 and the US Census Bureau's projections showed that within the context of the impending urology workforce shortage, there will be an exaggerated shortage of total urologists per capita for populations aged 65 years and older.

Meaning These findings highlight the need for structural changes and advocacy to increase the available urology workforce.

+ Invited Commentary

Author affiliations and article information are listed at the end of this article.

Introduction

Multiple estimates have found impending workforce shortages across surgical fields due to the Balanced Budget Act of 1997, which limits the funding necessary to train residents and caps the number of government-subsidized residency positions. This workforce shortage will be exacerbated by the silver tsunami, where by 2030, the youngest members of the Baby Boomer generation will be in the Medicare age group that heavily uses health care services.[1-3] Urology is no exception, and our current supply of practicing urologists of 13 044 is still far short of the 14 400 urologists that the US Department of Health projected to be necessary to meet the demand for urological services.[1] The American Urological Association (AUA) has recognized the workforce shortage as a federal advocacy priority, with only 38% of all US counties having practicing urologists, recent declines in the number of urologists per capita, and older median age of urologists.[4] In addition, because the Medicare population uses urological services 3 times more often than the general population, there have been projections that even if we maintain the current number of urologists per capita, there will be a shortage of urologists by 46% in 2035.[5] This has substantial downstream consequences on access to care, delays for surgical evaluation, longer travel time for rural patients, and heightened pressure on practicing urologists to meet the increased demands, placing them at risk for burnout.[6] In addition to concerns of the workforce shortage, there have been concerns about how the future urology workforce can better reflect our patient population, particularly with regard to race and gender.[7] Despite growth of female representation in urology compared with other specialties, it continues to be a heavily male-dominated field with only 9.9% of practicing urologists being female.[8,9] Female urologists continue to be underrepresented relative to the 30% of urological patient population being female.[7]

There has not been an updated projection of the urology workforce per capita beyond 2035 with an understanding of the present-day urology workforce. The US Department of Health and Human Services recognizes that at least a decade is required to enact policies and programs to increase the physician workforce, given the length of training and time required to change physician training infrastructure.[1] Therefore, it is time critical to have a nuanced understanding of the impending workforce shortage in urology. Our study projects the urology workforce per capita and demographic representation over the next 40 years under guided assumptions with 2 stock and flow models. We hypothesize that in our continued growth model, there will be a recovery beyond the current 2020 urology workforce per capita, whereas in our growth stagnant model, we will see a continued decline in the urology workforce per capita. We also hypothesize that the urology workforce shortage per capita will be more severe for the population aged 65 years and older. Finally, we hypothesize that in the context of a decreasing number of urologists per capita in the next 4 decades, there will be an overall growth per capita of female urologists.

Methods

Because we used publicly available data, our institution deemed this analysis exempt from institutional review board oversight. Informed consent was waived by our institution for this reason. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines.

Current Practicing Urologists and US Population Data

According to the 2019 AUA Census, which defines the urologist population by National Provider Identifier, valid medical licenses of both urologists and pediatric urologists, and American Board of Urology certification records, there are currently 13 044 practicing urologists, including 11 758 men (90.1%) and 1286 women (9.9%).[10] The AUA Census provides the age distribution for all practicing urologists. These were used to estimate the number of practicing urologists by age and gender in 2020. Each gender and age are divided proportionally into 5-year age categories and used as the

estimate of practicing urologists by gender and age group in 2020. For US population data, we used the US Census Bureau 2017 national population projections based on the US Census data from 2010 using a cohort-component method and assumptions about demographic components of change, such as future trends in births, deaths, and net international migration from 2017 to 2060.[11]

Stock and Flow Model

The stock and flow model estimates the number of practicing urologists in a year with the addition of urology residents entering the current practicing urologist population and subtraction of the retiring urologists, as follows: $\text{urologists}_{i+1} = \text{urologists}_i + \text{residents}_i - \text{retirees}_i$, where i = half-decade increment in time. Given that 311 urologists entered the workforce in 2018 according to the Accreditation Council for Graduate Medical Education Data Resource Book, we assume that 320 urologists would enter the workforce annually.[8,10,12] Among those entering workforce in 2018, 24.4% were female.[12] The median age of those entering the workforce is 32 years.[8] We assume the future proportion will continue to be 25% female and 75% male and that they enter at 32 years of age.[8] For the growth model, we assume continued growth of urologists entering the workforce by 13.8% every 5 years using the Accreditation Council for Graduate Medical Education growth rate from 2013 to 2018.[12] For the stagnant model, the number of incoming urologists is constant at 320.

The flow portion of the model subtracts the retiring urologists from the population using the 2019 AUA Census. The 2019 AUA Census provided the proportion of urologists in 5-year increments of planned age at full retirement separately by gender. On the basis of the stable planned retirement age in AUA census from 2016 to 2020, we assume that these retirement proportions would remain constant throughout the time projected.[10,13,14] We performed a sensitivity analysis to see how this projection would change with the planned retirement age of 70 years.

Per Capita Estimates

The per capita estimates are calculated using the estimated urologist population and dividing by the US population. We calculated total urologists, male urologists, and female urologists per total capita. We also calculated the number of urologists per the population aged 65 years and older and urologists per matching gender per capita. We then calculated the number of urologists needed to maintain the current urologists per capita and how many additional urology residency slots would need to be added annually to maintain the current level of 4 urologists per 100 000.

Statistical Analysis

Stock and flow models were generated in Excel software version 2016 (Microsoft). Data analysis was performed from June 2020 to March 2021.

Results

In 2019, according to the AUA census, there were 3.99 urologists per 100 000 in the US (total, 13 044 urologists; 11 758 male [90.1%] and 1286 female [9.9%]).[8] The median age range of urologists was 55 to 59 years. In 2020, using our assumptions listed in the **Table**, we project that there were 13 365 total practicing urologists, with 11 999 (89.8%) being men and 1366 (10.2%) being women.

In our continued growth model of 13.8% more urologists joining practice every 5 years, 2030 will have the lowest urologists per capita of 3.3 urologists per 100 000 persons (**Figure 1**A). By 2060, there will be 5.2 urologists per 100 000 persons. For the Medicare population, there are currently 23.8 urologists per 100 000 persons aged 65 years and older in 2020 (**Figure 2**A). This ratio will be the lowest in 2035, with 15.8 urologists per 100 000 persons aged 65 years and older, and increases to 22.3 by 2060 and never recovers to its 2020 baseline level. When matching female urologists to the female population, there are 0.8 female urologists for 100 000 female persons in 2020, which increases at each time interval to 2.5 female urologists to 100 000 female persons by 2060 (**Figure 3**A).

In our stagnant growth model of 0%, there will be a continued decrease of urologists per capita to 3.1 urologists per 100 000 persons in 2035 and beyond (Figure 1B). For the Medicare population, there is a continued decrease at each time point with 13.1 urologists per 100 000 persons aged 65 years and older by 2060 (Figure 2B). When matching female urologists to the female population, there is continued growth that plateaus at 1.5 female urologists to 100 000 female persons in 2050 and beyond (Figure 3B).

Our sensitivity analysis examining retirement age of 70 years showed no significant changes from our primary analyses and conclusions. Finally, we found that to maintain the current urologists per capita to 2060, an additional 3851 urologists are required. This translates to an increase of at least 96 urology residency slots annually until 2060.

Discussion

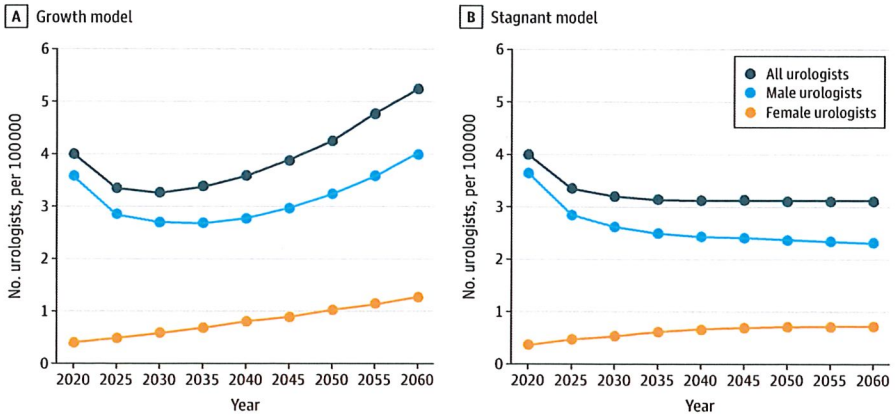
To our knowledge, this cross-sectional study is the first to project the urology workforce per capita and demographic characteristics of urologists over the next 40 years and has 3 key findings. First, the

Table. Key Forecast Assumptions

Variable	Key assumption	Sources
Baseline practicing urologists, No.	13 044	2019 AUA Census[10]
Male vs female practicing urologists, No. (%)		2019 AUA Census[10]
Male	11 758 (90.1)	
Female	1286 (9.9)	
Age of male vs female practicing urologists, median, y		2019 AUA Census[10]
Male	55-59	
Female	40-44	
Baseline new annual urologists	320 (vs 311 on ACGME 2018)	2018 ACGME workbook[8]
Age of male vs female new urologists annually, y	32	2019 AUA Census[10]
Graduating resident No. growth per 5 y, %	0 Baseline growth	
	13.8 Baseline growth	ACGME workbook; from 2013 to 2018, 13.8% growth in No. of active urology residents[8]
New female urologists annually, %	25 (vs 24.4 on ACGME 2018)	2018 ACGME workbook[8]
Age of male vs female planned age of retirement, median, y		2019 AUA Census[10]
Male	69	
Female	65	

Abbreviations: ACGME, Accreditation Council for Graduate Medical Education; AUA, American Urological Association Annual.

Figure 1. Projected Number of Urologists per Capita From 2020 to 2060

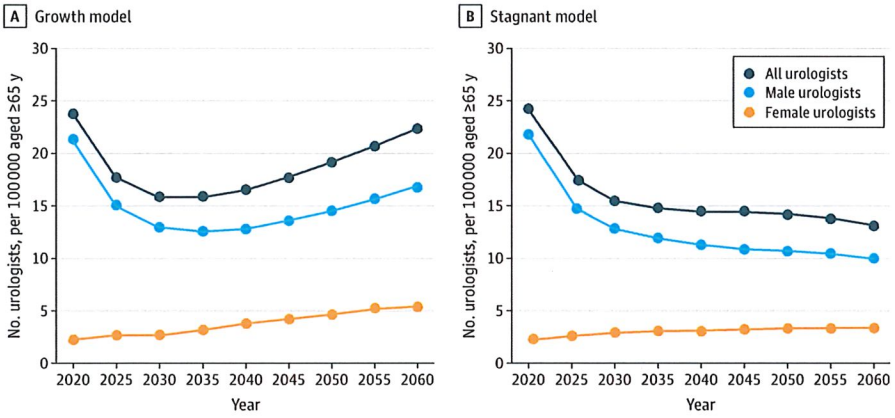


A, Graph shows projected number of urologists under the continued 13.8% growth stock and flow model. B, Graph shows projected number of urologists under the 0% stagnant growth stock and flow model. In both panels, each dot represents the number of urologists per 100 000 persons corresponding to the year.

total number of practicing urologists per capita will decrease in the coming decades, even with sustained growth of the resident complement across urology training programs, and will not recover to baseline until 2060. Second, there will be an exaggerated shortage of total urologists per population aged 65 years and older in both models of our projections. Finally, female urologists per capita will continue to increase in the context of decreasing urologists per capita in both continued growth and growth stagnant models. Collectively, these projections highlight the severity of the impending shortage of urologists and importance of structural change and advocacy to maximize our available urology workforce. On the basis of our model, we found that to maintain the current urologists per capita to 2060, an additional 3851 urologists are required. To meet the demands of more urologists, we would need to increase at least 96 urology residency slots annually.

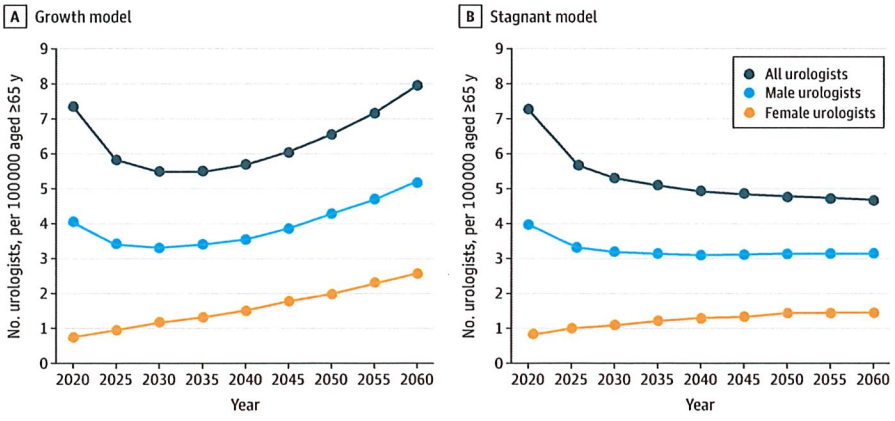
Our analysis demonstrates that prior efforts to increase the urology workforce have been insufficient, with problems escalating in the decades to come. Specifically, despite an additional 14 accredited urology residency programs between 2013 and 2018, our current supply of practicing urologists of 13 044 is still far short of the 14 400 urologists projected necessary to meet the demand for urological services.[1,12] Our projections demonstrate that the disparity will worsen in the coming decades even with continued growth of 13.8% graduating urologists every 5 years.[1] Because of the number of retiring urologists, the number of urologists per capita will not reach baseline 2020 levels until 2050. Without additional growth of training positions, the workforce shortage will become even more severe, with a continued decline in urologists per capita through 2060. We provided these 2

Figure 2. Projected Number of Urologists per 100 000 People Aged 65 Years or Older From 2020 to 2060



A, Graph shows projected number of urologists under the continued 13.8% growth stock and flow model. B, Graph shows projected number of urologists under the 0% stagnant growth stock and flow model. In both panels, each dot represents the number of urologists per 100 000 persons aged 65 years or older corresponding to the year.

Figure 3. Projected Number of Urologists per Capita by Matching Gender From 2020 to 2060



A, Graph shows projected number of urologists under the continued 13.8% growth stock and flow model. B, Graph shows projected number of urologists under the 0% stagnant growth stock and flow model. In both panels, each dot represents the number of urologists per 100 000 persons by matching gender corresponding to the year.

alternate models for workforce projections, understanding that the actual urology workforce will most likely fall between these 2 projections. Regardless, our field must be prepared to face a growing shortage of physicians for the next 40 years, and possibly beyond.

The impending shortage will be felt most keenly by the elderly and most medically vulnerable patients. Given the increased prevalence of urological conditions in an aging population, the Medicare population heavily uses urology services.[15] Etzioni et al[16] found that the group of patients aged 65 years and older used 64.8% of all urological services. McKibben et al[5] reaffirmed that adults aged 65 years and older use urological services at a rate 3 times higher than the general population. This is consistent with findings of Urologic Diseases in America project,[5] which documented substantial and growing incidence and prevalence of a number of urological conditions, such as benign prostatic hyperplasia, incontinence, and urological cancers, that affect the older population. Although it is possible that some Medicare physicians overuse urological services, this finding has been confirmed by multiple authors and is consistent with how commonly urological conditions affect elderly patients more than the rest of the population. Both of our models show a decline in urologists per 100 000 persons aged 65 years and older in the coming years, which is particularly concerning given that this population heavily uses urology services, thereby exacerbating the existing shortage of urologist supply relative to the demand.[5] This has major downstream consequences on access to care, delays for surgical evaluation, and potential for worse patient outcomes.[6]

It is worthwhile to consider the impact of telemedicine in this context. Although urology has pioneered the integration of telemedicine to provide care for our patients, it is still largely unknown whether video visits in urology can serve as a substitute for clinic evaluations and how it affects clinical efficiency.[17,18] In addition, the patients who use telemedicine to access care tend to be younger and female, which may still preclude providing care for the elderly patient population.[17] However, we anticipate that telemedicine will continue to be an integral part of providing care for our patients and will be further used by the Medicare population as this population becomes more accustomed to technological advances required for telemedicine.

One positive aspect of the projections in this study is that the number of female urologists consistently increases in both projection models. Although both male and female urologists provide urological care for diverse patient populations, there are substantial differences in practice patterns by gender. Almost one-half of female urologists see a majority of female patients as part of their practice, whereas only 3.5% of male urologists see a majority of female patients as part of their practice.[10] Although this is partially owing to more female urologists subspecializing in female pelvic medicine and reconstructive surgery, when comparing general urologists of each gender, female general urologists logged 2.2 times the number of urogynecological cases compared with their male counterparts.[19,20] Currently, with 0.8 female urologists per 100 000 female population, there is substantial underrepresentation of female urologists for a gender-concordant population in the US.[7] This is particularly noteworthy given that 30% of urology patients are female, and patient surveys have highlighted patient preference for gender-concordant urologists for urinary incontinence.[21] With an increasing number of female urologists in our projection, they have not only increased availability to provide care for female patients but also increase the likelihood of mutually respective care for diverse patient populations by contributing to the diversity of the urology workforce.[9]

Limitations and Strengths

Our study has several limitations. The projections of the workforce model are dependent on assumptions listed in the Table. Although 24.4% of the current urology resident workforce is female, which is much higher than previously, we did not think that this growth in representation would be linear. Therefore, we assumed that approximately 25% of the resident workforce will be female, understanding that this could be an underestimate. We also used planned retirement age as a surrogate for actual retirement age because that was the closest data we had available. We assumed that because the planned retirement age was stable from 2016 to 2020, it would remain constant

throughout the projection.[13,14] If all urologists delay retiring until age 70 years, the greatest increase made would be, at most, 2% more urologists in 2060 compared with our original models. Thus, the results and conclusions do not change overall. There are limited longitudinal data for some of our assumptions, but the 2 scenarios of continued and stagnant growth were modeled to account for possible variability, understanding that the actual urology workforce will most likely fall between these 2 models. Next, we cannot account for the changes in urologist practice variation with the increasing number of practicing urologists. For example, approximately 10% of the urologists who currently plan to retire at age 70 or beyond listed that their reasoning for continuing to practice is their inability to recruit a replacement.[10] If there are more urologists available, the decision-making process regarding retirement or total work hours could be affected, which is not accounted for in our modeling. Finally, our US population projection is based on the US Census Bureau projections from 2017, which could deviate from the actual population in the future but is the best estimate and projection of each time point available.

These limitations notwithstanding, our findings highlight the time sensitivity and importance of continued advocacy for increased graduate medical education funding and other policies to ensure that we effectively mitigate the impending urology workforce shortage by funding additional urology residency positions. Without such interventions, there will be negative downstream consequences for patient care and outcomes.[6] One clinical example is evaluation of hematuria, a common diagnosis that leads to referral from primary care or the emergency department and requires further urological workup to identify 1 in 10 patients who may have a life-threatening malignancy or other treatable condition.[22] Many studies looking at diagnostic evaluation, such as cystoscopy, of patients with hematuria, have already identified multifactorial reasons for delay in full evaluation that have led to later stage of diagnosis, higher disease burden, and less favorable cancer outcomes.[22-25] Given the impending urology workforce shortage, we can project that the further delay in patient care would lead to worse patient outcomes. Continued utilization of advanced practice practitioners may bridge the gap between patient's access to care by serving as vital partners in providing quality care to patients.[5] However, it is crucial to sustain growth in the number of urologists alongside that of advanced practice practitioners given that urologists are key practitioners of surgical services and the extent of advanced practice practitioners' practice within urology is understudied at this time.[26] Physician burnout remains a constant threat to a stable urology workforce.[14] Creating organizational cultures where urologists are supported through greater autonomy and flexibility, improvements in work-life balance, more diverse and inclusive work communities, and greater efficiency will help buffer against burnout and lead to a more robust, stable, and productive workforce.

Conclusions

In our projection of the urology workforce to 2060, we found that the total number of practicing urologists per capita will decrease in the coming decades, with a nadir in the year 2030, even with sustained growth of the resident complement across urology training programs. Second, there will be an exaggerated shortage of total urologists for the population aged 65 years and older in both models of our projections. Finally, the number of female urologists per female capita will continue to increase in the context of decreasing urologists per capita in both continued growth and stagnant growth models. Given the length of training and time required to change physician training and practice infrastructure, there is an urgent need for advocacy for increasing the graduate medical education budget to train more urologists and mitigate other factors, such as burnout, that contribute to the urology workforce shortage.

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ORIGINAL PAPER

Trends in the prevalence of kidney stones in the United States from 2007 to 2016

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Abstract

The overall prevalence of kidney stones (KS) in the US rose from 3.2% in 1980 to 10.1% in 2016, but the trends in important subgroups have not been reported. We examined the prevalence trends of KS in subgroups of age, sex and race in the US and identified relevant laboratory factors associated with a history of KS using National Health and Nutrition Examination Survey (NHANES) data. We conducted a cross-sectional study among 28,209 US adults aged ≥ 20 years old in the NHANES from 2007 to 2016. We calculated the prevalence of a self-reported history of KS by using weights and standardized to the 2010 US Census population. We also compared relevant laboratory values according to the history of KS. The prevalence of KS decreased from 8.7% in 2007–2008 to 7.2% in 2011–2012 but then increased to 9.0% in 2013–2014 and 10.1% in 2015–2016. However, the overall prevalence of KS increased over 2007–2016 (p-trend = 0.02). Prevalence of KS among men was higher than women. Among men aged 20–79, there were significant quadratic trends in the prevalence of KS. Whereas, the prevalence of KS increased as a linear trend among women aged 20–59 years over 2007–2016. There were no consistent trends in the prevalence of KS by race. The prevalence trend of KS among non-Hispanic whites was 9.8% from 2007 to 2010 then dropped to 7.9% in 2011–2012 and increased to 10.6% in 2013–2014 and 12.1% in 2015–2016. A similar trend was also observed among non-Hispanic blacks. Among Hispanic, the prevalence of KS was 7.6% in 2007–2008 and 7.4% in 2009–2010 and then fluctuated over the next several time periods. For non-Hispanic Asians, the range was 4.4–4.6%. Regarding relevant laboratory factors, after adjusting for sex, race, age, BMI, smoking status, alcohol drinking, history of diabetes and gout, urine albumin-creatinine ratio and serum osmolality were independently associated with the history of KS in women and men. In conclusion, there was substantial variability in KS prevalence across individual 2-year time periods. This variation of period-specific prevalence values emphasizes the importance of looking at long-term trends and using more than a single 2-year cycle in analyses to increase the precision of the estimate. However, there was an overall increase in the prevalence of KS over 2007-2016.

Keywords Kidney stone · Nephrolithiasis · Prevalence · Trends · NHANES

Introduction

Kidney stones (KS) are common in the US and cost billions of dollars due to treatment and lost worker productivity [1]. Moreover, KS cause pain and hematuria and have been associated with chronic kidney disease (CKD) [2, 3], end-stage kidney disease (ESKD) [4, 5], osteoporosis [6, 7] and cardiovascular disease [8, 9]. A study based on National Health and Nutrition Examination Survey (NHANES) data reported that the overall prevalence of kidney stones has continued to rise from 3.2% in 1980 to 10.1% in 2014 [10]. Possible explanations for this growing trend include the obesity epidemic, higher prevalences of gout and diabetes, and poor

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diet [11, 12]. However, updated information is needed on the prevalence trends of KS across age, sex and race groups.

We examined the prevalence trends of KS in subgroups of age, sex, and race in the US. Additionally, we identified laboratory factors associated with a history of KS using National Health and Nutrition Examination Survey (NHANES) data from 2007 to 2016.

Methods

Data sources

NHANES is an ongoing evaluation of the health and nutritional status of children and adults in the United States. The survey includes interviews, physical examinations and laboratory measurements. All public-use de-identified data sets in NHANES were exempted from the requirement for institutional review board approval.

Study population

We conducted a serial cross-sectional study in the NHANES from 2007 to 2016. The population included 28,209 US males and females aged ≥ 20 years old who responded to the questions regarding a history of kidney stones contained in the household survey component.

Outcomes

The primary outcome was the prevalence of a self-reported history of KS from the response to the question, "Have you ever had kidney stones?". However, given that some KS may be incidental findings on imaging performed for another indication, the secondary outcome was the prevalence of a history of symptomatic stone disease based on the response to the question, "How many times have you passed a kidney stone?"

Covariates

Covariates of interest included age, sex, race, ethnicity, cigarette smoking status, alcohol consumption, history of diabetes and history of gout. Participants were divided into four age groups: 20–39, 40–59, 60–79 and over 80 years old. Ethnicity/race categories included non-Hispanic white, non-Hispanic black, non-Hispanic Asian (data are available after 2011 NHANES cycle), Hispanic (Mexican–American and other Hispanic), and other race/multiracial. BMI was categorized as < 18.5, 18.5–24.9, 25–29.9 and ≥ 30 kg/m^2. Cigarette smoking status was categorized as never, past and current smokers. Alcohol consumption was divided into 5 groups: life-long abstainer, former drinker, current drinker reporting ≤ 1 drink/week, 1–14 drinks/week and more than 14 drinks/week. We defined diabetic individuals as those answering "yes" to the question "Other than during pregnancy, have you ever been told by a doctor or health professional that you have diabetes or sugar diabetes?" or having a hemoglobin A1C (HbA1C) more than 6.5%. Individuals with a history of gout were defined as those who answered "yes" to the question "Has a doctor or other health professional ever told you that you had gout?"

Statistical analysis

We calculated the prevalence of a self-reported history of KS and the prevalence of self-reported passing at least one stone (symptomatic stone disease) by incorporating survey weights and design factors in all estimations to account for the unequal probabilities of selection, oversampling, and nonresponse. All estimates were standardized to the 2010 US Census population, using age adjustment [13]. Linear and quadratic trends overall and stratified by sex, age, diabetes, history of gout, alcohol consumption and cigarette smoking status were examined in regression models with 2-year survey cycles modeled as an orthogonal polynomial. We summarized characteristics and compared some relevant laboratory factors between individuals with the history of KS and without the history of KS after adjusting for age. Due to a skewed distribution, urine albumin-creatinine ratio, urine flow rate and serum copper were log-transformed. The mean values of these log-transformed variables were calculated for each group and these means were back-transformed exponentially to represent geometric means. Moreover, we categorized serum 25-OH vitamin D (25(OH)D) into three categories including vitamin D deficiency defined as 25(OH)D < 50 nmol/l, vitamin D insufficiency defined as 50 ≤ 25(OH)D < 75 nmol/l and replete vitamin D defined as 25(OH)D ≥ 75 nmol/l [14].

Additionally, we used multivariable logistic regression accounting for the survey weights to evaluate the association between relevant laboratory values and self-reported history of KS. We adjusted in the multivariable model for potential confounders specified a priori, including age, sex, race, BMI, cigarette smoking status, alcohol consumption, history of diabetes and history of gout. Given that some laboratory values are not available in all NHANES cycles, we created four models additionally adjusted for other laboratory values to evaluate whether that particular laboratory value was independently associated with the history of KS based on the availability of the data in each NHANES cycle. Model 1 was using data from NHANES cycle 2007–2014 since the data for 25(OH)D are available from only 2007–2014. In model 2, we added serum trace elements as predictors using data from NHANES cycle 2011–2014 since the data for 25(OH)D along with serum trace elements are available only from

2011 to 2014. For model 3 adding serum estrogen, we used data from NHANES cycle 2013–2014 among women since serum estrogen along with other laboratory parameters are available only in 2013–2014. For model 4 adding serum testosterone, we used data from NHANES cycle 2011–2014 among men given that serum testosterone and other laboratory parameters are available only from 2011 to 2014.

All statistical analyses were conducted using STATA 15.1 (StataCorp LLC, Texas, USA). Results were considered statistically significant with two-sided $\alpha < 0.05$ unless otherwise specified.

Results

Among 28,209 individuals in NHANES who responded to the kidney stone question, the weighted and age-standardized overall prevalence of KS from 2007 to 2016 was 9.3% (95% CI 8.8–9.8). Men were more likely to report a history of KS (10.6% [95% CI 9.9–11.3]) than women (8.1% [95% CI 7.3–8.8]). The prevalence of KS fluctuated during these years initially decreasing from 8.7% (95% CI 7.7–9.8) in 2007–2008 to 8.6% (95% CI 7.9–9.2) in 2009–2010 and 7.2% (95% CI 6.0–8.5) in 2011–2012 and then increased to 9.0% (95% CI 7.9–10.0) in 2013–2014 and 10.1% (95% CI 8.9–11.4) in 2015–2016. However, there was a significant overall increase in a quadratic trend (p-trend = 0.02) in the prevalence of kidney stones from 2007 to 2016. There was no significant trend for the secondary outcome of symptomatic KS (Table 1).

The prevalence of KS among men fluctuated during 2007–2016 initially decreasing from 11.8% (95% CI 9.8–13.8) in 2007–2008 to 10.2% (95% CI 8.8–11.6) in 2009–2010 and 7.8% (95% CI 6.0–9.3) in 2011–2012 and then increased to 10.5% (95% CI 9.3–11.8) in 2013–2014 and 13.0% (95% CI 11.5–14.6) in 2015–2016 (p for quadratic trend < 0.001). Overall, the prevalence of KS in men increased with age. The highest prevalence was found among male individuals with age ≥ 80 years which was 19.7% (95% CI 16.9–22.5) followed by age of 60-79 which was 18.8% (95% CI 16.8–20.7), age of 40–59 which was 11.5% (95% CI 10.1–12.9) and age of 20–39 which was 5.1% (95% CI 4.3–6.0). Among women, the prevalence of KS increased from 6.0% (95% CI 4.9–7.0) in 2007–2008 to 7.3% (95% CI 6.3–8.4) in 2009–2010 and 8.0% (95% CI 5.8–10.3) in 2011–2012 and then increased to 9.4% (95% CI 7.6–11.3) in 2013–2014 and 9.8% (95% CI 7.7–11.8) in 2015–2016 with an overall increasing linear trend (p-trend < 0.001). Supplementary Table 1. The prevalence of KS in women was similar among those aged ≥ 80 which was 10.6% (95% CI 8.1–13.0), aged 60–79 which was 9.2% (95% CI 7.9–10.5) and aged 40–59 which was 9.8% (95% CI 8.5–11.1). However, the prevalence of KS among women aged 20–39 years was only 5.8% (95% CI 4.9–6.6). Moreover, the prevalence of KS among women was lower than men except at age 20–39 years.

Among men across the ages of 20–79, there were significant quadratic trends from 2007 to 2016 as prevalence trends of KS initially decreased from 2007 to 2008 to the nadir in 2011–2012 then increased again in 2015–2016. However, for men aged ≥ 80 years, the prevalence varied substantially during the study period with no statistically significant trend. The prevalence initially decreased from 21.5% (95% CI 13.33–29.7) in 2007-2008 to 14.5% (95% CI 8.9–20.2) in 2009–2010 then increased to 23.8% (95% CI 15.3–32.3) in 2011–2012 but decreased to 16.6% (95% CI 11.8–21.5) in 2013–2014 then increased again to 22.1% (95% CI 16.1–28.1). Among women aged 20–79 years, the prevalence of KS gradually increased from 2007–2008 to 2015–2016. However, linear trends were significant only among women aged 20–59 years. In women aged ≥ 80 years, the prevalence of KS also varied substantially as evidenced by no statistically significant trend (Table 2, Fig. 1a, b). A quadratic trend for a secondary outcome of symptomatic KS was seen among men aged 40–59 years while an increasing linear trend for symptomatic KS was seen among women aged 20–39 years (Table 3, Fig. 1c, d).

Among different races, non-Hispanic whites had the highest prevalence of KS at 9.9% (95% CI 8.9–10.9) followed by Hispanic which was 8.3% (95% CI 7.4–9.3), non-Hispanic blacks which was 4.9% (95% CI 4.3–5.5) and non-Hispanic Asians which had the lowest prevalence of KS at 4.4% (95% CI 3.4–5.3). However, the prevalence of KS among non-Hispanic Asians and non-Hispanic blacks

Table 1 The prevalence of kidney stones over a decade from 2007 to 2016

	2007–2008	2009–2010	2011–2012	2013–2014	2015–2016	Overall 2007–2016	p-value for linear trend	p-value for quadratic trend
Prevalence of kidney stones	8.7% (7.7–9.8)	8.6% (7.9–9.2)	7.2% (6.0–8.5)	9.0% (7.9–10.0)	10.1% (8.9–11.4)	9.3% (8.8–9.8)	< 0.001	0.02
Prevalence of passing at least one kidney stone	7.5% (6.4–8.7)	7.2% 6.5–8.0)	6.1% (4.6–7.6)	7.7% (6.6–8.7)	–	7.5% (6.9–8.1)	0.30	0.16

Data was standardized by age to 2010 US census

Table 2 The prevalence of kidney stones over a decade from 2007 to 2016 stratified by age

Age	Male						*p*-value for Trend	
	2007–2008	2009–2010	2011–2012	2013–2014	2015–2016	Overall 2007–2016	Linear	Quadratic
20–39	6.0% (3.2–8.7)	5.1% (3.4–6.7)	3.3% (1.7–5.0)	4.6% (2.7–6.6)	6.5% (4.8–8.3)	5.1% (4.3–6.0)	0.61	0.01
40–59	12.9% (10.1–15.6)	10.0% (7.3–12.8)	8.8% (5.5–12.1)	12.5% (9.6–15.4)	14.3% (10.3 – 18.3)	11.5% (10.1–12.9)	0.26	0.05
60–79	20.2% (17.6–22.7)	19.7% (16.1–23.2)	14.0% (10.4–17.6)	17.4% (13.8–20.9)	22.2% (16.3–28.2)	18.8% (16.8–20.7)	0.79	0.04
≥ 80	21.5% (13.33–29.7)	14.5% (8.9–20.2)	23.8% (15.3–32.3)	16.6% (11.8–21.5)	22.1% (16.1–28.1)	19.7% (16.9–22.5)	0.70	0.55
Age	Female						*p*-value for Trend	
	2007–2008	2009–2010	2011–2012	2013–2014	2015–2016	Overall 2007–2016	Linear	Quadratic
20-39	3.3% (2.2-4.3)	4.9% (3.3-6.5)	6.4% (4.0-8.9)	7.3% (5.5-9.1)	7.1% (4.6-9.6)	5.8% (4.9-6.6)	0.001	0.38
40-59	7.2% (5.1-9.4)	9.1% (7.1-11.1)	9.1% (6.2-11.9)	11.2% (8.3-14.1)	12.0% (7.7-16.3)	9.8% (8.5-11.1)	0.03	0.90
60-79	8.5% (5.3-11.6)	8.5% (5.3-11.6)	9.0% (4.8-13.2)	10.1% (6.9-13.2)	10.4% (8.4-12.4)	9.2% (7.9-10.5)	0.22	0.89
≥ 80	10.0% (4.8-15.1)	15.6% (10.1-21.2)	8.4% (3.6-13.3)	8.9% (2.3-15.6)	9.9% (3.6-16.2)	10.6% (8.1-13.0)	0.37	0.99

Data were standardized by age to 2010 US census

was not significantly different. For non-Hispanic whites, the prevalence of KS was stable at 9.8% (95% CI 8.4–11.3 in 2007–2008 and 8.8–10.9 in 2009–2010) from 2007 to 2010 then declined to 7.9% (95% CI 5.7–10.0) in 2011–2012 but then increased to 10.6% (95% CI 9.2–12.0) in 2013–2014 and 12.1% (95% CI 10.0–14.2) in 2015–2016. Regarding Hispanic, the prevalence of KS was stable at 7.6% (95% CI 6.1–9.1) in 2007–2008 and 7.4% (95% CI 6.1–8.8) in 2009–2010 and then fluctuated over the next several time periods. The prevalence of KS among non-Hispanic blacks also slightly fluctuated. For non-Hispanic Asians, the prevalence of KS was stable at 4.4–4.6% from 2011 to 2016 (Table 4 and Fig. 2a). There were no significant trends for the prevalence of KS across any race. Similar findings were seen in the secondary outcome of symptomatic KS (Table 5 and Fig. 2b).

