PSAs and Prostate Cancer: Mayhem and Gore
How to beat the "healthcare" system and save money

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www.urologyweb.com

DECISION MAKING STEPS on whether to submit for a prostate cancer screening PSA blood test and for any possible evaluation for prostate cancer and its treatment can be extraordinarily difficult. Not only is this true for individual men but for all physicians, simply because of the overwhelming amount of bias, misinformation, misrepresentation and the pervasive "creative" reporting on treatment results by the prostate cancer industry. In addition, for the commonly low-risk prostate cancer, there exists the potential for delivering incredible therapy harm while no significant curative benefit is realized.

Prostate cancer is a frequently diagnosed cancer in men. In 2010 some 220,000 (0.32% of the 2010 US male population over 40) were diagnosed with prostate cancer. Although prostate cancer increases with age and is detected increasingly because of inappropriate PSA use, the lifetime risk of being diagnosed with prostate cancer is now about 1 in 12. However, these numbers over-emphasize the importance of prostate cancer as the majority of these prostate cancers detected are low-risk with about 50 men needing harmful treatment in order to "save" one life.

Prostate Cancer Awareness then, is NOT so much about the misguided focus on "awareness" and having a common, low-risk, insignificant prostate cancer. It is much more about understanding exactly what particular prostate cancer you have and AWARENESS of what NOT to do, controlling your emotions and being very, very wary and then proceeding very, very cautiously.

Be AWARE that;
> the Gleason 3+3 prostate cancer cell divides VERY SLOWLY, taking about 475 days,
> the Gleason 3+3 cancer has about a 82-year natural history,
> at this rate it takes about 40 years to reach a tumor diameter about 1 cm,
> some 75% of all prostate cancers are Gleason 3+3 low -risk cancers,
> the majority of these low-risk prostate cancers DO NOT NEED TREATMENT,
> the risk of TREATMENT HARM with a Gleason 3+3 is greater than the risk of the cancer,
> at 20 years, most men are survivors of treatment NOT survivors of prostate cancer,
> most men are given the wrong message about their prostate cancer and EXPLOITED,
> the embarrassing USPSTF report did not endorse PSA screening or prostate surgery.

Much of the prostate cancer industry's work is a charade and nothing more than a

sophisticated deception and exploitation of men made vulnerable by the word cancer. It is a very false show of patient advocacy not uncommonly associated with physician coercion rather than counselling and treatment debilitation rather than cure. In fact, meritless treatments and false hope have been combined very successfully by the prostate cancer industry and have positioned these physicians on par with the hucksters parlaying bogus “treatments” with junk science.

This extraordinary medical business of urologists dealing in scientifically unproven robotic treatments and debilitating men on the pretext of saving lives while wasting billions of healthcare dollars continues today without conscience.

SUMMARY AND INDEX FOR DECISION MAKING STEPS

EMOTIONS: NORMAL but WASTED on PROSTATE CANCER

Fear for prostate cancer is misguided because the odds of you being impacted by this cancer are very low. Much more common is the fact that you will die from something else and without knowledge of your prostate cancer. In general, there is much self-serving advertising to generate misplaced concern for prostate cancer because the prostate cancer business is a very lucrative industry.

The word CANCER can come as a very big shock. I can attest to the feelings of disbelief, disappointment, shock and anger associated with that earth-shattering word.

Your Questions

Is the diagnosis correct? Do we have it diagnosed in time? Is it contained and localized? How can I deal with it quickly so I can try to get on with my life? Will I be cured? Will I be a survivor? How should I discuss this with my family? What is the chance of recurrence? How long do I have?
This cancer word can suck the life out of you and appear to make time stand still. These emotions, anxiety and stress come to all men and women upon hearing that dreadful word cancer because we all know of some horrible cancers that can present enormous challenges.

Your Feelings

Dealing with the word cancer may well lead to some emotional distress. You may be consumed and preoccupied by the thoughts listed above, have trouble sleeping, not be very hungry, feel less energetic, feel negative about most issues, have trouble socializing or even have the blues.

STOP: your questions and feelings are NORMAL but MOST Prostate cancers DO NOT deserve this kind of drama. Be sure to talk to your family and get their understanding and support.

Feeling especially vulnerable and emotionally labile will happen to varying degrees in most men upon getting a diagnosis of prostate cancer. It is very common for you not to be thinking rationally, but it is vitally important that you realize this and get yourself together to resist any impulsive decision making by you or from your wife or partner. Especially, resist the intuitive but misguided, "let's cut it out so I can forget about it". This approach may well have you wake up every day after your robotic prostatectomy with profound regret for the rest of your life simply because of the postoperative sexual and urinary complications and absence of significant benefit. (Prostate Cancer Surgery? Lies, lies and more damned lies)
Also, get the help of a caring physician and do not let your feelings turn to depression.

There are several very important considerations you should ponder:

> the word "cancer" in a Gleason 3+3 prostate cancer is essentially a misnomer,

> low-risk Gleason 3+3 prostate cancer is more of an observation than a disease,
> micro-focal and low volume prostate cancer are part of the aging process,
> a man is highly unlikely to be impacted by a Gleason 3+3 prostate cancer,
> the Gleason 3+3 tends to have no metastatic potential and is mainly a pseudo cancer,
> for most men, the risks of evaluation and treatment are far worse than the risks of the low-risk Gleason 3+3 prostate cancer disease itself,
> most men with low-risk prostate cancers are OVERTREATED,
> most men are 20-year survivors irrespective of the type of treatment for their low-risk Gleason 3+3 cancer and whether they are treated or not,
> most low-risk prostate cancers have a long natural history often beginning in the 30s,
> surgeons will lead you to surgery (and tell you that radiation may also be associated with a small risk for rectal cancer but this is minor compared to the surgeon's 20-40% incidence of residual cancer or cancer left behind after their debilitating surgery), radiation oncologists will lead you to radiation.

For ALL of these reasons, you should take particular care NOT to let your vulnerability and emotions lead you to take inappropriate, impulsive and regretful treatment actions. Some surgeons are quite adept at delivering a self-serving message, taking advantage of the word cancer and your vulnerability and steer you towards treatment actions that are NOT in your best interests. They will even show you "exceptional" cure rates. Rates which were achieved by treating low-risk Gleason 3+3 cancers and which NEVER required treatment.(Prostate Cancer? Why radical surgery/robotic prostatectomy is NOT for you).

There is NO health-risk emergency requiring action especially for the Gleason 3+3 prostate cancer. You should also discuss openly your condition and concerns with your wife/partner. As well, there is NO possible concern for passing these low-risk prostate cancer cells to your wife through sexual activity.

This journey of yours can be made a lot easier through education, regular moderate exercise, stopping smoking and following a lean, healthy diet. Also comforting is having a physician who has the ability to combine empathy and compassion with real patient advocacy along with real prostate cancer knowledge and an ability to undertake minimally invasive treatments such as hifu or cryoablation if required. Run away from anybody suggesting robotic prostatectomy. (The Imperfect PSA, the Fraudulent Robotic Prostatectomy and Medical Ethics) I never want another patient coming to me for prostate cancer management and telling me he made the biggest mistake of his life by having robotic prostatectomy for his prostate cancer.

Prostate Cancer

The prostate gland sits at the base of the bladder and urine is passed through the central channel of the prostate. The prostate can be examined by passing a finger into the rectum (digital rectal exam or DRE) to evaluate its surface and texture and a cancer can

be felt as a nodule in the prostate sometimes.

Prostate cancer develops when the growth of prostate cells becomes uncontrolled.
> prostate cancer probably starts in the second to third decade of life.
> Gleason 3+3 prostate cancer growth rate is extremely slow.
> the Gleason 3+3 prostate cancer cell takes about 475 plus or minus 56 days to replicate.
> at this rate, it takes about 40 years for a Gleason 3+3 to grow from inception to a volume 1 cm in diameter.
> prostate cancer may take 50 years or more for progression to pathologically detectable metastatic disease.
> these simple calculations underscore the importance of factoring in a man's age into the treatment paradigm, particularly for the low-risk Gleason 3+3 prostate cancer.
> 95% of prostate cancers are adenocarcinomas, developing predominantly in the peripheral zone and apex of the prostate.
Prostate cancer development is under the promotional hormonal influence of testosterone and its metabolite dihydrotestosterone.
Prostate cancer is not seen in eunuchs or men with congenital deficiency of 5 alpha reductase.
Androgen/testosterone deprivation therapy (ADT) by orchiectomy or through medications will result in death of most prostate cancer cells.

Prostate Cancer Prevalence

> the rate of prostate cancer diagnosis is rising because of increasing misuse of the PSA test.
> prostate cancer is the most common cancer diagnosed in men after skin cancer. However, its importance is over emphasized, over diagnosed and over treated.
> the incidence of prostate cancer (mostly low-risk Gleason 3+3) affects about 8% of all men.
> 32% of men in their 50s have histological prostate cancer.
> 75% of cancers are diagnosed in men > 65 years of age.
> the mean age of diagnosis is 72 years of age.
> 75% of men have low-risk Gleason 3+3 prostate cancer which is UNLIKELY to impact them ever.
> most men will die with their prostate cancer, not from it.
> some 3% of men will die from their high-risk prostate cancer NOT from the low-risk cancer.
> survival rates for prostate cancer are rising NOT because of the definitive treatments but because of better general healthcare and the overtreatment (unnecessary treatment) of increasing amounts of insignificant and low-risk Gleason 3+3 prostate cancer.

What is the PSA?

