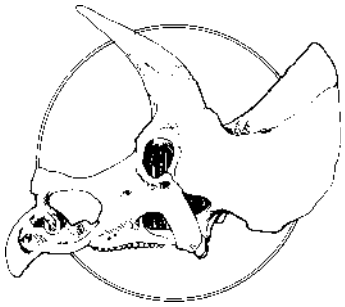
COMMENTARIES

Really Dead



I was recently invited to participate in a bioethics conference at my hospital with medical students, housestaff and attendings. I was invited because I am a neurologist, not an ethicist. The starting point was a case in which a teenage boy dying from an inoperable brainstem tumor wanted his organs to be used for transplantation. He also expressed fear that his organs might be taken before he was truly dead. The situation was complicated by his desire to die at home, his insurer's desire that he not die in a hospital because of the expense, and the transplant team's need to harvest the organs within a very short time after his heart had ceased to beat (should he die a cardiopulmonary rather than a brain death). Real life, not following the Hollywood script, had the boy dying at home and he was not brought to the hospital in time to allow for use of any body parts other than his corneas. The bioethics discussion centered on the issue of death and the modern concept of "brain death." Also considered was the distinction that most people have between cardiopulmonary death and brain death. The latter is too often an abstract concept which interferes with transplant attempts.

"Brain death" was a consequence following the development and clinical use of mechanical ventilators. With ventilators, people who were unable to breathe could now be artificially ventilated and thus kept alive and, in many cases, recover sufficiently to breathe without mechanical assistance. It rapidly became clear that some patients would never recover the ability to breathe but were otherwise reasonably intact, that some survived in a persistent vegetative state and that others never regained brain function of any type. Since this last group almost invariably suffered a cardiorespiratory death within a short period of time, and since health care economics was not then in a crisis mode, the need for a definition of death was not needed. What forced the need to conceptualize or define death was the success of mechanical ventilation. State attorneys-general demanded a clear and unequivocal definition of death so that limited resources could be better employed and that no legal challenges could be mounted when "the plug was pulled."

Over time the main issue became transplantation. Survival for transplants depends critically on the amount of time the organ is inadequately perfused, i.e. how long the heart stopped before the organ was removed. After a certain critical period of under-perfusion, the organs become useless. So a rigid set of criteria was developed to define death as a brain event rather than as a cardiopulmonary one. This introduced the notion that there were two distinguishable forms of death. In the public's and perhaps physician's mind, was the notion that brain death was a somehow less stringent definition than the cessation of heartbeat. In fact, prior to the development of brain criteria to define death there had been no definition of death. Medical science's definition of death was in a state closely analogous to the "definition" of pornography: "I know it when I see it." And, unfortunately that analogy was applicable to the gray areas as well. Can a transplant team remove a kidney one-minute, two minutes, five minutes, etc after the heart stops? Is the last heart beat a palpable pulse, an auscultated sound or an electrical event recorded in an EKG? Does the timing of the last breath count? Is pCO2 important? Given the litigious nature of our society and the strongly held ethical beliefs of some people who believe that modern medicine too often crosses ethical lines, the need for a legal definition became crucial.

The history of death then was, as best I can tell, legally uncharted territory until the first state adopted a definition of death. All states in the US now have criteria for the definition of death, which are brain criteria. Most pronouncements of death are based on failure of detectable heartbeat and brain criteria are used uncommonly, primarily for transplant purposes but also to remove needless care. The practice of medicine does not include ministering to the dead.

It is my contention that the phrase "brain dead" should be removed from the medical lexicon, because it introduces a sense of doubt, that "brain dead" is different than "dead", that one might be "brain dead" today and "really dead" tomorrow. One might imagine individuals or groups defining death in idiosyncratic ways, having "liver death" or "pancreas death" or some other seemingly far-fetched notion.

Many years ago a case report was published in which a young adult was "brain dead" in a state that had not yet adopted legal death criteria. The patient had a heartbeat for the next two or three months before it too stopped. At autopsy, when the cranial vault was opened, the liquefied brain content poured out.

Two terms should be used to describe the state of death. Dead or "legally dead." Continued use of "brain death" clouds the public's consciousness and makes the public believe the pronouncement of death is a subjective decision fraught with the possibility of irretrievable error. While a family has no qualms about discontinuing life support on a dead relative, they may on a "brain dead" relative. The law, however, defines death and patients meeting these criteria are no longer patients.

– Joseph H. Friedman, MD

Rhode Island's First Hospitals

Seaports were colonial America's first great centers of commerce and industry. But because of their maritime traffic, they were also America's sites of entry for the devastating contagions of the 17th and 18th Centuries. Each new epidemic of smallpox in Boston, for example, began with a sailing vessel disembarking someone in the acute, communicable phase of smallpox. And thus Boston experienced sustained epidemics of smallpox in 1677, 1689, 1702, 1721, 1751, and 1775.

Newport, in the early years of the 18th Century, was Rhode Island's leading port as well as its commercial center. Smallpox first entered the community in 1716 via an arriving merchant vessel. In addition to the customary quarantine measures for those stricken with smallpox, Newport constructed a small infirmary on an offshore island. This modest undertaking represented Rhode Island's first attempt at providing its very sick with both isolation and rudimentary protection from the elements; this primitive house of contagion was Rhode Island's first hospital.

In 1752 Providence established its own smallpox hospital. And in the next five decades the city at the head of Narragansett Bay built two more so-called fever hospitals consisting of little more than dormitories and attached kitchen.

Yet another epidemic scourge invaded Providence in 1798, a puzzling disorder called yellow fever. Under the mistaken presumption that the disease was directly communicable, the city hastily constructed a two-story house on the western shore of the mouth of the Providence River to isolate victims of the disease. The yellow fever epidemic abated rapidly and the city, left with an empty fever house, designated it as a marine hospital solely for the care and housing of disabled shipboard personnel.