The prevalence of KS among diabetic participants was higher than those without diabetes (13.1% vs 8.0%; $p<0.001$) and the prevalence of KS among participants with the history of gout was higher than those without a history of gout (16.6% vs 8.5%; $p<0.001$). In terms of cigarette smoking status, the prevalence of KS among past smokers and current smokers were higher than never smokers. For alcohol consumption, the prevalence of KS among former drinkers was higher than life-long abstainers while the prevalence of KS among participants who drank more than 1 drink/week was lower than life-long abstainers. Overall from 2007 to 2016, there were no significant trends for the prevalence of KS across either history of diabetes, history of gout, smoking or alcohol drinking status (Supplementary Table 3). The age-standardized laboratory values among stone formers and non-stone formers are shown in Table 6. Although statistically significant, individuals with a history of KS had no clinically significant differences in mean serum creatinine (0.88 vs 0.86 mg/dl; $p=0.01$) or estimated glomerular filtration rate (eGFR) (95.4 vs 96.5 ml/min/1.73 m^2; $p=0.01$), serum phosphate (3.7 vs 3.8 mg/dl; $p=0.0001$), serum chloride (104.1 vs 103.8 mmol/l; $p=0.001$), serum bicarbonate (24.6 vs 25.0 mmol/l; $p<0.0001$) and serum osmolality (278.2 vs 277.9 mmol/kg; $p=0.004$). Individuals with a history of KS had slightly higher albumin-creatinine ratio (8.7 vs 7.8 mg/g; $p=0.0001$) and a slightly lower urine flow rate (0.8 vs 0.9 ml/min; $p=0.02$). While many laboratory values were statistically different, the only ones that were clinically different were serum estrogen which was lower among female stone formers (74.5 vs 108.5 pg/ml; $p=0.003$) and serum testosterone which was lower among male stone formers (393.5 vs 416.4 ng/dl; $p=0.02$).

In multivariate analyses, we adjusted for age, sex, race, BMI category, history of DM, gout, smoking status and alcohol drinking in every model. In model 1 including available laboratory data of eGFR, log urine flow rate, log albumin-creatinine ratio, serum osmolality, serum calcium, phosphate, 25(OH)D categories from NHANES

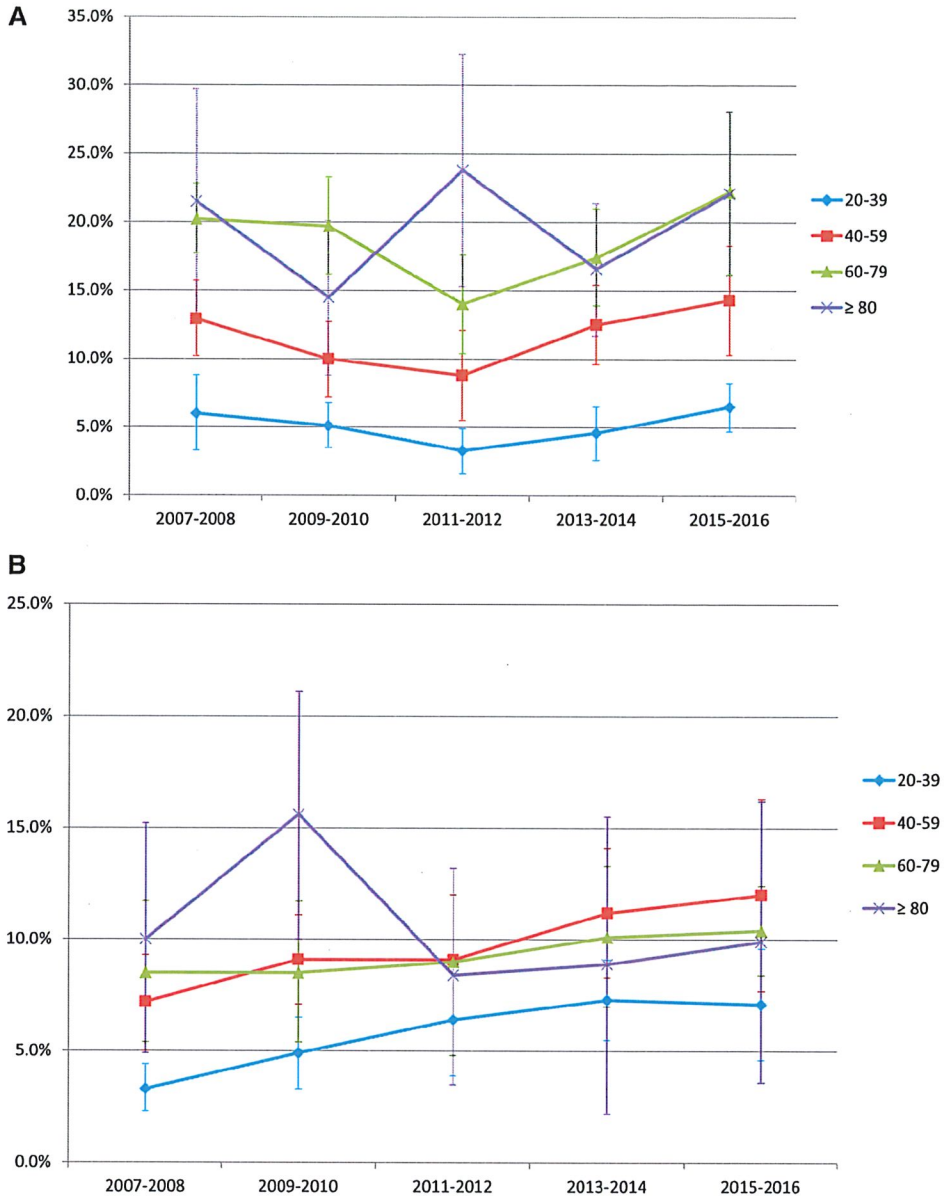


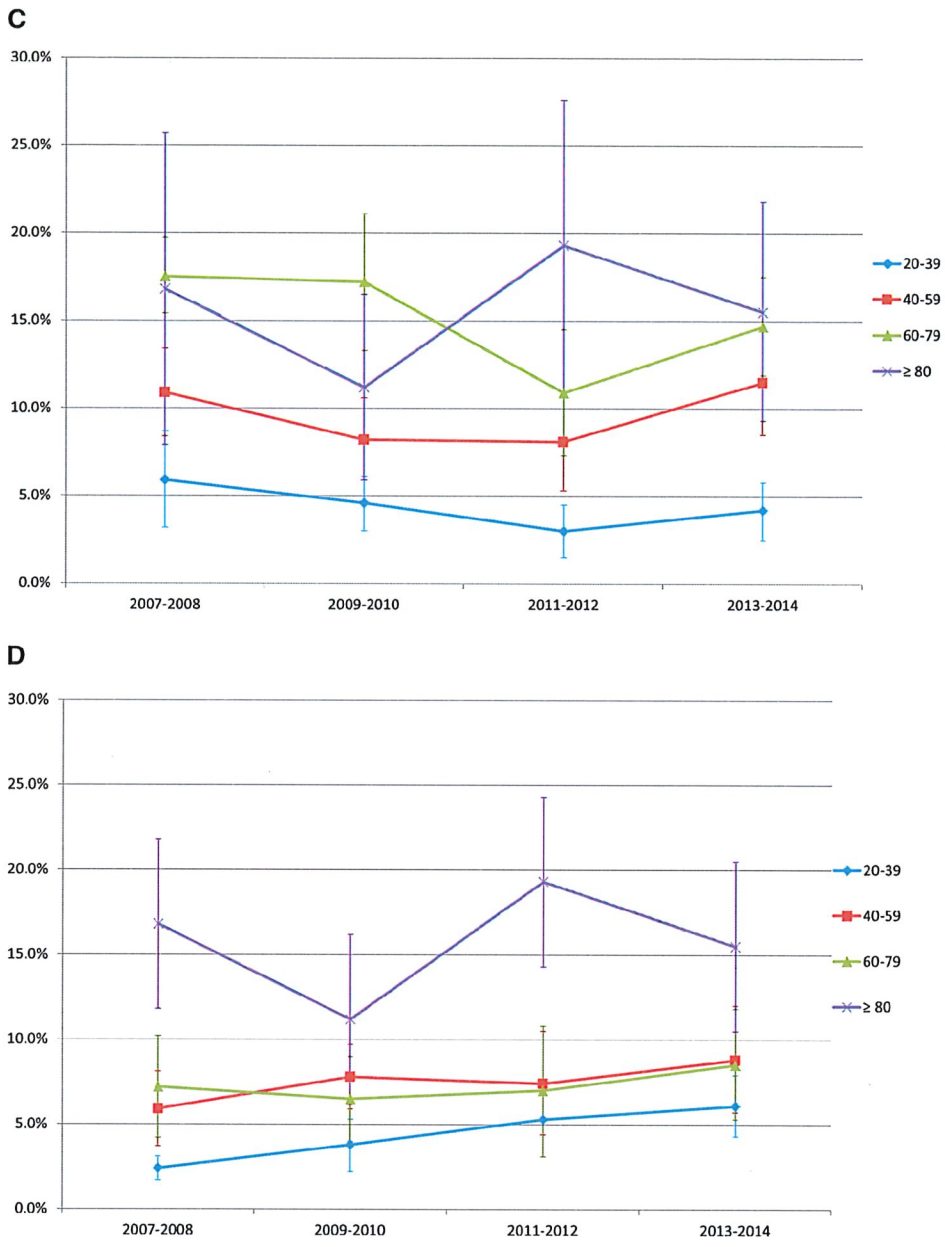
Fig. 1 **a** Weighted prevalence of kidney stone by age among male from 2007 to 2016. **b** Weighted prevalence of kidney stone by age among female from 2007 to 2016. **c** Weighted prevalence of symptomatic kidney stone by age among male from 2007 to 2016. **d** Weighted prevalence of symptomatic kidney stone by age among female from 2007 to 2016

cycle 2007–2014, we found that higher log urine albumin-creatinine ratio and serum osmolality were independently associated with higher odds of history of KS. In model 2 after adding serum trace elements, we found independently association between higher serum copper and lower odds of history of KS among men (OR = 0.85 [95% CI 0.77–0.95] per 10 μg/L) but not women (OR = 1.01 [95% CI 0.91–1.11] per 10 μg/L) (p interaction = 0.02). After adding serum estrogen and trace elements, none of the laboratory values were associated with a history of KS among women (model 3). However, in model 4, after adding serum testosterone and serum trace elements, higher serum copper was independently associated with lower odds of history of KS among men (Table 7).

Discussion

The prevalence of KS, defined as a history of KS, has continued to rise over the past three decades in the US from 3.2% in 1980 [15] to 5.2% in 1994 [15, 16], 8.8% in 2010 [17] and 10.1% in 2016. However, the NHANES data for the decade 2007–2016, demonstrates substantial variability over many 2-year cycles. For example, the prevalence of KS in the US decreased from 2007 to 2010 but then increased after 2011. This is most likely due to random variability as it is very unlikely that there were abrupt changes in the true population prevalence over such a short period of time. It is also unlikely that increasing use and sensitivity of imaging studies led to an increase in incidental findings since we

Fig. 1 (continued)



observed similar trends of prevalence for symptomatic KS. However, we found an overall increase in the quadratic trend of the prevalence of KS from 2007 to 2016.

Previous literature using NHANES for chronic diseases such as the study by Yoon et al. [18] of trends in blood pressure among adults with hypertension, the study by Hales et al. [19] of trends in obesity and severe obesity prevalence in US youth and adults, the study by Palmer et al. [20] of trends in diabetes as well as the study by Chen-Xu et al. [21] of the trends in gout and hyperuricemia also demonstrated variability in prevalence between 2-year cycles as we observed for kidney stones. This emphasizes the importance of examining long-term trends. From 2007 to 2016, our study observed an overall increase in the trend of the prevalence of KS. However, after stratified by diabetes and a history of gout, we did not find any significant trends in the prevalence of KS. These findings suggested that the increase in trend of the prevalence of KS might be explained in part by the increasing prevalence of diabetes [19] and diabetes is associated with a higher risk of KS. The prevalence of KS varied by age and sex. On average, among women aged 20–79 years, the prevalence of KS was increasing since 2007. We observed a quadratic trend for the prevalence trend of KS among men aged 20–79 with the nadir in 2011–2012. Nonetheless, for both men and women aged ≥ 80 years, the variability from cycle to cycle was larger than other age

Table 3 The prevalence of symptomatic kidney stone from 2007 to 2014 stratified by age

Age	Male					*p*-value for Trend	
	2007–2008	2009–2010	2011–2012	2013–2014	Overall 2007–2014	Linear	Quadratic
20-39	5.9% (3.1-8.6)	4.6% (3.1-6.2)	3.0% (1.5-4.5)	4.2% (2.6-5.9)	4.4% (3.5-5.2)	0.15	0.26
40-59	10.9% (8.4-13.4)	8.2% (5.8-10.5)	8.1% (5.3-10.9)	11.5% (8.5-14.5)	9.6% (8.2-11.0)	0.56	0.03
60-79	17.5% (15.3-19.6)	17.2% (13.3-21.1)	10.9% (7.3-14.5)	14.7% (11.9-17.5)	15.1% (13.4-16.9)	0.16	0.12
≥ 80	16.8% (7.9-25.7)	11.2% (5.9-16.5)	19.3% (11.0-27.7)	15.5% (9.2-21.7)	15.7% (12.3-19.1)	0.75	0.87
Age	Female					*p*-value for Trend	
	2007–2008	2009–2010	2011–2012	2013–2014	Overall 2007–2014	Linear	Quadratic
20-39	2.4% (1.7-3.1)	3.8% (2.3-5.4)	5.3% (3.1-7.5)	6.1% (4.3-7.9)	4.5% (3.6-5.3)	0.001	0.95
40-59	5.9% (3.7-8.1)	7.8% (5.9-9.7)	7.4% (4.3-10.4)	8.8% (5.6-11.9)	7.6% (6.3-8.8)	0.13	0.81
60-79	7.2% (4.2-10.2)	6.5% (4.0-9.0)	7.0% (3.2-10.9)	8.5% (5.2-11.7)	7.1% (5.6-8.5)	0.71	0.71
≥ 80	8.6% (3.9-13.2)	11.8% (6.4-17.2)	7.5% (3.1-12.0)	6.9% (1.4-12.5)	8.7% (6.2-11.1)	0.35	0.46

Data were standardized by age to 2010 US census

No information for NHANES 2015–2016 cycle

Table 4 The prevalence of kidney stones over a decade from 2007-2016 stratified by race

Race	2007–2008	2009–2010	2011–2012	2013–2014	2015–2016	Overall 2007–2016	*p*-value for linear trend	*p*-value for quadratic trend
Non-Hispanic White	9.8% (8.4-11.3)	9.8% (8.8-10.9)	7.9% (5.7-10.0)	10.6% (9.2-12.0)	12.1% (10.0-14.2)	9.9% (8.9-10.9)	0.14	0.52
Non-Hispanic Black	4.8% (2.9-6.7)	4.6% (3.2-6.0)	4.2% (3.3-5.1)	5.0% (3.7-6.3)	5.7% (4.8-6.7)	4.9% (4.3-5.5)	0.56	0.97
Hispanic	7.6% (6.1-9.1)	7.4% (6.1-8.8)	8.7% (6.6-10.9)	7.5% (5.7-9.4)	9.1% (7.7-10.5)	8.3% (7.4-9.3)	0.13	0.07
Non-Hispanic Asian	Included in other races	Included in other races	4.4% (2.9-5.9)	4.6% (2.7-6.5)	4.5% (2.1-6.9)	4.4% (3.4-5.3)	0.86	0.78
Other races	3.9% (2.2-5.5)	7.4% (5.0-9.7)	8.7% (5.7-11.7)	9.1% (4.6-13.6)	9.9% (6.2-13.6)	11.0% (8.0-14.0)	0.18	0.09

Data was standardized by age to 2010 US census

ranges as we observed the substantial fluctuating prevalence from 2007 to 2016. Moreover, we noticed larger confidence intervals among men and women aged ≥ 80 years, likely explained by smaller sample size in this age group. Furthermore, we also found that the prevalence of KS among women was higher than men at age 20–39 years. We postulated that this reproductive age group was the time when most of the pregnancies occurred. As pregnancy is the risk of KS [22], it might be the reason for the higher prevalence of KS among women compared to men in this age group.

Regarding race/ethnicity, the overall prevalence was lowest among non-Hispanic Asians, followed by non-Hispanic blacks, Hispanic and non-Hispanic whites, respectively. For the prevalence of symptomatic KS, the lowest prevalence was found among non-Hispanic blacks. However, there was no significant difference between non-Hispanic blacks and non-Hispanic Asians. These findings across all races including Asians were consistent with the previous nationwide study using data from the Cancer Prevention Survey (CPS II). The lower prevalence of kidney stones among

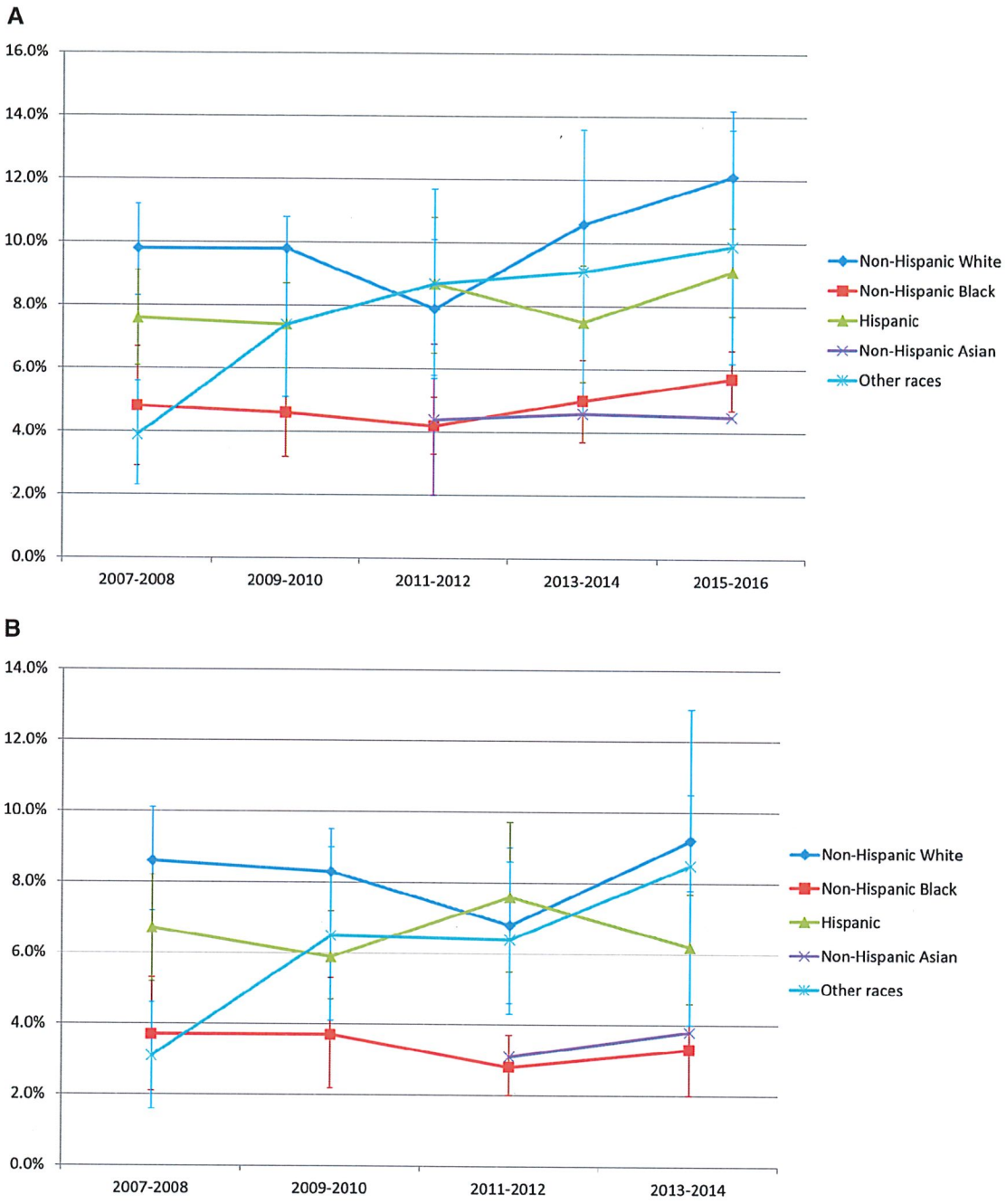


Fig. 2 **a** Weighted prevalence of kidney stone by race over a decade from 2007 to 2016. **b** Weighted prevalence of symptomatic kidney stone by race from 2007 to 2014

non-Hispanic blacks than non-Hispanic whites might be explained by the lower urinary calcium excretion leading to a lower relative urinary supersaturation of calcium salts [23]. Although there appeared to be an increase in the prevalence of kidney stone among non-Hispanic blacks, it was not statistically significant. The increasing prevalence trend might be explained by the lower vegetable intake among non-Hispanic blacks [24]. Future studies should focus on 24-h urinary chemistries and dietary intake among Asians to better understand the lower prevalence in this group.

Risk factors for stone formation include family history of KS, renal tubular acidosis (RTA) [25], inflammatory bowel disease (IBD) [26], sarcoidosis [27], obesity, diabetes [28], metabolic syndrome [29] and urine risk factors including urine oxalate, urine calcium and urine citrate [30–32]. The increasing trends in the prevalence of IBD [33], obesity [19],

Table 5 The prevalence of symptomatic KS over a decade from 2007 to 2014 stratified by race

Race	2007–2008	2009–2010	2011–2012	2013–2014	Overall 2007–2014	*p*-value for linear trend	*p*-value for quadratic trend
Non-Hispanic White	8.6% (7.1–10.0)	8.3% (7.1–9.4)	6.8% (4.6–9.0)	9.2% (7.9–10.6)	8.0% (6.7–9.2)	0.08	0.08
Non-Hispanic Black	3.7% (2.1–5.3)	3.7% (2.1–5.2)	2.8% (1.9–3.6)	3.3% (2.0–4.6)	3.0% (2.2–3.7)	0.53	0.53
Hispanic	6.7% (5.2–8.2)	5.9% (4.6–7.1)	7.6% (5.5–9.7)	6.2% (4.7–7.8)	6.8% (5.7–7.9)	0.19	0.19
Non-Hispanic Asian	Included in other races	Included in other races	3.1% (1.7–4.5)	3.8% (2.2–5.5)	3.2% (2.3–4.1)	0.78	0.78
Other races	3.1% (1.6–4.6)	6.5% (4.0–8.9)	6.4% (4.2–8.5)	8.5% (4.1–13.0)	9.2% (6.7–11.8)	0.48	0.48

Data was standardized by age to 2010 US census

No information for NHANES 2015–2016 cycle

Table 6 Laboratory values comparing individuals with and without a history of kidney stone

Relevant laboratory factors	Kidney Stone		*p*-value
	Non-stone formers (n = 25601)	Stone formers (n = 2608)	
Serum creatinine (mg/dl)	0.86 (0.003)	0.88 (0.007)	0.01
eGFR (mL/min/1.73 m^2)	96.5 (0.24)	95.4 (0.52)	0.01
Albumin-creatinine ratio (mg/g)†	7.8 (0.10)	8.7 (0.24)	0.0001
Urine flow rate (ml/min)*,†	0.9 (0.01)	0.8 (0.02)	0.02
Serum uric acid (mg/dl)	5.4 (0.01)	5.5 (0.04)	0.004
Serum calcium (mg/dl)	9.4 (0.007)	9.4 (0.02)	0.46
Serum phosphate (mg/dl)	3.8 (0.007)	3.7 (0.02)	0.0001
Serum sodium (mmol/L)	139.2 (0.06)	139.2 (0.08)	0.66
Serum potassium (mmol/L)	4.0 (0.006)	4.0 (0.010)	0.50
Serum chloride (mmol/L)	103.8 (0.08)	104.1 (0.11)	0.001
Serum bicarbonate (mmol/L)	25.0 (0.06)	24.6 (0.09)	< 0.0001
Serum osmolality (mmol/kg)	277.9 (0.11)	278.2 (0.18)	0.004
Serum vitamin D (25OHD2 + 25OHD3) (nmol/l)**	68.7 (0.78)	69.3 (1.18)	0.52
Vitamin D deficiency group (25(OH)D < 50 nmol/l)**	18.9%	17.0%	0.16
Vitamin D insufficiency group (50 ≤ 25(OH)D < 75 nmol/l)**	27.6%	30.0%	
Normal vitamin D (25(OH)D ≥ 75 nmol/l)**	53.5%	53.0%	
Serum estrogen (pg/ml) in females***	108.5 (9.70)	74.5 (0.48)	0.003
Serum testosterone (ng/dl) in males****	416.4 (4.78)	393.5 (8.58)	0.02
Serum copper (μg/dL)***,†	115.3 (0.81)	115.5 (1.53)	0.90
Serum selenium (μg/L)***	129.9 (0.59)	128.5 (0.84)	0.14
Serum zinc (μg/dL)***	82.0 (0.43)	80.5 (0.85)	0.06

Analysis was weighed to account for survey design and to reflect national population estimates. Data was age-standardized

*Information for urine flow rate was only available from 2009 to 2016

**Information for vitamin D was only available from 2007 to 2014

***Information for serum copper, selenium, zinc and total testosterone was only available from 2011 to 2016

****Information for serum estrogen was only available from 2013 to 2016

†The data was skewed so we transformed using the natural logarithm and back-transformed to represent geometric mean

Table 7 Odds ratio for history of kidney stone for each laboratory value

Relevant laboratory factors	Odds ratios for the history of KS			
	Model 1	Model 2	Model 3	Model 4
eGFR (mL/min/1.73 m^2)	1.00 (0.99, 1.01)	0.99 (0.98, 1.00)	0.99 (0.97, 1.01)	1.00 (0.98, 1.01)
Log urine albumin-creatinine ratio	1.10 (1.00, 1.20)	0.99 (0.83, 1.19)	1.36 (0.93, 1.98)	1.03 (0.80, 1.32)
Log urine flow rate	0.88 (0.76, 1.01)	0.84 (0.68, 1.05)	0.96 (0.60, 1.55)	0.77 (0.51, 1.16)
Serum osmolality (5 mmol/kg)	1.10 (1.03, 1.17)	1.05 (0.87, 1.25)	1.01 (0.75, 1.38)	0.85 (0.67, 1.07)
Serum calcium (mg/dl)	0.95 (0.66, 1.35)	0.80 (0.41, 1.56)	0.40 (0.08, 1.99)	1.22 (0.57, 2.61)
Serum phosphate (mg/dl)	0.82 (0.67, 1.01)	0.94 (0.63, 1.40)	0.69 (0.36, 1.33)	0.93 (0.49, 1.75)
Vitamin D deficiency group (25(OH)D < 50 nmol/l)	Reference	Reference	Reference	Reference
Vitamin D insufficiency group (50 ≤ 25(OH)D < 75 nmol/l)	1.03 (0.85, 1.24)	1.19 (0.75, 1.89)	1.12 (0.36, 3.47)	1.08 (0.57, 2.03)
Replete vitamin D (25(OH)D ≥ 75 nmol/l)	0.99 (0.78, 0.96)	1.40 (0.84, 2.35)	1.06 (0.33, 3.43)	0.87 (0.37, 2.04)
Serum copper (10 μg/L)		0.95 (0.87, 1.03)	1.02 (0.90, 1.15)	0.85 (0.76, 0.96)
Serum selenium (10 μg/L)		0.94 (0.87, 1.02)	0.99 (0.90, 1.10)	0.91 (0.81, 1.03)
Serum zinc (10 μg/dL)		1.00 (0.86, 1.16)	0.82 (0.62, 1.08)	1.03 (0.87, 1.23)
Serum estrogen (10 pg/ml)			0.97 (0.92, 1.03)	
Serum testosterone (10 ng/dl)				0.99 (0.97, 1.01)

Model 1 is performed in NHANES cycle 2007–2014 since the data for vitamin D is available from only 2007–2014 adjusted for age, sex, race, BMI, DM, gout, smoking, alcohol. The model also included eGFR, log urine flow rate, log albumin-creatinine ratio, serum osmolality, serum calcium, phosphate, 25-OH vitamin D

Model 2 is performed in NHANES cycle 2011–2014 since the data for vitamin D along with serum copper, zinc and selenium is available from only 2011–2014 adjusted for age, sex, race, BMI, DM, gout, smoking, alcohol. The model also included eGFR, log albumin-creatinine ratio, log urine flow rate, serum osmolality, serum calcium, phosphate, 25-OH vitamin D, serum copper, selenium and zinc

Model 3 is performed in NHANES cycle 2013–2014 only among female since the data for serum estrogen along with other parameters is available from only 2013–2014 adjusted for age, race, BMI, DM, gout, smoking, alcohol. The model also included eGFR, log albumin-creatinine ratio, log urine flow rate, serum osmolality, serum calcium, phosphate, 25-OH vitamin D, serum copper, selenium, zinc and estrogen

Model 4 is performed in NHANES cycle 2011–2014 only among male since the data for serum testosterone along with other parameters is available from only 2011–2014 adjusted for age, race, BMI, DM, gout, smoking, alcohol. The model also included eGFR, log albumin-creatinine ratio, serum osmolality, serum calcium, phosphate, 25-OH vitamin D, copper, selenium, zinc and testosterone

diabetes [34], and metabolic syndrome [35] over time might increase in affecting the rate of kidney stones. However, regarding laboratory risk factors, there are limited data from the previous literature. Our study investigated the association between sex hormones and the risk of KS. Interestingly, we found that serum testosterone among male stone formers was lower than non-stone formers in contrast with the previous purported belief that testosterone may promote calcium oxalate stone formation. Testosterone enhances the activity of hepatic glycolic acid oxidase, suppresses osteopontin in the kidney and increases urinary oxalate excretion [36–38]. Nonetheless, more recent studies reported low serum testosterone levels in men were associated with a higher risk of KS [39, 40]. Potential explanations for these findings are obesity and metabolic syndrome including diabetes and hypertension, which confound the association between low serum testosterone and risk of KS. Metabolic syndrome and obesity are strongly associated with a higher risk of kidney stones [29] and are associated with lower testosterone levels [41, 42]. Obesity and metabolic syndrome including insulin resistance increase inflammatory cytokine leading to a suppression of testosterone production [43] as well as precipitating kidney stone formation through the expression of monocyte chemoattractant protein 1, osteopontin and macrophage infiltration [44]. Similarly, for estrogen, we observed lower mean serum estrogen among female stone formers compared to non-stone formers. Estrogen has antilithogenic effects: it inhibits bone resorption and increases calcium absorption in the distal tubule, and increases urine citrate excretion [45–47]. Nevertheless, we did not find a significant association between serum estrogen and KS. Thus, the multivariable-adjusted model demonstrated that the differences in testosterone and estrogen levels by KS status could be explained by other factors. Future studies should explore these complex interactions between estrogen and testosterone and risk of KS along with assessing 24-h urine chemistry.

After multivariable adjustment, higher albumin-creatinine ratio and serum osmolality in model 1 were independently associated with higher odds of history of KS. Having a history of KS might increase the risk of CKD and proteinuria [48]. Additionally, higher serum osmolality was associated with higher odds of history of KS. The most likely explanation is lower fluid consumption, one of the strongest risk

factors for stone formation [49, 50]. However, these findings were not significant in either model 2, 3 or 4 possibly due to confounding by serum trace elements and sex hormones on urine albumin-creatinine ratio and serum osmolality. Furthermore, using data from NHANES cycle 2011–2014, we unexpectedly found that higher serum copper was independently associated with lower odds of history of KS among men but not women, and the interaction of serum copper and sex was statistically significant. Some studies postulated that copper might have a modest inhibitory effect on calcium phosphate crystallization [51, 52]. However, lithogenic effects of copper still remain unclear since a study by Ferraro et al. [53] revealed that higher total intake of copper was associated with a higher risk of KS; however, this association was significant only among women. Furthermore, serum copper was no longer associated with lower odds of history of KS after Bonferroni adjustment (Bonferroni p-value = 0.06).

Regarding vitamin D, there was no significant difference in serum 25(OH)D level between stone formers and non-stone formers in our study. A previous study from the UK reported that ~ 30% of stone formers had vitamin D deficiency while only 18% of stone formers had vitamin D deficiency in our study. However, it is difficult to compare across studies since the distributions of ethnicity, dietary patterns, geographic location, seasonal variation and the technique of vitamin D measurement might be different. Moreover, in our study, it appears that replete vitamin D, defined as serum 25(OH)D level ≥ 75 nmol/l, was not significantly associated with odds of KS. It is uncertain whether vitamin D supplementation, especially among individuals with vitamin D deficiency, would increase the risk of KS. Previous studies did not show a significant risk of KS even though there was a non-significant rise in 24-h urine calcium excretion [54]. Furthermore, a study by Ferraro et al. did not find a significant association between vitamin D intake in typical amounts and risk of KS. The relationship between vitamin D intake, circulating level of 25(OH)D and risk of kidney stones is complex as the active metabolite 1,25(OH)2D, a pivotal factor of calcium stone formation is tightly regulated by the activity of 1-alpha-hydroxylase enzyme and PTH axis [55–57].

Prior studies by Scales et al. [17] focused on responses to the 2007–2010 NHANES and Chen et al. [10] performed analysis using data from 2007 to 2014. While these studies examined overall trends over periods of time, neither one reported statistical tests for the time trends across age, sex and races. Our study updated the prevalence of KS with the newest available data in NHANES and age-standardized to 2010 US Census to compare populations at more than two-time points and to remove the impact of different age distributions. Additionally, we also examined risk factors of kidney stones based upon various laboratory chemistries including sex hormones and trace elements. Compared to previous studies using different cohorts by Tasian et al. [58] based on South Carolina Medical Encounter data and Kittanamongkolchai et al. [59] based on Rochester Epidemiology Project data results from all studies including our study demonstrated the overall increasing rates of KS. There was a significant increasing rate of KS among female. This increase in the rate of KS parallels with the increase in female obesity in the US [19, 60]. However, the change in rates of KS among male was not consistent across studies. Our results did not show a significant change in the linear trend of the rate of KS consistent with the study by Tasian et al. that reported a relatively stable rate of KS among men but in contrast to the study by Kittanamongkolchai et al. that showed a significant increase in KS rate in men. In terms of race, although there were increasing rates of KS among non-Hispanic whites and blacks, these trends were not statistically significant in our study. Similarly, the study by Tasian et al. pointed out that the rates of kidney stones were increasing in whites and blacks. However, they found that the change in the rate of KS was greater among blacks.