The Prostatic Specific Antigen (PSA) is a serine protease produced by the prostate to

liquefy the ejaculate and allow sperms to migrate once deposited within the vagina. Disruption of the prostatic gland architecture like in cancer, allows greater amounts of PSA to enter the bloodstream.
> the commonly used PSA, or total PSA is a very UNRELIABLE blood test with a very low sensitivity for prostate cancer, especially when used in screening for prostate cancer.
> the cut-off level of 4 ng/ml or less as being normal and anything above this level being abnormal is ARBITRARY and a PSA < 10 ng/ml is more reliable for BENIGN prostate disease than for prostate cancer.
> the bigger the prostate, the greater the PSA.
> the more inflammatory cells (chronic prostatitis), the greater the PSA.
> in reality, there is NO SAFE LEVEL of PSA for which you cannot have cancer.
> in addition, you should be aware of those drugs that can lower your PSA such as Statins, NSAIDS, Thiazides and 5 alpha reductase inhibitors (proscar, avodart). These drugs lower PSA levels artificially and this lowering MAY have no protective value from developing prostate cancer. Furthermore, there are situations which can raise your PSA in the absence of a cancer and give you a false-positive reading such as after sexual activity, a DRE, a prostate biopsy or a urinary tract infection.
> the PSA is unable to distinguish SIGNIFICANT aggressive prostate cancer from INSIGNIFICANT prostate cancer.
> the PSA under 10 ng/ml does not correlate well with prostate cancer in presence or amount.
> a man with a "normal" PSA under 4 ng/ml will have an approximately 15% chance of having prostate cancer, mostly insignificant.
> a man with a PSA between 4-10 ng/ml will have a 30% chance of having prostate cancer.
> a man with a PSA over 10 ng/ml has a 40-70% chance of having prostate cancer.
> 75% of the prostate cancers detected will be low-risk Gleason 3+3.
> a man of 65 years with a PSA < 1 ng/ml is unlikely to benefit from more PSA testing.
> a man of 75 years with a PSA < 3 ng/ml is unlikely to benefit from more PSA testing.

WHY YOU MAY NOT WANT TO CHECK YOUR PSA

> urologists are still unable to determine accurately which prostate cancers have the propensity for spreading by blood stream and which demand treatment from prostate cancers which do not.
Future BIOMARKERS may have reliable predictive value as to whom really needs treatment.
> many PSAs are elevated because of the associated benign prostate enlargement and NOT from the small area of insignificant, low-risk prostate cancer detected serendipitously.
(PSA and Prostate Cancer Screening? Maybe, Carefully and Selectively)
> needle biopsies of the prostate can be risky although not as risky as OVERTREATMENT.

> cancer will be identified in less than 5% of asymptomatic men screened for prostate cancer.
> many prostate cancers are low-risk Gleason 3+3 and OVERTREATED (especially with robotic prostatectomy) when they should have been monitored through active surveillance.
> treatments (especially with robotic prostatectomy) are risky, unlikely to be curative and often diminish quality of life because of urinary leakage, shortened penis, altered sexual experience, loss of ejaculation, infertility and impotence (or discharge of urine if fortunate enough to have some sexual function/orgasm) along with a general loss of manhood.
> the prostate cancer industry has a culture along with a well-oiled media machine, where there is pervasive use of self-serving definitions, gross subjectivity issues affecting imaging and pathology interpretations, inaccuracies in so-called "data bases", philosophical approaches to treatment, pervasive use of scientifically unproven treatments, conjecture and creative reporting of "results" along with a lack of sincere end-result accountability that have clouded severely any appearance of patient advocacy.
> the credibility of urological surgeons is tainted even further by the manner in which the cancer "message" is delivered by many of these doctors.

WHY YOU MAY WANT TO CHECK YOUR PSA

Refining eligibility for PSA testing MAY be reasonable. First, you should consider reviewing an informed consent because of the many possible negative downstream effects stemming from evaluation and treatment for prostate cancer (The Imperfect PSA, the Fraudulent Robotic Prostatectomy and Medical Ethics).

PSA testing may be reasonable for:

> concerned healthy men with at least 20 years or so of anticipated active life and without significant co-morbidities such as a cardiac or diabetes history which may impact survival.
> those with an abnormal prostate examination. The digital rectal examination (DRE) is a very subjective test and firmness or a lump/nodule in your prostate MAY mean an area of cancer. Simple asymmetry of your prostate is not a valid reason for a prostate biopsy.
> an abnormal DRE in the presence of a so-called normal PSA under 4 ng/ml has about a 30% chance of an associated prostate cancer.
> older men; prostate cancer increases with age faster than any other cancer and 75% of prostate cancers are diagnosed in men after age 65 years but mostly low-risk Gleason 3+3 (about 70% of 90-year-olds can have asymptomatic prostate cancer).
> men with low serum testosterone and in particular those with low percent-free testosterone.
> men of African heritage (particularly Jamaican).
> obese men.
> men with a family history of prostate cancer; some 5% of prostate cancers may be

inherited.
> men with low-risk prostate cancer undertaking active surveillance (AS) and monitoring PSA doubling time.
> monitoring after prostate cancer treatment.

STEP 1.
WHICH PSAs and WHAT PSA ENDPOINT may SUGGEST the NEED for a PROSTATE BIOPSY?
It is difficult to determine at what PSA endpoint there is enough of a concern for you to consider a prostate needle biopsy in order to determine the possible presence of a significant cancer.
Each patient and his physician will need to come to a consensus as to what level of PSA causes concern for a possible prostate cancer.
> PSA Derivatives (total, free PSA and percent free PSA)

TABLE

PSA (ng/ml)	percent free PSA	Estimated Probability of cancer
0-2.5	?	?
2.6-4.0	0-27	24%
4.1-10	0-10	56%
	11-15	28%
	16-20	20%
	21-25	16%
	>or =26	8%
> 10	N/A	> 50%

It is evident from this table that as the percent free PSA rises, the probability of prostate cancer diminishes. This is the converse of what a high total PSA can mean.
Rather than using just the common total PSA, using PSA derivatives such as the free PSA to determine the percent free PSA can approximate the "estimated probability of having a cancer". From the Table, the lower the percentage free PSA, the greater the probability of prostate cancer. ie with a percent free between 0-10 you have a 56% estimated "probability" of having a prostate cancer.
However, these estimates are NOT foolproof and may vary with age, ethnicity, family history and DRE findings. Furthermore, although the diagnostic usefulness of the percent free PSA has not been established in men with a total PSA below 2.6 ng/ml, I do begin to pay attention to this number when the PSA reaches a level somewhere between 1.8-2 ng/ml.
Values obtained from different testing methods and laboratories cannot be used interchangeably.

> PSA Kinetics (velocity, PSAV and doubling time, PSADT)
A PSA increase (velocity) of 0.75 ng/ml/y in a PSA range of 4-10 ng/ml over at least 18 months is considered to be significant.
Determining the PSADT, which is the length of time in months for a PSA to double based upon exponential growth with a shorter (but faster) doubling time having a poorer outlook, may be meaningful. For example, a PSADT of under 2 years should raise suspicion for either the presence of a prostate cancer or a cancer on active surveillance which may be progressing. A long PSA doubling time has a low likelihood of significant impact.

> PSA density
The dPSA is measured by dividing the weight of your prostate into your current PSA. A dPSA > 0.15 may be significant.

> age-specific PSA ranges
Using tables showing the normal increasing PSA ranges for advancing age.

> evaluating the PSA after a 3-month course of finasteride (proscar)
To see if the PSA drops by about 50% after a 3-month course of finasteride; if so, it is thought that the chances of having a prostate cancer are diminished.

> performing the PCa3 test
This involves a vigorous prostatic massage and an mRNA analysis of the seminal fluid washed out in the initial urine sample after the massage. This test may be useful when the information is combined with the PSA derivatives. On its own, the PCa3 is associated with too many false positive and false negative results to be reliable.

> ultrasensitive PSAs
May be more useful for detecting prostate cancer recurrences after a treatment.

> newer biomarkers
Blood biomarkers like the pro-PSA and others as well as new urinary and tissue biomarkers like the PTEN are still undergoing evaluation. These new biomarkers may predict reliably prostate cancer progression and which cancers truly demand treatment.

Some caveats;
> unlike its inaccuracy as a prostate cancer screening marker, the PSA is a reliable indicator of presence or absence of cancer after prostate cancer treatment.
> high-risk or aggressive prostate cancers such as small cell cancers may produce little if any PSA rise, even with prostate cancer progression.
> the upgrading of a residual prostate cancer to a more aggressive prostate cancer may occur after ANY TREATMENT option without a significant rise in PSA. Therefore, PSA

monitoring needs to be interpreted very judiciously.

STEP 2.
DETECTING PROSTATE CANCER
more caveats;
> better and earlier prostate cancer DETECTION does NOT necessarily equate with SIGNIFICANCE of the prostate cancer detected,
> many of the 75% prostate cancers detected are low-risk and INSIGNIFICANT and UNLIKELY to impact men ever,
> most early prostate cancer detection results, in OVER DIAGNOSIS and OVER TREATMENT,
> early detection and early treatment has NOT resulted in significant lives saved,
> the risks associated with over treatment are greater than the risk of a Gleason 3+3 cancer,
> most men treated for their Gleason 3+3 cancers are treatment survivors NOT cancer survivors.

a). Imaging
While significant imaging advances have been made, we have NOT yet reached the point where we can detect SIGNIFICANT prostate cancer lesions reliably through imaging, thus dispensing with the prostate needle biopsy (transrectal is more risky than transperineal) either for diagnosis or to determine progression of prostate cancer during active surveillance monitoring.

1. Enhanced Ultrasound Modalities (EUM), including color and power Doppler, contrast-enhancement, harmonic and flash replenishment imaging and elastography have also improved cancer detection rates over standard grayscale ultrasound methods by targeting areas with increased vascularity or firmness.

2. Multi-Parametric 3T MRI may allow detection, localization and staging of prostate cancer, especially by focusing on microvascular alterations. Here anatomic imaging with T1 and T2-weighted imaging is combined with functional techniques including diffusion-weighted imaging and dynamic contrast-enhanced MR imaging.
Although the multi-parametric 3T MRI studies appear to be a very promising non-invasive method for use in prostate cancer detection, staging and possibly for active surveillance, the goals of enhanced diagnostic power detection to allow for non-invasive detection and or targeted biopsies of suspicious areas to minimize risky random biopsies, as well as noninvasive monitoring, have not been realized yet because of significant numbers of false-positive and false-negative interpretations.

3. MRI Spectroscopy is based on the knowledge that healthy prostate tissue in the peripheral zone of the prostate produces large amounts of citrate while choline is elevated in prostate cancer tissue as a result of increased cell membrane turnover as

well as an increased cell surface relative to healthy tissue. Therefore, the choline + creatine/citrate ratio has been used to try to identify prostate cancer on MR spectroscopy. However, once again, the addition of MR spectroscopy has NOT improved significantly the accuracy of prostate cancer detection.

To date, these various imaging studies of the prostate continue to be unreliable with too many false positives and too many false negatives **as well as a huge disconnect between DETECTION of prostate cancer and the SIGNIFICANCE of the cancer detected in that most are INSIGNIFICANT**. In addition, some of these cancers "detected" through imaging studies are not in the same area of the prostate as detected by the needle biopsy. Currently, the presence or absence of cancer can only be established reliably by the invasive and somewhat risky needle biopsy of the prostate and pathological review.