New England's first general hospital, the Massachusetts General Hospital, had been constructed in 1811. New Haven built its own hospital in 1832; and Hartford Hospital was chartered by Connecticut's legislature and opened in 1854. In contrast to the episodic usage of fever houses, these new institutions in Boston, New Haven and Hartford were expressly designed to meet the continuing inpatient needs of the local civilian communities.

In the years immediately preceding the Civil War, Rhode Island relied almost exclusively on the home for the care of its very sick. There also was an institution, built in 1828, called the Dexter Asylum for Paupers. This was an ill-conceived institution which, in the words of one local physician, was an overly crowded dwelling for the city's paupers, the victims of debauchery, the uncontrollably insane, homeless women in labor, and the many malnourished immigrants recently arrived from Europe. There was, in addition, the excellent Butler Hospital, built in 1847, but it confined its admissions to the mentally ill.

Since hospitals are sometimes constructed as adjuncts to medical schools, Rhode Island had an opportunity to establish a general hospital of its own when Brown inaugurated New England's third medical school [Harvard, 1782; Dartmouth, 1798]. It was a modest effort with a faculty of three and a small campus building housing an anatomy amphitheater, a pathology museum, a small library and a few classrooms. The faculty maintained private practices and some of their patients were sometimes used for didactic purposes. But until medical students had access to a hospital ward, their education would remain a bloodless sequence of blackboard exercises. The Brown medical school accepted its first students in 1811, trained almost one hundred physicians in the next 16 years, but then closed its doors in 1827 because of a dispute between faculty and administration. And thus a possible stimulus for the establishment of a general hosptial in Rhode Island was lost.

The practicing physicians of Rhode Island had repeatedly appealed both to the State Legislature and the philanthropic community for funds to construct and maintain a hospital within the state, but to no avail. During the early decades of the 19th Century Providence citizens identifid the grim Dexter Asylum as its sole inpatient facility, but more in shame than pride.

A Brown University graduate, Thomas Poynton Ives [Class of 1854], was the initiating force which finally accomplished the task of building a fine general hospital for Providence. Ives had been trained as a physician at the College of Physicians and Surgeons in New York and was then apprenticed to Dr. J. Ely, a prominent Providence practitioner.

The economic disaster of 1857, with the closing of many of the local textile factories, and the Civil War of 1861 effectively aborted any efforts to build a local hospital. Prodded by the Ives family, the Rhode Island legislature finally incorporated the Rhode Island Hospital in 1863 and donated the 12 acres of the old marine hospital for its site. The Ives family provided $75,000 for construction of the hospital.

A total of $305,000 was eventually subscribed and construction was begun in December of 1864. This effort represented the largest single charitable drive in the state's history. The architects envisioned a handsome dark brick building, some three stories high in the Italian gothic style with two distinctive and imposing steepled towers. The building consisted of a central unit housing the administration, chapel, auditorium, library, kitchens and central apothecary; and two wings extending in a north-south direction. The wards were spacious 24-bed units with adequate ventilation and sunlight. The Board authorized the opening of about 70 beds to serve the immediate medical needs of the Providence population, then about 70,000. The original hospital had an eventual capacity of about 120 beds.

On the first day of October, 1868, the Rhode Island Hospital opened its doors. The president of the hospital's Board, Robert Ives, said these words in the invocation: "Except the Lord build the house, they labor in vain that build it." And on October 6, 1868, John Sutherland, a local shoemaker, was the first patient to be admitted. He suffered from a deep abscess of his jaw-bone. Surgery was successfully undertaken and within two months he walked out of the hospital with his disease healed.

Rhode Island Hospital has kept its door open, without interruption now, for 134 years. In times of peace it has provided the best of medical care for the Rhode Island community; and in times of war it has recruited its physicians and nurses to form army hospital units which have served with distinction in France, India and Burma. Today it is the state's leading hospital and the premier clinical teaching facility for Brown's new medical school.

– Stanley M. Aronson, MD, MPH

Introduction

Barry Stein, MD

The fear of women is the basis of good (men's) health

- Old Spanish Proverb

It is indeed a pleasure to edit this month's issue of *Medicine & Health/Rhode Island*, devoted to men's health. The concept of "women's health" is well ingrained in our consciousness, but men's health concerns are just beginning to surface. It has been my impression, re-enforced by 25 years as a urologist, that often if not for the women in their lives, men might never come forward for health care. Women tend to be more vocal than men about their health care, and lobby more successfully for research dollars. For example, prostate and breast cancer have a similar incidence, yet the **National Cancer Institute (NCI)** devoted $1.145 billion for breast cancer research from 1998-2000, but only $353 million for prostate cancer. In 1997 the NCI spent $1,787 in research on prostate cancer for each prostate cancer death, while the same year it spent $18,800 on breast cancer research per death due to breast cancer. One article in this issue covers osteoporosis in men. With the exception of drug-induced osteoporosis, Medicare does not pay for Dexa scanning in men, while it covers tests for any woman. While osteoporosis occurs more frequently in women, it does affect ~12% of men over the age of 50; and men have a higher mortality rate associated with an osteoporotic hip fracture than women, as high as one out of three in some series.