Limitations include the cross-sectional study design of NHANES. Hence, the temporal relationship between KS and laboratory values cannot be determined. We could only estimate the associations but not causal effects. In addition, since NHANES data are self -reported, response to kidney stone questions in the survey might not be as accurate as coded data. Validation of a history of kidney stone might be needed. However, a recent population-based study in Olmsted County, Minnesota identified participants based upon ICD-9 codes and manual chart review. This study also found the rate of kidney stones had been increasing from 1984 to 2012, especially among men and women aged 18-60 years old [59]. Finally, NHANES did not have information on some bone-mineral markers and no 24-hour urine data.

In conclusion, there was substantial variability in the prevalence of KS during individual 2-year time periods. However, there was an overall increase in prevalence of KS over 2007-2016. Future analyses of NHANES data on kidney stones as well as other chronic conditions should keep this variability in mind before drawing conclusions about abrupt changes in prevalence. The variability of period-specific prevalence values emphasizes the importance of examining long-term trends using more than a single 2-year cycle in analyses to increase the precision of the estimate.

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Ureteroscopy and Shock Wave Lithotripsy Trends from 2012 to 2019 Within the US Medicare Dataset: Sharp Growth in Ureteroscopy Utilization

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Abstract

Introduction and Objective: Both ureteroscopy (URS) and shock wave lithotripsy (SWL) are cornerstones in the surgical management of urolithiasis in the United States. We hypothesized that URS utilization outpaced SWL utilization in recent years and quantified the magnitude of change over time for caseloads of URS and SWL among urologists from a national Medicare database.

Methods: Using the public "Medicare Physician & Other Practitioners" database (https://data.cms.gov), we determined case numbers of SWL (current procedural terminology [CPT] 50590) and URS (CPT 52356 or 52353) from 2012 to 2019. In a subanalysis, we identified "high-volume stone urologists" as those in the upper quartile of case numbers for both SWL and URS in baseline years of either 2012 or 2013 and trended their caseload from 2012 to 2019. Linear estimation models assessed annual rates of change and their statistical significance.

Results: In 2012, urologists performed 41,135 SWL procedures *vs* 21,184 URS. URS overtook SWL in 2017 and by 2019 was the dominant modality (60,063 URS *vs* 43,635 SWL). Between 2012 and 2019, total URS cases annually increased by 5700 (15%/year, $p<0.001$), while the number of SWL cases peaked in 2015 and has since declined on average −1.6%/year ($p=0.020$). The number of urologists performing URS steadily rose from 1147 in 2012 to 2809 in 2019, reflecting an additional 246 urologists (21%/year) performing URS annually. The caseload of high-volume stone urologists showed similar trends with average URS cases increasing by 2.9/year/urologist (9.8%/year, $p<0.001$) and average SWL cases declining by 0.9/year/urologist (−1.7%/year, $p=0.023$).

Conclusions: URS utilization has increased dramatically and outpaced SWL utilization from 2012 to 2019 within the Medicare population. URS was increasingly used by both the general urologist population and high-volume stone urologists while SWL utilization has begun to decline.

Keywords: urolithiasis, ureteroscopy, shock wave lithotripsy, trend, Medicare

Introduction and Objective

KIDNEY STONES ARE a common problem with a steadily rising prevalence, affecting roughly 10% of all Americans.[1, 2] The American Urological Association recommends surgical management of renal and ureteral stones <20 mm with either shock wave lithotripsy (SWL) or ureteroscopy (URS) with selection of modality influenced by stone size/location, patient anatomy, and surgeon and patient preference.[3] While SWL technology has remained relatively stagnant over time, optics and laser technology used in URS have dramatically improved over the last two decades increasing the overall effectiveness of URS.[4]

Prior studies have reported on the increasing use of URS and declining use of SWL.[5] Using the 5% Medicare Public Use Files (a subset of the Medicare dataset containing a 5%

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random sample of beneficiaries) and selecting patients with a diagnosis of renal calculi, Seklehner et al found that SWL was the dominant modality in 2001, accounting for 91.6% of stone procedures, but declined to 79.4% in 2010[6]. The same authors found that ureteral stones were predominantly managed with URS, the utilization of which increased from 63% of stone procedures in 2001 to 70% in 2010.[7] Using administrative databases in Ontario, Canada, Ordon et al performed a cross-sectional time series analysis on all SWL, URS, and percutaneous nephrolithotomy procedures from 1999 to 2010. Their results demonstrated that the use of URS increased from 25% to 59% of all procedures while SWL declined from 68% to 34%[8].

These studies examined trends in stone surgery of the first decade of the 21st century. While more recent reports of trends in other countries have been published[9, 10], to our knowledge, recent publications on the broad utilization trends of URS and SWL in the United States are lacking. Our primary objective was to elucidate contemporary SWL and URS utilization within the US Medicare population. We aimed to quantify both the absolute and relative annual changes in total case numbers of URS *vs* SWL over the 8-year period spanning 2012–2019.

To further understand utilization trends, we analyzed the trends of high-volume stone urologists to reveal whether the practice pattern trends of these "more clinically active" stone urologists were congruent or discordant with all urologists. Our rationale for this query was that high-volume stone urologists may be more likely to fill the bulk of their clinical time treating urolithiasis and thus serve as a proxy for "experts" in the surgical management of urolithiasis. The final objective was to analyze regional relative utilization of URS *vs* SWL and the rate of transition to predominantly URS by region.

Methods

Using the public data available from the Centers for Medicare & Medicaid services within the "Medicare Physician & Other Practitioners" dataset (https://data.cms.gov), we determined case volumes of SWL (CPT 50590) and URS (CPT 52356 or 52353) for urologists spanning the years between 2012 and 2019. This dataset includes Healthcare Common Procedure Coding System codes (which includes CPT codes) organized by National Provider Identifier (NPI). Urologists' NPIs were used to link individual annual datasets together to form a cohesive dataset spanning 8 years. The first year, in which a unique NPI was introduced into the dataset, was used as the urologist's baseline demographic year and location of service. Of note, to protect the privacy of Medicare beneficiaries, any urologist who performed 10 or fewer procedures is excluded from the dataset. IRB waiver was granted for this research involving publicly available administrative de-identified data.

Total counts of SWL and URS procedures were graphically plotted with time on the x-axis. Linear regression estimation was utilized to estimate rates of annual change, and *p*-values were generated to assess whether time was significantly linearly correlated. Urologists were categorized as to whether they performed URS only, SWL only, or both procedures, and the percentage within each category was charted across time to generate a graphical representation of urologists' practice patterns. Average caseloads of URS and SWL procedures by high-volume stone urologists were trended over time.

We considered a "high-volume stone urologist" as those in the upper quartile of case volumes for both SWL and URS in either the baseline years of 2012 or 2013. The average number of procedures performed by this group of urologists was then trended from 2012 to 2019. The average Medicare reimbursements for SWL and URS were examined over time to identify if Medicare reimbursement was correlated with utilization trends.

In examining regional trends of SWL and URS utilization, we chose to define regions according to the nine U.S Census Bureau Census Divisions (New England, Middle Atlantic, East North Central, West North Central, South Atlantic, East South Central, West South Central, Mountain, and Pacific, see https://www2.census.gov/geo/pdfs/maps-data/maps/reference/us_regdiv.pdf). To show the relative use trends more clearly within each region, we compared the ratio of URS:SWL cases over time within each region and used linear regression to estimate an annualized rate of change of this ratio.

Results

The dataset included a total of 6169 urologists, all of whom performed 11 or more SWL or URS procedures on Medicare patients between the years of 2012 and 2019. The number of urologists performing SWL in 2012 was 1661 and rose to a peak of 1859 in 2015 followed by a decline to 1772 in 2019. In contrast, the number of urologists performing URS steadily rose from 1147 in 2012 to 2809 in 2019, reflecting an additional 246 urologists (21%/year) performing URS per year. These trends mirror the overall case volume trends of SWL and URS.

In 2012, SWL was the preferred modality with 41,135 SWL (66%) performed *vs* 21,184 URS (33%) procedures. URS volume overtook SWL in 2017 and by 2019 was the clear dominant treatment modality (60,063 URS [58%] *vs* 43,635 SWL [42%], Fig. 1). The overall increase in combined URS and SWL procedures was 9.5%/year, rising from 62,319 procedures in 2012 to 103,698 procedures in 2019.

From 2012 to 2019, an estimated growth of 5700 total URS cases/year (15%/year, $p < 0.001$) was observed, while SWL cases did not significantly increase (370 cases/year, $p = 0.21$). In fact, after 2015, SWL declined on average −1.6%/year ($p = 0.020$). The average URS caseload for urologists who

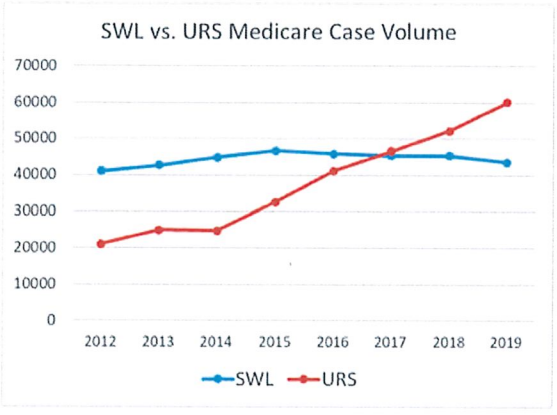

FIG. 1. Total annual Medicare SWL case numbers compared to total URS case volumes. SWL, shock wave lithotripsy; URS, ureteroscopy. Color graphics are available online.

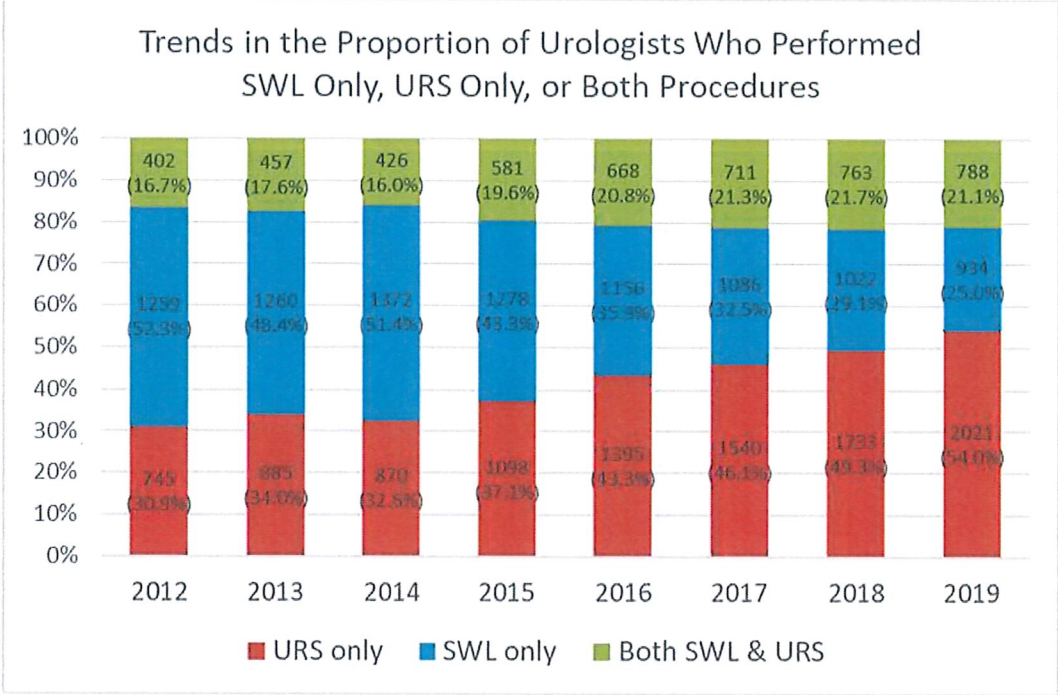

FIG. 2. One hundred percent stacked *column* chart showing the proportional trends of urologists who performed URS only, SWL only, and both SWL and URS. Absolute urologist number above the percentage proportion in *parenthesis*. Color graphics are available online.

performed any URS increased from 18.5 in 2012 to 21.4 in 2019. In contrast, the average SWL caseload for urologists who performed any SWL remained steady at roughly 25 cases/year throughout the observation period.

Figure 2 displays trends of urologists' use of only URS, only SWL, or both procedures. While the percentage of urologists who performed 10 or more of each procedure stayed roughly constant, ranging from 17% in 2012 to 22% in 2018, the percentage of urologists performing only SWL and only URS changed significantly overtime. In 2012, 52% of urologists performed only SWL, which declined to 25% of urologists by 2019. In contrast, the percentage of urologists who only performed URS steadily grew from 31% in 2012 to 54% in 2019.

Among urologists meeting criteria for a high-volume stone urologist, defined as those in the upper quartiles for both URS (20) and SWL (27) procedures in 2012 or 2013, the mean URS caseload grew from 31.9 in 2012 to 53.6 in 2019, representing an average annual increase of 2.9 URS/year/urologist (9.7%/year, $p<0.001$) (Fig. 3). Conversely, mean SWL caseloads declined from 65.6 in 2012 to 58.3 in 2019, reflecting a rate of –0.9 SWL/year/urologist (–1.5%/year, $p=0.023$). Thus, the general practice patterns of high-volume stone urologists who increasingly utilized more URS while performing marginally fewer SWL was like that of the overall case volume trends of SWL and URS.

Average Medicare reimbursements for SWL and URS were compared across all 8 years, and the mean Medicare payment for SWL was $\$445 \pm \$66$ compared with $\$327 \pm \$53$ for URS ($p<0.001$). There was no significant change in reimbursement from 2012 to 2019 for URS procedures ($3.56/year, $p=0.068$), but SWL reimbursement marginally increased an average of $3.24/year ($p=0.006$).

Figure 4 shows regional URS and SWL utilization over time. In 2012, SWL procedures outnumbered URS in all nine geographical regions. The URS:SWL ratio ranged from 0.43 in the West South Central region to 0.67 in the West North Central region. By 2019, all regions except the West South Central had higher URS caseloads compared to SWL. There was significant variation in the annual linear rates of change in the URS:SWL ratio between regions. Compared to the East South Central region, which had the lowest annual rate increase in the URS:SWL ratio (0.07/year), the West North Central Region had more than twofold this increase (0.17/year).

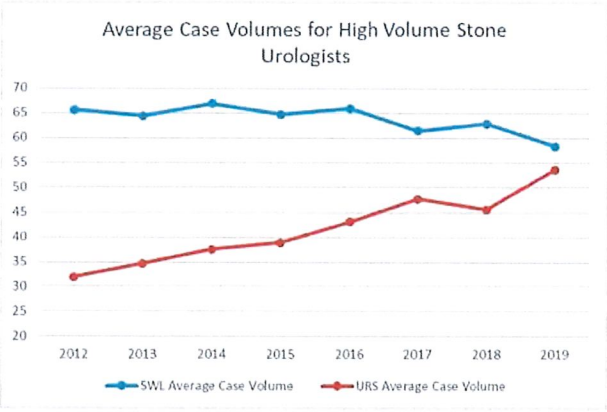

FIG. 3. Average case volumes for high-volume stone urologists (within the upper quartile of URS and SWL procedures in baseline years of 2012 or 2013). Color graphics are available online.

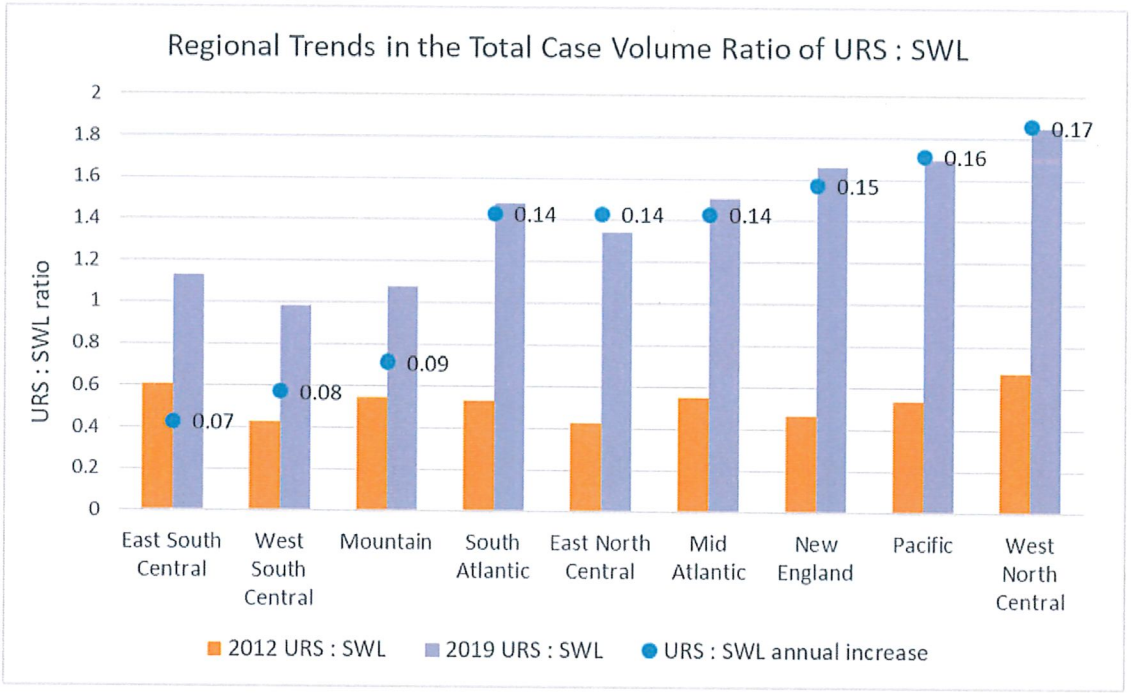

FIG. 4. Regional trends in the total case volume ratio of the URS:SWL comparing 2012 with 2019. The linear estimated annual rate of change of this ratio is plotted as *blue dots* with specified values. Color graphics are available online.

The three regions with the lowest annual rate increase in the URS:SWL ratio—West South Central (0.08/year), Mountain (0.09/year), and East South Central (0.07/year)—all ended 2019 with the lowest URS:SWL ratios, ranging from 0.98 to 1.13. This contrasts with the three regions with the highest annual rate increase in the URS:SWL ratio—New England (0.15/year), Pacific (0.16/year), and West North Central (0.17/year)—all of which ended 2019 with the highest URS:SWL ratios, ranging from 1.65 to 1.84.

Discussion

Medicare case numbers of URS surpassed SWL in 2017 and have increased at a rate of 15%/year since 2012 while SWL case numbers have declined at a rate of −1.6%/year since 2015. Our study confirms that URS is now the dominant modality over SWL for the treatment of stones in the United States. The increase of URS in the United States is considerable when compared to a similar analysis of Australia's Medicare database that showed an average URS volume increase of 9.3%/year while SWL decreased by −3.5%/year.[11] In the present study, the overall combined increase of URS and SWL at 9.5%/year surpasses the expected growth of stone surgery if considering the annual average growth rate of the United States population from 2012 to 2019 of 0.6%/year[12] and the 2% rise in the prevalence of kidney stones during this time period.[1]

We found that the practice patterns of high-volume stone urologists generally reflected the utilization trends of the entire urology population. Interestingly, despite average SWL caseloads in a downward trend for high-volume stone urologists, their average SWL caseloads remained slightly higher than URS even in 2019 (Fig. 3), showing that high-volume stone urologists are more likely to utilize SWL when compared to the entire urologist population. Reduction in SWL utilization in the Medicare population has been less pronounced when compared to the Ontario utilization study that showed URS utilization overtaking SWL in 2004 with SWL representing only 34% of all stone procedures by 2010 [8]. Increased Medicare reimbursement for SWL may be a contributing factor in SWL's slower decline in the United States in addition to other practice pattern differences and differing demographics of the study populations.

Despite the seemingly slow decline in the absolute number of SWL cases since 2015, the percentage of urologists who utilized SWL fell substantially from 69% in 2012 to 46% in 2019. Combining this trend with the 21%/year increase in the number of new urologists performing URS, we can deduce that new urologists favor URS over SWL. Factors driving decreasing relative utilization of SWL may include diminishing access to lithotripters, lower confidence in the treatment results, senior urologists leaving the workforce, and changing practice patterns of newer urologists.

Factors driving the increased utilization of URS are probably multifactorial. As Medicare reimbursement has remained steady throughout the years with SWL reimbursing higher than URS, Medicare financial incentives are not likely to be the driving factor of increased URS utilization. Potential factors contributing to the increased utilization of URS are the constantly improving ureteroscope[13] and laser capabilities,[14] residency and endourology fellowship training that emphasize management with URS over SWL, and the development of single-use ureteroscopes that may improve the attractiveness of URS for lower volume providers.[15,16] Other factors to consider include cost and quality of life outcomes; while URS has been shown to be more cost

effective than SWL in a meta-analysis, which may favor clinician preference for URS[17], more research is needed on whether one modality has superior quality of life outcomes.[18]

Regional discrepancies for URS and SWL utilization were observed as were differences in the rate of change for more URS utilization over SWL. Although all regions trended toward use of more URS compared to SWL over time, the Southern and Mountain regions had the slowest transition toward a URS dominant practice. The West South-Central region was the only region in which a greater proportion of SWL *vs* URS utilization persisted throughout the 8-year period. Coastal and Northern regions generally saw a similar rate of increasing preference for URS over SWL. The fact that such regional discrepancies exist suggest differential engagement with surgical stone guidelines and possible variable access to technology.

The limitations of our study stem from using a large administrative Medicare dataset that lacks clinical detail. As an administrative dataset that organizes billing codes by NPI, there are no data available on individual patient demographics, whether repeat surgeries were performed on the same patient, or any information regarding diagnosis codes that might hint at stone location, stone characteristics, or indications for procedures. Furthermore, the dataset represents only claims made for Medicare beneficiaries with Part B fee-for-service coverage. It does not include patients who are enrolled in any form of Medicare Advantage plan, private insurance, Medicaid, or the uninsured and is thus not fully representative of all the URS and SWL performed in the United States representing <20% of total insurance coverage in the United States.

Despite this limitation, we believe the Medicare population provides a reasonable approximation for URS and SWL utilization trends in the United States as the data are reliable from a single source and the procedures do not have any significant age bias to our knowledge. Another important limitation is the dataset's omission of providers who performed 10 or fewer procedures, which results in an inaccurate count of the total procedures performed and of the total number of urologists who performed URS or SWL. This 10 or fewer procedure cutoff likely slightly skews the results toward an underestimation of total URS cases compared to SWL cases, as a higher proportion of total URS *vs* SWL cases were done by urologists with lower caseloads. We suspect that had the entire caseload of URS and SWL been completely represented in this dataset, URS may have become the predominant modality even before 2017.

Conclusions

Our results show that in the Medicare population from 2012 to 2019, URS utilization dramatically outpaced SWL with URS now the dominant modality. The utilization of URS rose on average 15%/year with utilization similar trends observed between and high-volume stone urologists and the entire urologist population. In contrast, SWL case numbers began to slowly decline after 2015. Overall, the increase in the combined numbers of SWL and URS at 9%/year exceeded that which could be expected from United States population growth and rising prevalence of urolithiasis, revealing that stone surgery utilization has increased relative to the total population growth. Finally, substantial regional variation for utilization of URS over SWL and the rate of transition toward URS was observed, which may be the result of varying access to technology or training differences.

Authors' Contributions

C.R.H.: protocol/project development, data collection/management, data analysis, and article writing/editing. S.L.: data collection/management, data analysis. M.A.K.: protocol/project development and article writing/editing. K.L.P.: protocol/project development and article writing/editing. S.Y.N.: protocol/project development and article writing/editing.

Author Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

CPT = current procedural terminology
NPI = National Provider Identifier
SWL = shock wave lithotripsy
URS = ureteroscopy

Accreditation Council for
Graduate Medical Education

ACGME Program Requirements for Graduate Medical Education in Urology

ACGME approved major revision: June 10, 2018; effective July 1, 2019

ACGME Program Requirements for Graduate Medical Education in Urology

Common Program Requirements are in BOLD

Where applicable, text in italics describes the underlying philosophy of the requirements in that section. These philosophic statements are not program requirements and are therefore not citable.

Introduction

Int. A. **Residency is an essential dimension of the transformation of the medical student to the independent practitioner along the continuum of medical education. It is physically, emotionally, and intellectually demanding, and requires longitudinally-concentrated effort on the part of the resident.**

The specialty education of physicians to practice independently is experiential, and necessarily occurs within the context of the health care delivery system. Developing the skills, knowledge, and attitudes leading to proficiency in all the domains of clinical competency requires the resident physician to assume personal responsibility for the care of individual patients. For the resident, the essential learning activity is interaction with patients under the guidance and supervision of faculty members who give value, context, and meaning to those interactions. As residents gain experience and demonstrate growth in their ability to care for patients, they assume roles that permit them to exercise those skills with greater independence. This concept--graded and progressive responsibility--is one of the core tenets of American graduate medical education. Supervision in the setting of graduate medical education has the goals of assuring the provision of safe and effective care to the individual patient; assuring each resident's development of the skills, knowledge, and attitudes required to enter the unsupervised practice of medicine; and establishing a foundation for continued professional growth.

Int. B. Urology ~~is the specialty that~~ evaluates and treats patients with disorders of the genitourinary tract, including the adrenal gland and external genitalia. Specialists in this discipline must demonstrate knowledge of the basic and clinical sciences related to the normal and diseased genitourinary system, as well as attendant skills in medical and surgical therapy. Residency programs must educate physicians in the prevention and treatment of genitourinary disease, including the diagnosis, medical, and surgical management, and reconstruction of the genitourinary tract.

Int. C. Duration and Scope of Education

The educational program in urology must be 60 months in length. (Core)

~~A minimum of 48 months of clinical urology education is required. Within the final 24 months of urology education, residents must serve at least 12 months as a chief resident.~~ (Core)

I. Institutions

I.A. Sponsoring Institution

One sponsoring institution must assume ultimate responsibility for the program, as described in the Institutional Requirements, and this responsibility extends to resident assignments at all participating sites. (Core)

The sponsoring institution and the program must ensure that the program director has sufficient protected time and financial support for his or her educational and administrative responsibilities to the program. (Core)

I.A.1. The program director must devote at least 20 percent of his or her professional effort to the administrative and educational activities of the program and receive corresponding financial support for this time. (Core)

I.A.2. The program director must not be required to generate clinical or other income to finance this administrative time. (Core)

I.B. Participating Sites

I.B.1. There must be a program letter of agreement (PLA) between the program and each participating site providing a required assignment. The PLA must be renewed at least every five years. (Core)

The PLA should:

I.B.1.a) identify the faculty who will assume both educational and supervisory responsibilities for residents; (Detail)

I.B.1.b) specify their responsibilities for teaching, supervision, and formal evaluation of residents, as specified later in this document; (Detail)

I.B.1.c) specify the duration and content of the educational experience; and, (Detail)

I.B.1.d) state the policies and procedures that will govern resident education during the assignment. (Detail)

I.B.2. The program director must submit any additions or deletions of participating sites routinely providing an educational experience, required for all residents, of one month full time equivalent (FTE) or more through the Accreditation Council for Graduate Medical Education (ACGME) Accreditation Data System (ADS). (Core)

I.B.3. ~~Assignments at participating sites must be of sufficient length to ensure a quality educational experience, and should provide sufficient opportunity for continuity of care. Although the number of participating sites may vary, all participating sites must demonstrate the ability to promote the program goals.~~ (Core)

I.B.4. ~~The inclusion of more than four~~ Addition of participating sites for required rotations must be based on sound educational rationale and approved in advance by the Review Committee. ~~Two or more residents should rotate to each participating site to maintain peer interaction.~~ (~~Detail~~Core)

I.B.4.a) Assignments to distant sites must be ~~justified~~based on the ~~basis of~~ educational resources that are not available at the ~~sponsoring institution~~ primary clinical site or at a nearby participating site. (~~Detail~~ Core)

II. Program Personnel and Resources

II.A. Program Director

II.A.1. There must be a single program director with authority and accountability for the operation of the program. The sponsoring institution's GMEC must approve a change in program director. (Core)

II.A.1.a) The program director must submit this change to the ACGME via the ADS. (Core)

II.A.2. The program director should continue in his or her position for a length of time adequate to maintain continuity of leadership and program stability. (Detail)

II.A.2.a) ~~The program director should continue in his or her position for a minimum of six years.~~ (~~Detail~~)

II.A.2.b) An absence of three months or more for the program director must be reported to the Review Committee. In such situations, an interim program director must be appointed and approved by the Review Committee. (Core)

II.A.3. Qualifications of the program director must include:

II.A.3.a) requisite specialty expertise and documented educational and administrative experience acceptable to the Review Committee; (Core)

II.A.3.b) **current certification in the specialty by the American Board of** Urology**, or specialty qualifications that are acceptable to the Review Committee;** (Core)

II.A.3.c) current medical licensure and appropriate medical staff appointment; (Core)

II.A.3.d) documented clinical and teaching skills and scholarly ~~expertise~~activity in urology; and, (Core)

II.A.4. **The program director must administer and maintain an educational environment conducive to educating the residents in each of the ACGME competency areas.** (Core)

The program director must:

II.A.4.a) **oversee and ensure the quality of didactic and clinical education in all sites that participate in the program;** (Core)

II.A.4.b) **approve a local director at each participating site who is accountable for resident education;** (Core)

II.A.4.b).(1) The local site director must be a urologist in good standing at the participating site and have the majority of his or her practice at that site~~;~~. (Core)

II.A.4.b).(2) ~~The local site director must be responsible for the education of the residents at the participating site; and,~~ (~~Detail~~)

II.A.4.b).(3) ~~The local site director must be responsible for the supervision of all educational and clinical activities of the program at that site.~~ (~~Detail~~)

II.A.4.c) **approve the selection of program faculty as appropriate;** (Core)

II.A.4.d) **evaluate program faculty;** (Core)

II.A.4.e) **approve the continued participation of program faculty based on evaluation;** (Core)

II.A.4.f) **monitor resident supervision at all participating sites;** (Core)

II.A.4.g) **prepare and submit all information required and requested by the ACGME.** (Core)

II.A.4.g).(1) **This includes but is not limited to the program application forms and annual program updates to the ADS, and ensure that the information submitted is accurate and complete.** (Core)

II.A.4.h) **ensure compliance with grievance and due process procedures as set forth in the Institutional Requirements and implemented by the sponsoring institution;** (Detail)

II.A.4.i) **provide verification of residency education for all residents, including those who leave the program prior to completion;** (Detail)

II.A.4.j) **implement policies and procedures consistent with the institutional and program requirements for resident duty**

hours and the working environment, including moonlighting, (Core)

and, to that end, must:

II.A.4.j).(1) distribute these policies and procedures to the residents and faculty; (Detail)

II.A.4.j).(2) monitor resident duty hours, according to sponsoring institutional policies, with a frequency sufficient to ensure compliance with ACGME requirements; (Core)

II.A.4.j).(3) adjust schedules as necessary to mitigate excessive service demands and/or fatigue; and, (Detail)

II.A.4.j).(4) if applicable, monitor the demands of at-home call and adjust schedules as necessary to mitigate excessive service demands and/or fatigue. (Detail)

II.A.4.k) monitor the need for and ensure the provision of back up support systems when patient care responsibilities are unusually difficult or prolonged; (Detail)

II.A.4.l) comply with the sponsoring institution's written policies and procedures, including those specified in the Institutional Requirements, for selection, evaluation and promotion of residents, disciplinary action, and supervision of residents; (Detail)

II.A.4.m) be familiar with and comply with ACGME and Review Committee policies and procedures as outlined in the ACGME Manual of Policies and Procedures; (Detail)

II.A.4.n) obtain review and approval of the sponsoring institution's GMEC/DIO before submitting information or requests to the ACGME, including: (Core)

II.A.4.n).(1) all applications for ACGME accreditation of new programs; (Detail)

II.A.4.n).(2) changes in resident complement; (Detail)

II.A.4.n).(3) major changes in program structure or length of training; (Detail)

II.A.4.n).(4) progress reports requested by the Review Committee; (Detail)

II.A.4.n).(5) requests for increases or any change to resident duty hours; (Detail)

II.A.4.n).(6) **voluntary withdrawals of ACGME-accredited programs;** (Detail)

II.A.4.n).(7) **requests for appeal of an adverse action; and,** (Detail)

II.A.4.n).(8) **appeal presentations to a Board of Appeal or the ACGME.** (Detail)

II.A.4.o) **obtain DIO review and co-signature on all program application forms, as well as any correspondence or document submitted to the ACGME that addresses:** (Detail)

II.A.4.o).(1) **program citations, and/or,** (Detail)

II.A.4.o).(2) **request for changes in the program that would have significant impact, including financial, on the program or institution.** (Detail)

II.A.4.p) ensure that the operative procedures performed by residents are entered in the ACGME Case Log System; and, (Core)

II.A.4.p).(1) The program director must review the Case Logs of each resident at least semi-annually and at graduation to ensure an even distribution, volume, and variety of operative experiences. (Core)

II.A.4.p).(2) ~~The annual and final logs must be signed by both the resident and the program director as a statement of their accuracy.~~ (Core)

II.A.4.p).(3) Upon graduation, the program director must ~~submit~~ provide each resident~~'s~~ with his or her final aggregate Case Log ~~of the urology years to the ACGME~~. (Core)

II.A.4.q) ~~conduct and document ongoing and final reviews of operative logs with residents to ensure an even distribution, volume, and variety of operative experiences;~~ (Detail)

II.A.4.r) notify each resident in writing, prior to admission, of the required length of the educational program, including both accredited and non-accredited time. (Core)

II.A.4.r).(1) The educational program's required length ~~may~~must not be changed without mutual agreement with the resident, unless there is a significant break in his or her educational program or unless the resident requires remedial education. (Core)

II.A.4.r).(2) ~~All educational program length changes for any resident must be approved in advance by the Review Committee;~~ (Core)

II.B. Faculty

II.B.1. At each participating site, there must be a sufficient number of faculty with documented qualifications to instruct and supervise all residents at that location. (Core)

The faculty must:

II.B.1.a) devote sufficient time to the educational program to fulfill their supervisory and teaching responsibilities; and to demonstrate a strong interest in the education of residents; and, (Core)

II.B.1.b) administer and maintain an educational environment conducive to educating residents in each of the ACGME competency areas. (Core)

II.B.2. The physician faculty must have current certification in the specialty by the American Board of Urology**, or possess qualifications judged acceptable to the Review Committee.** (Core)

II.B.2.a) To provide a ~~diverse~~well-rounded educational experience, ~~several~~ some faculty members should have subspecialty education and/or concentrate their practice in one or more ~~of the following~~ subspecialized urological domains~~:~~ (e.g., voiding dysfunction; female urology; reconstruction~~,~~; oncology; calculus disease; pediatrics; sexual dysfunction; and infertility). (Detail)

II.B.2.b) The faculty should include individuals with experience with the following urologic techniques: endo-urology; minimally-invasive intra-abdominal and pelvic surgical techniques (such as laparoscopy and robotic surgery); major flank and pelvic surgery; urologic imaging; and microsurgery. (~~Core~~Detail)

II.B.2.c) ~~Residents should have clinical interaction with faculty members having expertise in geriatrics, infectious disease, renovascular disease, renal transplantation, trauma, interventional radiology, plastic surgery, and medical oncology.~~ (~~Detail~~)