4. CAT scans and bone scans are still used inappropriately to prove that the cancer is localized to the prostate only. These tests are insensitive and valueless for detecting micro deposits or possible early spread of prostate cancer until the PSA reaches about 20 ng/ml. Much more accurate but invasive, are bone marrow aspiration studies.

b) The Prostate Needle Biopsy

The decision to proceed with a prostate needle biopsy should be based upon several findings:

> suspicious DRE findings with an abnormal-feeling area in the prostate,
> several abnormal estimations of the PSA/free PSA/percent free PSA, PSA kinetics and PSA density,
> a man's age, general health and life expectancy,
> family history of prostate cancer,
> ethnicity and,
> prior prostate biopsy findings, if any.

TRUS/BX (transrectal ultrasound and needle biopsy)

The TRUS/BX uses a transrectal ultrasound to guide a needle into an area of the prostate for biopsy. The ultrasound images the prostate and seminal vesicles using a 7.5 MHz rectal probe of about 1.5 cm in diameter.

> needle biopsies DO NOT spread prostate cancer or cause needle tracking of prostate cancer for stages T1c- T2b.
> the needle biopsy samples generally less than 1% of the prostate volume.
> the more needle core samples taken, the more likely INSIGNIFICANT cancer disease is detected.
> the more needle cores taken, the greater the risk of bleeding or sepsis.
> the transrectal ultrasound guided prostate needle biopsy process is very operator dependent and involves considerable subjectivity as to where the biopsy needle is actually placed in the base, middle or apex of the prostate for obtaining a specimen.

> MOST prostate cancers CANNOT BE IDENTIFIED BY ULTRASOUND IMAGING.

Several approaches to the prostate ultrasound and needle biopsy are recognized with the majority of these being performed in doctors offices under local anesthetic (periprostatic nerve block) and oral antibiotics.
However, I perform them routinely under outpatient sedation (to minimize discomfort) along with IV antibiotics (to minimize risk of sepsis). There is a small risk for bleeding and control may require an intra-rectal swab soaked with vaso-constricting adrenaline (epinephrine) 1:10,000 and local pressure or, a colonoscopy and clipping of the bleeding hemorrhoidal vessel. The risk of bleeding is much less in the perineal approach but this approach is performed uncommonly due to the extra equipment needed along with anesthesia.

i) transrectal (standard)
12 core, systematic but random, sextant (prostate is divided into 6 zones arbitrarily) needle biopsies with 2 biopsies in each sextant, laterally and medially, base, middle and apex, right and left sides, using an 18 g, spring-loaded, trucut needle. Most of the sampling is from the peripheral zone of the prostate where the majority of prostate cancers occur.
Greater sampling through an extended biopsy protocol with 12-20 needle biopsies or the saturation protocol with greater than 20 needle cores may only be diagnosing increasing numbers of insignificant cancers, leading usually, to overtreatment and harm.
The 12 core needle biopsy approach appears to deliver a reasonable balance between detection of possible significant prostate cancers from overdiagnosis of insignificant low-risk Gleason 3+3 prostate cancers which usually do not need treatment.
The standard 12 core needle biopsy of the prostate has about a 70% reliability for detecting a cancer. Certainly, laterally directed needles into the peripheral zone increases the cancer detection rate significantly but again, most of the cancers detected will be the low-risk Gleason score 3+3. Apical areas and especially distal apical regions of the prostate deserve extra attention as prostate cancer is found commonly here.

In the unlikelihood of a “SIGNIFICANT” cancer being missed on the first standard 12 core biopsy, close follow-up monitoring with PSA kinetics and another biopsy some 6-12 months later should there be continued concern, will detect any SIGNIFICANT prostate cancers.

ii) transperineal
transrectal ultrasound and template based transperineal guided biopsy under anesthesia.

My biopsy was clear. Is there a way to prevent me from having Prostate Cancer?
Because there is a huge disconnect between detection of prostate cancer compared to

significance of the cancer detected, the number of men who may benefit from prostate cancer prevention or chemoprevention (using either Proscar/finasteride or Avodart/dutasteride) where chemo intervention will actually interrupt the natural history of a potentially significant prostate cancer is small and remains controversial. In addition, chemoprevention can be associated with the side effects of decreased libido, impotence, breast discomfort or breast enlargement.
Although there appears to be a reduction in prostate cancer incidence for men undergoing chemoprevention, the reduction of insignificant disease which was never going to impact them, as well as the possible side effects from the medications, probably negates any benefits. Furthermore, the studies suggested a greater incidence of higher grade cancers in those on chemoprevention and chemoprevention has not been approved by the FDA.
However, the men who MAY stand to gain the most from chemoprevention are men at risk.
General non-medical interventions that are considered to be helpful include stopping smoking, moderate exercise and eating smaller portions of a lean and healthy diet.

STEP 3.
HOW SHOULD I VIEW MY BIOPSY and PATHOLOGY REPORTS?
Always obtain a copy of your transrectal ultrasound and prostate biopsy (TRUS/BX) report performed by your urologist as well as the pathology report on your prostate needle biopsy.
1. On your TRUS/BX report note;
a. size of your prostate in grams.
b. any anatomical concerns with your prostate, ie cysts, calcifications, etc.

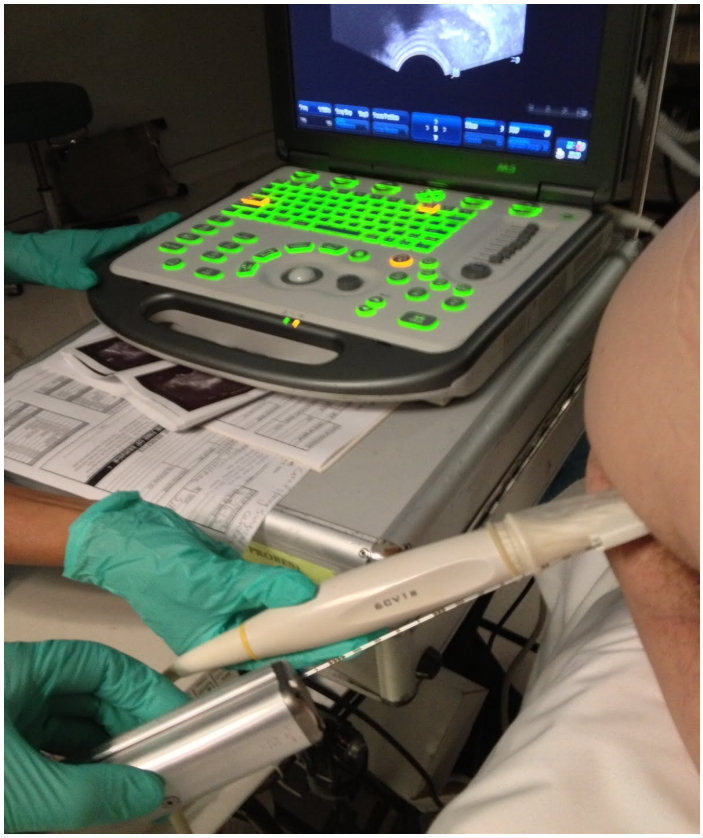
2. For your PATHOLOGY REPORT;
First and foremost, ALWAYS obtain a Second Opinion regarding your pathology diagnosis.
WHY? Because there exists considerable subjectivity between pathologists in the interpretation of your prostate disease diagnosis.
You should request that ALL of your slides be sent to a nationally recognized reference laboratory for a validation of your prostate pathological diagnosis.

Second Opinion/validation for prostate pathology may be obtained from the following laboratory:
Jonathan Epstein M.D., Dept of Pathology, Johns Hopkins Hospital, Baltimore, Md
There may also be a handful of other experienced and reliable prostate pathology reference laboratories around the country.

Only after having had your prostate biopsy slides read by a nationally recognized prostate reference laboratory should you review that pathology report in detail and then work through the steps suggested below. Write yourself a summary according to the

important issues listed after the biopsy report.

Trans Rectal Ultrasound and Needle Biopsy of the Prostate (TRUS/BX)



A typical 12-core prostate needle biopsy pathology report is shown below and in this case, mirrored the validated pathology report from the reference laboratory.
The PSA at the time of biopsy was 5.8, percent free 3

AURORA DIAGNOSTICS
Mark & Kambour Pathology

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CORAL GABLES, FLORIDA 33146
P: (866) 669-3471 / F: (305) 668-2026

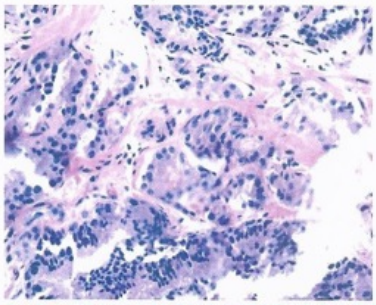
PATHOLOGY REPORT

PATIENT INFORMATION	SPECIMEN INFORMATION		ORDERED BY
[redacted] Sex:Male Age: 74, DOB: [redacted] **ACCESSION #:** [redacted]	COLLECTED:	01/29/2013	Bert Vorstman, M.D. Florida Urologic Assoc 1725 University Drive # 400 Coral Springs, FL 33071 P:(954) 752-3166
	RECEIVED:	01/29/2013	
	REPORTED:	01/30/2013	
	CHART/MRN #:	[redacted]	

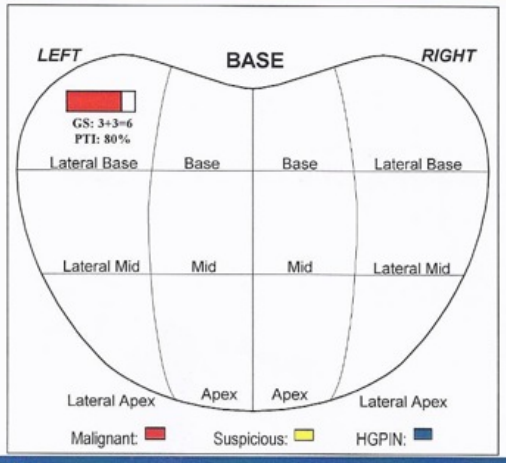
FINAL DIAGNOSIS

PHOTOGRAPH

A - PROSTATE, LEFT LATERAL BASE:



PROSTATIC ADENOCARCINOMA GLEASON SCORE 3+3=6,



DIAGNOSIS

A PROSTATE, LEFT LATERAL BASE, NEEDLE BIOPSY:
- **PROSTATIC ADENOCARCINOMA GLEASON SCORE 3+3=6,**
- **DISCONTINUOUSLY INVOLVING APPROXIMATELY 80% OF THE BIOPSY.**

B PROSTATE, LEFT MEDIAL BASE, NEEDLE BIOPSY:
- **BENIGN PROSTATIC TISSUE.**

C PROSTATE, LEFT LATERAL MID, NEEDLE BIOPSY:
- **BENIGN PROSTATIC TISSUE.**

D PROSTATE, LEFT MEDIAL MID, NEEDLE BIOPSY:
- **BENIGN PROSTATIC TISSUE.**

E PROSTATE, LEFT LATERAL APEX, NEEDLE BIOPSY:
- **BENIGN PROSTATIC TISSUE.**

F PROSTATE, LEFT MEDIAL APEX, NEEDLE BIOPSY:
- **BENIGN PROSTATIC TISSUE.**

G PROSTATE, RIGHT LATERAL BASE, NEEDLE BIOPSY:
- **BENIGN PROSTATIC TISSUE.**

H PROSTATE, RIGHT MEDIAL BASE, NEEDLE BIOPSY:
- **BENIGN PROSTATIC TISSUE.**

PATHOLOGY PERFORMED MARK AND KAMBOUR PATHOLOGY ASSOCIATES CLIA# 10D0952918

When required, some of the immunohistochemical tests performed by Mark & Kambour Pathology Associates had their performance characteristics determined by M&K. Although not cleared or approved by the U.S. FDA, the FDA has determined that such clearance or approval is not necessary. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

CLINICIAN: Vorstman, M.D., Bert

[redacted]

AURORA DIAGNOSTICS

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Sex:Male	RECEIVED:	01/29/2013	Florida Urologic Assoc
Age: 74, DOB: [redacted]	REPORTED:	01/30/2013	1725 University Drive # 400
ACCESSION #: [redacted]	CHART/MRN #:	[redacted]	Coral Springs, FL 33071
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DIAGNOSIS

I PROSTATE, RIGHT LATERAL MID, NEEDLE BIOPSY:
- BENIGN PROSTATIC TISSUE.

J PROSTATE, RIGHT CENTRAL, NEEDLE BIOPSY:
- BENIGN PROSTATIC TISSUE.

K PROSTATE, RIGHT MEDIAL MID, NEEDLE BIOPSY:
- BENIGN PROSTATIC TISSUE.

L PROSTATE, RIGHT LATERAL APEX, NEEDLE BIOPSY:
- BENIGN PROSTATIC TISSUE.

M PROSTATE, RIGHT MEDIAL APEX, NEEDLE BIOPSY:
- BENIGN PROSTATIC TISSUE.

COMMENTS: Dr. Kambour concurs.

CLINICAL AND SPECIMEN INFORMATION

CLINICAL HISTORY: Elevated PSA.

GROSS DESCRIPTION:

A. 1 cores, 8 mm in length.-0.
B. 1 cores, 14 mm in length.-0.
C. 2 cores, 12 mm in length.-0.
D. 1 cores, 13 mm in length.-0.
E. 1 cores, 11 mm in length.-0.
F. 1 cores, 7 mm in length.-0.
G. 1 cores, 8 mm in length.-0.
H. 1 cores, 14 mm in length.-0.
I. 1 cores, 8 mm in length.-0.
J. 1 cores, 14 mm in length.-0.
K. 1 cores, 17 mm in length.-0.
L. 1 cores, 5 mm in length.-0.
M. 2 cores, 12 mm in length.-0.

Senen Rodriguez, M.D.
Electronically Signed: 1/30/2013

CLINICIAN: Vorstman, M.D., Bert

[redacted]

> you will have taken note of your PSA, free PSA and percent free PSA (the PSA derivatives) and PSA kinetics (PSA velocity, PSA doubling time) and the PSA density that led to your undergoing the prostate needle biopsy.
> you will have noted the size/volume of your prostate in grams which was measured during the transrectal ultrasound part of your trus/bx.
> from the actual validated/second opinion pathology report note,
* the number of needle biopsy cores taken, ideally about 12.
* the optimal prostate needle biopsy core length should be at least 12-15 mm.
* that the histology specimens were prepared using triple immunohistochemistry stains.
* perineural infiltration (on its own may not be significant prognostic indicator).
* the location within the prostate, particularly whether in the apex of the prostate.
* the number of positive cores containing prostate cancer.
* the percentage of prostate cancer within each of the positive needle cores.
* the Gleason score of the prostate cancer in each of these cores.
* the highest level of Gleason score recorded.

Gleason Score
Under the microscope and under low power, prostate cancer frequently exhibits several patterns of growth. The most common pattern of cancer is identified and graded from 1-5 with 5 being the most aggressive grade and 1 the least. The grade for the most common or predominating pattern seen under the microscope is shown as the first number in this score of two grades. The second number is simply the highest Gleason grade detected and this number is added to the first number for a Gleason score.
For example, the predominating cancer pattern seen under the microscope is the first number and may be given a grade of 3, and say the highest grade detected was a 3 then the Gleason score is arrived at by adding these two numbers (3+3) for a score of 6. However, if the highest grade seen was a 4, then grades 3+4 would mean a Gleason score of 7.

The Gleason score of 7 prognosis depends upon whether it is a 3+4 or 4+3.
The Gleason score of 3+4 behaves more like a low-risk Gleason 6.
The Gleason 4+3 is also a Gleason score of 7 but this behaves more like a high-risk Gleason 4+4 or score of 8.
This grading is quite subjective and can vary between pathologists and experience.
In practice, 75% of cancers are low-risk and have a Gleason score of 6 (3+3) or 7 (3+4).
A small percentage of prostate cancers have a lower Gleason score.
Some 15% of prostate cancers have a Gleason score of 8-10 and are high-risk.
It is also important to appreciate that the prostate cancer interpretation for Gleason scoring can be difficult after hormonal manipulation.
Prostate cancers may upgrade to a higher, more aggressive Gleason grade after any definitive treatment for prostate cancer but this MAY NOT be associated with a

significant, or in fact, any PSA rise.

STEP 4

Is my Cancer Localized/Confined/Contained to the Prostate?

Although the majority of prostate cancers detected are in the T1c (localized and cannot be felt on DRE) stage category, low-risk (about 75% of all prostate cancers) and BELIEVED to be organ-confined or confined to the prostate, this T1c stage does NOT determine your prostate cancer RISK (for progression) level. The T1c stage category is a mixed bag of prostate cancers including all prostate cancer Gleason scores and tumor volumes as long as the prostate cancer was identified only through an abnormal PSA only.

The approximate proportion of men with organ confined prostate cancer disease is about;

> 80% when PSA less than 4.0 ng/ml,

> 70% when PSA between 4-10 ng/ml,

> about 50% when PSA greater than 10 ng/ml.

Imaging studies to STAGE and detect spread of disease (inaccurate)

> the imaging studies used currently (CAT scans, Tc99 bone scans and Prostascint scans) to attempt to detect local infiltration or metastatic disease are insensitive until the PSA reaches about 15-20 ng/ml and therefore their routine use for the T1c stage is VALUELESS. Similarly, the multi-parametric 3T MRI is unreliable currently for detecting local infiltration of cancer outside of the prostate and for prostate cancer staging because of too many false positives and false negatives. Local infiltration of prostate cancer outside of the prostate can be determined through biopsies targeting the margins of the prostate. If cancer is detected at the margins of the prostate, the cancer has infiltrated and is no longer confined to the prostate and minimally invasive treatments using cryoablation and hifu or especially the ill conceived surgery, will be incomplete. They may, however, be helpful in downsizing the cancer.

> sodium fluoride PET/CAT scans are much more sensitive for detecting metastatic bone disease than conventional bone scans and can be useful even with PSAs at about 10-15 ng/ml.

> bone marrow studies are somewhat invasive but much more accurate at detecting metastatic prostate cancer than the inaccurate imaging formats focusing on possible pelvic lymph node enlargement. Men with clinically significant prostate cancers are very likely to have disease already spread to their bone marrow because of prostate cancer's predilection for bone marrow rather than lymph nodes. Bone marrow aspiration to estimate bone marrow prostatic acid phosphatase and prostatic specific antigen as well as special staining techniques for cytokeratin-18 or using other sophisticated immunohistochemistry techniques have identified bone marrow metastases well before even pelvic lymph node enlargement can be detected on MRIs. The presence of these circulating prostate cancer cells correlates with clinical deterioration. Although this test is invasive, only bone marrow aspiration techniques

and not imaging studies have the sensitivity to identify micrometastatic spread of prostate cancer to the marrow.
Metastatic prostate cancer cells in the bone marrow replicate in a shorter time frame than the Gleason 3+3 cells which take 475 days but these metastatic cells still take a number of years before the cancers manifest themselves. In part, some of this metastatic growth will be controlled by the prostate cancer cell's inability to survive while other cells will be affected by the body's protective immune surveillance mechanisms.

STEP 5.
WHAT IS MY PROSTATE CANCER RISK LEVEL?

For most men, this is a non-issue as some 75% of men have low-risk Gleason 3+3 prostate cancer which is unlikely to need treatment ever.
Risk assessment and risk for prostate cancer disease progression can be estimated by reviewing your Gleason score, number of positive cores, percentage of positivity, PSA and cancer stage. These criteria stratify your prostate cancer risk level and the treatment options suitable for these risk categories of "localized" prostate cancer.

Staging of your prostate cancer is done using the TNM format with the T category identifying the status of the prostate tumor essentially from T1a to T4 but usually up to T3b only for localised prostate cancer and with no obvious involvement of regional nodes(N) and no obvious distant metastases (M). For example, most prostate cancers are staged as T1c N0 M0.
Again, if your PSA is UNDER 20 ng/ml, most imaging studies attempting to detect metastatic spread are valueless while the more accurate bone marrow aspiration studies are rarely performed

All of this information listed above allows one to estimate your prostate cancer risk level, commonly now, favorable-risk or uncommonly, high-risk.
The previous intermediate-risk category for Gleason 7 has been reclassified by some in the following manner;
> the Gleason 4+3 has been moved to high-risk as it behaves like a Gleason 4+4 and,
> the Gleason 3+4 has been moved to low-risk as it behaves more like a Gleason 3+3 and this group is now called favorable-risk instead of low-risk.