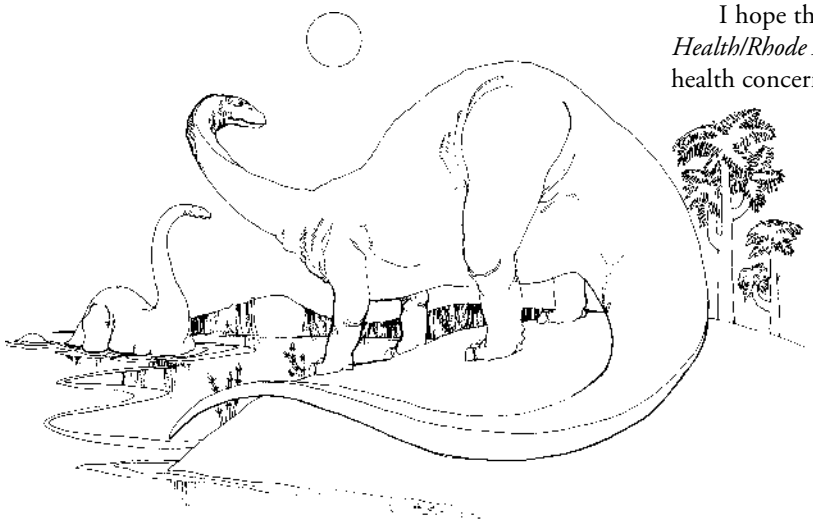
This issue features four articles on men's health. The first from Drs. Fulton and Marable of the Rhode Island Department of Health gives us a sense of the scope of men's health issues in an aging population. As we baby boomers reach Medicare age the number of older men will increase precipitously. In fact, the largest growing age segment is those over 85. According to Drs. Fulton and Marable, the number of men in Rhode Island over the age of 50 is expected to increase 62% between 1995 and 2025, while the number of men over age 85 is expected to increase 105% over the same time frame. Rhode Island is currently in a virtual tie with Pennsylvania as the second "grayest" state, with 15.6% of our population over age 65. This means that we must prepare for the unique problems of the aging male, including the topics in this Journal, but also including the new concepts such as andropause, and male depression.

The second article discusses the current status in the treatment of the most common disease of the aging male, benign prostatic hyperplasia. New developments in both the medical and surgical treatment of this disease are providing greater benefits with decreasing risks. Medical therapy, particularly with alpha blocker therapy often means that older men failing this treatment present with larger prostate glands. Newer office-based therapies, such as Trans-Uretheral Needle Ablation are springing up to treat the failures of medical treatment.

The third article, written by Dr. Kim, covers the current status of male urinary incontinence, and its treatment options. Unfortunately, the majority of cases in men are iatrogenic, and follow as a complication of radical prostatectomy. Newer techniques in radical prostatectomy are hopefully leading to a decrease in this debilitating complication. The management of the non-iatrogenic urinary incontinence in men, related to the aging process, is also well covered.

The last contribution covers a newly emerging problem on the men's health docket - osteoporosis. A large number of these cases are also iatrogenic, and relate to androgen deprivation therapy associated with the treatment of advanced prostate cancer. Preventative therapy can reverse osteopenia, and prevent osteoporotic fractures.

I hope that dialogues such as this issue of *Medicine & Health/Rhode Island* will promote better recognition of men's health concerns.



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Older Men in Rhode Island, 1995-2025: Population, Life Expectancy, and Men's Health Issues

John P. Fulton, PhD, and Sharon Marable, MD, MPH

To evaluate the need for older men's health care resources over the next 25 years, the **Rhode Island Department of Health (HEALTH)** assembled and constructed projections of population, life expectancy, disease prevalence, and disease incidence through 2025. The evaluation focused on: men ages 50 and over, life expectancy at 65 years of age, the prevalence of benign prostatic hyperplasia, osteopenia/osteoporosis, urinary incontinence, and the incidence of prostate cancer.

Methods

Sources of Data

Projections of Population

The latest projections of the male population of Rhode Island by age and race or ethnicity (Hispanic status) were obtained from the United States Bureau of the Census for the period 1995-2025.[1] Census projections are constructed in sets of low, preferred, and high, based on differing assumptions about the components of population growth (fertility, mortality, and migration). Preferred projections, which represent the Census Bureau's best estimates of the size and composition of future population, were selected for use in this analysis.

Projections of Mortality

Projections of life expectancy at age 65 for males in the United States, by age and race or ethnicity (Hispanic status), were obtained from the Census for the period 1995-2025.[2] The projections of mortality selected for use in the present analysis were used by the Census to construct preferred projections of the United States population, 1995-2005.

Estimates of Disease Prevalence

Estimates of the current prevalence of **benign prostatic hyperplasia (BPH)**, osteopenia, osteoporosis, and incontinence were derived from the medical literature:

- A variety of clinical studies have reported estimates of the prevalence of BPH at microscopic, macroscopic, and clinical levels. Estimates of BPH, by age, were derived by averaging data from available studies.[3-9] (Table 1)
- Estimates of the prevalence of osteopenia and osteoporosis were obtained from a national study of 3090 U.S. men ages 50 and over.[10] All the men had received bone mineral density tests of the hip. Estimates varied according to that part of the hip studied. Using the trochanter as a reference point, 28% of men ages 50 and over are osteopenic, and 3% are osteoporotic. Using the femur neck as a reference point, 47% are osteopenic and 6% are osteoporotic. The latter estimates were used in this analysis.
- Low and high estimates of the prevalence of urinary incontinence in U.S. men ages 65 and over were derived from the National Institutes of Health Consensus Development Conference Statement, *Urinary Incontinence in Adults* (October 3-5, 1988).[11] The following statement was used to derive estimates:

"Estimates of the occurrence of urinary incontinence depend on the nature of the study population and definition of disorder. Prevalence rates range from 8 to 51%; an estimate of 15 to 30% for community-dwelling older persons seems reasonable, and of these, 20 to 25% may be classified as severe. Prevalence rates are twice as high in women as in men..." [11]

Table 1. Prevalence of benign prostatic hyperplasia per 10 000, as reported in the literature.