II.B.2.d) In addition to the program director, there must be ~~at least~~a minimum of two core clinical urology faculty members who devote sufficient time to supervise and teach the residents, and who are committed fully to the educational objectives of the ~~residency~~ program. (Core)

II.B.2.e) There must be a core faculty-to-resident ratio of at least 1:2 ~~in the total program~~. (Core)

II.B.2.e).(1) ~~The program director must be counted as one of the faculty members in determining this ratio.~~ (~~Core~~)

II.B.2.e).(2) ~~The program director must notify the Review Committee if the number of clinical urology faculty members drops below three, or if the ratio falls below 1:2 and remains below that level longer than one year.~~ (Core)

II.B.3. **The physician faculty must possess current medical licensure and appropriate medical staff appointment.** (Core)

II.B.4. **The nonphysician faculty must have appropriate qualifications in their field and hold appropriate institutional appointments.** (Core)

II.B.5. **The faculty must establish and maintain an environment of inquiry and scholarship with an active research component.** (Core)

II.B.5.a) **The faculty must regularly participate in organized clinical discussions, rounds, journal clubs, and conferences.** (Detail)

II.B.5.b) **Some members of the faculty should also demonstrate scholarship by one or more of the following:**

II.B.5.b).(1) **peer-reviewed funding;** (Detail)

II.B.5.b).(2) **publication of original research or review articles in peer reviewed journals, or chapters in textbooks;** (Detail)

II.B.5.b).(3) **publication or presentation of case reports or clinical series at local, regional, or national professional and scientific society meetings; or,** (Detail)

II.B.5.b).(4) **participation in national committees or educational organizations.** (Detail)

II.B.5.c) **Faculty should encourage and support residents in scholarly activities.** (Core)

II.C. Other Program Personnel

The institution and the program must jointly ensure the availability of all necessary professional, technical, and clerical personnel for the effective administration of the program. (Core)

II.C.1. The program must include a program coordinator who devotes a minimum of 20 percent of his or her effort per every five residents in the program. (Core)

II.D. Resources

The institution and the program must jointly ensure the availability of adequate resources for resident education, as defined in the specialty program requirements. (Core)

II.D.1. There must be adequate space and equipment for the educational program, including meeting rooms and classrooms with audiovisual and other educational aids; appropriate office space for residents; diagnostic, therapeutic, and research facilities; and outpatient facilities, clinic, and office space accessible to residents for pre-operative evaluation and post-operative follow-up. (Core)

II.D.2. Clinical facilities must contain state-of-the-art equipment to perform diagnostic and therapeutic procedures. (Core)

II.D.2.a) Equipment to perform the following procedures must be available: flexible cystoscopy; ureteroscopy; percutaneous endoscopy; percutaneous renal access~~, extracorporeal shock wave lithotripsy~~; ultrasonography and biopsy; fluoroscopy; laparoscopy~~, and~~; laser therapy; and renal and prostate ultrasound. (Core)

II.D.2.b) Urodynamic equipment ~~should~~must be present at a minimum of one site. (Core)

II.D.2.c) Video imaging ~~should~~must be available to allow adequate supervision and education during endoscopic procedures. (Core)

II.D.3. A sufficient number and variety of inpatient ambulatory adult and pediatric patients with urologic disease must be available for resident education. (Core)

II.E. Medical Information Access

Residents must have ready access to specialty-specific and other appropriate reference material in print or electronic format. Electronic medical literature databases with search capabilities should be available. (Detail)

III. Resident Appointments

III.A. Eligibility Criteria

The program director must comply with the criteria for resident eligibility as specified in the Institutional Requirements. (Core)

III.A.1. Eligibility Requirements – Residency Programs

III.A.1.a) All prerequisite post-graduate clinical education required for initial entry or transfer into ACGME-accredited residency programs must be completed in ACGME-accredited residency programs, or in Royal College of Physicians and Surgeons of Canada (RCPSC)-accredited or College of Family Physicians of Canada (CFPC)-accredited residency programs located in Canada. Residency programs must receive verification of each applicant's level of competency in the required clinical

field using ACGME or CanMEDS Milestones assessments from the prior training program. (Core)

III.A.1.a).(1) Program policies for resident selection should recognize the value and importance of diversity. (Detail)

III.A.1.a).(2) Based on educational objectives, an alternative format for admission to a urology residency includes a prerequisite of one year of education in an ACGME-accredited surgery program or an RCPSC-accredited surgery program located in Canada. (Core)

III.A.1.a).(3) ~~The prerequisite for admission to a urology residency program is a minimum of one year of education in an ACGME-accredited surgery program or an RCPSC-accredited surgery program located in Canada.~~ (Core)

III.A.1.a).(3).(a) ~~Based on educational objectives, two years of general surgery is an alternative format. During these one or two years, residents must spend a minimum of three months in general surgery, as well as a minimum of three months in the core surgical rotations of critical care, vascular surgery, or trauma. Additional clinical assignments must enhance the resident education and prepare residents for the practice of urology. If there is only a single year of general surgery, dedicated research time during that period is not allowed. The educational program for the general surgery period is developed by the program director of the respective surgery residency program with the input and approval of the respective urology program director.~~ (Detail)

III.A.1.b) **A physician who has completed a residency program that was not accredited by ACGME, RCPSC, or CFPC may enter an ACGME-accredited residency program in the same specialty at the PGY-1 level and, at the discretion of the program director at the ACGME-accredited program may be advanced to the PGY-2 level based on ACGME Milestones assessments at the ACGME-accredited program. This provision applies only to entry into residency in those specialties for which an initial clinical year is not required for entry.** (Core)

III.A.1.c) **A Review Committee may grant the exception to the eligibility requirements specified in Section III.A.2.b) for residency programs that require completion of a prerequisite residency program prior to admission.** (Core)

III.A.1.d) Review Committees will grant no other exceptions to these eligibility requirements for residency education. (Core)

III.A.2. Eligibility Requirements – Fellowship Programs

All required clinical education for entry into ACGME-accredited fellowship programs must be completed in an ACGME-accredited residency program, or in an RCPSC-accredited or CFPC- accredited residency program located in Canada. (Core)

III.A.2.a) Fellowship programs must receive verification of each entering fellow's level of competency in the required field using ACGME or CanMEDS Milestones assessments from the core residency program. (Core)

III.A.2.b) Fellow Eligibility Exception

A Review Committee may grant the following exception to the fellowship eligibility requirements:

An ACGME-accredited fellowship program may accept an exceptionally qualified applicant**, who does not satisfy the eligibility requirements listed in Sections III.A.2. and III.A.2.a), but who does meet all of the following additional qualifications and conditions: (Core)

III.A.2.b).(1) Assessment by the program director and fellowship selection committee of the applicant's suitability to enter the program, based on prior training and review of the summative evaluations of training in the core specialty; and (Core)

III.A.2.b).(2) Review and approval of the applicant's exceptional qualifications by the GMEC or a subcommittee of the GMEC; and (Core)

III.A.2.b).(3) Satisfactory completion of the United States Medical Licensing Examination (USMLE) Steps 1, 2, and, if the applicant is eligible, 3, and; (Core)

III.A.2.b).(4) For an international graduate, verification of Educational Commission for Foreign Medical Graduates (ECFMG) certification; and, (Core)

III.A.2.b).(5) Applicants accepted by this exception must complete fellowship Milestones evaluation (for the purposes of establishment of baseline performance by the Clinical Competency Committee), conducted by the receiving fellowship program within six weeks of matriculation. This evaluation may be waived for an applicant who has completed an ACGME International-accredited

residency based on the applicant's Milestones evaluation conducted at the conclusion of the residency program. (Core)

III.A.2.b).(5).(a) **If the trainee does not meet the expected level of Milestones competency following entry into the fellowship program, the trainee must undergo a period of remediation, overseen by the Clinical Competency Committee and monitored by the GMEC or a subcommittee of the GMEC. This period of remediation must not count toward time in fellowship training.** (Core)

**** An exceptionally qualified applicant has (1) completed a non-ACGME-accredited residency program in the core specialty, and (2) demonstrated clinical excellence, in comparison to peers, throughout training. Additional evidence of exceptional qualifications is required, which may include one of the following: (a) participation in additional clinical or research training in the specialty or subspecialty; (b) demonstrated scholarship in the specialty or subspecialty; (c) demonstrated leadership during or after residency training; (d) completion of an ACGME-International-accredited residency program.**

III.B. Number of Residents

The program's educational resources must be adequate to support the number of residents appointed to the program. (Core)

III.B.1. **The program director may not appoint more residents than approved by the Review Committee, unless otherwise stated in the specialty-specific requirements.** (Core)

III.B.2. Any ~~change~~increase in the number of residents~~, whether permanent or temporary,~~ must receive the prior approval of the Review Committee. (Core)

III.B.2.a) ~~Requests~~A request for ~~changes~~an increase in the resident complement of a program must be based on a strong educational rationale. (Core)

III.B.2.a).(1) The program must have a status of Continued Accreditation to request an increase in the resident complement. (Core)

III.B.2.a).(2) The program must demonstrate sufficient clinical volume for the increased complement, adequate faculty-to-resident ratio, and an appropriate plan for integrating new residents into the program. (Core)

III.B.2.b) ~~A vacancy in a resident complement, if filled, must be at the same level in which the vacancy occurs, unless otherwise approved by the Review Committee.~~ (~~Core~~)

III.C. Resident Transfers

III.C.1. Before accepting a resident who is transferring from another program, the program director must obtain written or electronic verification of previous educational experiences and a summative competency-based performance evaluation of the transferring resident. (Detail)

III.C.2. A program director must provide timely verification of residency education and summative performance evaluations for residents who may leave the program prior to completion. (Detail)

III.D. Appointment of Fellows and Other Learners

The presence of other learners (including, but not limited to, residents from other specialties, subspecialty fellows, PhD students, and nurse practitioners) in the program must not interfere with the appointed residents' education. (Core)

III.D.1. The program director must report the presence of other learners to the DIO and GMEC in accordance with sponsoring institution guidelines. (Detail)

III.D.2. A log that details the operative experience of all fellows (accredited and non-accredited) who may impact the core urology residents' experience must be maintained and be available for review by the Review Committee upon request. (Core)

III.D.2.a) ~~If a program's residents rotate to a participating site that offers an accredited or non-accredited fellowship program, the operative log of the fellow(s) at that site must be maintained.~~ (~~Core~~)

IV. Educational Program

IV.A. The curriculum must contain the following educational components:

IV.A.1. Overall educational goals for the program, which the program must make available to residents and faculty; (Core)

IV.A.2. Competency-based goals and objectives for each assignment at each educational level, which the program must distribute to residents and faculty at least annually, in either written or electronic form; (Core)

IV.A.3. Regularly scheduled didactic sessions; (Core)

IV.A.3.a) The curriculum must include didactic instruction in the core domains of:

IV.A.3.a).(1) calculus disease; (Core)

IV.A.3.a).(2) female pelvic medicine; (Core)

IV.A.3.a).(3) geriatric urology; (Core)

IV.A.3.a).(4) infertility and sexual dysfunction; (Core)

IV.A.3.a).(5) pediatric urology; (Core)

IV.A.3.a).(6) reconstruction; (Core)

IV.A.3.a).(7) urologic oncology; ~~and,~~ (Core)

IV.A.3.a).(8) urologic trauma; and, (Core)

IV.A.3.a).(9) voiding dysfunction. (Core)

IV.A.4. Delineation of resident responsibilities for patient care, progressive responsibility for patient management, and supervision of residents over the continuum of the program; and, (Core)

IV.A.5. ACGME Competencies

The program must integrate the following ACGME competencies into the curriculum: (Core)

IV.A.5.a) Patient Care and Procedural Skills

IV.A.5.a).(1) Residents must be able to provide patient care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health. (Outcome)

IV.A.5.a).(2) Residents must be able to competently perform all medical, diagnostic and surgical procedures considered essential for the area of practice. Residents: (Outcome)

IV.A.5.a).(2).(a) must ~~develop~~ demonstrate competence in providing direct patient care with increasing levels of responsibility in patient management as they advance through the program; (Outcome)

IV.A.5.a).(2).(b) must, under supervision, demonstrate competence in providing for the total care of the patient, including initial evaluation, establishment of diagnosis, selection of appropriate therapy,

providing that therapy, and management of complications; (Outcome)

IV.A.5.a).(2).(c) must ~~develop~~ demonstrate competence in providing continuity of patient care through pre-~~operative~~ and post-operative clinics and inpatient contact; ~~and,~~ (Outcome)

IV.A.5.a).(2).(c).(i) When residents participate in pre-~~operative~~ and post-operative care in a clinic or private office setting, the program director must ensure that the resident functions with an appropriate degree of responsibility under supervision. (Outcome)

IV.A.5.a).(2).(d) must be given responsibility ~~based upon~~commensurate with their individual knowledge, problem-solving ability, technical skills, experience, and the severity and complexity of each patient's status~~.~~; and, (Outcome)

IV.A.5.a).(2).(e) must develop competence in the following core techniques:

IV.A.5.a).(2).(e).(i) endo-urology; (Outcome)

IV.A.5.a).(2).(e).(ii) major open flank and pelvic surgery; (Outcome)

IV.A.5.a).(2).(e).(iii) ~~microsurgery; (Outcome)~~

IV.A.5.a).(2).(e).(iv) minimally-invasive intra-abdominal and pelvic surgical techniques including, laparoscopy and robotics; (Outcome)

IV.A.5.a).(2).(e).(v) perineal and genital surgery; and, (Outcome)

IV.A.5.a).(2).(e).(vi) urologic imaging including fluoroscopy, ~~interventional radiology,~~ and ultrasound. (Outcome)

IV.A.5.a).(3) ~~must demonstrate procedural competence by performing~~Each graduating resident must perform the minimum number of essential operative cases and case categories as established by the Review Committee. (Core)

IV.A.5.b) Medical Knowledge

Residents must demonstrate knowledge of established and evolving biomedical, clinical, epidemiological and social-behavioral sciences, as well as the application of this knowledge to patient care. Residents: (Outcome)

IV.A.5.b).(1) must ~~develop~~demonstrate knowledge of the following curricular topics:

IV.A.5.b).(1).(a) bioethics; (Outcome)

IV.A.5.b).(1).(b) biostatistics; (Outcome)

IV.A.5.b).(1).(c) calculus disease; (Outcome)

IV.A.5.b).(1).(d) epidemiology; (Outcome)

IV.A.5.b).(1).(e) evidence-based medicine; (Outcome)

IV.A.5.b).(1).(f) female pelvic medicine; (Outcome)

IV.A.5.b).(1).(g) infectious disease; (Outcome)

IV.A.5.b).(1).(h) infertility and sexual dysfunction; (Outcome)

IV.A.5.b).(1).(i) geriatrics; (Outcome)

IV.A.5.b).(1).(j) medical oncology; (Outcome)

IV.A.5.b).(1).(k) patient safety and quality improvement; (Outcome)

IV.A.5.b).(1).(l) pediatric urology; (Outcome)

IV.A.5.b).(1).(m) plastic surgery; (Outcome)

IV.A.5.b).(1).(n) pre-~~operative~~, intra-~~operative~~, and post-operative~~, and,~~ aspects of:

IV.A.5.b).(1).(n).(i) endoscopic-urology; (Outcome)

IV.A.5.b).(1).(n).(ii) major open flank and pelvic surgery; (Outcome)

IV.A.5.b).(1).(n).(iii) microsurgery; (Outcome)

IV.A.5.b).(1).(n).(iv) minimally-invasive intra-abdominal and pelvic surgical techniques, including laparoscopy and robotic surgery; (Outcome)

IV.A.5.b).(1).(n).(v) perineal and genital surgery; and, (Outcome)

IV.A.5.b).(1).(n).(vi) urologic imaging, including fluoroscopy, interventional radiology, and ultrasound. (Outcome)

IV.A.5.b).(1).(o) radiation safety; (Outcome)

IV.A.5.b).(1).(p) reconstruction; (Outcome)

IV.A.5.b).(1).(q) renal transplantation; (Outcome)

IV.A.5.b).(1).(r) renovascular disease; (Outcome)

IV.A.5.b).(1).(s) trauma; (Outcome)

IV.A.5.b).(1).(t) urologic oncology; and, (Outcome)

IV.A.5.b).(1).(u) voiding dysfunction. (Outcome)

IV.A.5.c) Practice-based Learning and Improvement

Residents must demonstrate the ability to investigate and evaluate their care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and life-long learning. (Outcome)

Residents are expected to develop skills and habits to be able to meet the following goals:

IV.A.5.c).(1) **identify strengths, deficiencies, and limits in one's knowledge and expertise;** (Outcome)

IV.A.5.c).(2) **set learning and improvement goals;** (Outcome)

IV.A.5.c).(3) **identify and perform appropriate learning activities;** (Outcome)

IV.A.5.c).(4) **systematically analyze practice using quality improvement methods, and implement changes with the goal of practice improvement;** (Outcome)

IV.A.5.c).(5) **incorporate formative evaluation feedback into daily practice;** (Outcome)

IV.A.5.c).(6) **locate, appraise, and assimilate evidence from scientific studies related to their patients' health problems;** (Outcome)

IV.A.5.c).(7) **use information technology to optimize learning; and,** (Outcome)

IV.A.5.c).(8) **participate in the education of patients, families, students, residents and other health professionals.** (Outcome)

IV.A.5.d) Interpersonal and Communication Skills

Residents must demonstrate interpersonal and communication skills that result in the effective exchange of information and collaboration with patients, their families, and health professionals. (Outcome)

Residents are expected to:

IV.A.5.d).(1) communicate effectively with patients, families, and the public, as appropriate, across a broad range of socioeconomic and cultural backgrounds; (Outcome)

IV.A.5.d).(2) communicate effectively with physicians, other health professionals, and health related agencies; (Outcome)

IV.A.5.d).(3) work effectively as a member or leader of a health care team or other professional group; (Outcome)

IV.A.5.d).(4) act in a consultative role to other physicians and health professionals; and, (Outcome)

IV.A.5.d).(5) maintain comprehensive, timely, and legible medical records, if applicable. (Outcome)

IV.A.5.e) Professionalism

Residents must demonstrate a commitment to carrying out professional responsibilities and an adherence to ethical principles. (Outcome)

Residents are expected to demonstrate:

IV.A.5.e).(1) compassion, integrity, and respect for others; (Outcome)

IV.A.5.e).(2) responsiveness to patient needs that supersedes self-interest; (Outcome)

IV.A.5.e).(3) respect for patient privacy and autonomy; (Outcome)

IV.A.5.e).(4) accountability to patients, society and the profession; and, (Outcome)

IV.A.5.e).(5) sensitivity and responsiveness to a diverse patient population, including but not limited to diversity in gender, age, culture, race, religion, disabilities, and sexual orientation. (Outcome)

IV.A.5.f) Systems-based Practice

Residents must demonstrate an awareness of and responsiveness to the larger context and system of health care, as well as the ability to call effectively on other

resources in the system to provide optimal health care. (Outcome)

Residents are expected to:

IV.A.5.f).(1) **work effectively in various health care delivery settings and systems relevant to their clinical specialty;** (Outcome)

IV.A.5.f).(2) **coordinate patient care within the health care system relevant to their clinical specialty;** (Outcome)

IV.A.5.f).(3) **incorporate considerations of cost awareness and risk-benefit analysis in patient and/or population-based care as appropriate;** (Outcome)

IV.A.5.f).(4) **advocate for quality patient care and optimal patient care systems;** (Outcome)

IV.A.5.f).(5) **work in interprofessional teams to enhance patient safety and improve patient care quality; and,** (Outcome)

IV.A.5.f).(6) **participate in identifying system errors and implementing potential systems solutions.** (Outcome)

IV.A.6. Curriculum Organization and Resident Experiences

IV.A.6.a) The program director must be responsible for the design, implementation, and oversight of the Uro-1 (PGY-1) year. The Uro-1 year must include: (Core)

IV.A.6.a).(1) at least six months of core surgical education in rotations outside of urology designed to foster competence in basic surgical skills, the peri-operative care of surgical patients, and inter-disciplinary patient care coordination, including: (Core)

IV.A.6.a).(1).(a) at least three months of general surgery; and, (Core)

IV.A.6.a).(1).(b) at least three months of additional non-urological surgical training. (Core)

IV.A.6.a).(2) at least a four week assignment on each non-urology rotation; (Core)

IV.A.6.a).(3) at least three months of urology rotations designed to develop competence in basic urological skills, general care of the urology patient both in the in-patient and ambulatory setting, management of urology patients in the emergency department, and a foundation of urology knowledge; and, (Core)

IV.A.6.a).(4) no more than three months total of non-surgical rotations designed to complement urological education which must be selected from the following: anesthesiology, interventional radiology, and nephrology. (Core)

IV.A.6.b) Uro-2 (PGY--2) through Uro-5 (PGY-5) years must include 48 months of education dedicated to didactic, clinical, and surgical urology. (Core)

IV.A.6.b).(1) Within the final 24 months of urology education, residents must serve at least 12 months as a chief resident. (Core)

IV.A.6.b).(1).(a) The clinical and academic experience as a chief resident should prepare the resident for an independent practice of urology. (Detail)

IV.A.6.b).(1).(b) ~~As such, t~~This chief resident experience should include management of patients with complex urologic disease, advanced procedures, and, with appropriate supervision, a high level of responsibility and independence. (Detail)

IV.A.6.c) ~~ensure that the d~~Didactic conferences must include:

IV.A.6.c).(1) ~~combined~~ morbidity and mortality ~~conferences for all participating sites~~; (Core)

IV.A.6.c).(2) urological imaging review ~~conferences~~; and, (Core)

IV.A.6.c).(3) ~~urological pathology conferences; and,~~ (Core)

IV.A.6.c).(4) journal review. (Core)

IV.A.6.d) ~~maintain a list of conferences.~~ (Core)

IV.A.6.e) Didactic ~~C~~conferences must be ~~well~~-attended by residents and core faculty members, and the list of conferences must include the date, conference topic, the name of the presenter(s), and the names of the faculty members and residents present for each conference. (Core)

IV.B. Residents' Scholarly Activities

IV.B.1. The curriculum must advance residents' knowledge of the basic principles of research, including how research is conducted, evaluated, explained to patients, and applied to patient care. (Core)

IV.B.2. Residents should participate in scholarly activity. (Core)

IV.B.2.a) A research rotation in the clinical years must not occur during the Uro-1 or Uro-5 year. Dedicated research time must not exceed six months in the eligible (Uro-2, Uro-3, and Uro-4) accredited years. (Core)

~~IV.B.2.b) Residents must demonstrate scholarly activity, including manuscript preparation, lectures, teaching activities, abstracts, and/or active performance of research or participation in clinical studies and reviews. (Outcome)~~

~~IV.B.2.c) Research included in the clinical years should not exceed a maximum of six months, and regular clinical duties must be assigned concurrently. (Core)~~

IV.B.3. The sponsoring institution and program should allocate adequate educational resources to facilitate resident involvement in scholarly activities. (Detail)

V. Evaluation

V.A. Resident Evaluation

V.A.1. The program director must appoint the Clinical Competency Committee. (Core)

V.A.1.a) At a minimum the Clinical Competency Committee must be composed of three members of the program faculty. (Core)

V.A.1.a).(1) The program director may appoint additional members of the Clinical Competency Committee.

V.A.1.a).(1).(a) These additional members must be physician faculty members from the same program or other programs, or other health professionals who have extensive contact and experience with the program's residents in patient care and other health care settings. (Core)

V.A.1.a).(1).(b) Chief residents who have completed core residency programs in their specialty and are eligible for specialty board certification may be members of the Clinical Competency Committee. (Core)

V.A.1.a).(2) The Clinical Competency Committee must include at least two core faculty members. (Core)

V.A.1.b) There must be a written description of the responsibilities of the Clinical Competency Committee. (Core)

V.A.1.b).(1) The Clinical Competency Committee should:

V.A.1.b).(1).(a) review all resident evaluations semi-annually; (Core)

V.A.1.b).(1).(b) prepare and ensure the reporting of Milestones evaluations of each resident semi-annually to ACGME; and, (Core)

V.A.1.b).(1).(c) advise the program director regarding resident progress, including promotion, remediation, and dismissal. (Detail)

V.A.2. Formative Evaluation

V.A.2.a) The faculty must evaluate resident performance in a timely manner during each rotation or similar educational assignment, and document this evaluation at completion of the assignment. (Core)

V.A.2.b) The program must:

V.A.2.b).(1) provide objective assessments of competence in patient care and procedural skills, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice based on the specialty-specific Milestones; (Core)

V.A.2.b).(2) use multiple evaluators (e.g., faculty, peers, patients, self, and other professional staff); (Detail)

V.A.2.b).(2).(a) There must be a minimum of three different ~~types~~sources of evaluations. (Detail)

V.A.2.b).(3) document progressive resident performance improvement appropriate to educational level; and, (Core)

V.A.2.b).(4) provide each resident with documented semiannual evaluation of performance with feedback. (Core)

V.A.2.c) The evaluations of resident performance must be accessible for review by the resident, in accordance with institutional policy. (Detail)

V.A.2.d) Assessment must specifically include monitoring the resident's medical knowledge by use of a formal examination such as the American Urological Association In-Service Examination or other cognitive examinations. (Core)

V.A.2.d).(1) Test results ~~must~~should be assessed annually ~~based on the specialty specific Milestones~~ and utilized to guide program curriculum and individual resident study plans. (Detail)

V.A.2.d).(2) Test results should not be used as the sole criterion of resident knowledge and should not be used as the sole criterion for promotion to a subsequent PG level. (Detail)

V.A.3. Summative Evaluation

V.A.3.a) The specialty-specific Milestones must be used as one of the tools to ensure residents are able to practice core professional activities without supervision upon completion of the program. (Core)

V.A.3.b) The program director must provide a summative evaluation for each resident upon completion of the program. (Core)

This evaluation must:

V.A.3.b).(1) become part of the resident's permanent record maintained by the institution, and must be accessible for review by the resident in accordance with institutional policy; (Detail)

V.A.3.b).(2) document the resident's performance during the final period of education; and, (Detail)

V.A.3.b).(3) verify that the resident has demonstrated sufficient competence to enter practice without direct supervision. (Detail)

V.B. Faculty Evaluation

V.B.1. At least annually, the program must evaluate faculty performance as it relates to the educational program. (Core)

V.B.2. These evaluations should include a review of the faculty's clinical teaching abilities, commitment to the educational program, clinical knowledge, professionalism, and scholarly activities. (Detail)

V.B.3. This evaluation must include at least annual written confidential evaluations by the residents. (Detail)

V.C. Program Evaluation and Improvement

V.C.1. The program director must appoint the Program Evaluation Committee (PEC). (Core)

V.C.1.a) The Program Evaluation Committee:

V.C.1.a).(1) must be composed of at least two program faculty members and should include at least one resident; (Core)

V.C.1.a).(1).(a) The Program Evaluation Committee must include at least two core faculty members. (Core)

V.C.1.a).(2) must have a written description of its responsibilities; and, (Core)

V.C.1.a).(3) should participate actively in:

V.C.1.a).(3).(a) planning, developing, implementing, and evaluating educational activities of the program; (Detail)

V.C.1.a).(3).(b) reviewing and making recommendations for revision of competency-based curriculum goals and objectives; (Detail)

V.C.1.a).(3).(c) addressing areas of non-compliance with ACGME standards; and, (Detail)

V.C.1.a).(3).(d) reviewing the program annually using evaluations of faculty, residents, and others, as specified below. (Detail)

V.C.2. The program, through the PEC, must document formal, systematic evaluation of the curriculum at least annually, and is responsible for rendering a written, annual program evaluation. (Core)

The program must monitor and track each of the following areas:

V.C.2.a) resident performance; (Core)

V.C.2.b) faculty development; (Core)

V.C.2.c) graduate performance, including performance of program graduates on the certification examination; (Core)

V.C.2.c).(1) At least 80 percent of the program's graduates from the preceding three years who take either the American Board of Urology Qualifying Examination or the American Board of Osteopathic Surgery-Urological Surgery written qualifying examination for the first time must pass. (Outcome)

V.C.2.c).(2) The results of residents' annual objective tests (such as the In-service Examination and the Qualifying Examination) must be included in the assessment of the strengths and weaknesses of the program. (Detail)

V.C.2.d) program quality; and, (Core)

V.C.2.d).(1) Residents and faculty must have the opportunity to evaluate the program confidentially and in writing at least annually, and (Detail)

V.C.2.d).(2) The program must use the results of residents' and faculty members' assessments of the program together with other program evaluation results to improve the program. (Detail)

V.C.2.e) progress on the previous year's action plan(s). (Core)

V.C.3. The PEC must prepare a written plan of action to document initiatives to improve performance in one or more of the areas listed in section V.C.2., as well as delineate how they will be measured and monitored. (Core)

V.C.3.a) The action plan should be reviewed and approved by the teaching faculty and documented in meeting minutes. (Detail)

VI. The Learning and Working Environment

Residency education must occur in the context of a learning and working environment that emphasizes the following principles:

- *Excellence in the safety and quality of care rendered to patients by residents today*
- *Excellence in the safety and quality of care rendered to patients by today's residents in their future practice*
- *Excellence in professionalism through faculty modeling of:*
  - *the effacement of self-interest in a humanistic environment that supports the professional development of physicians*
  - *the joy of curiosity, problem-solving, intellectual rigor, and discovery*
- *Commitment to the well-being of the students, residents, faculty members, and all members of the health care team*

VI.A. Patient Safety, Quality Improvement, Supervision, and Accountability

VI.A.1. Patient Safety and Quality Improvement

All physicians share responsibility for promoting patient safety and enhancing quality of patient care. Graduate medical education must prepare residents to provide the highest level of clinical care with

continuous focus on the safety, individual needs, and humanity of their patients. It is the right of each patient to be cared for by residents who are appropriately supervised; possess the requisite knowledge, skills, and abilities; understand the limits of their knowledge and experience; and seek assistance as required to provide optimal patient care.

Residents must demonstrate the ability to analyze the care they provide, understand their roles within health care teams, and play an active role in system improvement processes. Graduating residents will apply these skills to critique their future unsupervised practice and effect quality improvement measures.

It is necessary for residents and faculty members to consistently work in a well-coordinated manner with other health care professionals to achieve organizational patient safety goals.

VI.A.1.a) **Patient Safety**

VI.A.1.a).(1) **Culture of Safety**

A culture of safety requires continuous identification of vulnerabilities and a willingness to transparently deal with them. An effective organization has formal mechanisms to assess the knowledge, skills, and attitudes of its personnel toward safety in order to identify areas for improvement.

VI.A.1.a).(1).(a) **The program, its faculty, residents, and fellows must actively participate in patient safety systems and contribute to a culture of safety.** (Core)

VI.A.1.a).(1).(b) **The program must have a structure that promotes safe, interprofessional, team-based care.** (Core)

VI.A.1.a).(2) **Education on Patient Safety**

Programs must provide formal educational activities that promote patient safety-related goals, tools, and techniques. (Core)

VI.A.1.a).(3) **Patient Safety Events**

Reporting, investigation, and follow-up of adverse events, near misses, and unsafe conditions are pivotal mechanisms for improving patient safety, and are essential for the success of any patient safety program. Feedback and experiential learning are essential to developing true competence in the ability

to identify causes and institute sustainable systems-based changes to ameliorate patient safety vulnerabilities.

VI.A.1.a).(3).(a) Residents, fellows, faculty members, and other clinical staff members must:

VI.A.1.a).(3).(a).(i) know their responsibilities in reporting patient safety events at the clinical site; (Core)

VI.A.1.a).(3).(a).(ii) know how to report patient safety events, including near misses, at the clinical site; and, (Core)

VI.A.1.a).(3).(a).(iii) be provided with summary information of their institution's patient safety reports. (Core)

VI.A.1.a).(3).(b) Residents must participate as team members in real and/or simulated interprofessional clinical patient safety activities, such as root cause analyses or other activities that include analysis, as well as formulation and implementation of actions. (Core)

VI.A.1.a).(4) Resident Education and Experience in Disclosure of Adverse Events

Patient-centered care requires patients, and when appropriate families, to be apprised of clinical situations that affect them, including adverse events. This is an important skill for faculty physicians to model, and for residents to develop and apply.

VI.A.1.a).(4).(a) All residents must receive training in how to disclose adverse events to patients and families. (Core)

VI.A.1.a).(4).(b) Residents should have the opportunity to participate in the disclosure of patient safety events, real or simulated. (Detail)

VI.A.1.b) Quality Improvement

VI.A.1.b).(1) Education in Quality Improvement

A cohesive model of health care includes quality-related goals, tools, and techniques that are necessary in order for health care professionals to achieve quality improvement goals.

VI.A.1.b).(1).(a) Residents must receive training and experience in quality improvement processes, including an understanding of health care disparities. (Core)

VI.A.1.b).(2) Quality Metrics

Access to data is essential to prioritizing activities for care improvement and evaluating success of improvement efforts.

VI.A.1.b).(2).(a) Residents and faculty members must receive data on quality metrics and benchmarks related to their patient populations. (Core)

VI.A.1.b).(3) Engagement in Quality Improvement Activities

Experiential learning is essential to developing the ability to identify and institute sustainable systems-based changes to improve patient care.

VI.A.1.b).(3).(a) Residents must have the opportunity to participate in interprofessional quality improvement activities. (Core)

VI.A.1.b).(3).(a).(i) This should include activities aimed at reducing health care disparities. (Detail)

VI.A.2. Supervision and Accountability

VI.A.2.a) *Although the attending physician is ultimately responsible for the care of the patient, every physician shares in the responsibility and accountability for their efforts in the provision of care. Effective programs, in partnership with their Sponsoring Institutions, define, widely communicate, and monitor a structured chain of responsibility and accountability as it relates to the supervision of all patient care.*

Supervision in the setting of graduate medical education provides safe and effective care to patients; ensures each resident's development of the skills, knowledge, and attitudes required to enter the unsupervised practice of medicine; and establishes a foundation for continued professional growth.