STEP 6.
MANAGEMENT PATHWAYS FOR LOCALIZED PROSTATE CANCER
i. HIGH-RISK PROSTATE CANCERS DEMAND TREATMENT

Men who present in the high-risk group have Gleason scores considered SIGNIFICANT enough to warrant a definitive treatment as long as there is NO obvious spread outside of the prostate. These men have;
> a Gleason score of 8 to 10.
> a Gleason 4+3 score (which behaves like a Gleason 4+4).
However, despite possibly having "localized" or even organ-confined disease to the

prostate, the chances are very high that a man with high-risk prostate cancer has cancer immediately outside of the prostate or even beyond the prostate in the bone marrow. This micrometastatic disease is undetectable by current imaging formats except through bone marrow aspiration techniques.
Bone marrow aspiration studies are very accurate for detecting prostate cancer cells in the marrow but these studies are rarely performed as they are invasive.
High-risk prostate cancer spreads through a variety of ways but it is the spreading through the bloodstream and to bone marrow that eventually kills.
Sodium fluoride PET/CT bone scan tests are a little more sensitive and may detect metastatic disease to the bones when the PSA is about 10-15 ng/ml.

Definitive Treatment for men with LOCALIZED HIGH-RISK prostate cancer
This is fairly standard for those with Gleason scores 8-10 or those with 4+3 disease.
Androgen Deprivation Therapy (ADT) is given for several months prior to commencing treatment and may continue for several months to 2 years after treatment with:
> radiation; various IMRT protocols are in use with or without a brachytherapy (seeds) booster.
> outpatient nerve-sparing cryoablation in selected cases
> outpatient nerve-sparing HIFU in selected cases
> proton beam (similar results, benefits and downsides to IMRT but much more costly)

ii. FAVORABLE-RISK PROSTATE CANCERS
THESE ARE GLEASON 3+3 (and with MAYBE a little Gleason 3+4) PROSTATE CANCERS. THESE CANCERS ARE HIGHLY UNLIKELY TO NEED TREATMENT EVER.
THEY ARE MONITORED THROUGH ACTIVE SURVEILLANCE.
Goals of Active Surveillance
Previous active surveillance parameters for low-risk Gleason 3+3 prostate cancers were too restrictive.The goal of active surveillance for favorable-risk prostate cancer currently, is making the INITIAL active surveillance parameters less restrictive and include,
> men of all ages
> all Gleason 3+3 tumor volumes
> all microfocal prostate cancers
> all precancerous lesions
> some small volume Gleason 3+4
Active surveillance is promoted to prevent OVERTREATMENT and HARM to the great number of gullible and vulnerable men with favorable-risk Gleason 3+3 who failed to educate themselves and would otherwise have been steered towards towards an invasive treatment which was without any benefit.
Active surveillance monitoring of these men with favorable-risk Gleason 3+3 prostate cancer is considered far less harmful than the risks and harm associated with

overtreatment, particularly from robotic prostatectomy.
This prostate cancer monitoring through active surveillance also allows us to detect those FEW MEN who progress or UPGRADE their Gleason 3+3 prostate cancer significantly, are reclassified and MAY NOW BENEFIT from treatment.
Currently, younger men with about 50% of their biopsy cores involved with cancer MAY be considered for treatment. However, the basis for this management in younger men is disputed as it is believed that the Gleason 3+3 does NOT have metastatic potential and is therefore a pseudo cancer. However, greater volumes of 3+3 may have associated 3+4 which was undetected or may have a greater propensity to upgrade to a 3+4 which may have metastatic potential.

Benefits of active surveillance for favorable-risk Gleason 3+3:
> knowledge that the Gleason 3+3 takes 20 years or more to manifest itself
> that the Gleason 3+3 is NOT life threatening
> that the Gleason 3+3 does NOT appear to have significant metastatic potential
> most men die WITH their Gleason 3+3 prostate cancer NOT from it

Risks of active surveillance for Gleason 3+3:
> anxiety and fear
> additional biopsies, although risks of biopsy are less than risks of OVERTREATMENT
> possibly underestimating Gleason grade

CLOSER active surveillance monitoring MAY be more appropriate for,
> younger men
> very healthy men with no comorbidities and at least 20 years of life expectancy
> those with about 50% or more of positive cores
> those with Gleason 3+4
> those with perineural infiltration (possibly)
Once we have RELIABLE tissue and circulating BIOMARKERS that can predict progression of a prostate cancer reliably we may be able to select out those men that require very close surveillance and or treatment of their prostate cancer. The PTEN histochemical study of the prostate cancer cell's DNA can suggest a more aggressive prostate cancer if both copies of the PTEN protein are missing.

ACTIVE SURVEILLANCE PROGRAM for FAVORABLE-RISK 3+3 or small volume 3+4 PROSTATE CANCER
a) First 12 months of Active Surveillance AFTER initial prostate biopsy
> confirmation needle biopsy of the prostate at about 6-12 months after the initial biopsy including additional biopsies of antero-lateral areas/distal apex of the prostate and any areas suggested on a multi-parametric 3T MRI (more so when the MRI becomes more reliable at detecting SIGNIFICANT prostate cancers).
If this REPEAT needle biopsy of the prostate at about 6-12 months shows NO real

worsening in percentage of positive core volumes or number of cores involved or significant percentage upgrading with a Gleason 4, active surveillance can be continued.

b) Ongoing Active Surveillance for STABLE Favorable-Risk 3+3 prostate cancer

About 80% of T1c stage favorable-risk Gleason 3+3 disease does NOT appear to progress significantly and does NOT appear to have metastatic or spreading potential. Stable favorable-risk 3+3 disease is NOT a health risk.

Most prostate cancer treatments are of greater health risk than the Gleason 3+3 cancer presence.

Subsequent active surveillance monitoring AFTER a STABLE REPEAT BIOPSY at about 6-12 months includes;

> PSA kinetics every 6 months.

> PSA density every 6 months or so.

> DRE yearly.

> depending upon PSA doubling time and PSA density, previous prostate biopsy findings, ethnicity and family history, a possible repeat prostate biopsy every 2-5 years or longer after that second confirmatory biopsy, may be reasonable. The prostate needle biopsies may be more frequent depending upon the extent of disease at the confirmatory biopsy, PTEN findings or PSA doubling time as well as any new BIOMARKERS which can predict reliably, disease at risk for progression of cancer.

TRIGGER POINTS INDICATING POSSIBLE NEED FOR TREATMENT

This may occur in 20% or less of men on active surveillance for Gleason 3+3 disease. Since the Gleason 3+3 grows very slowly active surveillance is not an immediate health risk.

Risk is associated more with high volume Gleason 3+3 where grade 4 cancers may have been missed in the biopsy or have mutated and upgraded from a Gleason 3+3.

If, after a period of active surveillance there is,

> a decrease in the PSA doubling time (shorter time for PSA to double, usually under 2 years suggests progression of cancer),

> an increase in the PSA density >0.15,

> development of a prostate nodule on DRE,

> new reliable technology and biomarkers which can indicate reliably those prostate cancers that have the potential to progress, then another needle biopsy of the prostate should be considered.

Treatment is suggested for those men where their Gleason 3+3 shows the following changes on a repeat biopsy:

> about 50% or more biopsy needle cores involved with tumor,

> increased tumor volume within the cores,

> a new finding of a greater than 10% Gleason 4,

> a new finding of perineural infiltration and/or significant involvement of the apex of the prostate, or new biomarkers/MRIs able to detect reliably, significant prostate cancer disease at risk for progression.

TREATMENT OPTIONS IF LOCALIZED FAVORABLE-RISK Gleason 3+3 CANCER PROGRESSES

The pervasive overtreatment of Gleason 3+3 prostate cancer and the great harm created by misguided treatment, in the absence of any benefit, has been well documented.
The treatment of favorable-risk Gleason 3+3 prostate cancer that has progressed or upgraded can be undertaken with non-invasive or minimally invasive methods. All treatment options MAY be curative but, in addition, will likely lead to infertility.
There is NO PLACE for high-risk, irreversible surgical or robotic prostatectomy.

NON-INVASIVE TREATMENTS

These are identical to those described above for treatment of high-risk prostate cancer but usually without ADT.
> focused stereotactic body radiotherapy (SBRT) over about 5 days
> intensity modulated radiation therapy (IMRT) over about 5 weeks
> proton beam over several weeks

MINIMALLY INVASIVE TREATMENTS

Utilizing outpatient general or regional anesthesia.
> brachytherapy (radioactive "seed" implants)
> hifu (High Intensity Focused Ultrasound, undergoing FDA trials in the US but available in most other countries) SONACARE in the US
> cryoablation (freezing)
> interstitial laser thermotherapy
> radiofrequency ablation (RFA)
> microwave coagulation
> vascular targeted photodynamic therapy (VTPT)
> irreversible electroporation (IRE)

HOW to MAKE a CHOICE FOR NON-INVASIVE or MINIMALLY INVASIVE TREATMENT OPTIONS

Since the survival benefits for all of these treatment options listed above for favorable-risk Gleason 3+3 prostate cancer are similar, how do I make a choice?
> time frame for treatment; radiation can take several weeks versus one minimally invasive option performed under an outpatient anesthetic
> radiation options are not delivered focally but to the total prostate
> complications tend to be less in focal rather than in total prostate treatment

FOCAL TREATMENT versus TOTAL PROSTATE TREATMENT

Focal treatment of prostate cancer has been considered the male equivalent of the breast "lumpectomy".
The following technologies are available for focal prostate cancer therapy:
i. hifu (may also be performed as total ablation) (see http://www.hifurx.com)
ii. cryoablation (may also be performed as total ablation)
iii. interstitial laser therapy
iv. others such as irreversible electroporation (IRE) and vascular targeted photodynamic therapy (VTP) are treatment options offered uncommonly and only in a few centers.

Possible Advantages of Focal Prostate Cancer Ablation

> focal therapy can be performed as an outpatient in one treatment.
> focal treatment focuses on the index (main) lesion and downsizes or ablates this main area of cancer while ignoring the insignificant satellite cancers in the prostate.
> focal therapy preserves part of the prostate to allow some ejaculation which may be important, especially for younger men.
> focal therapy is able to preserve at least one or possibly both neurovascular bundles to preserve erections.