	Age Group				
Sources	**40-49**	**50-59**	**60-69**	**70-79**	**80+**
Microscopic (Average)	**2233**	**4167**	**6767**	**8033**	**8600**
Lytton 1 (a)	2300	4200	7100	8200	8800
Isaacs and Coffey (b)	2200	4200	6200	7900	9000
Barry (c)	2200	4100	7000	8000	8000
Macroscopic (Average)	**800**	**2230**	**2930**	**4065**	**4605**
Isaacs and Coffey (b)	800	2100	3500	4400	5300
Lytton (d)		2360	3730	3910	
Clinical Evidence (Average)	**1380**	**1712**	**2859**	**3306**	**3010**
Isaacs and Coffey (b)		1800	830	1900	2500
Lytton (d)		2000	3500	4290	
Watanabe (e)		1340	1755	2670	5420
Lytton (f)		1050	3910	3670	1110
Garraway et al. (g)	1380	2370	4300	4000	

Sources:

a. Lytton B. Demographic factors in benign prostatic hyperplasia. In: Fitzpatrick JM, Krane RJ (eds) The Prostate. London: Churchill Livingstone, 1989: pp 85-9.
b. Isaacs JT, Coffey DS. Etiology and disease process of benign prostatic hyperplasia. Prostate Supplement 1989; 2: 33-50.
c. Barry MJ. Epidemiology and natural history of benign prostatic hyperplasia. Urologic Clinics of North America 1990; 17(3): 495-507.
d. Lytton B. Interracial incidence of benign prostatic hypertrophy. In: Hinman F (ed) Benign Prostatic Hypertrophy. New York: Springer-Verlag, 1983: pp 22-6.
e. Watanabe H. Natural history of benign prostatic hypertrophy. Ultrasound in Med and Biol 1986; 12(7): 567-71.
f. Lytton B. Emery JM, Harvard BM. The incidence of benign prostatic obstruction. J Urol 1968; 99: 639-45.
g. Garraway WM, Collins GN, Lee RJ. High prevalence of benign prostatic hypertrophy in the community. Lancet 1991; 338 (24 August): 469-71.

Table 2. The male population of Rhode Island, by year, age, and race or ethnicity, projected to 2025

Age	Race Or Ethnicity	Year 1995	2000	2005	2010	2015	2020	2025	% Change 1995-2025
50–	Total	119256	126857	139106	155828	171830	185490	192875	62
50–	White	114814	121462	132245	147023	160938	172453	177943	55
50–	African Am	2922	3438	4276	5382	6529	7650	8626	195
50–	Native Am	304	319	358	431	494	561	613	102
50–	Asian	1216	1638	2227	2992	3869	4826	5693	368
50+	Total	119256	126857	139106	155828	171830	185490	192875	62
50+	Hispanic	3066	4348	6120	8587	11700	15285	18740	511
50+	Non-Hispanic	116190	122509	132986	147241	160130	170205	174135	50
65–	Total	60688	58470	57041	59790	68584	81064	96075	58
65–	White	59077	56739	55033	57499	65467	76905	90605	53
65–	African Am	1135	1178	1277	1463	1864	2475	3258	187
65–	Native Am	121	103	101	108	134	167	207	71
65+	Asian	355	450	630	820	1119	1517	2005	465
65+	Total	60688	58470	57041	59790	68584	81064	96075	58
65+	Hispanic	1140	1631	2286	3142	4393	6114	8469	643
65+	Non-Hispanic	59548	56839	54755	56648	64191	74950	87606	47
85+	Total	4600	5551	6614	7885	8651	8645	9412	105
85+	White	4549	5491	6522	7749	8453	8383	9048	99
85+	African Am	29	36	57	86	126	165	226	679
85+	Native Am	8	4	5	5	7	9	12	50
85–	Asian	14	20	30	45	65	88	126	800
85–	Total	4600	5551	6614	7885	8651	8645	9412	105
85–	Hispanic	91	185	322	596	953	1379	1921	2011
85–	Non-Hispanic	4509	5366	6292	7289	7698	7266	7491	66

Source: Campbell, Paul R., 1996. Population Projections for States by Age, Sex, Race, and Hispanic Origin: 1995 to 2025, U. S. Bureau of the Census, Population Division, PPL-47.

Using the following information and assumptions, the prevalence of urinary incontinence among U.S. males ages 65 and over was estimated to range from 9 to 18%:

- The prevalence of urinary incontinence among all community-dwelling persons ages 65 and over in the United States (persons of both sexes and all races) ranges from 15 to 30%.[11]

- The prevalence of urinary incontinence among all community-dwelling persons ages 65 and over in the United States (persons of both sexes and all races) is twice as high in women as in men.[11]

- Among persons of all races ages 65 and over who resided in Rhode Island in 2000, men represented 39% of the population.[1]

Measures of Disease Incidence

The incidence of prostate cancer among Rhode Island males ages 50 and over, by age and race, was calculated from newly diagnosed cases of prostate cancer reported to the Rhode Island Cancer Registry (Rhode Island's statewide central cancer registry) for calender years 1994-1998, inclusive. Incidence as opposed to prevalence was chosen as the best measure of prostate cancer, because the basis of available prevalence estimates for prostate cancer in Rhode Island does not take into account the rapid increase in prostate cancer incidence which occurred in the 1990s.[12]

The life expectancy at age 65 of U.S. males is expected to increase 2.5 years between 1995 and 2025, from 15.5 to 18.0.

Methods of Analysis

Estimates of the Rhode Island male population ages 50 and over by age and year were combined with incidence and prevalence rates (assumed to be constant over time) to construct estimated counts of newly diagnosed cases of disease (incidence) or existing cases of disease (prevalence) among Rhode Island men every 5 years from 1995 to 2025, inclusive. Race-specific statistics were computed for newly diagnosed cases of prostate cancer. Percent change from 1995 to 2025 was computed for the number of resident Rhode Island men ages 50 and over, years of expected life at age 65, and counts of newly diagnosed or existing cases of disease.