VI.A.2.a).(1) Each patient must have an identifiable and appropriately-credentialed and privileged attending physician (or licensed independent practitioner as specified by the applicable Review Committee) who is responsible and accountable for the patient's care. (Core)

VI.A.2.a).(1).(a) **This information must be available to residents, faculty members, other members of the health care team, and patients.** (Core)

VI.A.2.a).(1).(b) **Residents and faculty members must inform each patient of their respective roles in that patient's care when providing direct patient care.** (Core)

VI.A.2.a).(1).(c) The Review Committee recognizes only physician faculty members as appropriate faculty supervisors for residents. (Core)

VI.A.2.b) ***Supervision may be exercised through a variety of methods. For many aspects of patient care, the supervising physician may be a more advanced resident or fellow. Other portions of care provided by the resident can be adequately supervised by the immediate availability of the supervising faculty member, fellow, or senior resident physician, either on site or by means of telephonic and/or electronic modalities. Some activities require the physical presence of the supervising faculty member. In some circumstances, supervision may include post-hoc review of resident-delivered care with feedback.***

VI.A.2.b).(1) **The program must demonstrate that the appropriate level of supervision in place for all residents is based on each resident's level of training and ability, as well as patient complexity and acuity. Supervision may be exercised through a variety of methods, as appropriate to the situation.** (Core)

VI.A.2.c) **Levels of Supervision**

To promote oversight of resident supervision while providing for graded authority and responsibility, the program must use the following classification of supervision: (Core)

VI.A.2.c).(1) **Direct Supervision – the supervising physician is physically present with the resident and patient.** (Core)

VI.A.2.c).(2) **Indirect Supervision:**

VI.A.2.c).(2).(a) **with Direct Supervision immediately available – the supervising physician is physically within the hospital or other site of patient care, and is immediately available to provide Direct Supervision.** (Core)

VI.A.2.c).(2).(b) with Direct Supervision available – the supervising physician is not physically present within the hospital or other site of patient care, but is immediately available by means of telephonic and/or electronic modalities, and is available to provide Direct Supervision. (Core)

VI.A.2.c).(3) Oversight – the supervising physician is available to provide review of procedures/encounters with feedback provided after care is delivered. (Core)

VI.A.2.d) The privilege of progressive authority and responsibility, conditional independence, and a supervisory role in patient care delegated to each resident must be assigned by the program director and faculty members. (Core)

VI.A.2.d).(1) The program director must evaluate each resident's abilities based on specific criteria, guided by the Milestones. (Core)

VI.A.2.d).(2) Faculty members functioning as supervising physicians must delegate portions of care to residents based on the needs of the patient and the skills of each resident. (Core)

VI.A.2.d).(3) Senior residents or fellows should serve in a supervisory role to junior residents in recognition of their progress toward independence, based on the needs of each patient and the skills of the individual resident or fellow. (Detail)

VI.A.2.e) Programs must set guidelines for circumstances and events in which residents must communicate with the supervising faculty member(s). (Core)

VI.A.2.e).(1) Each resident must know the limits of their scope of authority, and the circumstances under which the resident is permitted to act with conditional independence. (Outcome)

VI.A.2.e).(1).(a) Initially, PGY-1 residents must be supervised either directly, or indirectly with direct supervision immediately available. (Core)

VI.A.2.f) Faculty supervision assignments must be of sufficient duration to assess the knowledge and skills of each resident and to delegate to the resident the appropriate level of patient care authority and responsibility. (Core)

VI.B. Professionalism

VI.B.1. Programs, in partnership with their Sponsoring Institutions, must educate residents and faculty members concerning the professional responsibilities of physicians, including their obligation to be appropriately rested and fit to provide the care required by their patients. (Core)

VI.B.2. The learning objectives of the program must:

VI.B.2.a) be accomplished through an appropriate blend of supervised patient care responsibilities, clinical teaching, and didactic educational events; (Core)

VI.B.2.b) be accomplished without excessive reliance on residents to fulfill non-physician obligations; and, (Core)

VI.B.2.c) ensure manageable patient care responsibilities. (Core)

VI.B.3. The program director, in partnership with the Sponsoring Institution, must provide a culture of professionalism that supports patient safety and personal responsibility. (Core)

VI.B.4. Residents and faculty members must demonstrate an understanding of their personal role in the:

VI.B.4.a) provision of patient- and family-centered care; (Outcome)

VI.B.4.b) safety and welfare of patients entrusted to their care, including the ability to report unsafe conditions and adverse events; (Outcome)

VI.B.4.c) assurance of their fitness for work, including: (Outcome)

VI.B.4.c).(1) management of their time before, during, and after clinical assignments; and, (Outcome)

VI.B.4.c).(2) recognition of impairment, including from illness, fatigue, and substance use, in themselves, their peers, and other members of the health care team. (Outcome)

VI.B.4.d) commitment to lifelong learning; (Outcome)

VI.B.4.e) monitoring of their patient care performance improvement indicators; and, (Outcome)

VI.B.4.f) accurate reporting of clinical and educational work hours, patient outcomes, and clinical experience data. (Outcome)

VI.B.5. All residents and faculty members must demonstrate responsiveness to patient needs that supersedes self-interest. This includes the recognition that under certain circumstances, the best

interests of the patient may be served by transitioning that patient's care to another qualified and rested provider. (Outcome)

VI.B.6. Programs must provide a professional, respectful, and civil environment that is free from mistreatment, abuse, or coercion of students, residents, faculty, and staff. Programs, in partnership with their Sponsoring Institutions, should have a process for education of residents and faculty regarding unprofessional behavior and a confidential process for reporting, investigating, and addressing such concerns. (Core)

VI.C. Well-Being

In the current health care environment, residents and faculty members are at increased risk for burnout and depression. Psychological, emotional, and physical well-being are critical in the development of the competent, caring, and resilient physician. Self-care is an important component of professionalism; it is also a skill that must be learned and nurtured in the context of other aspects of residency training. Programs, in partnership with their Sponsoring Institutions, have the same responsibility to address well-being as they do to evaluate other aspects of resident competence.

VI.C.1. This responsibility must include:

VI.C.1.a) efforts to enhance the meaning that each resident finds in the experience of being a physician, including protecting time with patients, minimizing non-physician obligations, providing administrative support, promoting progressive autonomy and flexibility, and enhancing professional relationships; (Core)

VI.C.1.b) attention to scheduling, work intensity, and work compression that impacts resident well-being; (Core)

VI.C.1.c) evaluating workplace safety data and addressing the safety of residents and faculty members; (Core)

VI.C.1.d) policies and programs that encourage optimal resident and faculty member well-being; and, (Core)

VI.C.1.d).(1) Residents must be given the opportunity to attend medical, mental health, and dental care appointments, including those scheduled during their working hours. (Core)

VI.C.1.e) attention to resident and faculty member burnout, depression, and substance abuse. The program, in partnership with its Sponsoring Institution, must educate faculty members and residents in identification of the symptoms of burnout, depression, and substance abuse, including means to assist those who experience these

conditions. Residents and faculty members must also be educated to recognize those symptoms in themselves and how to seek appropriate care. The program, in partnership with its Sponsoring Institution, must: (Core)

VI.C.1.e).(1) encourage residents and faculty members to alert the program director or other designated personnel or programs when they are concerned that another resident, fellow, or faculty member may be displaying signs of burnout, depression, substance abuse, suicidal ideation, or potential for violence; (Core)

VI.C.1.e).(2) provide access to appropriate tools for self-screening; and, (Core)

VI.C.1.e).(3) provide access to confidential, affordable mental health assessment, counseling, and treatment, including access to urgent and emergent care 24 hours a day, seven days a week. (Core)

VI.C.2. There are circumstances in which residents may be unable to attend work, including but not limited to fatigue, illness, and family emergencies. Each program must have policies and procedures in place that ensure coverage of patient care in the event that a resident may be unable to perform their patient care responsibilities. These policies must be implemented without fear of negative consequences for the resident who is unable to provide the clinical work. (Core)

VI.D. Fatigue Mitigation

VI.D.1. Programs must:

VI.D.1.a) educate all faculty members and residents to recognize the signs of fatigue and sleep deprivation; (Core)

VI.D.1.b) educate all faculty members and residents in alertness management and fatigue mitigation processes; and, (Core)

VI.D.1.c) encourage residents to use fatigue mitigation processes to manage the potential negative effects of fatigue on patient care and learning. (Detail)

VI.D.2. Each program must ensure continuity of patient care, consistent with the program's policies and procedures referenced in VI.C.2, in the event that a resident may be unable to perform their patient care responsibilities due to excessive fatigue. (Core)

VI.D.3. The program, in partnership with its Sponsoring Institution, must ensure adequate sleep facilities and safe transportation options for residents who may be too fatigued to safely return home. (Core)

VI.E. Clinical Responsibilities, Teamwork, and Transitions of Care

VI.E.1. Clinical Responsibilities

The clinical responsibilities for each resident must be based on PGY level, patient safety, resident ability, severity and complexity of patient illness/condition, and available support services. (Core)

VI.E.1.a) The program director must establish written guidelines for the assignment of clinical responsibilities by ~~the~~ PGY level, including clinic volume, on-call frequency and back-up requirements, and the appropriate role in surgical procedures. (Core)

VI.E.2. Teamwork

Residents must care for patients in an environment that maximizes communication. This must include the opportunity to work as a member of effective interprofessional teams that are appropriate to the delivery of care in the specialty and larger health system. (Core)

VI.E.2.a) Each resident must have the opportunity to interact with nurses, ~~other specialists,~~ social workers, and ~~mid-level~~other health care providers. (Core)

VI.E.3. Transitions of Care

VI.E.3.a) Programs must design clinical assignments to optimize transitions in patient care, including their safety, frequency, and structure. (Core)

VI.E.3.b) Programs, in partnership with their Sponsoring Institutions, must ensure and monitor effective, structured hand-over processes to facilitate both continuity of care and patient safety. (Core)

VI.E.3.c) Programs must ensure that residents are competent in communicating with team members in the hand-over process. (Outcome)

VI.E.3.d) Programs and clinical sites must maintain and communicate schedules of attending physicians and residents currently responsible for care. (Core)

VI.E.3.e) Each program must ensure continuity of patient care, consistent with the program's policies and procedures referenced in VI.C.2, in the event that a resident may be unable to perform their patient care responsibilities due to excessive fatigue or illness, or family emergency. (Core)

VI.F. Clinical Experience and Education

Programs, in partnership with their Sponsoring Institutions, must design an effective program structure that is configured to provide residents with educational and clinical experience opportunities, as well as reasonable opportunities for rest and personal activities.

VI.F.1. Maximum Hours of Clinical and Educational Work per Week

Clinical and educational work hours must be limited to no more than 80 hours per week, averaged over a four-week period, inclusive of all in-house clinical and educational activities, clinical work done from home, and all moonlighting. (Core)

VI.F.2. Mandatory Time Free of Clinical Work and Education

VI.F.2.a) The program must design an effective program structure that is configured to provide residents with educational opportunities, as well as reasonable opportunities for rest and personal well-being. (Core)

VI.F.2.b) Residents should have eight hours off between scheduled clinical work and education periods. (Detail)

VI.F.2.b).(1) There may be circumstances when residents choose to stay to care for their patients or return to the hospital with fewer than eight hours free of clinical experience and education. This must occur within the context of the 80-hour and the one-day-off-in-seven requirements. (Detail)

VI.F.2.c) Residents must have at least 14 hours free of clinical work and education after 24 hours of in-house call. (Core)

VI.F.2.d) Residents must be scheduled for a minimum of one day in seven free of clinical work and required education (when averaged over four weeks). At-home call cannot be assigned on these free days. (Core)

VI.F.3. Maximum Clinical Work and Education Period Length

VI.F.3.a) Clinical and educational work periods for residents must not exceed 24 hours of continuous scheduled clinical assignments. (Core)

VI.F.3.a).(1) Up to four hours of additional time may be used for activities related to patient safety, such as providing effective transitions of care, and/or resident education. (Core)

VI.F.3.a).(1).(a) Additional patient care responsibilities must not be assigned to a resident during this time. (Core)

VI.F.4. Clinical and Educational Work Hour Exceptions

VI.F.4.a) In rare circumstances, after handing off all other responsibilities, a resident, on their own initiative, may elect to remain or return to the clinical site in the following circumstances:

VI.F.4.a).(1) to continue to provide care to a single severely ill or unstable patient; (Detail)

VI.F.4.a).(2) humanistic attention to the needs of a patient or family; or, (Detail)

VI.F.4.a).(3) to attend unique educational events. (Detail)

VI.F.4.b) These additional hours of care or education will be counted toward the 80-hour weekly limit. (Detail)

VI.F.4.c) A Review Committee may grant rotation-specific exceptions for up to 10 percent or a maximum of 88 clinical and educational work hours to individual programs based on a sound educational rationale.

The Review Committee for Urology will not consider requests for exceptions to the 80-hour limit to the residents' work week.

VI.F.4.c).(1) In preparing a request for an exception, the program director must follow the clinical and educational work hour exception policy from the *ACGME Manual of Policies and Procedures*. (Core)

VI.F.4.c).(2) Prior to submitting the request to the Review Committee, the program director must obtain approval from the Sponsoring Institution's GMEC and DIO. (Core)

VI.F.5. Moonlighting

VI.F.5.a) Moonlighting must not interfere with the ability of the resident to achieve the goals and objectives of the educational program, and must not interfere with the resident's fitness for work nor compromise patient safety. (Core)

VI.F.5.b) Time spent by residents in internal and external moonlighting (as defined in the ACGME Glossary of Terms) must be counted toward the 80-hour maximum weekly limit. (Core)

VI.F.5.c) PGY-1 residents are not permitted to moonlight. (Core)

VI.F.6. In-House Night Float

Night float must occur within the context of the 80-hour and one-day-off-in-seven requirements. (Core)

VI.F.6.a) Residents cannot be assigned more than eight weeks of night float per year. (Detail)

VI.F.6.b) ~~Night float rotations must not exceed 16 weeks total during the URO-1 and URO-2 years.~~ (Detail)

VI.F.7. Maximum In-House On-Call Frequency

Residents must be scheduled for in-house call no more frequently than every third night (when averaged over a four-week period). (Core)

VI.F.8. At-Home Call

VI.F.8.a) Time spent on patient care activities by residents on at-home call must count toward the 80-hour maximum weekly limit. The frequency of at-home call is not subject to the every-third-night limitation, but must satisfy the requirement for one day in seven free of clinical work and education, when averaged over four weeks. (Core)

VI.F.8.a).(1) At-home call must not be so frequent or taxing as to preclude rest or reasonable personal time for each resident. (Core)

VI.F.8.b) Residents are permitted to return to the hospital while on at-home call to provide direct care for new or established patients. These hours of inpatient patient care must be included in the 80-hour maximum weekly limit. (Detail)

***

*__Core Requirements:__ Statements that define structure, resource, or process elements essential to every graduate medical educational program.

__Detail Requirements:__ Statements that describe a specific structure, resource, or process, for achieving compliance with a Core Requirement. Programs and sponsoring institutions in substantial compliance with the Outcome Requirements may utilize alternative or innovative approaches to meet Core Requirements.

__Outcome Requirements:__ Statements that specify expected measurable or observable attributes (knowledge, abilities, skills, or attitudes) of residents or fellows at key stages of their graduate medical education.

Osteopathic Recognition

For programs seeking Osteopathic Recognition for the entire program, or for a track within the program, the Osteopathic Recognition Requirements are also applicable. (http://www. acgme. org/Portals/0/PFAssets/ProgramRequirements/Osteopathic_Recogniton_Requirements. pdf)

ACGME Program Requirements for Graduate Medical Education in Urology

ACGME-approved Focused Revision: February 7, 2022; effective July 1, 2022

Contents

ACGME Program Requirements for Graduate Medical Education in Urology

Common Program Requirements (Residency) are in BOLD

Where applicable, text in italics describes the underlying philosophy of the requirements in that section. These philosophic statements are not program requirements and are therefore not citable.

Introduction

Int.A. ***Graduate medical education is the crucial step of professional development between medical school and autonomous clinical practice. It is in this vital phase of the continuum of medical education that residents learn to provide optimal patient care under the supervision of faculty members who not only instruct, but serve as role models of excellence, compassion, professionalism, and scholarship.***

Graduate medical education transforms medical students into physician scholars who care for the patient, family, and a diverse community; create and integrate new knowledge into practice; and educate future generations of physicians to serve the public. Practice patterns established during graduate medical education persist many years later.

Graduate medical education has as a core tenet the graded authority and responsibility for patient care. The care of patients is undertaken with appropriate faculty supervision and conditional independence, allowing residents to attain the knowledge, skills, attitudes, and empathy required for autonomous practice. Graduate medical education develops physicians who focus on excellence in delivery of safe, equitable, affordable, quality care; and the health of the populations they serve. Graduate medical education values the strength that a diverse group of physicians brings to medical care.

Graduate medical education occurs in clinical settings that establish the foundation for practice-based and lifelong learning. The professional development of the physician, begun in medical school, continues through faculty modeling of the effacement of self-interest in a humanistic environment that emphasizes joy in curiosity, problem-solving, academic rigor, and discovery. This transformation is often physically, emotionally, and intellectually demanding and occurs in a variety of clinical learning environments committed to graduate medical education and the well-being of patients, residents, fellows, faculty members, students, and all members of the health care team.

Int.B. **Definition of Specialty**

Urology evaluates and treats patients with disorders of the genitourinary tract, including the adrenal gland and external genitalia. Specialists in this discipline demonstrate knowledge of the basic and clinical sciences related to the normal

and diseased genitourinary system, as well as attendant skills in medical and surgical therapy. Residency programs educate physicians in the prevention and treatment of genitourinary disease, including the diagnosis, medical, and surgical management, and reconstruction of the genitourinary tract.

Int.C. Length of Educational Program

The educational program in urology must be 60 months in length. (Core)*

I. Oversight

I.A. Sponsoring Institution

The Sponsoring Institution is the organization or entity that assumes the ultimate financial and academic responsibility for a program of graduate medical education, consistent with the ACGME Institutional Requirements.

When the Sponsoring Institution is not a rotation site for the program, the most commonly utilized site of clinical activity for the program is the primary clinical site.

Background and Intent: Participating sites will reflect the health care needs of the community and the educational needs of the residents. A wide variety of organizations may provide a robust educational experience and, thus, Sponsoring Institutions and participating sites may encompass inpatient and outpatient settings including, but not limited to a university, a medical school, a teaching hospital, a nursing home, a school of public health, a health department, a public health agency, an organized health care delivery system, a medical examiner's office, an educational consortium, a teaching health center, a physician group practice, federally qualified health center, or an educational foundation.

I.A.1. The program must be sponsored by one ACGME-accredited Sponsoring Institution. (Core)

I.B. Participating Sites

A participating site is an organization providing educational experiences or educational assignments/rotations for residents.

I.B.1. The program, with approval of its Sponsoring Institution, must designate a primary clinical site. (Core)

I.B.1.a) To provide an adequate interdisciplinary educational experience, the primary clinical site must participate in an ACGME-accredited general surgery program through the same Sponsoring Institution as the urology program, unless an exception is granted by the Review Committee. (Core)

I.B.2. There must be a program letter of agreement (PLA) between the program and each participating site that governs the relationship

between the program and the participating site providing a required assignment. (Core)

I.B.2.a) The PLA must:

I.B.2.a).(1) be renewed at least every 10 years; and, (Core)

I.B.2.a).(2) be approved by the designated institutional official (DIO). (Core)

I.B.3. The program must monitor the clinical learning and working environment at all participating sites. (Core)

I.B.3.a) At each participating site there must be one faculty member, designated by the program director as the site director, who is accountable for resident education at that site, in collaboration with the program director. (Core)

Background and Intent: While all residency programs must be sponsored by a single ACGME-accredited Sponsoring Institution, many programs will utilize other clinical settings to provide required or elective training experiences. At times it is appropriate to utilize community sites that are not owned by or affiliated with the Sponsoring Institution. Some of these sites may be remote for geographic, transportation, or communication issues. When utilizing such sites the program must ensure the quality of the educational experience. The requirements under I.B.3. are intended to ensure that this will be the case.

Suggested elements to be considered in PLAs will be found in the ACGME Program Director's Guide to the Common Program Requirements. These include:

- **Identifying the faculty members who will assume educational and supervisory responsibility for residents**
- **Specifying the responsibilities for teaching, supervision, and formal evaluation of residents**
- **Specifying the duration and content of the educational experience**
- **Stating the policies and procedures that will govern resident education during the assignment**

I.B.4. The program director must submit any additions or deletions of participating sites routinely providing an educational experience, required for all residents, of one month full time equivalent (FTE) or more through the ACGME's Accreditation Data System (ADS). (Core)

I.B.5. Addition of participating sites for required rotations must be based on sound educational rationale and approved by the Review Committee. (Core)

I.B.5.a) Assignments to distant sites must be based on the educational resources that are not available at the primary clinical site or at a nearby participating site. (Core)

I.C. **The program, in partnership with its Sponsoring Institution, must engage in practices that focus on mission-driven, ongoing, systematic recruitment and retention of a diverse and inclusive workforce of residents, fellows (if present), faculty members, senior administrative staff members, and other relevant members of its academic community.** (Core)

Background and Intent: It is expected that the Sponsoring Institution has, and programs implement, policies and procedures related to recruitment and retention of minorities underrepresented in medicine and medical leadership in accordance with the Sponsoring Institution's mission and aims. The program's annual evaluation must include an assessment of the program's efforts to recruit and retain a diverse workforce, as noted in V.C.1.c).(5).(c).

I.D. **Resources**

I.D.1. **The program, in partnership with its Sponsoring Institution, must ensure the availability of adequate resources for resident education.** (Core)

I.D.1.a) There must be adequate space and equipment for the educational program, including meeting rooms and classrooms with audiovisual and other educational aids; appropriate office space for residents; diagnostic, therapeutic, and research facilities; and outpatient facilities, clinic, and office space accessible to residents for pre-operative evaluation and post-operative follow-up. (Core)

I.D.1.b) Clinical facilities must contain state-of-the-art equipment to perform diagnostic and therapeutic procedures. (Core)

I.D.1.b).(1) Equipment to perform the following procedures must be available: flexible cystoscopy; ureteroscopy; percutaneous endoscopy; percutaneous renal access; ultrasonography and biopsy; fluoroscopy; laparoscopy; laser therapy; and renal and prostate ultrasound. (Core)

I.D.1.b).(2) Urodynamic equipment must be present at a minimum of one site. (Core)

I.D.1.b).(3) Video imaging must be available to allow adequate supervision and education during endoscopic procedures. (Core)

I.D.1.c) A sufficient number and variety of inpatient ambulatory adult and pediatric patients with urologic disease must be available for resident education. (Core)

I.D.2. **The program, in partnership with its Sponsoring Institution, must ensure healthy and safe learning and working environments that promote resident well-being and provide for:** (Core)

I.D.2.a) **access to food while on duty;** (Core)

I.D.2.b) safe, quiet, clean, and private sleep/rest facilities available and accessible for residents with proximity appropriate for safe patient care; (Core)

Background and Intent: Care of patients within a hospital or health system occurs continually through the day and night. Such care requires that residents function at their peak abilities, which requires the work environment to provide them with the ability to meet their basic needs within proximity of their clinical responsibilities. Access to food and rest are examples of these basic needs, which must be met while residents are working. Residents should have access to refrigeration where food may be stored. Food should be available when residents are required to be in the hospital overnight. Rest facilities are necessary, even when overnight call is not required, to accommodate the fatigued resident.

I.D.2.c) clean and private facilities for lactation that have refrigeration capabilities, with proximity appropriate for safe patient care; (Core)

Background and Intent: Sites must provide private and clean locations where residents may lactate and store the milk within a refrigerator. These locations should be in close proximity to clinical responsibilities. It would be helpful to have additional support within these locations that may assist the resident with the continued care of patients, such as a computer and a phone. While space is important, the time required for lactation is also critical for the well-being of the resident and the resident's family, as outlined in VI.C.1.d).(1).

I.D.2.d) security and safety measures appropriate to the participating site; and, (Core)

I.D.2.e) accommodations for residents with disabilities consistent with the Sponsoring Institution's policy. (Core)

I.D.3. Residents must have ready access to specialty-specific and other appropriate reference material in print or electronic format. This must include access to electronic medical literature databases with full text capabilities. (Core)

I.D.4. The program's educational and clinical resources must be adequate to support the number of residents appointed to the program. (Core)

I.E. The presence of other learners and other care providers, including, but not limited to, residents from other programs, subspecialty fellows, and advanced practice providers, must enrich the appointed residents' education. (Core)

I.E.1. The program must report circumstances when the presence of other learners has interfered with the residents' education to the DIO and Graduate Medical Education Committee (GMEC). (Core)

Background and Intent: The clinical learning environment has become increasingly complex and often includes care providers, students, and post-graduate residents and fellows from multiple disciplines. The presence of these practitioners and their learners enriches the learning environment. Programs have a responsibility to monitor the learning environment to ensure that residents' education is not compromised by the presence of other providers and learners.

II. Personnel

II.A. Program Director

II.A.1. There must be one faculty member appointed as program director with authority and accountability for the overall program, including compliance with all applicable program requirements. (Core)

II.A.1.a) The Sponsoring Institution's GMEC must approve a change in program director. (Core)

II.A.1.b) Final approval of the program director resides with the Review Committee. (Core)

Background and Intent: While the ACGME recognizes the value of input from numerous individuals in the management of a residency, a single individual must be designated as program director and have overall responsibility for the program. The program director's nomination is reviewed and approved by the GMEC. Final approval of the program director resides with the applicable ACGME Review Committee.

II.A.1.c) The program must demonstrate retention of the program director for a length of time adequate to maintain continuity of leadership and program stability. (Core)

Background and Intent: The success of residency programs is generally enhanced by continuity in the program director position. The professional activities required of a program director are unique and complex and take time to master. All programs are encouraged to undertake succession planning to facilitate program stability when there is necessary turnover in the program director position.

II.A.2. The program director and, as applicable, the program's leadership team, must be provided with support adequate for administration of the program based upon its size and configuration. (Core)

II.A.2.a) At a minimum, the program director must be provided with support equal to a dedicated minimum of 0.2 FTE for administration of the program. (Core)

Background and Intent: To achieve successful graduate medical education, individuals serving as education and administrative leaders of residency programs, as well as those significantly engaged in the education, supervision, evaluation, and mentoring of residents, must have sufficient dedicated professional time to perform the vital activities required to sustain an accredited program.

The ultimate outcome of graduate medical education is excellence in resident education and patient care.

The program director and, as applicable, the program leadership team, devote a portion of their professional effort to the oversight and management of the residency program, as defined in II.A.4.-II.A.4.a).(16). Both provision of support for the time required for the leadership effort and flexibility regarding how this support is provided are important. Programs, in partnership with their Sponsoring Institutions, may provide support for this time in a variety of ways. Examples of support may include, but are not limited to, salary support, supplemental compensation, educational value units, or relief of time from other professional duties.

Program directors and, as applicable, members of the program leadership team, who are new to the role may need to devote additional time to program oversight and management initially as they learn and become proficient in administering the program. It is suggested that during this initial period the support described above be increased as needed.

II.A.3. Qualifications of the program director:

II.A.3.a) must include specialty expertise and at least three years of documented educational and/or administrative experience, or qualifications acceptable to the Review Committee; (Core)

Background and Intent: Leading a program requires knowledge and skills that are established during residency and subsequently further developed. The time period from completion of residency until assuming the role of program director allows the individual to cultivate leadership abilities while becoming professionally established. The three-year period is intended for the individual's professional maturation.

The broad allowance for educational and/or administrative experience recognizes that strong leaders arise through diverse pathways. These areas of expertise are important when identifying and appointing a program director. The choice of a program director should be informed by the mission of the program and the needs of the community.

In certain circumstances, the program and Sponsoring Institution may propose and the Review Committee may accept a candidate for program director who fulfills these goals but does not meet the three-year minimum.

II.A.3.b) must include current certification in the specialty for which they are the program director by the American Board of Urology or by the American Osteopathic Board of Surgery, or specialty qualifications that are acceptable to the Review Committee; (Core)

II.A.3.c) must include current medical licensure and appropriate medical staff appointment; (Core)

II.A.3.d) must include ongoing clinical activity; and, (Core)

Background and Intent: A program director is a role model for faculty members and residents. The program director must participate in clinical activity consistent with the specialty. This activity will allow the program director to role model the Core Competencies for the faculty members and residents.

II.A.3.e) should include scholarly activity. (Core)

II.A.4. Program Director Responsibilities

The program director must have responsibility, authority, and accountability for: administration and operations; teaching and scholarly activity; resident recruitment and selection, evaluation, and promotion of residents, and disciplinary action; supervision of residents; and resident education in the context of patient care. (Core)

II.A.4.a) The program director must:

II.A.4.a).(1) be a role model of professionalism; (Core)

Background and Intent: The program director, as the leader of the program, must serve as a role model to residents in addition to fulfilling the technical aspects of the role. As residents are expected to demonstrate compassion, integrity, and respect for others, they must be able to look to the program director as an exemplar. It is of utmost importance, therefore, that the program director model outstanding professionalism, high quality patient care, educational excellence, and a scholarly approach to work. The program director creates an environment where respectful discussion is welcome, with the goal of continued improvement of the educational experience.

II.A.4.a).(2) design and conduct the program in a fashion consistent with the needs of the community, the mission(s) of the Sponsoring Institution, and the mission(s) of the program; (Core)

Background and Intent: The mission of institutions participating in graduate medical education is to improve the health of the public. Each community has health needs that vary based upon location and demographics. Programs must understand the social determinants of health of the populations they serve and incorporate them in the design and implementation of the program curriculum, with the ultimate goal of addressing these needs and health disparities.

II.A.4.a).(3) administer and maintain a learning environment conducive to educating the residents in each of the ACGME Competency domains; (Core)

Background and Intent: The program director may establish a leadership team to assist in the accomplishment of program goals. Residency programs can be highly complex. In a complex organization, the leader typically has the ability to delegate authority to others, yet remains accountable. The leadership team may include

physician and non-physician personnel with varying levels of education, training, and experience.

II.A.4.a).(4)	develop and oversee a process to evaluate candidates prior to approval as program faculty members for participation in the residency program education and at least annually thereafter, as outlined in V.B.; (Core)
II.A.4.a).(5)	have the authority to approve program faculty members for participation in the residency program education at all sites; (Core)
II.A.4.a).(6)	have the authority to remove program faculty members from participation in the residency program education at all sites; (Core)
II.A.4.a).(7)	have the authority to remove residents from supervising interactions and/or learning environments that do not meet the standards of the program; (Core)

Background and Intent: The program director has the responsibility to ensure that all who educate residents effectively role model the Core Competencies. Working with a resident is a privilege that is earned through effective teaching and professional role modeling. This privilege may be removed by the program director when the standards of the clinical learning environment are not met.

There may be faculty in a department who are not part of the educational program, and the program director controls who is teaching the residents.

II.A.4.a).(8)	submit accurate and complete information required and requested by the DIO, GMEC, and ACGME; (Core)
II.A.4.a).(9)	provide applicants who are offered an interview with information related to the applicant's eligibility for the relevant specialty board examination(s); (Core)
II.A.4.a).(10)	provide a learning and working environment in which residents have the opportunity to raise concerns and provide feedback in a confidential manner as appropriate, without fear of intimidation or retaliation; (Core)
II.A.4.a).(11)	ensure the program's compliance with the Sponsoring Institution's policies and procedures related to grievances and due process; (Core)
II.A.4.a).(12)	ensure the program's compliance with the Sponsoring Institution's policies and procedures for due process when action is taken to suspend or dismiss, not to promote, or not to renew the appointment of a resident; (Core)

Background and Intent: A program does not operate independently of its Sponsoring Institution. It is expected that the program director will be aware of the Sponsoring Institution's policies and procedures, and will ensure they are followed by the program's leadership, faculty members, support personnel, and residents.

II.A.4.a).(13) ensure the program's compliance with the Sponsoring Institution's policies and procedures on employment and non-discrimination; (Core)

II.A.4.a).(13).(a) Residents must not be required to sign a non-competition guarantee or restrictive covenant. (Core)

II.A.4.a).(14) document verification of program completion for all graduating residents within 30 days; (Core)

II.A.4.a).(15) provide verification of an individual resident's completion upon the resident's request, within 30 days; and, (Core)

Background and Intent: Primary verification of graduate medical education is important to credentialing of physicians for further training and practice. Such verification must be accurate and timely. Sponsoring Institution and program policies for record retention are important to facilitate timely documentation of residents who have previously completed the program. Residents who leave the program prior to completion also require timely documentation of their summative evaluation.

II.A.4.a).(16) obtain review and approval of the Sponsoring Institution's DIO before submitting information or requests to the ACGME, as required in the Institutional Requirements and outlined in the ACGME Program Director's Guide to the Common Program Requirements. (Core)

II.B. Faculty

Faculty members are a foundational element of graduate medical education – faculty members teach residents how to care for patients. Faculty members provide an important bridge allowing residents to grow and become practice-ready, ensuring that patients receive the highest quality of care. They are role models for future generations of physicians by demonstrating compassion, commitment to excellence in teaching and patient care, professionalism, and a dedication to lifelong learning. Faculty members experience the pride and joy of fostering the growth and development of future colleagues. The care they provide is enhanced by the opportunity to teach. By employing a scholarly approach to patient care, faculty members, through the graduate medical education system, improve the health of the individual and the population.

Faculty members ensure that patients receive the level of care expected from a specialist in the field. They recognize and respond to the needs of the patients, residents, community, and institution. Faculty members provide appropriate levels of supervision to promote patient safety. Faculty members create an effective learning environment by acting in a professional manner and attending to the well-being of the residents and themselves.

Background and Intent: "Faculty" refers to the entire teaching force responsible for educating residents. The term "faculty," including "core faculty," does not imply or require an academic appointment.

II.B.1. **At each participating site, there must be a sufficient number of faculty members with competence to instruct and supervise all residents at that location.** (Core)

II.B.1.a) To provide a well-rounded educational experience, some faculty members should have subspecialty education and/or concentrate their practice in one or more subspecialized urological domains (e.g., voiding dysfunction; female urology; reconstruction oncology; calculus disease; pediatrics; sexual dysfunction; and infertility). (Core)

II.B.1.b) The faculty should include individuals with experience with the following urologic techniques: endo-urology; minimally-invasive intra-abdominal and pelvic surgical techniques (such as laparoscopy and robotic surgery); major flank and pelvic surgery; urologic imaging; and microsurgery. (Detail)†

II.B.2. **Faculty members must:**

II.B.2.a) **be role models of professionalism;** (Core)

II.B.2.b) **demonstrate commitment to the delivery of safe, quality, cost-effective, patient-centered care;** (Core)

Background and Intent: Patients have the right to expect quality, cost-effective care with patient safety at its core. The foundation for meeting this expectation is formed during residency and fellowship. Faculty members model these goals and continually strive for improvement in care and cost, embracing a commitment to the patient and the community they serve.

II.B.2.c) **demonstrate a strong interest in the education of residents;** (Core)

II.B.2.d) **devote sufficient time to the educational program to fulfill their supervisory and teaching responsibilities;** (Core)

II.B.2.e) **administer and maintain an educational environment conducive to educating residents;** (Core)

II.B.2.f) regularly participate in organized clinical discussions, rounds, journal clubs, and conferences; and, (Core)

II.B.2.g) pursue faculty development designed to enhance their skills at least annually: (Core)

Background and Intent: Faculty development is intended to describe structured programming developed for the purpose of enhancing transference of knowledge, skill, and behavior from the educator to the learner. Faculty development may occur in a variety of configurations (lecture, workshop, etc.) using internal and/or external resources. Programming is typically needs-based (individual or group) and may be specific to the institution or the program. Faculty development programming is to be reported for the residency program faculty in the aggregate.

II.B.2.g).(1) as educators; (Core)

II.B.2.g).(2) in quality improvement and patient safety; (Core)

II.B.2.g).(3) in fostering their own and their residents' well-being; and, (Core)

II.B.2.g).(4) in patient care based on their practice-based learning and improvement efforts. (Core)

Background and Intent: Practice-based learning serves as the foundation for the practice of medicine. Through a systematic analysis of one's practice and review of the literature, one is able to make adjustments that improve patient outcomes and care. Thoughtful consideration to practice-based analysis improves quality of care, as well as patient safety. This allows faculty members to serve as role models for residents in practice-based learning.