Possible Disadvantages of Focal Prostate Cancer Ablation

> most prostate cancers are Gleason 3+3 and MOST do not need treatment.
> focal treatment may require more intensive PSA kinetics follow-up, possible repeat imaging and possible future needle biopsies of the prostate.
> possible incomplete treatment and need for retreatment

Although 75% prostate cancers are commonly multifocal with several cancerous areas of involvement in the prostate (5-7 areas), the largest of these tumors (and probably the most significant cancer) is called the index lesion. It is this index lesion that is believed to have the potential for progression and spread (unlikely with favorable-risk Gleason 3+3) but not the cancerous satellite lesions. A tumor volume of 0.5 mls or so is believed to be SIGNIFICANT (although some believe a significant tumor volume can be smaller) as estimated from an imaging study such as the multi-parametric 3T MRI (but not always reliable) and the histological grade obtained from a targeted needle biopsy of this prostatic lesion (subjective). The most graphic example of an index lesion is the prostate nodule found in a stage T2 prostate cancer.

Location of Cancer within the Prostate affecting Minimally Invasive Total and Focal Treatments

Because of the proximity of the apex of the prostate to the urethral sphincter and the potential for treatment damage here and causing urinary incontinence, delivering focal hifu or cryoablation at the apex may be difficult to achieve completely. Too much therapy may compromise the urinary sphincter while too little therapy will result in

incomplete prostate cancer ablation. Minor involvement of the apex with prostate cancer can be treated more accurately using hifu than cryoablation.

The apex of the prostate represents a smaller cross-sectional area than the rest of the prostate and many cancers originate here and especially in the distal apex or, show an extension into the the distal apex. The inferior pedicle of nerves and blood vessels to the prostate penetrates the apical prostatic region directly. This pedicle can facilitate perineural cancer infiltration although this issue is believed to be less significant than previously thought. Also, the apical area is devoid of any covering fascia anteriorly and this fact may facilitate direct cancer spread into the membranous urethra and sphincter and prevent minimally invasive options from treating significant apical cancers completely. Men with significant apical disease are likely to have the apical margins of their prostate involved with cancer so with these findings they should be considering one of the non-invasive radiation options which may be able to treat the cancer adjacent to the sphincter more completely than a minimally invasive treatment option.

Prostate Size Constraints affecting Minimally Invasive Total Treatments

In order for total prostate ablation with minimally invasive options to be successful, some treatment options have prostate size constraints and to some extent also, the shape of the prostate can influence treatment success. The following are approximate prostate size maximums above which treatment may be imperfect.

a. about 60 gms for brachytherapy
b. about 60 gms or less for total cryoablation
c. about 40 gms or less for total hifu

Focal therapy is less likely to be affected by prostate size.

Controlling or downsizing your prostate to a smaller size/volume or TEMPORARILY HALTING the possible progression of your prostate cancer is quite feasible as the prostate and prostate cancer are very responsive to hormone (testosterone) manipulation.

Therefore, if a man chooses to hold up on a definitive prostate cancer treatment temporarily or his prostate needs to be downsized to a more optimal size, he can be given a course of androgen deprivation therapy (ADT) to control not only the prostate cancer but to shrink his prostate to a more manageable size. He may choose this course for a period of months or one or two years.

Downsizing the prostate to accommodate some of these minimally invasive treatment options can be accomplished easily MEDICALLY, through ADT and the periodic administration of an agent such as lupron (and possibly along with avodart) or, SURGICALLY under an outpatient anesthetic using a bipolar vaporization technique. Prostate size can be monitored with periodic ultrasounds. Surgical downsizing may be preferable to ADT for most younger men because of the potential side effects from ADT, ie symptomatic side effects, mood swings, hot flashes (these can be counteracted by other medications), weight gain, and specific side effects of gynecomastia, shrinking

genitals, hair loss (pubic and underarm), erectile dysfunction, weight gain along with long-term problems of bone loss and cardiac disease. On the other hand, surgical downsizing is immediate and will lead to a better urinary flow but, retrograde ejaculation and infertility.

INVASIVE SURGICAL TREATMENT OPTIONS CANNOT BE RECOMMENDED

These include the following operations;
i. conventional retropubic radical prostate surgery
ii. perineal radical prostatectomy
iii. laparoscopic prostatectomy
iv. robotic prostatectomy

Why is Radical Surgery/Robotic Prostatectomy NOT Recommended? Mayhem and Gore.

Despite surgery having been offered to treat prostate cancer since 1905, it has failed the most fundamental premise of a cancer operation and that of saving significant numbers of lives at acceptable risk (Why Should the after effects of some Prostate cancer Treatments be worse than the Disease Itself?). In fact, the rampant and unnecessary treatment of favorable-risk Gleason 3+3 with surgery sets the stage for overtreatment malpractice.

On all counts the radical surgery/robotic prostatectomy FAILS:
1. to save significant numbers of lives of those treated for localized prostate cancer,
2. causes great and often, lasting harm,
3. fails to preserve erections reliably because of the overly simplistic nerve-sparing technique,
4. because of its many complications impacts negatively, men's quality of life and manhood.

That these graphic failures in post-treatment accountability have not pricked the conscience of most urologists is appalling. Instead of acknowledging these suboptimal results that are obvious even to the uneducated, urologists continue to obfuscate the real findings related to this ill conceived surgery and its misguided FDA endorsement. Even more misguided are the false and pseudo scientific recommendations of surgery for:
> locally advanced prostate cancer,
> aggressive or high-risk prostate cancers,
> prostate cancer found in younger men or,
> salvage prostatectomy after failure of other prostate cancer treatments.

POST PROSTATE CANCER TREATMENT MONITORING and FOLLOW-UP

You, your family and your medical team will want to see you remain in good health and will monitor your progress after your focal or total prostate cancer treatment.

Your particular prostate cancer, as well as its risk level, can assist in determining somewhat the effectiveness of your treatment as well as the frequency of post-treatment monitoring that may be necessary. There is always a possibility that the prostate cancer risk level was somewhat greater, or that the cancer was not completely eradicated. Prostate cancer recurrence means usually that your particular prostate cancer did not respond completely to the type of treatment you undertook. Detecting a recurrence/residual/incompletely treated prostate cancer early, in some situations, can provide a man a second chance to undergo an alternative definitive treatment.

The most important and fairly reliable test undertaken in your monitoring to ensure that treatment was adequate is the PSA test. This should be performed every 6 months or so. The DRE is not so accurate after a treatment and as long as the PSA remains stable, can be dispensed with.

WHEN ARE YOU CURED FROM PROSTATE CANCER?

It is impossible to pinpoint a time to know when a man is in "remission", "cured" or is a "survivor" from prostate cancer.

However, you can be a survivor and still have prostate cancer return and, you can be in remission but have the cancer return. That is why there are many, many interpretations of a prostate cancer survivor but this MAY NOT mean the man is permanently cured from his prostate cancer. Every man has the right to define his own meaning of what it means to be a survivor.

Generally, the Gleason 3+3 prostate cancer cell is a very slow growing cancer cell and tends NOT to have any metastasizing potential. It may be 20 years or more before there can be any talk of "cure" or of being a prostate cancer "survivor". In fact, many "cured" men have undetectable slow growing residual or recurrent prostate cancer but they, and their urologists are unaware of its existence. Furthermore, many preposterous claims of "95% cure rates" are nothing more than fiction because treatments consisted mainly of those with Gleason 3+3 disease, the majority of whom would have a 95% "cure" without any treatment. Furthermore, because of the constant advances in technology, it is ludicrous to attempt to compare so-called "cures" within the same technology let alone between differing technologies.

The best measure of treatment control (rather than success or cure) is the stability of the PSA.

After treatment there should be a fairly steady drop in your PSA.

Certain terms require explanation:

> nadir. For the PSA, this represents the lowest level reached after treatment.

After the misguided surgery, the PSA will fall to 0.2 ng/ml or less, except in the 20-40% of men who have positive margins or residual cancer after their prostatectomy when the PSA will begin to climb at some time.

After radiation, it can take 1-2 years for the PSA to reach its nadir, usually below 1 ng/ml.

> radiation bump/bounce. After radiation, there may occur a temporary phenomenon called a PSA “bump” or “bounce” which is manifested by a small rise in PSA some 6-24 months after treatment (usually below 1.5 ng/ml) and is thought to be due to an inflammatory response in the prostate.
After a minimally invasive procedure, the PSA nadir may be higher, especially for those men who underwent a focal or subtotal treatment where residual untreated benign prostate is still producing PSA.
If the exact reason behind an elevated or rising PSA after a treatment is unclear, you may need a prostate biopsy to verify the absence of residual or recurrent disease, or incomplete treatment. Incomplete treatment does not always mean the cancer was not completely treated but that some of the cancer cells were able to withstand the treatment.
Faster PSA doubling times (taking less than 2 years to double) can be more significant in terms of prostate cancer recurrence and progression.
> biochemical recurrence. This is an indifferent way of saying that your rising PSA indicates the presence of residual or recurrent cancer but its location cannot be determined as current imaging techniques are unable to identify small areas of tumor. However, for most men, a persistent slowly rising PSA after treatment means that prostate cancer cells are growing somewhere.
The definition of a meaningful rise in PSA from your nadir depends upon the definition used. Here we see a variety of definitions in prostate cancer management and various organizations (ASTRO, PHOENIX and STUTTGART) have all decided arbitrarily on different PSA levels for what defines a significant rise in PSA after treatment.
> no clinical evidence of disease. This may or may not mean you are cured as you can have no CLINICAL evidence of disease but have small recurrences somewhere and your PSA may or may not be elevated. Again, most prostate cancer cells take a year or two to divide so a treated man can be free of disease until 20-30 years later.
> zero PSA progression. This is another term designed to be meaningful and offer comfort when in reality it is the same as no clinical evidence of disease.