Results

Population

Between 1995 and 2025, the number of Rhode Island men ages 50 and over is expected to increase 62%. (Table 2) The number of men ages 85 and over is expected to increase even more (105%). The numbers of older African American, Native American, and Asian men are expected to grow faster than the number of older white men. Similarly, the number of older Hispanic men of any race is expected to grow faster than the number of older non-Hispanic men. These differentials, if correct, will alter the racial and ethnic mix of older Rhode Island men in the next quarter century. For example, African American, Native American, and Asian men, who represented 4.3% of Rhode Island men ages 50 and over in 2000, are expected to represent 7.8% of Rhode Island men ages 50 and over in 2025.

Life Expectancy

The life expectancy at age 65 of U.S. males is expected to increase 2.5 years between 1995 and 2025, from 15.5 to 18.0. (Table 3) This represents a 16% increase for all men ages 65 and over. Men of all races and men who are Hispanic will all benefit from an increase in life expectancy of from 9 to 20%. In 1995 at age 65, Asian men had the longest life expectancy (18.8 years), followed closely by Hispanic men of any race (18.5 years), then Native American men (17.9 years), white men (15.7 years), and Black men (13.6 years). In 2025 at age 65, about the same ordering is expected, with the exception that Hispanic men (22.2 years) are projected to take the lead over Asian men (20.4 years).

Prevalence of BPH, Osteopenia/Osteoporosis, and Urinary Incontinence

Because prevalence rates were assumed to be constant over time, the estimated proportional growth in the

Table 3. Life expectancy (in years) of men at age 65, by race or ethnicity, United States, projected to 2025

Age	Race Or Ethnicity	Year 1995	2000	2005	2010	2015	2020	2025	% Change 1995-2025
65	Total	15.5	15.9	16.4	16.8	17.2	17.6	18.0	16
65	White	15.7	16.2	16.8	17.3	17.8	18.3	18.8	20
65	African Am	13.6	13.8	14.0	14.3	14.6	14.8	15.1	11
65	Native Am	17.9	18.2	18.6	18.9	19.3	19.7	20.1	12
65	Asian	18.8	19.0	19.2	19.5	19.8	20.1	20.4	9
65	Hispanic, any race	18.5	19.1	19.8	20.4	21.0	21.6	22.2	20

Source: Day JC, Population Projections of the United States by Age, Sex, Race, and Hispanic Origin: 1995 to 2050, U.S. Bureau of the Census, Current Population Reports, P25-1130, U.S. Government Printing Office, Washington, DC, 1996.

Table 4. Prevalence of benign prostatic hyperplasia (BPH) and osteopenia/osteoporosis among men ages 50 and over, and incontinence among men ages 65 and over, Rhode Island, projected to 2025

Age	Problem	Year 1995	2000	2005	2010	2015	2020	2025	% Change 1995-2025
50+	BPH: Microscopic	76122	79091	84690	93884	104252	115319	123906	63
50+	BPH: Macroscopic	40952	42645	45810	50811	56269	62108	66758	63
50+	BPH: Clinical	30816	31886	34081	37861	42229	46798	50155	63
50+	Osteopenia	56050	59623	65380	73239	80760	87180	90651	62
50+	Osteoporosis	7155	7611	8346	9350	10310	11129	11573	62
65+	Incontinence (a)	5462	5262	5134	5381	6173	7296	8647	58
65+	Incontinence (b)	10924	10525	10267	10762	12345	14592	17294	58

a. Based on estimated minimum prevalence for men ages 65 and over (9 percent)
b. Based on estimated maximum prevalence for men ages 65 and over (18 percent)

number of men experiencing BPH, osteopenia, osteoporosis, and urinary incontinence between 1995 and 2025 parallels the estimated proportional growth in men ages 50 and over (62 - 63% for BPH, osteopenia, and osteoporosis) or the estimated proportional growth in men ages 65 and over (58% for urinary incontinence; Table 4). By 2025, over 50,000 men are projected to have clinical symptoms of BPH, between 11,000 and 12,000 men are projected to have osteoporosis, and between 8,000 and 17,000 men are projected to be incontinent of urine.

Incidence of Prostate Cancer

According to projections, over 1,200 men will be diagnosed with prostate cancer in 2025. (Table 5) Compared to 1995, the number of prostate cancer cases diagnosed among African American men in Rhode Island in the year 2025 will have tripled (increased 189%), in parallel with the number of African American men ages 50 and over.

Discussion

Caveats

These projections are based on many assumptions. Undoubtedly, some will prove to be better than others, while a few may prove to be totally incorrect. Such is the risk of projections.

Assumptions used by the Census Bureau to construct its estimates of the Rhode Island population by age, sex, and race or ethnicity are based on educated guesses about trends in mortality, fertility, and migration. Although trends in mortality are relatively stable in a modernized country like the U.S., trends in fertility and migration have a number of complex determinants, not the least of which are trends in the economies of the state, nearby New England, the nation, and the world, especially those parts of the world from which Rhode Island draws its immigrants. Rhode Island, because of its small area, small economy, and small population, may gain or lose a significant proportion of its people in response to unique economic events. For example, it has been estimated that the reassignment of warships from Newport Naval Base to other bases on the Atlantic coast in the early 1970s led to the loss of over 3% of the state's population in 1-2 years. Because the economy of the state is difficult to predict, especially over the course of 25 years, so is its population growth, and all that flows from it, such as the number, type, and severity of illnesses and conditions with which the health care system will have to cope.

The projections of prevalent and incident cases constructed here are based on the simplistic assumption that disease-specific incidence and mortality rates will not change between now and 2025. (Incidence rates affect both incident and prevalent cases. Mortality rates affect prevalent cases.) Incidence rates may be lowered by effective prevention methods. For example, in the next quarter century:

- Will we develop therapies so effective in preventing or reversing BPH in its early stages that symptoms of the condition will arise in a lower proportion of men, or will we extend the length of life far enough beyond present projections that we substantially increase the number of men with clinical BPH?