II.B.3. Faculty Qualifications

II.B.3.a) Faculty members must have appropriate qualifications in their field and hold appropriate institutional appointments. (Core)

II.B.3.b) Physician faculty members must:

II.B.3.b).(1) have current certification in the specialty by the American Board of Urology or the American Osteopathic Board of Surgery, or possess qualifications judged acceptable to the Review Committee. (Core)

II.B.3.c) Any non-physician faculty members who participate in residency program education must be approved by the program director. (Core)

Background and Intent: The provision of optimal and safe patient care requires a team approach. The education of residents by non-physician educators enables the resident to better manage patient care and provides valuable advancement of the residents' knowledge. Furthermore, other individuals contribute to the education of the resident in the basic science of the specialty or in research methodology. If the program director determines that the contribution of a non-physician individual is significant to the education of the residents, the program director may designate the individual as a program faculty member or a program core faculty member.

II.B.4. **Core Faculty**

Core faculty members must have a significant role in the education and supervision of residents and must devote a significant portion of their entire effort to resident education and/or administration, and must, as a component of their activities, teach, evaluate, and provide formative feedback to residents. (Core)

Background and Intent: Core faculty members are critical to the success of resident education. They support the program leadership in developing, implementing, and assessing curriculum, mentoring residents, and assessing residents' progress toward achievement of competence in and the independent practice of the specialty. Core faculty members should be selected for their broad knowledge of and involvement in the program, permitting them to effectively evaluate the program. Core faculty members may also be selected for their specific expertise and unique contribution to the program. Core faculty members are engaged in a broad range of activities, which may vary across programs and specialties. Core faculty members provide clinical teaching and supervision of residents, and also participate in non-clinical activities related to resident education and program administration. Examples of these non-clinical activities include, but are not limited to, interviewing and selecting resident applicants, providing didactic instruction, mentoring residents, simulation exercises, completing the annual ACGME Faculty Survey, and participating on the program's Clinical Competency Committee, Program Evaluation Committee, and other GME committees.

II.B.4.a) **Core faculty members must be designated by the program director.** (Core)

II.B.4.b) **Core faculty members must complete the annual ACGME Faculty Survey.** (Core)

II.B.4.c) In addition to the program director, there must be a minimum of two core clinical urology faculty members who devote sufficient time to supervise and teach the residents, and who are committed fully to the educational objectives of the program. (Core)

II.B.4.d) There must be a core faculty-to-resident ratio of at least 1:2. (Core)

II.C. **Program Coordinator**

II.C.1. **There must be a program coordinator.** (Core)

II.C.2. **The program coordinator must be provided with dedicated time and support adequate for administration of the program based upon its size and configuration.** (Core)

II.C.2.a) The program coordinator must be provided with support equal to a dedicated minimum of 0.5 FTE for administration of the program. (Core)

Background and Intent: The requirement does not address the source of funding required to provide the specified salary support.

Each program requires a lead administrative person, frequently referred to as a program coordinator, administrator, or as otherwise titled by the institution. This person will frequently manage the day-to-day operations of the program and serve as an important liaison and facilitator between the learners, faculty and other staff members, and the ACGME. Individuals serving in this role are recognized as program coordinators by the ACGME.

The program coordinator is a key member of the leadership team and is critical to the success of the program. As such, the program coordinator must possess skills in leadership and personnel management appropriate to the complexity of the program. Program coordinators are expected to develop in-depth knowledge of the ACGME and Program Requirements, including policies and procedures. Program coordinators assist the program director in meeting accreditation requirements, educational programming, and support of residents.

Programs, in partnership with their Sponsoring Institutions, should encourage the professional development of their program coordinators and avail them of opportunities for both professional and personal growth. Programs with fewer residents may not require a full-time coordinator; one coordinator may support more than one program.

II.D. Other Program Personnel

The program, in partnership with its Sponsoring Institution, must jointly ensure the availability of necessary personnel for the effective administration of the program. (Core)

Background and Intent: Multiple personnel may be required to effectively administer a program. These may include staff members with clerical skills, project managers, education experts, and staff members to maintain electronic communication for the program. These personnel may support more than one program in more than one discipline.

III. Resident Appointments

III.A. Eligibility Requirements

III.A.1. **An applicant must meet one of the following qualifications to be eligible for appointment to an ACGME-accredited program:** (Core)

III.A.1.a) **graduation from a medical school in the United States or Canada, accredited by the Liaison Committee on Medical Education (LCME) or graduation from a college of osteopathic medicine in the United States, accredited by the American Osteopathic Association Commission on Osteopathic College Accreditation (AOACOCA); or,** (Core)

III.A.1.b) **graduation from a medical school outside of the United States or Canada, and meeting one of the following additional qualifications:** (Core)

III.A.1.b).(1) **holding a currently valid certificate from the Educational Commission for Foreign Medical Graduates (ECFMG) prior to appointment; or,** (Core)

III.A.1.b).(2) **holding a full and unrestricted license to practice medicine in the United States licensing jurisdiction in which the ACGME-accredited program is located.** (Core)

III.A.2. **All prerequisite post-graduate clinical education required for initial entry or transfer into ACGME-accredited residency programs must be completed in ACGME-accredited residency programs, AOA-approved residency programs, Royal College of Physicians and Surgeons of Canada (RCPSC)-accredited or College of Family Physicians of Canada (CFPC)-accredited residency programs located in Canada, or in residency programs with ACGME International (ACGME-I) Advanced Specialty Accreditation.** (Core)

III.A.2.a) **Residency programs must receive verification of each resident's level of competency in the required clinical field using ACGME, CanMEDS, or ACGME-I Milestones evaluations from the prior training program upon matriculation.** (Core)

III.A.2.b) Based on educational objectives, an alternative format for admission to a urology residency may include a prerequisite of one year of education prior to the 60-month urology program, which must take place in a surgery program that satisfies the requirements under III.A.

III.A.2.b).(1) Programs using the alternative format must still comply with all of the curricular requirements for the 60-month urology program, including those for Uro-1 as outlined in IV.C.3.a)-IV.C.3.a).(2). (Core)

Background and Intent: Programs with ACGME-I Foundational Accreditation or from institutions with ACGME-I accreditation do not qualify unless the program has also achieved ACGME-I Advanced Specialty Accreditation. To ensure entrants into ACGME-accredited programs from ACGME-I programs have attained the prerequisite milestones for this training, they must be from programs that have ACGME-I Advanced Specialty Accreditation.

III.A.3. A physician who has completed a residency program that was not accredited by ACGME, AOA, RCPSC, CFPC, or ACGME-I (with Advanced Specialty Accreditation) may enter an ACGME-accredited residency program in the same specialty at the PGY-1 level and, at the discretion of the program director of the ACGME-accredited program and with approval by the GMEC, may be advanced to the PGY-2 level based on ACGME Milestones evaluations at the ACGME-accredited program. This provision applies only to entry into residency in those specialties for which an initial clinical year is not required for entry. (Core)

III.B. The program director must not appoint more residents than approved by the Review Committee. (Core)

III.B.1. All complement increases must be approved by the Review Committee. (Core)

III.C. Resident Transfers

The program must obtain verification of previous educational experiences and a summative competency-based performance evaluation prior to acceptance of a transferring resident, and Milestones evaluations upon matriculation. (Core)

IV. Educational Program

The ACGME accreditation system is designed to encourage excellence and innovation in graduate medical education regardless of the organizational affiliation, size, or location of the program.

The educational program must support the development of knowledgeable, skillful physicians who provide compassionate care.

In addition, the program is expected to define its specific program aims consistent with the overall mission of its Sponsoring Institution, the needs of the community it serves and that its graduates will serve, and the distinctive capabilities of physicians it intends to graduate. While programs must demonstrate substantial compliance with the Common and specialty-specific Program Requirements, it is recognized that within this framework, programs may place different emphasis on research, leadership, public health, etc. It is expected that the program aims will reflect the nuanced program-specific goals for it and its graduates; for example, it is expected that a program aiming to prepare physician-scientists will have a different curriculum from one focusing on community health.

IV.A. The curriculum must contain the following educational components: (Core)

IV.A.1. a set of program aims consistent with the Sponsoring Institution's mission, the needs of the community it serves, and the desired distinctive capabilities of its graduates; (Core)

IV.A.1.a) The program's aims must be made available to program applicants, residents, and faculty members. (Core)

IV.A.2. competency-based goals and objectives for each educational experience designed to promote progress on a trajectory to autonomous practice. These must be distributed, reviewed, and available to residents and faculty members; (Core)

Background and Intent: The trajectory to autonomous practice is documented by Milestones evaluation. The Milestones detail the progress of a resident in attaining skill in each competency domain. They are developed by each specialty group and allow evaluation based on observable behaviors. Milestones are considered formative and should be used to identify learning needs. This may lead to focused or general curricular revision in any given program or to individualized learning plans for any specific resident.

IV.A.3. delineation of resident responsibilities for patient care, progressive responsibility for patient management, and graded supervision; (Core)

Background and Intent: These responsibilities may generally be described by PGY level and specifically by Milestones progress as determined by the Clinical Competency Committee. This approach encourages the transition to competency-based education. An advanced learner may be granted more responsibility independent of PGY level and a learner needing more time to accomplish a certain task may do so in a focused rather than global manner.

IV.A.4. a broad range of structured didactic activities; (Core)

IV.A.4.a) Residents must be provided with protected time to participate in core didactic activities. (Core)

Background and Intent: It is intended that residents will participate in structured didactic activities. It is recognized that there may be circumstances in which this is not possible. Programs should define core didactic activities for which time is protected and the circumstances in which residents may be excused from these didactic activities. Didactic activities may include, but are not limited to, lectures, conferences, courses, labs, asynchronous learning, simulations, drills, case discussions, grand rounds, didactic teaching, and education in critical appraisal of medical evidence.

IV.A.5. advancement of residents' knowledge of ethical principles foundational to medical professionalism; and, (Core)

IV.A.6. advancement in the residents' knowledge of the basic principles of scientific inquiry, including how research is designed, conducted, evaluated, explained to patients, and applied to patient care. (Core)

IV.B. ACGME Competencies

Background and Intent: The Competencies provide a conceptual framework describing the required domains for a trusted physician to enter autonomous practice. These Competencies are core to the practice of all physicians, although the specifics are further defined by each specialty. The developmental trajectories in each of the Competencies are articulated through the Milestones for each specialty.

IV.B.1. The program must integrate the following ACGME Competencies into the curriculum: (Core)

IV.B.1.a) Professionalism

Residents must demonstrate a commitment to professionalism and an adherence to ethical principles. (Core)

IV.B.1.a).(1) Residents must demonstrate competence in:

IV.B.1.a).(1).(a) compassion, integrity, and respect for others; (Core)

IV.B.1.a).(1).(b) responsiveness to patient needs that supersedes self-interest; (Core)

Background and Intent: This includes the recognition that under certain circumstances, the interests of the patient may be best served by transitioning care to another provider. Examples include fatigue, conflict or duality of interest, not connecting well with a patient, or when another physician would be better for the situation based on skill set or knowledge base.

IV.B.1.a).(1).(c) respect for patient privacy and autonomy; (Core)

IV.B.1.a).(1).(d) accountability to patients, society, and the profession; (Core)

IV.B.1.a).(1).(e) respect and responsiveness to diverse patient populations, including but not limited to diversity in gender, age, culture, race, religion, disabilities, national origin, socioeconomic status, and sexual orientation; (Core)

IV.B.1.a).(1).(f) ability to recognize and develop a plan for one's own personal and professional well-being; and, (Core)

IV.B.1.a).(1).(g) appropriately disclosing and addressing conflict or duality of interest. (Core)

IV.B.1.b) Patient Care and Procedural Skills

Background and Intent: Quality patient care is safe, effective, timely, efficient, patient-centered, equitable, and designed to improve population health, while reducing per

capita costs. (See the Institute of Medicine [IOM]'s *Crossing the Quality Chasm: A New Health System for the 21st Century*, 2001 and Berwick D, Nolan T, Whittington J. *The Triple Aim: care, cost, and quality. Health Affairs.* 2008; 27(3):759-769.). In addition, there should be a focus on improving the clinician's well-being as a means to improve patient care and reduce burnout among residents, fellows, and practicing physicians.

These organizing principles inform the Common Program Requirements across all Competency domains. Specific content is determined by the Review Committees with input from the appropriate professional societies, certifying boards, and the community.

IV.B.1.b).(1) **Residents must be able to provide patient care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health.** (Core)

IV.B.1.b).(1).(a) Residents must demonstrate competence in providing direct patient care with increasing levels of responsibility in patient management as they advance through the program; (Core)

IV.B.1.b).(1).(b) Residents must, under supervision, demonstrate competence in providing for the total care of the patient, including initial evaluation, establishment of diagnosis, selection of appropriate therapy, providing that therapy, and management of complications; (Core)

IV.B.1.b).(1).(c) Residents must demonstrate competence in providing continuity of patient care through pre- and post-operative clinics and inpatient contact; (Core)

IV.B.1.b).(1).(c).(i) When residents participate in pre- and post-operative care in a clinic or private office setting, the program director must ensure that the resident functions with an appropriate degree of responsibility under supervision. (Core)

IV.B.1.b).(1).(d) Residents must be given responsibility commensurate with their individual knowledge, problem-solving ability, technical skills, experience, and the severity and complexity of each patient's status and, (Core)

IV.B.1.b).(2) **Residents must be able to perform all medical, diagnostic, and surgical procedures considered essential for the area of practice.** (Core)

IV.B.1.b).(2).(a) Residents must develop competence in the following core techniques:

IV.B.1.b).(2).(a).(i) endo-urology; (Core)

IV.B.1.b).(2).(a).(ii) major open flank and pelvic surgery; (Core)

IV.B.1.b).(2).(a).(iii) minimally-invasive intra-abdominal and pelvic surgical techniques including, laparoscopy and robotics; (Core)

IV.B.1.b).(2).(a).(iv) perineal and genital surgery; and, (Core)

IV.B.1.b).(2).(a).(v) urologic imaging including fluoroscopy, and ultrasound. (Core)

IV.B.1.c) Medical Knowledge

Residents must demonstrate knowledge of established and evolving biomedical, clinical, epidemiological and social-behavioral sciences, as well as the application of this knowledge to patient care. (Core)

IV.B.1.c).(1) Residents must demonstrate knowledge of the following curricular topics:

IV.B.1.c).(1).(a) bioethics; (Core)

IV.B.1.c).(1).(b) biostatistics; (Core)

IV.B.1.c).(1).(c) calculus disease; (Core)

IV.B.1.c).(1).(d) epidemiology; (Core)

IV.B.1.c).(1).(e) evidence-based medicine; (Core)

IV.B.1.c).(1).(f) female pelvic medicine; (Core)

IV.B.1.c).(1).(g) infectious disease; (Core)

IV.B.1.c).(1).(h) infertility and sexual dysfunction; (Core)

IV.B.1.c).(1).(i) geriatrics; (Core)

IV.B.1.c).(1).(j) medical oncology; (Core)

IV.B.1.c).(1).(k) patient safety and quality improvement; (Core)

IV.B.1.c).(1).(l) pediatric urology; (Core)

IV.B.1.c).(1).(m) plastic surgery; (Core)

IV.B.1.c).(1).(n)	pre-, intra-, and post-operative aspects of:
IV.B.1.c).(1).(n).(i)	endoscopic-urology; (Core)
IV.B.1.c).(1).(n).(ii)	major open flank and pelvic surgery; (Core)
IV.B.1.c).(1).(n).(iii)	microsurgery; (Core)
IV.B.1.c).(1).(n).(iv)	minimally-invasive intra-abdominal and pelvic surgical techniques, including laparoscopy and robotic surgery; (Core)
IV.B.1.c).(1).(n).(v)	perineal and genital surgery; and, (Core)
IV.B.1.c).(1).(n).(vi)	urologic imaging, including fluoroscopy, interventional radiology, and ultrasound. (Core)
IV.B.1.c).(1).(o)	radiation safety; (Core)
IV.B.1.c).(1).(p)	reconstruction; (Core)
IV.B.1.c).(1).(q)	renal transplantation; (Core)
IV.B.1.c).(1).(r)	renovascular disease; (Core)
IV.B.1.c).(1).(s)	trauma; (Core)
IV.B.1.c).(1).(t)	urologic oncology; and, (Core)
IV.B.1.c).(1).(u)	voiding dysfunction. (Core)

IV.B.1.d) **Practice-based Learning and Improvement**

Residents must demonstrate the ability to investigate and evaluate their care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and lifelong learning. (Core)

Background and Intent: Practice-based learning and improvement is one of the defining characteristics of being a physician. It is the ability to investigate and evaluate the care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and lifelong learning.

The intention of this Competency is to help a physician develop the habits of mind required to continuously pursue quality improvement, well past the completion of residency.

IV.B.1.d).(1) **Residents must demonstrate competence in:**

IV.B.1.d).(1).(a) identifying strengths, deficiencies, and limits in one's knowledge and expertise; (Core)

IV.B.1.d).(1).(b) setting learning and improvement goals; (Core)

IV.B.1.d).(1).(c) identifying and performing appropriate learning activities; (Core)

IV.B.1.d).(1).(d) systematically analyzing practice using quality improvement methods, and implementing changes with the goal of practice improvement; (Core)

IV.B.1.d).(1).(e) incorporating feedback and formative evaluation into daily practice; (Core)

IV.B.1.d).(1).(f) locating, appraising, and assimilating evidence from scientific studies related to their patients' health problems; and, (Core)

IV.B.1.d).(1).(g) using information technology to optimize learning. (Core)

IV.B.1.e) Interpersonal and Communication Skills

Residents must demonstrate interpersonal and communication skills that result in the effective exchange of information and collaboration with patients, their families, and health professionals. (Core)

IV.B.1.e).(1) Residents must demonstrate competence in:

IV.B.1.e).(1).(a) communicating effectively with patients, families, and the public, as appropriate, across a broad range of socioeconomic and cultural backgrounds; (Core)

IV.B.1.e).(1).(b) communicating effectively with physicians, other health professionals, and health-related agencies; (Core)

IV.B.1.e).(1).(c) working effectively as a member or leader of a health care team or other professional group; (Core)

IV.B.1.e).(1).(d) educating patients, families, students, residents, and other health professionals; (Core)

IV.B.1.e).(1).(e) acting in a consultative role to other physicians and health professionals; and, (Core)

IV.B.1.e).(1).(f) maintaining comprehensive, timely, and legible medical records, if applicable. (Core)

IV.B.1.e).(2) Residents must learn to communicate with patients and families to partner with them to assess their care goals, including, when appropriate, end-of-life goals. (Core)

Background and Intent: When there are no more medications or interventions that can achieve a patient's goals or provide meaningful improvements in quality or length of life, a discussion about the patient's goals, values, and choices surrounding the end of life is one of the most important conversations that can occur. Residents must learn to participate effectively and compassionately in these meaningful human interactions, for the sake of their patients and themselves.

Programs may teach this skill through direct clinical experience, simulation, or other means of active learning.

IV.B.1.f) Systems-based Practice

Residents must demonstrate an awareness of and responsiveness to the larger context and system of health care, including the social determinants of health, as well as the ability to call effectively on other resources to provide optimal health care. (Core)

IV.B.1.f).(1) Residents must demonstrate competence in:

IV.B.1.f).(1).(a) working effectively in various health care delivery settings and systems relevant to their clinical specialty; (Core)

Background and Intent: Medical practice occurs in the context of an increasingly complex clinical care environment where optimal patient care requires attention to compliance with external and internal administrative and regulatory requirements.

IV.B.1.f).(1).(b) coordinating patient care across the health care continuum and beyond as relevant to their clinical specialty; (Core)

Background and Intent: Every patient deserves to be treated as a whole person. Therefore it is recognized that any one component of the health care system does not meet the totality of the patient's needs. An appropriate transition plan requires coordination and forethought by an interdisciplinary team. The patient benefits from proper care and the system benefits from proper use of resources.

IV.B.1.f).(1).(c) advocating for quality patient care and optimal patient care systems; (Core)

IV.B.1.f).(1).(d) **working in interprofessional teams to enhance patient safety and improve patient care quality;** (Core)

IV.B.1.f).(1).(e) **participating in identifying system errors and implementing potential systems solutions;** (Core)

IV.B.1.f).(1).(f) **incorporating considerations of value, cost awareness, delivery and payment, and risk-benefit analysis in patient and/or population-based care as appropriate; and,** (Core)

IV.B.1.f).(1).(g) **understanding health care finances and its impact on individual patients' health decisions.** (Core)

IV.B.1.f).(2) **Residents must learn to advocate for patients within the health care system to achieve the patient's and family's care goals, including, when appropriate, end-of-life goals.** (Core)

IV.C. Curriculum Organization and Resident Experiences

IV.C.1. The curriculum must be structured to optimize resident educational experiences, the length of these experiences, and supervisory continuity. (Core)

IV.C.1.a) Chief resident rotations must be at least two months in length. (Core)

Background and Intent: In some specialties, frequent rotational transitions, inadequate continuity of faculty member supervision, and dispersed patient locations within the hospital have adversely affected optimal resident education and effective team-based care. The need for patient care continuity varies from specialty to specialty and by clinical situation, and may be addressed by the individual Review Committee.

IV.C.2. The program must provide instruction and experience in pain management if applicable for the specialty, including recognition of the signs of addiction. (Core)

IV.C.3. The program director must be responsible for the design, implementation, and oversight of the Uro-1 year. The Uro-1 year must include: (Core)

IV.C.3.a) at least six months of core surgical education in rotations outside of urology designed to foster competence in basic surgical skills, the peri-operative care of surgical patients, and inter-disciplinary patient care coordination, including: (Core)

IV.C.3.a).(1) at least three months of general surgery; and, (Core)

IV.C.3.a).(1).(a) General surgery rotations must focus on the care of general surgical patients with abdominal and/or pelvic conditions (e.g., general surgery, acute care surgery, colon and rectal surgery, surgical oncology, and trauma surgery.) (Core)

IV.C.3.a).(1).(a).(i) Daily work duties must include direct, hands-on, intra-operative and peri-operative care of patients.(Core)

IV.C.3.a).(2) at least three months of additional non-urological surgery.(Core)

IV.C.3.a).(2).(a) Non-urological surgery rotations must advance resident knowledge, skills, and abilities in the surgical care of patients relevant to the future practice of urology (e.g., advanced vascular surgery, pediatric surgery, transplant surgery, surgical critical care, and reconstructive plastic surgery). (Core)

IV.C.3.a).(2).(a).(i) Daily work duties must include direct, hands-on, intra-operative and peri-operative care of patients. (Core)

IV.C.3.b) at least a four week assignment on each non-urology rotation; (Core)

IV.C.3.c) at least three months of urology rotations designed to develop competence in basic urological skills, general care of the urology patient both in the in-patient and ambulatory setting, management of urology patients in the emergency department, and a foundation of urology knowledge and, (Core)

IV.C.3.d) no more than three months total of non-surgical rotations designed to complement urological education which must be selected from the following: anesthesiology, interventional radiology, and nephrology. (Core)

IV.C.4. Uro-2 through Uro-5 must include progressive education in clinical urology. (Core)

IV.C.4.a) During the Uro-2-4 years, up to six months may be devoted to non-urological clinical education and/or research consistent with the program aims, and at the discretion of the program director. (Core)

IV.C.4.b) Within the final 24 months of urology education, residents must serve at least 12 months as a chief resident. (Core)

IV.C.4.b).(1) The clinical and academic experience as a chief resident should prepare the resident for an independent practice of urology. (Detail)

IV.C.4.b).(2) This chief resident experience should include management of patients with complex urologic disease, advanced procedures, and, with appropriate supervision, a high level of responsibility and independence. (Detail)

IV.C.5. Didactic Curriculum

IV.C.5.a) The curriculum must include didactic instruction in the core domains of:

IV.C.5.a).(1) calculus disease; (Core)

IV.C.5.a).(2) female pelvic medicine; (Core)

IV.C.5.a).(3) geriatric urology; (Core)

IV.C.5.a).(4) infertility and sexual dysfunction; (Core)

IV.C.5.a).(5) pediatric urology; (Core)

IV.C.5.a).(6) reconstruction; (Core)

IV.C.5.a).(7) urologic oncology; (Core)

IV.C.5.a).(8) urologic trauma; and, (Core)

IV.C.5.a).(9) voiding dysfunction. (Core)

IV.C.5.b) Didactic conferences must include:

IV.C.5.b).(1) morbidity and mortality; (Core)

IV.C.5.b).(2) urological imaging review; and, (Core)

IV.C.5.b).(3) journal review. (Core)

IV.C.5.c) Didactic conferences must be attended by residents and core faculty members, and the list of conferences must include the date, conference topic, the name of the presenter(s), and the names of the faculty members and residents present for each conference. (Core)

IV.C.6. Each graduating resident must perform the minimum number of essential operative cases and case categories as established by the Review Committee. (Core)

IV.D. Scholarship

Medicine is both an art and a science. The physician is a humanistic scientist who cares for patients. This requires the ability to think critically, evaluate the literature, appropriately assimilate new knowledge, and practice lifelong learning. The program and faculty must create an environment that fosters the acquisition of such skills through resident participation in scholarly activities. Scholarly activities may include discovery, integration, application, and teaching.

The ACGME recognizes the diversity of residencies and anticipates that programs prepare physicians for a variety of roles, including clinicians, scientists, and educators. It is expected that the program's scholarship will reflect its mission(s) and aims, and the needs of the community it serves. For example, some programs may concentrate their scholarly activity on quality improvement, population health, and/or teaching, while other programs might choose to utilize more classic forms of biomedical research as the focus for scholarship.

IV.D.1. Program Responsibilities

IV.D.1.a) The program must demonstrate evidence of scholarly activities consistent with its mission(s) and aims. (Core)

IV.D.1.b) The program, in partnership with its Sponsoring Institution, must allocate adequate resources to facilitate resident and faculty involvement in scholarly activities. (Core)

IV.D.1.c) The program must advance residents' knowledge and practice of the scholarly approach to evidence-based patient care. (Core)

Background and Intent: The scholarly approach can be defined as a synthesis of teaching, learning, and research with the aim of encouraging curiosity and critical thinking based on an understanding of physiology, pathophysiology, differential diagnosis, treatments, treatment alternatives, efficiency of care, and patient safety. While some faculty members are responsible for fulfilling the traditional elements of scholarship through research, integration, and teaching, all faculty members are responsible for advancing residents' scholarly approach to patient care.

Elements of a scholarly approach to patient care include:

- Asking meaningful questions to stimulate residents to utilize learning resources to create a differential diagnosis, a diagnostic algorithm, and treatment plan
- Challenging the evidence that the residents use to reach their medical decisions so that they understand the benefits and limits of the medical literature
- When appropriate, dissemination of scholarly learning in a peer-reviewed manner (publication or presentation)
- Improving resident learning by encouraging them to teach using a scholarly approach

The scholarly approach to patient care begins with curiosity, is grounded in the principles of evidence-based medicine, expands the knowledge base through dissemination, and develops the habits of lifelong learning by encouraging residents to be scholarly teachers.

IV.D.2. Faculty Scholarly Activity

IV.D.2.a) Among their scholarly activity, programs must demonstrate accomplishments in at least three of the following domains: (Core)

- Research in basic science, education, translational science, patient care, or population health
- Peer-reviewed grants
- Quality improvement and/or patient safety initiatives
- Systematic reviews, meta-analyses, review articles, chapters in medical textbooks, or case reports
- Creation of curricula, evaluation tools, didactic educational activities, or electronic educational materials
- Contribution to professional committees, educational organizations, or editorial boards
- Innovations in education

IV.D.2.b) The program must demonstrate dissemination of scholarly activity within and external to the program by the following methods:

Background and Intent: For the purposes of education, metrics of scholarly activity represent one of the surrogates for the program's effectiveness in the creation of an environment of inquiry that advances the residents' scholarly approach to patient care. The Review Committee will evaluate the dissemination of scholarship for the program as a whole, not for individual faculty members, for a five-year interval, for both core and non-core faculty members, with the goal of assessing the effectiveness of the creation of such an environment. The ACGME recognizes that there may be differences in scholarship requirements between different specialties and between residencies and fellowships in the same specialty.

IV.D.2.b).(1) faculty participation in grand rounds, posters, workshops, quality improvement presentations, podium presentations, grant leadership, non-peer-reviewed print/electronic resources, articles or publications, book chapters, textbooks, webinars, service on professional committees, or serving as a journal reviewer, journal editorial board member, or editor; (Outcome)‡

IV.D.2.b).(2) peer-reviewed publication. (Outcome)

IV.D.3. Resident Scholarly Activity

IV.D.3.a) **Residents must participate in scholarship.** (Core)

IV.D.3.b) The program must advance residents' knowledge of the basic principles of research, including how research is conducted, evaluated, explained to patients, and applied to patient care. (Core)

V. Evaluation

V.A. Resident Evaluation

V.A.1. Feedback and Evaluation

Background and Intent: Feedback is ongoing information provided regarding aspects of one's performance, knowledge, or understanding. The faculty empower residents to provide much of that feedback themselves in a spirit of continuous learning and self-reflection. Feedback from faculty members in the context of routine clinical care should be frequent, and need not always be formally documented.

Formative and summative evaluation have distinct definitions. Formative evaluation is *monitoring resident learning* and providing ongoing feedback that can be used by residents to improve their learning in the context of provision of patient care or other educational opportunities. More specifically, formative evaluations help:

- **residents identify their strengths and weaknesses and target areas that need work**
- **program directors and faculty members recognize where residents are struggling and address problems immediately**

Summative evaluation is *evaluating a resident's learning* by comparing the residents against the goals and objectives of the rotation and program, respectively. Summative evaluation is utilized to make decisions about promotion to the next level of training, or program completion.

End-of-rotation and end-of-year evaluations have both summative and formative components. Information from a summative evaluation can be used formatively when residents or faculty members use it to guide their efforts and activities in subsequent rotations and to successfully complete the residency program.

Feedback, formative evaluation, and summative evaluation compare intentions with accomplishments, enabling the transformation of a neophyte physician to one with growing expertise.

V.A.1.a) **Faculty members must directly observe, evaluate, and frequently provide feedback on resident performance during each rotation or similar educational assignment.** (Core)

Background and Intent: Faculty members should provide feedback frequently throughout the course of each rotation. Residents require feedback from faculty members to reinforce well-performed duties and tasks, as well as to correct deficiencies. This feedback will allow for the development of the learner as they strive

to achieve the Milestones. More frequent feedback is strongly encouraged for residents who have deficiencies that may result in a poor final rotation evaluation.

V.A.1.b) **Evaluation must be documented at the completion of the assignment.** (Core)

V.A.1.b).(1) **For block rotations of greater than three months in duration, evaluation must be documented at least every three months.** (Core)

V.A.1.b).(2) **Longitudinal experiences, such as continuity clinic in the context of other clinical responsibilities, must be evaluated at least every three months and at completion.** (Core)

V.A.1.c) **The program must provide an objective performance evaluation based on the Competencies and the specialty-specific Milestones, and must:** (Core)

V.A.1.c).(1) **use multiple evaluators (e.g., faculty members, peers, patients, self, and other professional staff members); and,** (Core)

V.A.1.c).(1).(a) There must be a minimum of three different sources of evaluations. (Detail)

V.A.1.c).(2) **provide that information to the Clinical Competency Committee for its synthesis of progressive resident performance and improvement toward unsupervised practice.** (Core)

V.A.1.d) **The program director or their designee, with input from the Clinical Competency Committee, must:**

V.A.1.d).(1) **meet with and review with each resident their documented semi-annual evaluation of performance, including progress along the specialty-specific Milestones;** (Core)

V.A.1.d).(1).(a) This must include review of the procedural experiences of each resident, including the number of cases recorded to ensure that the operative procedures performed by residents are entered in the ACGME Case Log System. (Core)

V.A.1.d).(1).(b) This should include review of the procedural experiences of each resident to ensure there is equal opportunity for a variety of operative experiences. (Detail)

V.A.1.d).(2) **assist residents in developing individualized learning plans to capitalize on their strengths and identify areas for growth; and,** (Core)

V.A.1.d).(3) **develop plans for residents failing to progress, following institutional policies and procedures.** (Core)

Background and Intent: Learning is an active process that requires effort from the teacher and the learner. Faculty members evaluate a resident's performance at least at the end of each rotation. The program director or their designee will review those evaluations, including their progress on the Milestones, at a minimum of every six months. Residents should be encouraged to reflect upon the evaluation, using the information to reinforce well-performed tasks or knowledge or to modify deficiencies in knowledge or practice. Working together with the faculty members, residents should develop an individualized learning plan.

Residents who are experiencing difficulties with achieving progress along the Milestones may require intervention to address specific deficiencies. Such intervention, documented in an individual remediation plan developed by the program director or a faculty mentor and the resident, will take a variety of forms based on the specific learning needs of the resident. However, the ACGME recognizes that there are situations which require more significant intervention that may alter the time course of resident progression. To ensure due process, it is essential that the program director follow institutional policies and procedures.

V.A.1.e) **At least annually, there must be a summative evaluation of each resident that includes their readiness to progress to the next year of the program, if applicable.** (Core)

V.A.1.f) **The evaluations of a resident's performance must be accessible for review by the resident.** (Core)

V.A.1.g) Assessment must specifically include monitoring the resident's medical knowledge by use of a formal examination such as an in-service examination or other cognitive examinations. (Core)

V.A.1.g).(1) Test results should be reviewed annually and utilized to guide program curriculum and individual resident study plans. (Detail)

V.A.1.g).(2) Test results should not be used as the sole criterion of resident knowledge and should not be used as the sole criterion for promotion to a subsequent PG level. (Detail)

V.A.2. Final Evaluation

V.A.2.a) The program director must provide a final evaluation for each resident upon completion of the program. (Core)

V.A.2.a).(1) The specialty-specific Milestones, and when applicable the specialty-specific Case Logs, must be used as

tools to ensure residents are able to engage in autonomous practice upon completion of the program. (Core)

V.A.2.a).(2) The final evaluation must:

V.A.2.a).(2).(a) become part of the resident's permanent record maintained by the institution, and must be accessible for review by the resident in accordance with institutional policy; (Core)

V.A.2.a).(2).(b) verify that the resident has demonstrated the knowledge, skills, and behaviors necessary to enter autonomous practice; (Core)

V.A.2.a).(2).(c) consider recommendations from the Clinical Competency Committee; and, (Core)

V.A.2.a).(2).(d) be shared with the resident upon completion of the program. (Core)

V.A.3. A Clinical Competency Committee must be appointed by the program director. (Core)

V.A.3.a) At a minimum, the Clinical Competency Committee must include three members of the program faculty, at least one of whom is a core faculty member. (Core)

V.A.3.a).(1) Additional members must be faculty members from the same program or other programs, or other health professionals who have extensive contact and experience with the program's residents. (Core)

Background and Intent: The requirements regarding the Clinical Competency Committee do not preclude or limit a program director's participation on the Clinical Competency Committee. The intent is to leave flexibility for each program to decide the best structure for its own circumstances, but a program should consider: its program director's other roles as resident advocate, advisor, and confidante; the impact of the program director's presence on the other Clinical Competency Committee members' discussions and decisions; the size of the program faculty; and other program-relevant factors. The program director has final responsibility for resident evaluation and promotion decisions.

Program faculty may include more than the physician faculty members, such as other physicians and non-physicians who teach and evaluate the program's residents. There may be additional members of the Clinical Competency Committee. Chief residents who have completed core residency programs in their specialty may be members of the Clinical Competency Committee.