PSA RISES AND POSSIBLE TREATMENT FAILURE - ALL IS NOT LOST

Treatment failure is possible and is usually signalled by a rising PSA.
A rising PSA within the first 18 months or so after a radiation treatment may simply represent a radiation “bump or bounce” described above and should slowly settle and return to its baseline without any intervention required.
Treatment failure may not be apparent until 20 years or more after treatment because of an upgrading of a slow growing grade 3 to a grade 4 which does have metastatic potential. Men with high-risk Gleason 4+4 or greater, prostate cancer may present with PSA rises earlier.
However, sometimes PSAs may not reflect the true situation within the prostate as high-risk prostate cancers or prostate cancers that have upgraded to high-risk, may not reflect much of a PSA rise, and you may need to have your prostate re-biopsied sooner than later to ensure that there is no recurrent prostate cancer

which could benefit from another definitive treatment such as hifu or cryoablation. Your knowledge regarding these alternative treatment options of hifu and cryoablation is important as most urologists are untrained in these technologies and will fail to offer them or refer you to a urologist trained in these minimally invasive prostate cancer treatment techniques. If a retreatment or an alternative definitive therapy is being considered, you should not wait for the PSA to rise much more than about 1.5-2 ng/ml, but undergo a needle biopsy of the prostate to detect early, residual or recurrent organ-confined disease that may benefit from cryoablation or hifu treatment.

A failure of the PSA to drop below about 0.5 ng/ml or seeing your PSA creeping back up from its nadir may mean residual and or recurrent prostate cancer. However, if your prostate cancer was treated focally or subtotally, the remaining untreated prostate tissue will produce a small amount of PSA so this rise or return of PSA may not indicate residual or recurrent cancer but is simply a reflection of the remaining benign component of the prostate.

If there is concern for a possible cancer recurrence because of a rising PSA, a prostate needle biopsy of the prostate is much more important than an imaging study. It is important to understand once more that if your PSA is under about 15 ng/ml or so, all of the current imaging studies like CAT scans, bone scans, ProstaScint scans and sodium fluoride PET scans are not going to be helpful as they are just not sensitive enough to detect microscopic amounts of cancer. For these studies to be able to detect prostate cancer spread, the PSA needs to be about 15-20 ng/ml. Even multi-parametric 3T MRIs are still unreliable for detecting significant or recurrent disease within the prostate.

SECONDARY TREATMENT OPTIONS FOR RESIDUAL/RECURRENT PROSTATE CANCER

Unfortunately, some 40% or so of men treated for “localized” prostate cancer may require further treatment because of residual or recurrent prostate cancer. Since this cancer may not manifest until years later, it is important to continue life-long PSA follow up with your doctor after your treatment. Generally, your recurrent prostate cancer grows slowly and has NOT beaten you.

Although there are two types of prostate cancer recurrence

1. local recurrence
2. metastatic recurrence which can be either hormone sensitive or hormone resistant/refractory (castrate resistant).

The ADT drugs for prostate cancer that is still hormone sensitive are very effective as well as being cost effective. However, the same cannot be said for the medications used for hormone/castrate resistant prostate cancers.

These drugs are associated with some very creative marketing and come at extraordinary cost but predominantly, false hope and marginal effectiveness. (www.theprovengetrials.org/) In part, these drugs have been allowed to come to market because of a lowering of the bar by the FDA.

We will discuss only LOCAL RECURRENCE.

LOCAL RECURRENCE of Prostate Cancer after a Previous Definitive Treatment

Although it can be very difficult to ensure that an elevated PSA after a treatment represents a true local recurrence within the prostate only and not early metastatic disease, PSAs under 2 ng/ml may be considered as being due to a local recurrence and worthy, possibly, of investigation and treatment with an alternative treatment option.

In a man with a rising PSA after treatment, a needle biopsy of the prostate is the only definitive way a residual or recurrent prostate cancer (believed to be localized) can be detected.

> men who have been unfortunate enough to have had a prostatectomy (20-40% of men who chose to undertake the misguided surgery will have positive margins or cancer left behind). It is reasonable to perform a DRE to see if there is a nodule present in the prostatic fossa which can mean a local recurrence of the cancer. If the needle biopsy of this nodule confirms a recurrent/residual cancer, HIFU, radiation or proton beam are reasonable treatment options. Brachytherapy/seeds or cryoablation are unsuitable treatment options for local prostatic fossa recurrences after radical surgery/robotic prostatectomy as these treatments are unsafe with small volume prostate fossa cancer recurrences.

> residual/recurrent localized prostate cancer diagnosed on a needle biopsy after radiation/brachytherapy (seeds) or proton beam may be treated with hifu or cryoablation.

DO NOT EVER consider the unproven salvage prostatectomy as it will leave you debilitated.

> residual/recurrent disease diagnosed on a needle biopsy of the prostate after hifu may be retreated with hifu, cryoablation or radiation/proton beam or brachytherapy.

DO NOT EVER consider the unproven salvage prostatectomy as it will leave you debilitated.

> residual/recurrent disease diagnosed on a needle biopsy of the prostate after cryoablation may be retreated with cryoablation, hifu or radiation/proton beam or brachytherapy.

DO NOT EVER consider the unproven salvage prostatectomy as it will leave you debilitated.

> residual or recurrent localized disease diagnosed on a needle biopsy of the prostate after any definitive treatment option involving a patient with high-risk disease is likely to benefit from ADT for at least two years in addition to one of these second line treatments like cryoablation or hifu if the disease is still truly localised.

Men who do not desire further treatment of their recurrent prostate cancer may opt for a course of watchful waiting or a course of intermittent ADT with an agent such as lupron and monitoring the PSA periodically.

Importantly, all men diagnosed with prostate cancer need to understand their particular prostate cancer with knowledge of their treatment options and management along with

their desires for lifestyle and quality of life. As well, they need to understand that most urologists are unable to offer all of these minimally invasive treatment options.

SQUANDERED HEALTHCARE DOLLARS and QUESTIONABLE TREATMENTS

The extraordinary consumption and waste of taxpayer money in the name of modern US healthcare is not only unconscionable but is financially unsustainable. Unfortunately, most of the draw on the vault for healthcare dollars is initiated by physicians who are front and center for the ordering and dispensing of US healthcare. They are, therefore, responsible for most of the drain on precious healthcare funds.

Recently, the Institute of Medicine (IOM) reported that:

> the US healthcare fee-for-services model spent 2.5 trillion dollars or 18% of GDP and rising,
> wasted at least 765 billion dollars (30% of all medical expenses) for NO health benefit,
> wasted 210 billion dollars on unnecessary and inappropriate testing and treatments,
> resulted in at least a fifth of the patient load being readmitted to the hospital within 30 days of "treatment" and,
> harmed a significant number of citizens in the name of "healthcare" and "treatment" and,
> killed at least 98,000 people. Shockingly, it is estimated that some 50% of physicians wash their hands rarely, if at all, during patient interaction.
> the US is now ranked 19th in the world for preventable deaths.

Fundamentally, it is the problematic US healthcare fee-for-services payment model for physicians which induces unbridled incentivising for intervention rather than incentivising for prevention and quality. Like the salivating Pavlov's dog anticipating another reward, physicians have learned that the more you do, whether good or bad, whether right or wrong, you still get rewarded financially. The US healthcare fee-for-services model is essentially unchecked, without meaningful oversight or recourse for sub par health and care, and without significant ties to prevention, quality and outcome. Such an open door policy to financial rewards allows also treatment abuse.

Physicians Accelerate Consumption of Healthcare Dollars through:

> performing unnecessary treatments
> overtreatment of patients
> retreatment of patients
> using scientifically unproven treatment or treatments lacking evidence based medicine support
> defensive medicine
> ownership in medical companies or equipment
> upcoding

This unbridled consumption of healthcare dollars is due solely to the fee-for-service

model which has induced physicians to stray from the practice of medicine bounded by ethics, patient advocacy, evidence based medicine data and health building towards a greater focus on wealth building. (The Imperfect PSA, the fraudulent robotic prostatectomy and medical ethics) This wealth building focus by many physicians has not only led to patients now being seen as revenue streams but has also led to a greater use of pseudoscience to justify unworthy or scientifically unproven treatments simply to fool and exploit the public. Although the alternative medicine and paramedical fields are filled with junk science, misrepresentation and misinformation, some physicians and scientists have now stooped to using the same pseudoscience arguments and conjecture to advance the cause of their drug, treatment or procedure. Just like the financial industry required truth-in-lending laws, the medical and especially the pharmaceutical industry, are in very desperate need of laws to corral the flagrant use of half truths for capitalizing on false hope.
Shameless lying and the concealing of conflicts of interest along with a total absence of reportorial neutrality and balance simply to mislead and to promote the illusion of truth, correctness and consensus has infiltrated and tainted all forms and levels of media, judiciary, education, business, virtually all professions and agencies. In addition, the pervasive intent to misconstrue and the quests for purposefully dumbing down, lowering of the bar and the striving for mediocrity on nearly all matters by these players including Government, has resulted in the erosion of previously recognized and accepted elevated standards for normalcy, achievement, behavior and conduct. Shockingly, these lower standards for behavior and conduct are now seen as usual and customary, desirable, and without engendering embarrassment or remorse, even in the so-called educated. In fact, many individuals and agencies have the gall now to defend their questionable character, honesty, seedy practices and conduct, with righteous indignation when challenged.

The healthcare vault is huge, but when overall costs to the public of unnecessary and scientifically unproven treatments are added to the cost of treating complications, retreatments, time away from work and debilitation, the costs are staggering. Relying on physicians and their various Boards along with the Code of Ethics (which like healthcare may be an oxymoron) and the Hippocratic Oath to guide physicians to do the "right thing" and control financial waste is quite naive. Real change in physician's behavior towards seeing patients as revenue streams will come only from the placement of serious financial barriers, treatment accountability measures, oversight and recourse, at the feeding trough for these healthcare dollars. The need for these financial barriers and sincere oversight has been made even more urgent recently because of a huge rise in questionable radiation treatments for men with low-risk prostate cancer by urologists since their practices were purchased and incentivised by radiation companies. Although these referrals for radiation can represent overtreatment and a conflict of interest, the pervasive medical practice of performing unnecessary procedures is in part a response to the longstanding, unsavory and cryptic battle between physicians who are unfairly reimbursed for real services and the insurance industry gaming the system with

unconscionably discounted fees for services along with reprehensible disbursement withholding practices.
Furthermore, Health Insurance Companies have long figured out that by making most aspects of health and care require an authorization and by making these authorizations stupefyingly onerous, they can make doctors and patients give up their quest and therefore save the insurance companies a lot of money that they would have otherwise spent on health and care. The following represent some of the common and offensive practices adopted by the Health Insurance Companies on the pretext of "managing" health and care.
> requiring referrals to see physicians,
> requiring authorizations for generic medications,
> denial of generic medications in amounts greater than 1 months,
> requiring authorizations for common evaluations,
> requiring authorizations for common treatments,
> classing certain costly treatments as "experimental" simply to deny funding,
> appeals processes designed to generate denials again.
The Health Insurance Companies receive substantial amounts of tax dollars to dispense funds for health and care and it is galling that that these well known schemes practised by most, if not all, insurance companies continues without real oversight or recourse. There are many other well known schemes and tactics practised by Health Insurance Companies for the sole purpose of delaying or preferably, denying payments while those seeking health and care are sandwiched somewhere between two of the main players in healthcare. While healthcare is rife with waste and over treatment, the Health Insurance Industry is rife with conflicts of interest and self serving "rules" to control disbursements because of the Industry's allegiance to shareholders.
The unconscionable waste of funds generated by physicians as well as the Health Insurance Industry's unconscionable manipulation of funds reserved for needed healthcare will result in less money to provide for more and more real patient need and will lead to the dispensing of marginal, rationed, or even worse, denial of care. The strategies to corral this terrible abuse and waste of healthcare dollars and return the healthcare budget to financial sustainability are well known but never enacted. Government and the healthcare industry have simply lacked the leadership and the fortitude to implement these very important steps for true patient advocacy.