- Will we screen and treat osteopenia so effectively that we substantially reduce the incidence and prevalence of osteoporosis [See Note], or will we extend the length of life far enough beyond present projections that we increase the number of men with osteoporosis despite downward trends in incidence? Or yet, will the tobacco industry succeed in reversing the downward trend in tobacco use among adult men, thus increasing the prevalence of a potent risk factor for bone loss, and will this trend outstrip our health care system's ability to counter the problem with intensified screening and treatment?

- Will we reduce the natural and iatrogenic causes of urinary incontinence in older men, or will we increase the iatrogenic causes of urinary incontinence with new forms of therapy for other diseases and conditions?[16]

Table 5. Annual newly diagnosed cases of prostate cancer among white and black men ages 50 and over, Rhode Island, projected to 2025

Age	Race Or Ethnicity	Year 1995	2000	2005	2010	2015	2020	2025	% Change 1995-2025
50+	Total	766	763	788	863	981	1123	1253	64
50+	White	747	741	761	828	935	1064	1179	58
50+	African Am	19	21	24	30	37	46	55	189

Source: Rhode Island Cancer Registry, Rhode Island Department of Health.

- Will we find a preventive therapy for prostate cancer, or will we extend the length of life far enough beyond present projections that we substantially increase the number of men with diagnosed prostate cancer? Or yet, will we reduce the mortality from prostate cancer sufficiently that the prevalence of disease and the iatrogenic effects of its treatments (such as urinary incontinence) increase?

Summary of Findings

Assuming stable rates of disease incidence (therefore prevalence) over the next 25 years, and assuming (as does the Census) that the number of older men in the state will grow, Rhode Island will experience a steady increase in the number of prevalent cases of BPH, osteopenia, osteoporosis, urinary incontinence, and prostate cancer. (Even though we have been unable to project prostate cancer prevalence with confidence, the number of prevalent prostate cancer cases will certainly increase over time.) Proportionately, more older men will be African American, Native American, or Asian in 2025 than in 2000, and more will be Hispanic.

Comments

Assuming at least moderate stability in economic processes, demographic trends, and disease incidence rates, prevalent cases may increase by as much as 60% among older Rhode Island men (men ages 50 and over) by the year 2025. The growing population of older men will increase the demand for health care services that specifically address men's health, as well as the many health problems men share with women.

As we plan to meet the increasing demand for men's health services, we must be cognizant of the increasing cultural and linguistic diversity of older men in our state. Older men's varied responses to men's health issues, related as these issues are to personal identity, masculinity, and sexuality, are rooted in culture. As we can deduce from the racial and ethnic backgrounds of older men in Rhode Island, this culture is not monolithic. Rather, it is diverse, and, moreover, is becoming more diverse. Are we prepared for this diversity? Is the health care system ready to serve all men with cultural competence, gender sensitivity, and humility, or will the system soldier on, largely oblivious of culture, leaving many men alienated and thus unserved? The latter problem will grow, unless we build diversity into our thinking, planning, and ultimately, into our service.

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Note: We have great potential for osteoporosis prevention right now, were today's screening and treatment techniques to be applied systematically, and new approaches to prevention, such as hormone replacement therapy for men, to bear fruit.[13,14,15]

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The Evaluation and Treatment of BPH, 2002

Barry Stein, MD

Benign prostatic hyperplasia (BPH) is the most common medical problem in men over age 50. At age 40, only 8% of men have histologic characteristics of BPH; however, by age 50, 50% of men will exhibit BPH in their prostate and, by age 80, 90% or more of men will have histologic evidence of BPH.[1] The prostate grows approximately 4% per year, but this increase may occur even more rapidly between the ages of 30 and 50 than between 50 and 70. Approximately 25 - 50% of men will eventually exhibit symptoms of benign prostatic hyperplasia including, but not limited to, decreasing stream, frequency, urgency and nocturia.

The **International Prostate Symptom Score (IPSS)** sheet was validated as a tool useful for following the symptoms of men with BPH. (Figure 1) Although this score sheet does not in any way diagnose BPH as being the etiology of the symptoms, it does provide a means by which you can follow men with BPH from year to year to see if their symptoms are stable or deteriorating. Since a total of seven different symptoms are assessed, and are rated from zero (not at all) to five (almost always), the total symptom score can vary from zero to thirty-five.

The United States Department of Health and Human Services, through the Agency for Healthcare Policy and Research published clinical practice guidelines for BPH in 1994.[2] These are currently in the process of revision. Figure 2 is the algorithm summarizing these guidelines. In practice, one can use these guidelines to try and categorize the patient into one of three general categories. (Figure 3) The first category includes patients with mild symptoms, as determined by reviewing the IPSS, a normal digital rectal exam and, if appropriate, normal PSA level. These patients merely need to be educated that BPH is a part of the normal aging process in men and they should return in one year for a reevaluation. Group 2 includes patients with moderate symptoms on the IPSS sheet, and a normal digital rectal exam and normal PSA level. These patients may be appropriate for further evaluation such as uroflow testing, measurement of post-void residual or evaluation of upper tracts by ultrasound. Following this, it is appropriate to discuss with these patients four options (watchful waiting, medical therapy, minimally invasive surgical therapy, and surgery). Category 3 includes men with severe symptoms on the IPSS sheet or a complication of BPH, which include: urinary retention, recalcitrant hematuria, recalcitrant urinary tract infections, bladder stones, bladder diverticuli and upper tract obstruction. These patients are usually best treated by a surgical procedure.

Once the decision is made to treat the patient, the options fall into one of the following categories: phytotherapy, medical therapy, including the use of either finasteride and/or beta-blocker therapy, minimally invasive surgical therapy, such as **transurethral needle ablation (TUNA)**, or full surgical options.