V.A.3.b) The Clinical Competency Committee must:

V.A.3.b).(1) review all resident evaluations at least semi-annually; (Core)

V.A.3.b).(2) determine each resident's progress on achievement of the specialty-specific Milestones; and, (Core)

V.A.3.b).(3) meet prior to the residents' semi-annual evaluations and advise the program director regarding each resident's progress. (Core)

V.B. Faculty Evaluation

V.B.1. The program must have a process to evaluate each faculty member's performance as it relates to the educational program at least annually. (Core)

Background and Intent: The program director is responsible for the education program and for whom delivers it. While the term "faculty" may be applied to physicians within a given institution for other reasons, it is applied to residency program faculty members only through approval by a program director. The development of the faculty improves the education, clinical, and research aspects of a program. Faculty members have a strong commitment to the resident and desire to provide optimal education and work opportunities. Faculty members must be provided feedback on their contribution to the mission of the program. All faculty members who interact with residents desire feedback on their education, clinical care, and research. If a faculty member does not interact with residents, feedback is not required. With regard to the diverse operating environments and configurations, the residency program director may need to work with others to determine the effectiveness of the program's faculty performance with regard to their role in the educational program. All teaching faculty members should have their educational efforts evaluated by the residents in a confidential and anonymous manner. Other aspects for the feedback may include research or clinical productivity, review of patient outcomes, or peer review of scholarly activity. The process should reflect the local environment and identify the necessary information. The feedback from the various sources should be summarized and provided to the faculty on an annual basis by a member of the leadership team of the program.

V.B.1.a) This evaluation must include a review of the faculty member's clinical teaching abilities, engagement with the educational program, participation in faculty development related to their skills as an educator, clinical performance, professionalism, and scholarly activities. (Core)

V.B.1.b) This evaluation must include written, anonymous, and confidential evaluations by the residents. (Core)

V.B.2. Faculty members must receive feedback on their evaluations at least annually. (Core)

V.B.3. Results of the faculty educational evaluations should be incorporated into program-wide faculty development plans. (Core)

Background and Intent: The quality of the faculty's teaching and clinical care is a determinant of the quality of the program and the quality of the residents' future clinical care. Therefore, the program has the responsibility to evaluate and improve the program faculty members' teaching, scholarship, professionalism, and quality care. This section mandates annual review of the program's faculty members for this purpose, and can be used as input into the Annual Program Evaluation.

V.C. Program Evaluation and Improvement

V.C.1. The program director must appoint the Program Evaluation Committee to conduct and document the Annual Program Evaluation as part of the program's continuous improvement process. (Core)

V.C.1.a) The Program Evaluation Committee must be composed of at least two program faculty members, at least one of whom is a core faculty member, and at least one resident. (Core)

V.C.1.b) Program Evaluation Committee responsibilities must include:

V.C.1.b).(1) acting as an advisor to the program director, through program oversight; (Core)

V.C.1.b).(2) review of the program's self-determined goals and progress toward meeting them; (Core)

V.C.1.b).(3) guiding ongoing program improvement, including development of new goals, based upon outcomes; and, (Core)

V.C.1.b).(4) review of the current operating environment to identify strengths, challenges, opportunities, and threats as related to the program's mission and aims. (Core)

Background and Intent: In order to achieve its mission and train quality physicians, a program must evaluate its performance and plan for improvement in the Annual Program Evaluation. Performance of residents and faculty members is a reflection of program quality, and can use metrics that reflect the goals that a program has set for itself. The Program Evaluation Committee utilizes outcome parameters and other data to assess the program's progress toward achievement of its goals and aims.

V.C.1.c) The Program Evaluation Committee should consider the following elements in its assessment of the program:

V.C.1.c).(1) curriculum; (Core)

V.C.1.c).(2) outcomes from prior Annual Program Evaluation(s); (Core)

V.C.1.c).(3) ACGME letters of notification, including citations, Areas for Improvement, and comments; (Core)

V.C.1.c).(4) quality and safety of patient care; (Core)

V.C.1.c).(5) aggregate resident and faculty:

V.C.1.c).(5).(a) well-being; (Core)

V.C.1.c).(5).(b) recruitment and retention; (Core)

V.C.1.c).(5).(c) workforce diversity; (Core)

V.C.1.c).(5).(d) engagement in quality improvement and patient safety; (Core)

V.C.1.c).(5).(e) scholarly activity; (Core)

V.C.1.c).(5).(f) ACGME Resident and Faculty Surveys; and, (Core)

V.C.1.c).(5).(g) written evaluations of the program. (Core)

V.C.1.c).(6) aggregate resident:

V.C.1.c).(6).(a) achievement of the Milestones; (Core)

V.C.1.c).(6).(b) in-training examinations (where applicable); (Core)

V.C.1.c).(6).(c) board pass and certification rates; and, (Core)

V.C.1.c).(6).(d) graduate performance. (Core)

V.C.1.c).(7) aggregate faculty:

V.C.1.c).(7).(a) evaluation; and, (Core)

V.C.1.c).(7).(b) professional development. (Core)

V.C.1.d) The Program Evaluation Committee must evaluate the program's mission and aims, strengths, areas for improvement, and threats. (Core)

V.C.1.e) The annual review, including the action plan, must:

V.C.1.e).(1) be distributed to and discussed with the members of the teaching faculty and the residents; and, (Core)

V.C.1.e).(2) be submitted to the DIO. (Core)

V.C.2. The program must complete a Self-Study prior to its 10-Year Accreditation Site Visit. (Core)

V.C.2.a) A summary of the Self-Study must be submitted to the DIO. (Core)

Background and Intent: Outcomes of the documented Annual Program Evaluation can be integrated into the 10-year Self-Study process. The Self-Study is an objective, comprehensive evaluation of the residency program, with the aim of improving it. Underlying the Self-Study is this longitudinal evaluation of the program and its learning environment, facilitated through sequential Annual Program Evaluations that focus on the required components, with an emphasis on program strengths and self-identified areas for improvement. Details regarding the timing and expectations for the Self-Study and the 10-Year Accreditation Site Visit are provided in the *ACGME Manual of Policies and Procedures*. Additionally, a description of the Self-Study process, as well as information on how to prepare for the 10-Year Accreditation Site Visit, is available on the ACGME website.

V.C.3. *One goal of ACGME-accredited education is to educate physicians who seek and achieve board certification. One measure of the effectiveness of the educational program is the ultimate pass rate.*

The program director should encourage all eligible program graduates to take the certifying examination offered by the applicable American Board of Medical Specialties (ABMS) member board or American Osteopathic Association (AOA) certifying board.

V.C.3.a) For specialties in which the ABMS member board and/or AOA certifying board offer(s) an annual written exam, in the preceding three years, the program's aggregate pass rate of those taking the examination for the first time must be higher than the bottom fifth percentile of programs in that specialty. (Outcome)

V.C.3.b) For specialties in which the ABMS member board and/or AOA certifying board offer(s) a biennial written exam, in the preceding six years, the program's aggregate pass rate of those taking the examination for the first time must be higher than the bottom fifth percentile of programs in that specialty. (Outcome)

V.C.3.c) For specialties in which the ABMS member board and/or AOA certifying board offer(s) an annual oral exam, in the preceding three years, the program's aggregate pass rate of those taking the examination for the first time must be higher than the bottom fifth percentile of programs in that specialty. (Outcome)

V.C.3.d) For specialties in which the ABMS member board and/or AOA certifying board offer(s) a biennial oral exam, in the preceding six years, the program's aggregate pass rate of those taking the examination for the first time must be higher than the bottom fifth percentile of programs in that specialty. (Outcome)

V.C.3.e) For each of the exams referenced in V.C.3.a)-d), any program whose graduates over the time period specified in the requirement have achieved an 80 percent pass rate will have met this requirement, no matter the percentile rank of the program for pass rate in that specialty. (Outcome)

Background and Intent: Setting a single standard for pass rate that works across specialties is not supportable based on the heterogeneity of the psychometrics of different examinations. By using a percentile rank, the performance of the lower five percent (fifth percentile) of programs can be identified and set on a path to curricular and test preparation reform.

There are specialties where there is a very high board pass rate that could leave successful programs in the bottom five percent (fifth percentile) despite admirable performance. These high-performing programs should not be cited, and V.C.3.e) is designed to address this.

V.C.3.f) Programs must report, in ADS, board certification status annually for the cohort of board-eligible residents that graduated seven years earlier. (Core)

Background and Intent: It is essential that residency programs demonstrate knowledge and skill transfer to their residents. One measure of that is the qualifying or initial certification exam pass rate. Another important parameter of the success of the program is the ultimate board certification rate of its graduates. Graduates are eligible for up to seven years from residency graduation for initial certification. The ACGME will calculate a rolling three-year average of the ultimate board certification rate at seven years post-graduation, and the Review Committees will monitor it.

The Review Committees will track the rolling seven-year certification rate as an indicator of program quality. Programs are encouraged to monitor their graduates' performance on board certification examinations.

In the future, the ACGME may establish parameters related to ultimate board certification rates.

VI. The Learning and Working Environment

Residency education must occur in the context of a learning and working environment that emphasizes the following principles:

- *Excellence in the safety and quality of care rendered to patients by residents today*
- *Excellence in the safety and quality of care rendered to patients by today's residents in their future practice*
- *Excellence in professionalism through faculty modeling of:*

- *the effacement of self-interest in a humanistic environment that supports the professional development of physicians*
- *the joy of curiosity, problem-solving, intellectual rigor, and discovery*

- *Commitment to the well-being of the students, residents, faculty members, and all members of the health care team*

Background and Intent: The revised requirements are intended to provide greater flexibility within an established framework, allowing programs and residents more discretion to structure clinical education in a way that best supports the above principles of professional development. With this increased flexibility comes the responsibility for programs and residents to adhere to the 80-hour maximum weekly limit (unless a rotation-specific exception is granted by a Review Committee), and to utilize flexibility in a manner that optimizes patient safety, resident education, and resident well-being. The requirements are intended to support the development of a sense of professionalism by encouraging residents to make decisions based on patient needs and their own well-being, without fear of jeopardizing their program's accreditation status. In addition, the proposed requirements eliminate the burdensome documentation requirement for residents to justify clinical and educational work hour variations.

Clinical and educational work hours represent only one part of the larger issue of conditions of the learning and working environment, and Section VI has now been expanded to include greater attention to patient safety and resident and faculty member well-being. The requirements are intended to support programs and residents as they strive for excellence, while also ensuring ethical, humanistic training. Ensuring that flexibility is used in an appropriate manner is a shared responsibility of the program and residents. With this flexibility comes a responsibility for residents and faculty members to recognize the need to hand off care of a patient to another provider when a resident is too fatigued to provide safe, high quality care and for programs to ensure that residents remain within the 80-hour maximum weekly limit.

VI.A. Patient Safety, Quality Improvement, Supervision, and Accountability

VI.A.1. Patient Safety and Quality Improvement

All physicians share responsibility for promoting patient safety and enhancing quality of patient care. Graduate medical education must prepare residents to provide the highest level of clinical care with continuous focus on the safety, individual needs, and humanity of their patients. It is the right of each patient to be cared for by residents who are appropriately supervised; possess the requisite knowledge, skills, and abilities; understand the limits of their knowledge and experience; and seek assistance as required to provide optimal patient care.

Residents must demonstrate the ability to analyze the care they provide, understand their roles within health care teams, and play an active role in system improvement processes. Graduating residents

will apply these skills to critique their future unsupervised practice and effect quality improvement measures.

It is necessary for residents and faculty members to consistently work in a well-coordinated manner with other health care professionals to achieve organizational patient safety goals.

VI.A.1.a) Patient Safety

VI.A.1.a).(1) Culture of Safety

A culture of safety requires continuous identification of vulnerabilities and a willingness to transparently deal with them. An effective organization has formal mechanisms to assess the knowledge, skills, and attitudes of its personnel toward safety in order to identify areas for improvement.

VI.A.1.a).(1).(a) The program, its faculty, residents, and fellows must actively participate in patient safety systems and contribute to a culture of safety. (Core)

VI.A.1.a).(1).(b) The program must have a structure that promotes safe, interprofessional, team-based care. (Core)

VI.A.1.a).(2) Education on Patient Safety

Programs must provide formal educational activities that promote patient safety-related goals, tools, and techniques. (Core)

Background and Intent: Optimal patient safety occurs in the setting of a coordinated interprofessional learning and working environment.

VI.A.1.a).(3) Patient Safety Events

Reporting, investigation, and follow-up of adverse events, near misses, and unsafe conditions are pivotal mechanisms for improving patient safety, and are essential for the success of any patient safety program. Feedback and experiential learning are essential to developing true competence in the ability to identify causes and institute sustainable systems-based changes to ameliorate patient safety vulnerabilities.

VI.A.1.a).(3).(a) Residents, fellows, faculty members, and other clinical staff members must:

VI.A.1.a).(3).(a).(i) know their responsibilities in reporting patient safety events at the clinical site; (Core)

VI.A.1.a).(3).(a).(ii) know how to report patient safety events, including near misses, at the clinical site; and, (Core)

VI.A.1.a).(3).(a).(iii) be provided with summary information of their institution's patient safety reports. (Core)

VI.A.1.a).(3).(b) Residents must participate as team members in real and/or simulated interprofessional clinical patient safety activities, such as root cause analyses or other activities that include analysis, as well as formulation and implementation of actions. (Core)

VI.A.1.a).(4) Resident Education and Experience in Disclosure of Adverse Events

Patient-centered care requires patients, and when appropriate families, to be apprised of clinical situations that affect them, including adverse events. This is an important skill for faculty physicians to model, and for residents to develop and apply.

VI.A.1.a).(4).(a) All residents must receive training in how to disclose adverse events to patients and families. (Core)

VI.A.1.a).(4).(b) Residents should have the opportunity to participate in the disclosure of patient safety events, real or simulated. (Detail)

VI.A.1.b) Quality Improvement

VI.A.1.b).(1) Education in Quality Improvement

A cohesive model of health care includes quality-related goals, tools, and techniques that are necessary in order for health care professionals to achieve quality improvement goals.

VI.A.1.b).(1).(a) Residents must receive training and experience in quality improvement processes, including an understanding of health care disparities. (Core)

VI.A.1.b).(2) Quality Metrics

Access to data is essential to prioritizing activities for care improvement and evaluating success of improvement efforts.

VI.A.1.b).(2).(a) Residents and faculty members must receive data on quality metrics and benchmarks related to their patient populations. (Core)

VI.A.1.b).(3) Engagement in Quality Improvement Activities

Experiential learning is essential to developing the ability to identify and institute sustainable systems-based changes to improve patient care.

VI.A.1.b).(3).(a) Residents must have the opportunity to participate in interprofessional quality improvement activities. (Core)

VI.A.1.b).(3).(a).(i) This should include activities aimed at reducing health care disparities. (Detail)

VI.A.2. Supervision and Accountability

VI.A.2.a) *Although the attending physician is ultimately responsible for the care of the patient, every physician shares in the responsibility and accountability for their efforts in the provision of care. Effective programs, in partnership with their Sponsoring Institutions, define, widely communicate, and monitor a structured chain of responsibility and accountability as it relates to the supervision of all patient care.*

Supervision in the setting of graduate medical education provides safe and effective care to patients; ensures each resident's development of the skills, knowledge, and attitudes required to enter the unsupervised practice of medicine; and establishes a foundation for continued professional growth.

VI.A.2.a).(1) Each patient must have an identifiable and appropriately-credentialed and privileged attending physician (or licensed independent practitioner as specified by the applicable Review Committee) who is responsible and accountable for the patient's care. (Core)

VI.A.2.a).(1).(a) This information must be available to residents, faculty members, other members of the health care team, and patients. (Core)

VI.A.2.a).(1).(b) **Residents and faculty members must inform each patient of their respective roles in that patient's care when providing direct patient care.** (Core)

VI.A.2.a).(1).(b).(i) The Review Committee recognizes only physician faculty members as appropriate faculty supervisors for residents. (Core)

VI.A.2.b) ***Supervision may be exercised through a variety of methods. For many aspects of patient care, the supervising physician may be a more advanced resident or fellow. Other portions of care provided by the resident can be adequately supervised by the appropriate availability of the supervising faculty member, fellow, or senior resident physician, either on site or by means of telecommunication technology. Some activities require the physical presence of the supervising faculty member. In some circumstances, supervision may include post-hoc review of resident-delivered care with feedback.***

Background and Intent: Appropriate supervision is essential for patient safety and high-quality teaching. Supervision is also contextual. There is tremendous diversity of resident patient interactions, education and training locations, and resident skills and abilities even at the same level of the educational program. The degree of supervision is expected to evolve progressively as a resident gains more experience, even with the same patient condition or procedure. All residents have a level of supervision commensurate with their level of autonomy in practice; this level of supervision may be enhanced based on factors such as patient safety, complexity, acuity, urgency, risk of serious adverse events, or other pertinent variables.

VI.A.2.b).(1) **The program must demonstrate that the appropriate level of supervision in place for all residents is based on each resident's level of training and ability, as well as patient complexity and acuity. Supervision may be exercised through a variety of methods, as appropriate to the situation.** (Core)

VI.A.2.b).(2) **The program must define when physical presence of a supervising physician is required.** (Core)

VI.A.2.c) **Levels of Supervision**

To promote appropriate resident supervision while providing for graded authority and responsibility, the program must use the following classification of supervision: (Core)

VI.A.2.c).(1) **Direct Supervision:**

VI.A.2.c).(1).(a) **the supervising physician is physically present with the resident during the key portions of the patient interaction.** (Core)

VI.A.2.c).(1).(a).(i) **PGY-1 residents must initially be supervised directly, only as described in VI.A.2.c).(1).(a).** (Core)

VI.A.2.c).(1).(b) **the supervising physician and/or patient is not physically present with the resident and the supervising physician is concurrently monitoring the patient care through appropriate telecommunication technology.** (Core)

VI.A.2.c).(1).(b).(i) The use of telecommunication technology for direct supervision must be limited to non-procedural patient evaluations and examinations, in either the ambulatory or acute care settings. (Core)

VI.A.2.c).(2) **Indirect Supervision: the supervising physician is not providing physical or concurrent visual or audio supervision but is immediately available to the resident for guidance and is available to provide appropriate direct supervision.** (Core)

VI.A.2.c).(3) **Oversight – the supervising physician is available to provide review of procedures/encounters with feedback provided after care is delivered.** (Core)

VI.A.2.d) **The privilege of progressive authority and responsibility, conditional independence, and a supervisory role in patient care delegated to each resident must be assigned by the program director and faculty members.** (Core)

VI.A.2.d).(1) **The program director must evaluate each resident's abilities based on specific criteria, guided by the Milestones.** (Core)

VI.A.2.d).(2) **Faculty members functioning as supervising physicians must delegate portions of care to residents based on the needs of the patient and the skills of each resident.** (Core)

VI.A.2.d).(3) **Senior residents or fellows should serve in a supervisory role to junior residents in recognition of their progress toward independence, based on the needs of each patient and the skills of the individual resident or fellow.** (Detail)

VI.A.2.e) **Programs must set guidelines for circumstances and events in which residents must communicate with the supervising faculty member(s).** (Core)

VI.A.2.e).(1) Each resident must know the limits of their scope of authority, and the circumstances under which the resident is permitted to act with conditional independence. (Outcome)

Background and Intent: The ACGME Glossary of Terms defines conditional independence as: Graded, progressive responsibility for patient care with defined oversight.

VI.A.2.f) Faculty supervision assignments must be of sufficient duration to assess the knowledge and skills of each resident and to delegate to the resident the appropriate level of patient care authority and responsibility. (Core)

VI.B. Professionalism

VI.B.1. Programs, in partnership with their Sponsoring Institutions, must educate residents and faculty members concerning the professional responsibilities of physicians, including their obligation to be appropriately rested and fit to provide the care required by their patients. (Core)

VI.B.2. The learning objectives of the program must:

VI.B.2.a) be accomplished through an appropriate blend of supervised patient care responsibilities, clinical teaching, and didactic educational events; (Core)

VI.B.2.b) be accomplished without excessive reliance on residents to fulfill non-physician obligations; and, (Core)

Background and Intent: Routine reliance on residents to fulfill non-physician obligations increases work compression for residents and does not provide an optimal educational experience. Non-physician obligations are those duties which in most institutions are performed by nursing and allied health professionals, transport services, or clerical staff. Examples of such obligations include transport of patients from the wards or units for procedures elsewhere in the hospital; routine blood drawing for laboratory tests; routine monitoring of patients when off the ward; and clerical duties, such as scheduling. While it is understood that residents may be expected to do any of these things on occasion when the need arises, these activities should not be performed by residents routinely and must be kept to a minimum to optimize resident education.

VI.B.2.c) ensure manageable patient care responsibilities. (Core)

Background and Intent: The Common Program Requirements do not define "manageable patient care responsibilities" as this is variable by specialty and PGY level. Review Committees will provide further detail regarding patient care responsibilities in the applicable specialty-specific Program Requirements and accompanying FAQs. However, all programs, regardless of specialty, should carefully

assess how the assignment of patient care responsibilities can affect work compression, especially at the PGY-1 level.

VI.B.3. The program director, in partnership with the Sponsoring Institution, must provide a culture of professionalism that supports patient safety and personal responsibility. (Core)

VI.B.4. Residents and faculty members must demonstrate an understanding of their personal role in the:

VI.B.4.a) provision of patient- and family-centered care; (Outcome)

VI.B.4.b) safety and welfare of patients entrusted to their care, including the ability to report unsafe conditions and adverse events; (Outcome)

Background and Intent: This requirement emphasizes that responsibility for reporting unsafe conditions and adverse events is shared by all members of the team and is not solely the responsibility of the resident.

VI.B.4.c) assurance of their fitness for work, including: (Outcome)

Background and Intent: This requirement emphasizes the professional responsibility of faculty members and residents to arrive for work adequately rested and ready to care for patients. It is also the responsibility of faculty members, residents, and other members of the care team to be observant, to intervene, and/or to escalate their concern about resident and faculty member fitness for work, depending on the situation, and in accordance with institutional policies.

VI.B.4.c).(1) management of their time before, during, and after clinical assignments; and, (Outcome)

VI.B.4.c).(2) recognition of impairment, including from illness, fatigue, and substance use, in themselves, their peers, and other members of the health care team. (Outcome)

VI.B.4.d) commitment to lifelong learning; (Outcome)

VI.B.4.e) monitoring of their patient care performance improvement indicators; and, (Outcome)

VI.B.4.f) accurate reporting of clinical and educational work hours, patient outcomes, and clinical experience data. (Outcome)

VI.B.5. All residents and faculty members must demonstrate responsiveness to patient needs that supersedes self-interest. This includes the recognition that under certain circumstances, the best interests of the patient may be served by transitioning that patient's care to another qualified and rested provider. (Outcome)

VI.B.6. Programs, in partnership with their Sponsoring Institutions, must provide a professional, equitable, respectful, and civil environment that is free from discrimination, sexual and other forms of harassment, mistreatment, abuse, or coercion of students, residents, faculty, and staff. (Core)

VI.B.7. Programs, in partnership with their Sponsoring Institutions, should have a process for education of residents and faculty regarding unprofessional behavior and a confidential process for reporting, investigating, and addressing such concerns. (Core)

VI.C. Well-Being

Psychological, emotional, and physical well-being are critical in the development of the competent, caring, and resilient physician and require proactive attention to life inside and outside of medicine. Well-being requires that physicians retain the joy in medicine while managing their own real-life stresses. Self-care and responsibility to support other members of the health care team are important components of professionalism; they are also skills that must be modeled, learned, and nurtured in the context of other aspects of residency training.

Residents and faculty members are at risk for burnout and depression. Programs, in partnership with their Sponsoring Institutions, have the same responsibility to address well-being as other aspects of resident competence. Physicians and all members of the health care team share responsibility for the well-being of each other. For example, a culture which encourages covering for colleagues after an illness without the expectation of reciprocity reflects the ideal of professionalism. A positive culture in a clinical learning environment models constructive behaviors, and prepares residents with the skills and attitudes needed to thrive throughout their careers.

Background and Intent: The ACGME is committed to addressing physician well-being for individuals and as it relates to the learning and working environment. The creation of a learning and working environment with a culture of respect and accountability for physician well-being is crucial to physicians' ability to deliver the safest, best possible care to patients. The ACGME is leveraging its resources in four key areas to support the ongoing focus on physician well-being: education, influence, research, and collaboration. Information regarding the ACGME's ongoing efforts in this area is available on the ACGME website: www.acgme.org/physicianwellbeing.

The ACGME also created a repository for well-being materials, assessments, presentations, and more on the Well-Being Tools and Resources page in Learn at ACGME for programs seeking to develop or strengthen their own well-being initiatives. There are many activities that programs can implement now to assess and support physician well-being. These include the distribution and analysis of culture of safety surveys, ensuring the availability of counseling services, and paying attention to the safety of the entire health care team.

VI.C.1. The responsibility of the program, in partnership with the Sponsoring Institution, to address well-being must include:

VI.C.1.a) efforts to enhance the meaning that each resident finds in the experience of being a physician, including protecting time with patients, minimizing non-physician obligations, providing administrative support, promoting progressive autonomy and flexibility, and enhancing professional relationships; (Core)

VI.C.1.b) attention to scheduling, work intensity, and work compression that impacts resident well-being; (Core)

VI.C.1.c) evaluating workplace safety data and addressing the safety of residents and faculty members; (Core)

Background and Intent: This requirement emphasizes the responsibility shared by the Sponsoring Institution and its programs to gather information and utilize systems that monitor and enhance resident and faculty member safety, including physical safety. Issues to be addressed include, but are not limited to, monitoring of workplace injuries, physical or emotional violence, vehicle collisions, and emotional well-being after adverse events.

VI.C.1.d) policies and programs that encourage optimal resident and faculty member well-being; and, (Core)

Background and Intent: Well-being includes having time away from work to engage with family and friends, as well as to attend to personal needs and to one's own health, including adequate rest, healthy diet, and regular exercise.

VI.C.1.d).(1) Residents must be given the opportunity to attend medical, mental health, and dental care appointments, including those scheduled during their working hours. (Core)

Background and Intent: The intent of this requirement is to ensure that residents have the opportunity to access medical and dental care, including mental health care, at times that are appropriate to their individual circumstances. Residents must be provided with time away from the program as needed to access care, including appointments scheduled during their working hours.

VI.C.1.e) attention to resident and faculty member burnout, depression, and substance use disorders. The program, in partnership with its Sponsoring Institution, must educate faculty members and residents in identification of the symptoms of burnout, depression, and substance use disorders, including means to assist those who experience these conditions. Residents and faculty members must also be educated to recognize those symptoms in themselves and

how to seek appropriate care. The program, in partnership with its Sponsoring Institution, must: (Core)

Background and Intent: Programs and Sponsoring Institutions are encouraged to review materials to create systems for identification of burnout, depression, and substance use disorders. Materials and more information are available in Learn at ACGME (https://dl.acgme.org/pages/well-being-tools-resources).

VI.C.1.e).(1) encourage residents and faculty members to alert the program director or other designated personnel or programs when they are concerned that another resident, fellow, or faculty member may be displaying signs of burnout, depression, a substance use disorder, suicidal ideation, or potential for violence; (Core)

Background and Intent: Individuals experiencing burnout, depression, a substance use disorder, and/or suicidal ideation are often reluctant to reach out for help due to the stigma associated with these conditions, and are concerned that seeking help may have a negative impact on their career. Recognizing that physicians are at increased risk in these areas, it is essential that residents and faculty members are able to report their concerns when another resident or faculty member displays signs of any of these conditions, so that the program director or other designated personnel, such as the department chair, may assess the situation and intervene as necessary to facilitate access to appropriate care. Residents and faculty members must know which personnel, in addition to the program director, have been designated with this responsibility; those personnel and the program director should be familiar with the institution's impaired physician policy and any employee health, employee assistance, and/or wellness programs within the institution. In cases of physician impairment, the program director or designated personnel should follow the policies of their institution for reporting.

VI.C.1.e).(2) provide access to appropriate tools for self-screening; and, (Core)

VI.C.1.e).(3) provide access to confidential, affordable mental health assessment, counseling, and treatment, including access to urgent and emergent care 24 hours a day, seven days a week. (Core)

Background and Intent: The intent of this requirement is to ensure that residents have immediate access at all times to a mental health professional (psychiatrist, psychologist, Licensed Clinical Social Worker, Primary Mental Health Nurse Practitioner, or Licensed Professional Counselor) for urgent or emergent mental health issues. In-person, telemedicine, or telephonic means may be utilized to satisfy this requirement. Care in the Emergency Department may be necessary in some cases, but not as the primary or sole means to meet the requirement.

The reference to affordable counseling is intended to require that financial cost not be a barrier to obtaining care.

VI.C.2. There are circumstances in which residents may be unable to attend work, including but not limited to fatigue, illness, family emergencies, and parental leave. Each program must allow an appropriate length of absence for residents unable to perform their patient care responsibilities. (Core)

VI.C.2.a) The program must have policies and procedures in place to ensure coverage of patient care. (Core)

VI.C.2.b) These policies must be implemented without fear of negative consequences for the resident who is or was unable to provide the clinical work. (Core)

Background and Intent: Residents may need to extend their length of training depending on length of absence and specialty board eligibility requirements. Teammates should assist colleagues in need and equitably reintegrate them upon return.

VI.D. Fatigue Mitigation

VI.D.1. Programs must:

VI.D.1.a) educate all faculty members and residents to recognize the signs of fatigue and sleep deprivation; (Core)

VI.D.1.b) educate all faculty members and residents in alertness management and fatigue mitigation processes; and, (Core)

VI.D.1.c) encourage residents to use fatigue mitigation processes to manage the potential negative effects of fatigue on patient care and learning. (Detail)

Background and Intent: Providing medical care to patients is physically and mentally demanding. Night shifts, even for those who have had enough rest, cause fatigue. Experiencing fatigue in a supervised environment during training prepares residents for managing fatigue in practice. It is expected that programs adopt fatigue mitigation processes and ensure that there are no negative consequences and/or stigma for using fatigue mitigation strategies.

This requirement emphasizes the importance of adequate rest before and after clinical responsibilities. Strategies that may be used include, but are not limited to, strategic napping; the judicious use of caffeine; availability of other caregivers; time management to maximize sleep off-duty; learning to recognize the signs of fatigue, and self-monitoring performance and/or asking others to monitor performance; remaining active to promote alertness; maintaining a healthy diet; using relaxation techniques to fall asleep; maintaining a consistent sleep routine; exercising regularly; increasing sleep time before and after call; and ensuring sufficient sleep recovery periods.

VI.D.2. **Each program must ensure continuity of patient care, consistent with the program's policies and procedures referenced in VI.C.2–VI.C.2.b), in the event that a resident may be unable to perform their patient care responsibilities due to excessive fatigue.** (Core)

VI.D.3. **The program, in partnership with its Sponsoring Institution, must ensure adequate sleep facilities and safe transportation options for residents who may be too fatigued to safely return home.** (Core)

VI.E. Clinical Responsibilities, Teamwork, and Transitions of Care

VI.E.1. Clinical Responsibilities

The clinical responsibilities for each resident must be based on PGY level, patient safety, resident ability, severity and complexity of patient illness/condition, and available support services. (Core)

VI.E.1.a) The program director must establish written guidelines for the assignment of clinical responsibilities by Uro level, including clinic volume, on-call frequency and back-up requirements, and the appropriate role in surgical procedures. (Core)

Background and Intent: The changing clinical care environment of medicine has meant that work compression due to high complexity has increased stress on residents. Faculty members and program directors need to make sure residents function in an environment that has safe patient care and a sense of resident well-being. Some Review Committees have addressed this by setting limits on patient admissions, and it is an essential responsibility of the program director to monitor resident workload. Workload should be distributed among the resident team and interdisciplinary teams to minimize work compression.

VI.E.2. Teamwork

Residents must care for patients in an environment that maximizes communication. This must include the opportunity to work as a member of effective interprofessional teams that are appropriate to the delivery of care in the specialty and larger health system. (Core)

VI.E.2.a) Each resident must have the opportunity to interact with nurses, social workers, and other health care providers. (Core)

VI.E.3. Transitions of Care

VI.E.3.a) **Programs must design clinical assignments to optimize transitions in patient care, including their safety, frequency, and structure.** (Core)

VI.E.3.b) **Programs, in partnership with their Sponsoring Institutions, must ensure and monitor effective, structured hand-over processes to facilitate both continuity of care and patient safety.** (Core)

VI.E.3.c) Programs must ensure that residents are competent in communicating with team members in the hand-over process. (Outcome)

VI.E.3.d) Programs and clinical sites must maintain and communicate schedules of attending physicians and residents currently responsible for care. (Core)

VI.E.3.e) Each program must ensure continuity of patient care, consistent with the program's policies and procedures referenced in VI.C.2-VI.C.2.b), in the event that a resident may be unable to perform their patient care responsibilities due to excessive fatigue or illness, or family emergency. (Core)

VI.F. Clinical Experience and Education

Programs, in partnership with their Sponsoring Institutions, must design an effective program structure that is configured to provide residents with educational and clinical experience opportunities, as well as reasonable opportunities for rest and personal activities.

Background and Intent: In the new requirements, the terms "clinical experience and education," "clinical and educational work," and "clinical and educational work hours" replace the terms "duty hours," "duty periods," and "duty." These changes have been made in response to concerns that the previous use of the term "duty" in reference to number of hours worked may have led some to conclude that residents' duty to "clock out" on time superseded their duty to their patients.

VI.F.1. Maximum Hours of Clinical and Educational Work per Week

Clinical and educational work hours must be limited to no more than 80 hours per week, averaged over a four-week period, inclusive of all in-house clinical and educational activities, clinical work done from home, and all moonlighting. (Core)

Background and Intent: Programs and residents have a shared responsibility to ensure that the 80-hour maximum weekly limit is not exceeded. While the requirement has been written with the intent of allowing residents to remain beyond their scheduled work periods to care for a patient or participate in an educational activity, these additional hours must be accounted for in the allocated 80 hours when averaged over four weeks.

Scheduling
While the ACGME acknowledges that, on rare occasions, a resident may work in excess of 80 hours in a given week, all programs and residents utilizing this flexibility will be required to adhere to the 80-hour maximum weekly limit when averaged over a four-week period. Programs that regularly schedule residents to work 80 hours per week and still permit residents to remain beyond their scheduled work period are likely to exceed the 80-hour maximum, which would not be in substantial compliance with the requirement. These programs should adjust schedules so that residents are scheduled

to work fewer than 80 hours per week, which would allow residents to remain beyond their scheduled work period when needed without violating the 80-hour requirement. Programs may wish to consider using night float and/or making adjustments to the frequency of in-house call to ensure compliance with the 80-hour maximum weekly limit.

Oversight
With increased flexibility introduced into the Requirements, programs permitting this flexibility will need to account for the potential for residents to remain beyond their assigned work periods when developing schedules, to avoid exceeding the 80-hour maximum weekly limit, averaged over four weeks. The ACGME Review Committees will strictly monitor and enforce compliance with the 80-hour requirement. Where violations of the 80-hour requirement are identified, programs will be subject to citation and at risk for an adverse accreditation action.