Phytotherapy

My first line of medical therapy for patients with mild to moderate symptoms of BPH is herbal therapy, specifically saw palmetto. The phytotherapeutic compounds are characterized as food additives by the FDA, which permits a lack of standardization of the products. The most popular herbal product today is saw palmetto (*Serenoa repens*) which is derived from the berry of the American dwarf palm tree. Phytotherapeutic agents are plant extracts and not the actual plants themselves, a distinction which patients often miss. The process for extraction of the active ingredient varies greatly from brand to brand and may lead to great differences in potency. In the United States, this big business is worth between $1.5 and $2 billion dollars yearly in the treatment of BPH alone. An interesting article that spoke to the difficulties with phytotherapeutics can be found in "Herbal Therapy for Prostate Probems," Consumer Reports Magazine,[3] an article focused on saw palmetto. Although saw palmetto was considered a medicine for BPH in the early part of the twentieth century and was included in the **United States Pharmacopoeia (USP)** and the National Formulary until the 1950s, it was dropped from both in the 1950s. It was reinstated in 2000 as an acceptable treatment for BPH. The USP monograph concluded that the trials "provide evidence of moderate scientific quality. The commercial extracts of saw palmetto...are more effective than a placebo in relieving lower urinary tract symptoms from BPH."[3] The adverse effects are mild and rare and may include mild stomach upset or diarrhea. Although numerous reports in the literature suggest that saw palmetto is better than placebo, most of these are not long-term, prospective, randomized trials; so the exact effectiveness of saw palmetto remains in question. In addition, the mechanism of action remains in question, every theory having its proponents and detractors. Two large meta-analyses in the literature which

Figure 1

Over the past month...	Not at All	Less Than 1 Time in 5	Less Than Half the Time	About Half the Time	More Than Half the Time	Almost Always
1. How often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
2. How often have you had to urinate again less than 2 hours after you finished urinating?	0	1	2	3	4	5
3. How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
4. How often have you found it difficult to postpone urination?	0	1	2	3	4	5
5. How often have you had a weak urinary stream?	0	1	2	3	4	5
6. How often have you had to push or strain to begin urination?	0	1	2	3	4	5
7. **How many times** did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0 (None)	1 (1 time)	2 (2 times)	3 (3 times)	4 (4 times)	5 (5 or more times)

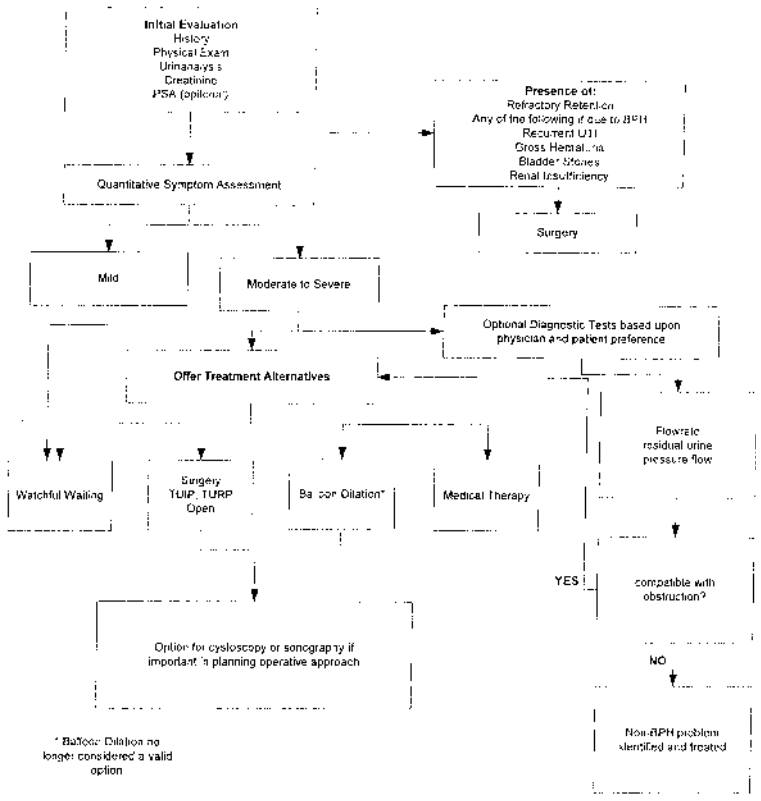

Figure 2.

together total over 5,000 men suggest, but do not prove, that saw palmetto is better than placebo.[4-5] Several studies, however, have shown that, although saw palmetto may improve the symptom score, it does not greatly change the urinary flow rate and has no effect on PSA, suggesting there is no 5-alpha reductase activity in saw palmetto.

Medical Therapy

Two categories of medical therapy are utilized for BPH. The first includes finasteride (Proscar) and the other includes alpha-blockers (terazosin, doxazosin and tamsulosin). When finasteride first became available, it was thought that this drug would be the panacea for BPH due to its ability to reduce the size of the prostate by up to 25-50%. Unfortunately, in the early studies, the effectiveness on reducing symptom scores or improving uroflow rates was modest. It has recently come to light, however, that one problem with the early studies was that many of the patients had small prostate glands and that finasteride should ideally be used in patients with prostate glands over 40 grams in size. The **Proscar long-term efficacy and safety study (PLESS)** was a 95-center study of over 3,000 patients randomized to either finasteride 5 mg or placebo and followed for over four years. In this study, the patients who were on placebo had a 14% growth in prostate volume over the four years time, whereas the patients on Proscar had an 18% reduction in prostate volume.[6] It has been shown that PSA is a stand-in for prostate size and men with PSA of over 1.6ng/ml at age 50, 2.0ng/ml at age 60, and 2.3ng/ml at age 70 are likely to have a prostate exceeding 40 grams.7 In fact, it was shown that the larger the prostate volume, the greater the improvement from finasteride in terms of symptom score reduction and flow improvement. In a study published in the *New England Journal of Medicine*, finasteride was shown to reduce the risk of acute urinary retention or need for surgical treatment for BPH in men with large prostates.[8] This was especially true in men with prostates over 60 grams in size, which correlated to a PSA of at least 3.3 mg/ml or greater. In this group, there was at least a 50% reduction in the development of acute urinary retention or need for surgery. For this reason, in men with prostates of 60 grams or more, and especially over 100 grams, I discuss finasteride as an option for chemo prevention. The other area of use for finasteride in men with BPH is recurrent hematuria.[9] A significant number of men have had a prior TUR of the prostate and are on anticoagulants such as aspirin, warfarin or other blood thinners. A number of studies show that when these men develop recurrent hematuria, finasteride may be useful. There exists a relationship between finasteride treatment and prostate involution and, especially, induction of angiogenesis inhibitor factors such as VEGF. There are also ongoing trials testing finasteride prior to TURP in order to reduce the blood loss, but the results are too preliminary to recommend this routinely.

My medical therapy of last resort is alpha-blocker therapy. The category of men best served by alpha-blockers includes: severely symptomatic men, those with increasing post-void residual, or those who have failed earlier therapy. It has been estimated that, of the pool of approximately 15 million men who have symptoms of BPH, 50% of these men overall will sometime receive an alpha-blocker for therapy. There have been innumerable studies over the past 15-20 years evaluating several different alpha-blockers and all of them have demonstrated efficacy. Taking into account all of the studies, there have been over 2,000 patients studied on alpha-blocker vs. placebo protocols. The mean improvement in symptom score in these men is 49%, with an average drop of 5 to 6.5 points. The average improvement in flow rates is 44%, with an increase in the maximum flow rate of between 2 to 3 ccs per second. Approximately, 93% of patients started on long-acting (alpha-blockers have had symptomatic improvement. In 1996, Lepor and associates published an article on the efficacy of terazosin, finasteride, or both in BPH in the *New England Journal of Medicine*.[10] In this VA multi-center study, the patients were blinded into four groups. One group was placebo only; one group was terazosin only; one group was finasteride only; and one group was terazosin plus finasteride. The conclusions were that the differences between terazosin and finasteride were statistically in favor of terazosin in terms of both symptom score and flow improvements. The combination, however, was shown to be no more effective than terazosin alone, leading to finasteride being labeled a placebo effect. However, having prostate glands that were smaller in size than current guidelines may have blemished this study. The

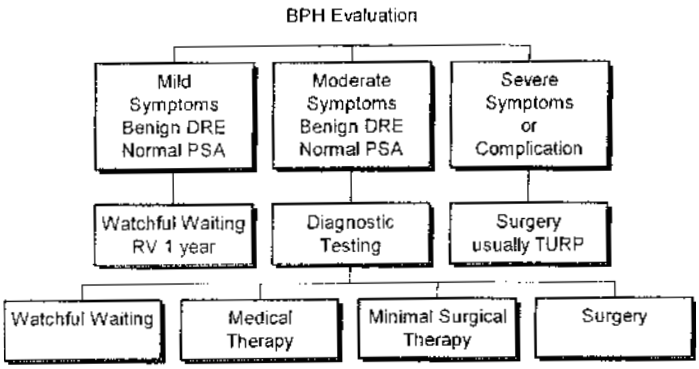

Figure 3.

newest alpha-blocker is tamsulosin which is a super selective alpha1a-blocker which is not indicated, therefore, for hypertension. Due to the lack of antihypertensive effect, this has become a very popular therapy with urologists who do not routinely need to treat hypertension. The ALLHAT trial, which was published in the *Journal of the AMA* in 2000, has been interpreted as a condemnation of the use of doxazosin for BPH, because the patients in the doxazosin arm had an increase in congestive heart failure and cardiovascular disease.[11] This study however may suggest only that alpha-blockers are not ideal treatment of hypertension since this study was not designed to evaluate BPH treatments.

Surgical Options

When patients have failed medical therapy, it becomes necessary to discuss surgical options. My minimally invasive surgical option of choice is **transurethral needle ablation (TUNA)**. This procedure seems particularly suited to both the younger man worried about his potency and ejaculation and the older man who may be a medical risk for anesthesia. We currently have an office-based protocol in which men are given Demerol and Vistaril IM, intravesical lidocaine, and intraurethral lidocaine. The TUNA procedure uses low energy radio frequency ablation, delivered via 2 small needles placed into the substance of the prostate. The actual treatment time has averaged 36 minutes over the cases I performed in 2001.[12] If the patient voids he is immediately discharged catheter-free; if he does not void, then a catheter is inserted for two days. The discomfort rates during treatment have been low, and patients overall have tolerated the office-based procedure well. The improvement in both the patient's symptoms and flow rates exceed that seen in medical therapy including alpha-blockers

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but are less than that seen with traditional surgical therapy such as TUR of the prostate. On the other hand, TUNA is an office-based treatment under local, there is little chance of impotence or ejaculatory disturbance, and no need for anesthesia. The long-term complications of TUNA treatment are indeed minimal. The down side is that the durability is not known and, in studies of up to six years now, the retreatment rates with TUNA do exceed retreatment rates with TURP.

For those patients who have a complication of BPH, or who fail prior minimal surgical therapy, the treatment of choice is TURP, or open prostatectomy for larger prostate glands. The technique has been improved over the years, and the mortality rates now are no more than 1%. The long-term complications include a risk of impotence of approximately 5-10%, retrograde ejaculation of approximately 100%, and possible need for transfusion of 5%. This is an operating room-based procedure, and hospital stays of 1-3 days are routine.

Conclusion

BPH is the most common disease entity in the aging male. Newer options now permit a better selection of the treatment to the patient.

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