Work from Home
While the requirement specifies that clinical work done from home must be counted toward the 80-hour maximum weekly limit, the expectation remains that scheduling be structured so that residents are able to complete most work on site during scheduled clinical work hours without requiring them to take work home. The new requirements acknowledge the changing landscape of medicine, including electronic health records, and the resulting increase in the amount of work residents choose to do from home. The requirement provides flexibility for residents to do this while ensuring that the time spent by residents completing clinical work from home is accomplished within the 80-hour weekly maximum. Types of work from home that must be counted include using an electronic health record and taking calls from home. Reading done in preparation for the following day's cases, studying, and research done from home do not count toward the 80 hours. Resident decisions to leave the hospital before their clinical work has been completed and to finish that work later from home should be made in consultation with the resident's supervisor. In such circumstances, residents should be mindful of their professional responsibility to complete work in a timely manner and to maintain patient confidentiality.

During the public comment period many individuals raised questions and concerns related to this change. Some questioned whether minute by minute tracking would be required; in other words, if a resident spends three minutes on a phone call and then a few hours later spends two minutes on another call, will the resident need to report that time. Others raised concerns related to the ability of programs and institutions to verify the accuracy of the information reported by residents. The new requirements are not an attempt to micromanage this process. Residents are to track the time they spend on clinical work from home and to report that time to the program. Decisions regarding whether to report infrequent phone calls of very short duration will be left to the individual resident. Programs will need to factor in time residents are spending on clinical work at home when schedules are developed to ensure that residents are not working in excess of 80 hours per week, averaged over four weeks. There is no requirement that programs assume responsibility for documenting this time. Rather, the program's responsibility is ensuring that residents report their time from home and that schedules are structured to ensure that residents are not working in excess of 80 hours per week, averaged over four weeks.

PGY-1 and PGY-2 Residents

PGY-1 and PGY-2 residents may not have the experience to make decisions about when it is appropriate to utilize flexibility or may feel pressured to use it when unnecessary. Programs are responsible for ensuring that residents are provided with manageable workloads that can be accomplished during scheduled work hours. This includes ensuring that a resident's assigned direct patient load is manageable, that residents have appropriate support from their clinical teams, and that residents are not overburdened with clerical work and/or other non-physician duties.

VI.F.2. Mandatory Time Free of Clinical Work and Education

VI.F.2.a) The program must design an effective program structure that is configured to provide residents with educational opportunities, as well as reasonable opportunities for rest and personal well-being. (Core)

VI.F.2.b) Residents should have eight hours off between scheduled clinical work and education periods. (Detail)

VI.F.2.b).(1) There may be circumstances when residents choose to stay to care for their patients or return to the hospital with fewer than eight hours free of clinical experience and education. This must occur within the context of the 80-hour and the one-day-off-in-seven requirements. (Detail)

Background and Intent: While it is expected that resident schedules will be structured to ensure that residents are provided with a minimum of eight hours off between scheduled work periods, it is recognized that residents may choose to remain beyond their scheduled time, or return to the clinical site during this time-off period, to care for a patient. The requirement preserves the flexibility for residents to make those choices. It is also noted that the 80-hour weekly limit (averaged over four weeks) is a deterrent for scheduling fewer than eight hours off between clinical and education work periods, as it would be difficult for a program to design a schedule that provides fewer than eight hours off without violating the 80-hour rule.

VI.F.2.c) Residents must have at least 14 hours free of clinical work and education after 24 hours of in-house call. (Core)

Background and Intent: Residents have a responsibility to return to work rested, and thus are expected to use this time away from work to get adequate rest. In support of this goal, residents are encouraged to prioritize sleep over other discretionary activities.

VI.F.2.d) Residents must be scheduled for a minimum of one day in seven free of clinical work and required education (when averaged over four weeks). At-home call cannot be assigned on these free days. (Core)

Background and Intent: The requirement provides flexibility for programs to distribute days off in a manner that meets program and resident needs. It is strongly recommended that residents' preference regarding how their days off are distributed be

considered as schedules are developed. It is desirable that days off be distributed throughout the month, but some residents may prefer to group their days off to have a "golden weekend," meaning a consecutive Saturday and Sunday free from work. The requirement for one free day in seven should not be interpreted as precluding a golden weekend. Where feasible, schedules may be designed to provide residents with a weekend, or two consecutive days, free of work. The applicable Review Committee will evaluate the number of consecutive days of work and determine whether they meet educational objectives. Programs are encouraged to distribute days off in a fashion that optimizes resident well-being, and educational and personal goals. It is noted that a day off is defined in the ACGME Glossary of Terms as "one (1) continuous 24-hour period free from all administrative, clinical, and educational activities."

VI.F.3. Maximum Clinical Work and Education Period Length

VI.F.3.a) Clinical and educational work periods for residents must not exceed 24 hours of continuous scheduled clinical assignments. (Core)

Background and Intent: The Task Force examined the question of "consecutive time on task." It examined the research supporting the current limit of 16 consecutive hours of time on task for PGY-1 residents; the range of often conflicting impacts of this requirement on patient safety, clinical care, and continuity of care by resident teams; and resident learning found in the literature. Finally, it heard a uniform request by the specialty societies, certifying boards, membership societies and organizations, and senior residents to repeal this requirement. It heard conflicting perspectives from resident unions, a medical student association, and a number of public advocacy groups, some arguing for continuation of the requirement, others arguing for extension of the requirement to all residents.

Of greatest concern to the Task Force were the observations of disruption of team care and patient care continuity brought about with residents beyond the PGY-1 level adhering to differing requirements. The graduate medical education community uniformly requested that the Task Force remove this requirement. The most frequently-cited reason for this request was the complete disruption of the team, separating the PGY-1 from supervisory faculty members and residents who were best able to judge the ability of the resident and customize the supervision of patient care for each PGY-1. Cited nearly as frequently was the separation of the PGY-1 from the team, delaying maturation of clinical skills, and threatening to create a "shift" mentality in disciplines where overnight availability to patients is essential in delivery of care.

The Task Force examined the impact of the request to consider 16-consecutive-hour limits for all residents, and rejected the proposition. It found that model incompatible with the actual practice of medicine and surgery in many specialties, excessively limiting in configuration of clinical services in many disciplines, and potentially disruptive of the inculcation of responsibility and professional commitment to altruism and placing the needs of patients above those of the physician.

After careful consideration of the information available, the testimony and position of all parties submitting information, and presentations to the Task Force, the Task Force removed the 16-hour-consecutive-time-on-task requirement for PGY-1 residents. It

remains crucial that programs ensure that PGY-1 residents are supervised in compliance with the applicable Program Requirements, and that resident well-being is prioritized as described in Section VI.C. of these requirements.

VI.F.3.a).(1) Up to four hours of additional time may be used for activities related to patient safety, such as providing effective transitions of care, and/or resident education. (Core)

VI.F.3.a).(1).(a) Additional patient care responsibilities must not be assigned to a resident during this time. (Core)

Background and Intent: The additional time referenced in VI.F.3.a).(1) should not be used for the care of new patients. It is essential that the resident continue to function as a member of the team in an environment where other members of the team can assess resident fatigue, and that supervision for post-call residents is provided. This 24 hours and up to an additional four hours must occur within the context of 80-hour weekly limit, averaged over four weeks.

VI.F.4. Clinical and Educational Work Hour Exceptions

VI.F.4.a) In rare circumstances, after handing off all other responsibilities, a resident, on their own initiative, may elect to remain or return to the clinical site in the following circumstances:

VI.F.4.a).(1) to continue to provide care to a single severely ill or unstable patient; (Detail)

VI.F.4.a).(2) humanistic attention to the needs of a patient or family; or, (Detail)

VI.F.4.a).(3) to attend unique educational events. (Detail)

VI.F.4.b) These additional hours of care or education will be counted toward the 80-hour weekly limit. (Detail)

Background and Intent: This requirement is intended to provide residents with some control over their schedules by providing the flexibility to voluntarily remain beyond the scheduled responsibilities under the circumstances described above. It is important to note that a resident may remain to attend a conference, or return for a conference later in the day, only if the decision is made voluntarily. Residents must not be required to stay. Programs allowing residents to remain or return beyond the scheduled work and clinical education period must ensure that the decision to remain is initiated by the resident and that residents are not coerced. This additional time must be counted toward the 80-hour maximum weekly limit.

VI.F.4.c) A Review Committee may grant rotation-specific exceptions for up to 10 percent or a maximum of 88 clinical and

educational work hours to individual programs based on a sound educational rationale.

The Review Committee for Urology will not consider requests for exceptions to the 80-hour limit to the residents' work week.

VI.F.5. Moonlighting

VI.F.5.a) Moonlighting must not interfere with the ability of the resident to achieve the goals and objectives of the educational program, and must not interfere with the resident's fitness for work nor compromise patient safety. (Core)

VI.F.5.b) Time spent by residents in internal and external moonlighting (as defined in the ACGME Glossary of Terms) must be counted toward the 80-hour maximum weekly limit. (Core)

VI.F.5.c) PGY-1 residents are not permitted to moonlight. (Core)

Background and Intent: For additional clarification of the expectations related to moonlighting, please refer to the Common Program Requirement FAQs (available at http://www.acgme.org/What-We-Do/Accreditation/Common-Program-Requirements).

VI.F.6. In-House Night Float

Night float must occur within the context of the 80-hour and one-day-off-in-seven requirements. (Core)

VI.F.6.a) Residents cannot be assigned more than eight weeks of night float per year. (Detail)

Background and Intent: The requirement for no more than six consecutive nights of night float was removed to provide programs with increased flexibility in scheduling.

VI.F.7. Maximum In-House On-Call Frequency

Residents must be scheduled for in-house call no more frequently than every third night (when averaged over a four-week period). (Core)

VI.F.8. At-Home Call

VI.F.8.a) Time spent on patient care activities by residents on at-home call must count toward the 80-hour maximum weekly limit. The frequency of at-home call is not subject to the every-third-night limitation, but must satisfy the requirement for one day in seven free of clinical work and education, when averaged over four weeks. (Core)

VI.F.8.a).(1) **At-home call must not be so frequent or taxing as to preclude rest or reasonable personal time for each resident.** (Core)

VI.F.8.b) **Residents are permitted to return to the hospital while on at-home call to provide direct care for new or established patients. These hours of inpatient patient care must be included in the 80-hour maximum weekly limit.** (Detail)

Background and Intent: This requirement has been modified to specify that clinical work done from home when a resident is taking at-home call must count toward the 80-hour maximum weekly limit. This change acknowledges the often significant amount of time residents devote to clinical activities when taking at-home call, and ensures that taking at-home call does not result in residents routinely working more than 80 hours per week. At-home call activities that must be counted include responding to phone calls and other forms of communication, as well as documentation, such as entering notes in an electronic health record. Activities such as reading about the next day's case, studying, or research activities do not count toward the 80-hour weekly limit.

In their evaluation of residency/fellowship programs, Review Committees will look at the overall impact of at-home call on resident/fellow rest and personal time.

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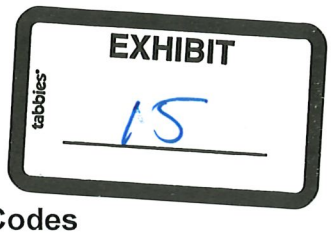
*__Core Requirements__: Statements that define structure, resource, or process elements essential to every graduate medical educational program.

†__Detail Requirements__: Statements that describe a specific structure, resource, or process, for achieving compliance with a Core Requirement. Programs and sponsoring institutions in substantial compliance with the Outcome Requirements may utilize alternative or innovative approaches to meet Core Requirements.

‡__Outcome Requirements__: Statements that specify expected measurable or observable attributes (knowledge, abilities, skills, or attitudes) of residents or fellows at key stages of their graduate medical education.

Osteopathic Recognition
For programs with or applying for Osteopathic Recognition, the Osteopathic Recognition Requirements also apply (www.acgme.org/OsteopathicRecognition).



Index Categories, Minimum Numbers, and Common CPT Codes for Urology Residents

(Prepared by ACGME Residency Review Committee for Urology – September 2012)

The Committee has reviewed the minimum number of procedures required for resident education. The index categories, minimum numbers, and common CPT codes are listed below.

Achievement of the minimum number of listed procedures does not signify achievement of competence of an individual resident in a particular procedure. A resident may need to perform an additional number of procedures before they are determined to be competent by the program director. Moreover, the list of minimum procedures represents only a fraction of the total operative experience expected of a resident within the residency. The intent is to establish a minimum of number of procedures to meet the minimum requirement for accreditation purposes, without distracting from the authority of the program director to determine the entire educational experience for each resident, taking into account each resident's particular abilities. All procedures should be recorded in the ACGME Case Log System regardless of whether the minima are met.

Please note that the minimum requirement for procedures does not supplant the requirement that, upon the resident's completion of the program, the program director must verify that the resident has demonstrated sufficient competence to enter practice without direct supervision.

	Min	Common CPT codes
ADULT UROLOGY		
General Urology	200	
Transurethral resection	100	52224 (bladder bx); 52234,25,40 (TURBT s/m/l); 52601 (TURP); 52648 (PVP)
TRUS/prostate biopsy	25	55700 (and 76872 for TRUS)
Scrotal/inguinal surgery	40	54530 (inguinal orchiectomy); 55040 (hydrocelec); 55250 (vasectomy); 55400 (vaso-vaso); 54900 (vaso-epi); 55530 (varicocele ligation)
Urodynamics (participate and interpret)	10	51797
Endourology/Stone Disease	120	
Shock wave lithotripsy	10	50590
Ureteroscopy	60	52344 (stricture); 52345 (UPJ obstruction); 52352 (stone removal); 52353 (laser); 52354 (tumor bx); 52355 (resection)
Percutaneous renal	10	50080 (<2cm); 50081 (>2cm); perc cryo (50593)
Laparoscopy	50	automatically counted
Reconstruction	60	50544 (lap pyeloplasty); 50780 (reimplant)
Male	15	
Penile/incontinence	10	54360 (plication); 54405 (IPP); 54440 (penile fx); 53440 (male sling); 53445 (AUS)
Urethra	5	53410 (urethroplasty); 53215 (urethrectomy)

Female	15	57288 (sling); 57260 (AP repair); 53500 (urethrolysis); 53230 (diverticulectomy); 57320 (VVF repair)
Intestinal diversion	8	automatically counted with cystectomy; otherwise use 50820 (ileal conduit); 51960 (augment); etc.
Oncology	100	
Pelvic	40	
Prostate	25	55866 (lap/robot RP); 55840/55842/55845 (RRP with no/limited/extended PLND)
Bladder	8	51595 (RC/conduit); 51596 (RC/continent diversion); 51597 (pelvic exent); 51550 (partial cx)
Retroperitoneal	40	38780 (RPLND); 60650 (lap Ax); 60540 (open Ax)
Kidney	30	50230 (ORN); 50240 (OPN); 50542 (lap tumor ablation); 50543 (LPN); 50545 (LRN); 50547 (lap donor); 50548 (lap NU)
PEDIATRIC UROLOGY		
Minor	30	
Endoscopy	5	52000 (cysto); 52005 (RPG); 52300 (ureterocele); 52327 (sting); 52332 (stent); 52400 (PUV); any ureteroscopy (see adult list)
Hydrocele/hernia	10	49496 (<6m); 49500 (6m-5y); 49505 (>5y)
Orchiopexy	10	54640/50/92 (orchiopexy via ing/abd/lap); 54600 (fixation for torsion)
Major	15	50220 (total Nx); 50240 (partial Nx); 50400 (pyeloplasty); 50845 (appendicoves)
Hypospadias	5	54322 (distal); 54324 (distal with flap); 54332 (prox)
Ureter	5	50780 (reimplant); 50782 (duplicated)

ACGME

Case Log Information: Urology
Review Committee for Urology

The Review Committee has defined index categories required for resident education in urology. The Review Committee uses Case Logs to assess individual resident experience, as well as the breadth and depth of a program's procedural training. This document provides information about the index categories, the minimum number of cases residents are required to perform, and properly logging procedural experiences.

Residents are expected to log all procedures. Most procedures count towards at least one index category. All logged procedures are included in the total procedure count.

A list of urology tracked procedures can be found in the Accreditation Data System (ADS) > Case Log Tab > Reports > Tracked Codes Report. The column "Idx Cat" indicates if a procedure counts towards one or more index category.

Contents *(Click the text to jump to section)*

Email Review Committee Executive Director Kathleen Quinn-Leering, PhD (kquinn@acgme.org) with questions.

Index Categories and Minimum Procedure Numbers

Category	Minimum
General Urology	250
Transurethral resection	100
Transrectal ultrasound (TRUS)/prostate biopsy	25
Fusion*	0
Scrotal/inguinal surgery	60
Urodynamic studies (UDS)	10
Endourology/Stone Disease	150
Ureteroscopy	90
Percutaneous renal procedure	10
Reconstructive Surgery	100
Male	30
Male penis/incontinence	15
Male urethra	5
Female	15
Intestinal diversion	10
Oncology	130
Pelvic	50
Pelvic-bladder	10
Pelvic-prostate	30
Retroperitoneal	50
Retroperitoneal-kidney	40
Pediatric-Minor	30
Endoscopy	5
Hydrocele/hernia	10
Orchiopexy	10
Pediatric-Major	15
Hypospadias	5
Ureter	5
Robotic	80

*Residents will have the option of logging magnetic resonance imaging (MRI) fusion as part of a prostate biopsy. Fusion biopsy numbers will be tracked, but there is not a set minimum.

Notes

- Minimum numbers represent what the Review Committee believes to be an acceptable minimal experience.
- Surgeon, Assistant, and Teaching Assistant roles are included in the minimum counts.
- Procedures that are given credit in an index **sub**category are also given credit in the corresponding index category. For example, pelvic-bladder procedures are mapped to three minimum categories: Pelvic-bladder; Pelvic; and Oncology.
- Minimum numbers are not a final target number and achievement does not signify competence.
- Program directors must ensure that residents continue to report their procedures in the Case Log System after minimums are achieved.

Surgeon, Assistant, and Teaching Assistant Roles

Resident participation in a surgical procedure will be credited as an index case whether the resident functions as **Surgeon**, **Assistant**, or **Teaching Assistant**.

To be recorded as **Surgeon**, a resident must perform 50 percent or more of the procedure, including a significant number of the critical steps. When two residents each complete one side of a bilateral procedure (e.g., orchidopexy, ureteral reimplant, nephrectomy), each resident may record the case as Surgeon.

To be recorded as **Assistant** surgeon, a resident must perform less than 50 percent of the procedure and/or not the key portion(s) of the procedure. Only one resident can claim credit as Assistant on a given procedure.

To be recorded as **Teaching Assistant**, the chief or senior resident directs and oversees major portions of the procedure being performed by a more junior resident surgeon, under the guidance of a supervising faculty member.

It is expected that over the course of the program, residents will develop the skills necessary to perform progressively greater proportions of cases. Involvement in pre-operative assessment and post-operative management of patients are important elements of resident participation.

Logging Robotic Procedures

Residents indicate a procedure was performed robotically by checking the Robotic checkbox under the CPT code description in the Case Log System. Only procedures that can be performed robotically have this option. When checked, credit is given towards the robotic minimum category. Credit is given regardless of the role chosen (Assistant, Surgeon, or Teaching Assistant).

In robotic cases, the resident typically fulfills one of two operative roles: console Surgeon or bedside Assistant.

To be recorded as **Surgeon**, a resident must act as console surgeon for some portion of the case. Because robotic cases require a unique set of skills gained through stepwise learning, residents are not expected to complete the majority of critical steps of a given robotic case to qualify as Surgeon. It is expected that over the course of the educational program, residents will develop the skills necessary to perform progressively greater proportions of robotic cases. For a situation in which two residents complete some portion of the case at the console, only one resident may log the case as Surgeon.

To be recorded as **Assistant**, a resident must serve as the bedside assistant. A resident may also log a case as Assistant if two residents complete some portion of a case at the console, but the other resident has a more significant role and will claim credit as Surgeon.

Examples for Correct Logging of Robotic Surgery Cases

Example A: A resident (1) assists in placement of robotic ports for a robotic-assisted laparoscopic prostatectomy. She then serves as the bedside Assistant while the attending Surgeon operates at the console for the entire case. She helps to remove the specimen and close port sites at the end of the case.

Resident	CPT Code	Procedure	Role	Index Credit?
1	55866	Laparoscopic/Robotic Radical Prostatectomy	Assistant	Yes

The resident did not complete any steps on the console, so she should log the role of Assistant for the case. She must check the Robotic checkbox to receive index case credit towards the minimum requirement for robotic.

Example B: A resident (1) assists in placement of robotic ports for a robotic-assisted laparoscopic prostatectomy. He then serves as the bedside Assistant for the case. The more senior resident (2) dissects the seminal vesicles, divides the endopelvic fascia, and completes a portion of the anastomotic sutures; the attending surgeon completes the majority of the case.

Resident	CPT Code	Procedure	Role	Index Credit?
1	55866	Laparoscopic/Robotic Radical Prostatectomy	Assistant	Yes
2	55866	Laparoscopic/Robotic Radical Prostatectomy	Surgeon	Yes

Resident 1 did not complete any steps on the console, so he should log the role of Assistant for the case. Resident 2 operated on the console for a portion of the case and may log the case as Surgeon even though he did not complete the majority of the case. Both residents must check the Robotic checkbox to receive index case credit towards the minimum requirement for robotic surgery cases.

Example C: A resident (1) assists in placement of robotic ports for a robotic-assisted laparoscopic prostatectomy. He scrubs out to complete the seminal vesicle dissection at the console, then returns to his role as bedside Assistant. The chief resident (2) then completes a number of steps at the console, under the supervision of the attending surgeon.

Resident	CPT Code	Procedure	Role	Index Credit?
1	55866	Laparoscopic/Robotic Radical Prostatectomy	Assistant	Yes
2	55866	Laparoscopic/Robotic Radical Prostatectomy	Surgeon	Yes

Although both residents operated on the console for a portion of the case, only one resident can log the case as Surgeon. Since Resident 2 completed more of the case at the console, Resident 1 should log the case as Assistant, and Resident 2 should log the case as Surgeon. Both residents must check the Robotic checkbox to receive index case credit towards the minimum requirement for robotic surgery cases.

Logging Ultrasound Procedures

Ultrasound cases include commonly performed procedures like transrectal ultrasound (TRUS) and less common procedures such as renal, pelvic, scrotal, and penile ultrasound cases. While TRUS for prostate biopsy remains an index case with a minimum number required (25), there is no minimum number of cases required for other ultrasound procedures.

Residents should use the CPT codes below when logging ultrasound procedures.

Procedure	CPT Code
Scrotal	76870
Renal	
Retroperitoneal, limited (kidney only)	76775
Retroperitoneal, complete (both kidney and bladder)	76770
Transplant kidney ultrasound	76776
US guidance, intra-operative (e.g., during partial nephrectomy)	76998
US guidance, parenchymal ablation (e.g., ablation of renal mass)	76940
Pelvic	
Residual urine measurement	51798
Limited (bladder or prostate/SVs)	76857
Complete (bladder and prostate/SVs; in females, must note uterus, adnexa, and endometrium)	76856
Prostate	
Transrectal ultrasound (TRUS)	76872
TRUS-guidance for needle placement (TRUS-biopsy)	76942
Prostate volume study for brachytherapy	76873
Prostate cryotherapy (includes US guidance and monitoring)	55873
Penile	
Duplex, complete	93980
Duplex, limited or follow-up	93981
Abdominal	
Abdominal; complete	76700
Abdominal; limited (e.g., single organ, quadrant, follow-up)	76705

Procedures Mapped to Two or More Minimum Categories

The Review Committee has identified procedures that provide a meaningful educational experience in more than one index category. These procedures are automatically mapped in the Case Log System to two or more index categories when minimum numbers are calculated. Note that the counting of procedures in more than one index category occurs **only** in the Urology Minimum Report and not in other Case Log reports.

There are three situations in which procedures are automatically mapped to more than one index category:

- Procedures that are given credit in an index **sub**category are also given credit in the corresponding index category. For example, pelvic-bladder procedures are mapped to three minimum categories: Pelvic-bladder; Pelvic; and Oncology.

- Procedures that are performed robotically are given credit in the urological procedure index category(ies) *and* in the robotic index category when the Robotic checkbox is checked.

- Specific pelvic-bladder oncology procedures that include reconstruction are mapped to both oncology and reconstructive surgery minimum categories. The procedures are:

Procedure	CPT Code
Cystectomy, complete, with ureterosigmoidostomy	51580
Cystectomy, complete, with ureterosigmoidostomy	51580
Cystectomy, complete, with ureterosigmoidostomy, with bilateral pelvic lymphadenectomy	51585
Cystectomy, complete, with ureteroileal conduit or sigmoid bladder, including intestine anastomosis	51590
Cystectomy, complete, with ureteroileal conduit or sigmoid bladder, including intestine anastomosis, with bilateral pelvic lymphadenectomy	51595
Cystectomy with continent diversion	51596
Pelvic exenteration	51597

Ureteroscopy vs. shock wave lithotripsy: Advances spell positive future for both

Oct 3, 2013
Stephen Y. Nakada, MD

In this interview, Brian R. Matlaga, MD, MPH, discusses factors to consider in the decision to utilize ureteroscopy versus shock wave lithotripsy, how to counsel patients on the optimal approach, how to minimize the morbidity of each modality, and why younger urologists are more likely to perform ureteroscopy.

In the treatment of stone disease, the choice between ureteroscopy and shock wave lithotripsy can be difficult and complex. In this interview, **Brian R. Matlaga, MD, MPH,** discusses factors to consider in the decision, how to counsel patients on the optimal approach, how to minimize the morbidity of each modality, and why younger urologists are more likely to perform ureteroscopy. Dr. Matlaga is associate professor at the James Buchanan Brady Urological Institute, Johns Hopkins Medical Institutions, Baltimore. He was interviewed by *Urology Times* Editorial Consultant **Stephen Y. Nakada, MD,** professor and chairman of urology at the University of Wisconsin, Madison.

How you decide between ureteroscopy and shock wave lithotripsy?

The decision making is often very challenging because so much of what we try to do now in urology is leverage our understanding of clinical evidence to guide and counsel our patients. With shock wave lithotripsy and ureteroscopy, it's a complex discussion because the evidence can be conflicting or unresolved in certain scenarios, and there may not be explicit guidelines to advise us. So it's a decision that you really have to involve the patient with in order to understand their expectations of the outcome and to discuss with them the relative advantages and disadvantages of each approach.

The nature of the two procedures is very different. Shock wave lithotripsy is typically a completely noninvasive modality that may have success rates that are a little lower than ureteroscopy. Ureteroscopy is little more invasive, but for certain stones success rates may be higher than that of shock wave lithotripsy.

Sometimes, patient bias will drive the decision. Does the patient want to maximize the chance of a successful outcome in a single procedure? Would they rather have a noninvasive procedure? It's about helping to educate the patients so they can understand what their own desires are as far as the outcome they would most prefer.

Do you think that the long-term risks of shock wave lithotripsy, such as hypertension and diabetes, are overstated?

It's very common now for patients who have been diagnosed with a stone to look up treatment options on the Internet and find reports about hypertension and diabetes being associated with lithotripsy.

I think hypertension and diabetes are two completely separate issues. In my opinion, the evidence may be slightly more compelling for the association of hypertension with shock wave lithotripsy. Although the literature is certainly not definitive, there may be a modest effect of shock wave lithotripsy on blood pressure, although it may not be clinically meaningful. The diabetes association was more sensationalized in the lay press, but I think the evidence is far less compelling than that for hypertension.

I counsel patients that our understanding of the literature is that there may be an association between lithotripsy and hypertension, and it is likely a dose-dependent relationship. If you have a single session of shock wave lithotripsy, it's unlikely to have an effect on blood pressure, but if you have many, many sessions over a long period of time, you may see an effect, but it may not have any clinical meaning. With diabetes, the literature is far less well characterized. At this point, I don't think that there is any good evidence that shock wave lithotripsy causes diabetes, so I feel comfortable reassuring patients about that.

What are some strategies to decrease the morbidity of shock wave lithotripsy?

Shock wave lithotripsy, unlike some of the other surgical approaches we have as urologists, is more of a "black box." Compared to other things we do in the operating room, such as endoscopic, laparoscopic, or open procedures, shock wave lithotripsy does not give us definitive, real-time feedback as to how the procedure is progressing. All urologists know, I think, that the fluoroscopic appearance of a stone during lithotripsy may not truly indicate the procedure's ultimate outcome. However, we can control patient selection; that is,

optimizing who we're going to treat with shock wave lithotripsy. That is probably the first step to controlling the morbidity of the procedure.

During the treatment, there are only a few parameters we can control. We can control the power settings of the lithotripter. Animal models have demonstrated that slowly ramping up treatment power during the initiation of shock wave lithotripsy can reduce injury to the kidney.

Urologists can also ensure that the patient is well coupled to the machine-the process by which the patient is joined to the lithotripter-which with modern dry-head lithotripters typically involves the use of a coupling medium such as a gel to maximize energy transfer into the patient. When the patient is properly coupled to the lithotripter, you maximize the amount of energy that's deposited in the stone, so you can minimize the number of treatment sessions and number of shock waves to which patients are exposed.

We can control the rate at which we deliver shock waves. From a clinical standpoint, a slower rate-in the neighborhood of 1 Hz or 60 shocks per minute-is associated with better clinical outcome. There is also evidence in animal models that this is associated with less injury to the kidney.

The other element we can control is the anesthetic technique we employ. There are reports that patients who are treated with a general anesthetic have better outcomes than patients who are treated with intravenous sedation.

Let's shift gears to ureteroscopy. More young urologists perform ureteroscopy; does this make sense to you?

I think so. We're in an endoscopic epoch of urology. In training programs now, urologists are being exposed to endoscopic surgical approaches much earlier than they were years ago. Flexible ureteroscopy has gone from being commonly performed at the chief resident level to being commonly performed at the junior resident level. The residents have much more robust experience with endoscopic surgery in the course of their training program, at least in the United States, such that as they finish, they oftentimes have performed many more ureteroscopic stone cases than they have shock wave lithotripsy procedures.

As a result, they have already passed that learning curve and they're very facile with the required surgical techniques. It's a true trend, and it makes sense, given how our training programs have evolved with regard to endoscopic surgery.

Do ureteroscopy patients always need a stent?

That's a very good question because more often than not, patients who undergo ureteroscopy have a stent placed in the course of that procedure. This is despite the fact that there are a number of studies suggesting that for uncomplicated ureteroscopy, patients don't need stents and their outcomes are no different than patients who have stents. Further, patients with stents tend to be more uncomfortable.

In my practice, we utilize ureteral stents following ureteroscopy fairly routinely. One of my mentors used to say that he never had to come into the hospital in the middle of the night to take out a stent-all it takes is one or two unplanned stent replacements to affect your practice patterns. In my experience, we use stents in the vast majority of cases.

What are the best technical advances in ureteroscopy of late?

From an endoscopic approach, the fiberoptic scopes we are using nowadays are very miniaturized. They are very deflectable and allow you to access all parts of the kidney: the lower pole, the upper pole, through tight stenotic infundibula into remote calyces of the kidney. The fiberoptic scopes are very durable and have a great ability to facilitate our navigation through the kidney.

Digital ureteroscopes aren't quite the workhorse, everyday type of scope yet, but they're likely where our endoscopic technology will be moving. As anyone who has used them will say, they produce amazingly beautiful pictures of the kidney. The detail you can see is far above what is seen with the fiberoptic scopes. I think we're in the process of moving toward digital technology.

The other advance we have seen is tremendous miniaturization of the implements we use. For example, through the flexible ureteroscope, anything you need to do can be done with a device that's less than 2F in diameter. Not only are they small, but they are

very durable. You can use a basket that's 1.5F or 1.9F in size, and it will last throughout the entire case. They're much more durable than they had been in the past.

We also have devices that can help get you out of difficult situations. For example, they allow you to more easily release stones when you grab them to minimize the chance of having an entrapped basket in the ureter, which is very anxiety provoking for a urologist. Other devices allow you to pass a laser fiber alongside the basket to fragment a stone if it is stuck in a basket.

What's the largest stone you would treat with ureteroscopy?

I don't know that there is a hard and fast cutoff, because so much depends not just on the stone but also on patient-specific factors. In an otherwise healthy patient without significant comorbidities, once you get a stone size in the neighborhood of 1.5 cm or so, that's where you're going to see ureteroscopy becoming technically challenging. You're dealing with a large volume of stone and as the stone fragments, you're dealing with a large volume of debris within the kidney. As a result, visualization may become problematic, and you are left with a lot of stone material that may have to be extracted at the end of the procedure. With a 1.5-cm stone, especially for a urologist for whom flexible ureteroscopy isn't a common part of their practice, the patient may require a multiple-stage approach.

When you get above 2 cm, you are very likely to require a staged treatment approach to ureteroscopy. It's important to make sure the patient understands that this is going to be a process rather than a single procedure.

In terms of patient-specific factors, sometimes a patient is just unfit for percutaneous surgery. For example, they may take an anticoagulation medicine that they can't safely stop due to medical comorbidity. In that patient, you may have to treat a larger stone ureteroscopically because shock wave lithotripsy is not an attractive option due to risk of hematoma, and percutaneous surgery is not an attractive option due to the risk of bleeding. There will be some outliers, but if you look at the average patient, once you are in the neighborhood of 1.5 to 2 cm, that's going to be a more technically complex procedure.

Are the numbers the same for shock wave lithotripsy?

I think so. The only caveat is that with ureteroscopy, we utilize stents routinely. The great putative benefit with shock wave lithotripsy is that it's a noninvasive technology, but when you get into the larger stone size, there's an increased likelihood of the kidney having a difficult time discharging all the stone fragments. That can lead to steinstrasse, which can be problematic for the patient postoperatively. The upper limit of ureteroscopy is probably also the upper limit of shock wave lithotripsy, and that's the size range where ureteral stents may be involved in that treatment.

If you had an 8-mm ureteral stone, which treatment would you want?

For stones in the ureter, we have a good understanding of the clinical evidence, which indicates that ureteroscopy tends to be associated with slightly improved stone-free outcome compared with shock wave lithotripsy. For shock wave lithotripsy, the efficacy in the ureter is not quite as robust as it is in the kidney. Treating a ureteral stone ureteroscopically is more straightforward than it was 5 to 10 years ago now that we have improved visualization with scopes, miniaturized laser fibers, and baskets. So my bias for ureteral stones in myself or for others is toward ureteroscopy.

What do you think the future holds?

I think the future in stones is really exciting. The question that comes up at scientific meetings is, is there is a role for shock wave lithotripsy in the future and can stones be treated entirely endoscopically? I think there's a place for both technologies, and I think that what urologists are trying to do now is better understand who is going to be best treated with shock wave lithotripsy and who is going to be best treated with ureteroscopy. The magnitude of the innovations we've seen with the endoscopic approach in the past decade has been very exciting to those of us who treat stones commonly, because we are able to do things now much more easily, much more safely, and much more rapidly than we could previously.

I think that's why we have seen this tremendous interest at the training level in ureteroscopic approaches. In practice, we are seeing more ureteroscopy being performed now than we have in the past. That trend may continue, but I think that the future is probably going

to be in better predicting treatment outcomes, including through imaging approaches, and then better counseling of our patients.

We will be able to better inform them that for certain stones, they can expect certain outcomes, and we will know who is going to be best treated with ureteroscopy and who is going to be best treated with shock wave lithotripsy.**UT**

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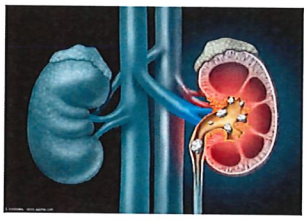

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