The corrective strategies for controlling healthcare spending must include:
> penalizing physicians for intentionally undertaking unnecessary services,
> penalizing the insurance industry for its outrageous and discriminatory individual health policy pricing,
> penalizing the insurance industry for withholding disbursements for services and care,
> penalizing the insurance industry for its gaming and false attempts at seeking presence of preexisting conditions, other insurances or workers comp. details,
> eliminating payments for scientifically unproven treatments,

> better financial and auditing control on costs of goods and services,
> competitive bidding by pharmaceutical companies in order to supply drugs,
> prevention of duplicated services, inefficiencies, errors and defensive medicine,
> prevention of administrative waste (including that from so-called gatekeepers and HMOs and now, ACOs) and,
> better fraud detection.

The following are some additional corrective strategies that need to be enacted in order to wall off wasteful spending and prevent future rationing of US healthcare :
> disallow any influences on Government bodies by lobbyists,
> adopt only screening methods proven scientifically to be beneficial,
> adopt only testing methods proven scientifically to be beneficial,
> make all Medical and Surgical Boards accountable for adopting and endorsing guidelines for evidence based medicine proven treatments only,
> have all Medical and Surgical Boards, FDA, IRB's, CMS, and all medical insurance companies use identical platforms for testing and treatment approvals and funding,
> removal of all procedure codes from reimbursement schedules not scientifically endorsed through evidence based medicine,
> reform pharmaceutical pricing, supply, patent approvals and control drug shortages,
> make pharmaceutical media marketing illegal,
> make many more medicines available without requiring doctor's prescriptions,
> make marketing of scientifically unproven treatments and procedures illegal,
> reform insurance industry on many fronts as well as disallowing collusion amongst insurers,
> tort reform,
> create special health courts for malpractice issues,
> have all patients accept some responsibility.

The recent Government implementation of some healthcare reform through the Affordable Care Act (ObamaCare) and the goal of providing "affordable" care for another 20 million people was laudable. However, somewhat incongruous, is the issue that Government now, as a recognized leader in inefficiency and wasteful spending of taxpayer dollars, desires to make health and care more "affordable", not so much by cutting the extraordinary waste in healthcare spending, but by increasing the size of the healthcare vault by raising taxes again. Raising taxes to channel more funds into the bottomless healthcare money pit without seeking serious financial accountability measures and cost restraints from the insurance, pharmaceutical, biotech and legal industries is NOT the solution and will not make US healthcare safer or more affordable. Unfortunately, without sincere and significant remodelling for accountability measures applied by Government to all of the many players in the healthcare industry and not just mainly physicians, this current attempt at healthcare reform will result in only partial healthcare reform and therefore, no substantive healthcare reform at all. About the only change the current attempt at reform will

achieve, and without significant cost savings, is to drive physicians away from more profitable entrepreneurial positions to salaried positions and unionization.

Making healthcare more affordable for the public then, is much more about the need for cutting the inefficiency and wasted revenue in healthcare than simply penalizing physicians and raising taxes to allow business as usual. We cannot afford business as usual nor allow real healthcare reform to be skewered constantly by self interest groups and their lobbyists (who even have a hand in writing the bills) leaving the public with only a representation of what could have been real healthcare reform. Instead, we are still left with a reform influenced by various healthcare industry conflicts of interest married to a Government weak in decisiveness, direction and also ethics. In fact, aside from the hypocrisy of Government pretending to be serious about cutting inefficiency and waste, the irony of the new affordable care is, and is likely to remain, an affordability of care not based upon healthcare being safe and cost effective for all but because this "reformed" healthcare is now again budgeted, dispensed marginally, rationed, or still denied but available to greater numbers of the public. This sort of healthcare is already experienced by many of the particularly financially challenged public through their interaction with the grossly inefficient and shameful Medicaid, and the amoral HMO capitation programs controlled by their insurance companies along with their physician "gatekeepers".
This "affordable" budget-style healthcare represents a level of care only slightly above the indifferent healthcare received by the self-pay public and those folks who can only find care and treatment in an emergency room. Furthermore, those folks in capitation programs, clinics or emergency rooms may not even get to see a physician and this situation is highly unlikely to change with the new, but flawed, accountable care organization (ACO) concept. A concept that is simply an updated version of HMOs and like HMOs, turns a blind eye to the conflicts of interest which allow cost and care shifting to make this care more "affordable". In reality, affordable care in whatever form remains a healthcare stratification based upon one's ability to afford healthcare. This stratification of healthcare access based upon ones ability to pay for some form of health insurance ("ObamaCare" after an additional tax and, not all insurances are equal), underscores the absolute injustice of being financially challenged. Poverty, or relative poverty, is a most despicable barrier to real and equal healthcare for all, especially for those with medical problems outside of their control, but even more, because the solutions to fund this care through minimizing healthcare dollar waste without the need for additional taxes are well known but never enacted.

Urologists and Over Treatment

Although the history of medicine has recorded many amazing discoveries and advances there are some equally disturbing examples where decisions made by egotistical physicians caused incredible harm and the tarnishing of the trust between doctor and patient. Some of this so-called medical care like the radical mastectomy continued unchecked and unchallenged for many, many years.

For a more current example of medical misadventure recording indelibly physician's departure from medical ethics and medical care accountability fundamentals is the prostate cancer industry and its treatment of localized and often, low or favorable-risk prostate cancer with the ill conceived radical surgery/robotic prostatectomy. Such failures in medical treatment accountability by physicians simply open the doors for those who will challenge and demand the need for corrective action. Recently, the USPSTF was concerned enough about PSA screening for prostate cancer to issue a warning to physicians and the public on two occasions now (US Preventive Services Task Force, screening for prostate cancer) while the legal profession, recognizing the obvious harm associated with the radical robotic prostatectomy, has begun a class action lawsuit against the robot makers. This legal wrangle however, may be somewhat misguided as the underlying problem is not with the robotic technology for prostatectomy but with the ill conceived surgical excision of the prostate itself.

Shamefully, there are historical parallels between the misguided radical breast surgery for cancer and the radical prostate surgery for cancer. The harm and negative quality of life resulting from both of these surgeries has never really been acknowledged or adequately addressed by most physicians. In fact, both procedures were conceived by a pair of Baltimore surgeons in the early 1900s but instead of saving many lives at acceptable risk, these two procedures have caused great debilitation in millions of men and women across the world, simply because of the very powerful but dangerous mix of surgeon's egos and ineffectual treatment outcome accountability measures. The disservice to mankind is incalculable.

Consider the following for prostate cancer screening and robotic surgical treatment:
> blatant marketing of falsehoods by hospitals, physicians and equipment makers,
> widespread misinformation and misrepresentation,
> creative reporting of treatment benefits and results,
> pervasive exploitation of men because of the misguided fear for prostate cancer,
> absence of evidence for any benefit from wholesale PSA screening,
> manipulation of men made emotionally vulnerable by the word cancer,
> pervasive unnecessary treatment of low or favorable-risk prostate cancer,
> continued endorsement of the scientifically unproven radical surgery/robotic prostatectomy,
> significant incidence of retained cancer after radical surgery/robotic prostatectomy,
> shameful explanations for residual prostate cancer after surgery as a treatment being a 2-step treatment process of surgery with radiation,
> significant incidence of debilitating complications,
> significant incidence of surgical treatments necessary to correct the complications of radical prostate surgery,
> absence of significant numbers of lives saved,
> absence of evidence based medicine support data,
> absence of scientific surgical treatment outcome accountability measures.

Amazingly, there has been recognition, finally, by the urology community that most favorable-risk Gleason 3+3 prostate cancers are overtreated. However, the same recognition has not been sparked for the misguided radical surgery/robotic treatment option for prostate cancer where there is still an absolute inability for most urologists to reconcile the great harm and debilitation generated by this surgery along with its failure to save significant numbers of lives. Although this appalling lack of scientific treatment accountability has plenty of historical precedent in medicine, another unpalatable issue, that of physicians closing rank when egos and treatment philosophies are challenged, is also well known and well recognized. Such a recalcitrance on the part of physicians to reexamine a treatment where the premise of benefit was not realized will certainly ensure another embarrassing medical legacy. Prostate cancer surgery, which under the guise of healthcare dared to call itself standard-of-care while failing to save significant numbers of lives, harming millions of men around the globe and wasting billions of healthcare dollars, is shameful. However, any healthcare lacking in sincere and scientific treatment accountability protocols, like insincere healthcare reform and the flawed ACO concept, is abusive and harmful, will continue to squander billions of precious healthcare dollars and is much more than shameful, it is indefensible and amoral.

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About Bert Vorstman MD, MS, FAAP, FRACS, FACS

Dr. Bert Vorstman is a Board Certified Urological Surgeon with some 30 years of experience. He is Fellowship trained in Pediatric and Adult Reconstructive urology at the Eastern Virginia Medical School in Norfolk, Virginia, a former NIH sponsored surgeon researcher and a former Urology Faculty member at the University of Miami, Florida. He also earned the honor of a Masters of Surgery Diploma through the Otago University, Dunedin, New Zealand for pioneering research on Urinary Bladder Reinnervation using nerve crossover techniques incorporating nerve grafts. This technique could have possible application in patients with neurogenic bladders.
Dr. Vorstman is well published and has lectured nationally and internationally. He belongs to a number of organizations including the prestigious Societe Internationale d'Urologie.
Dr. Vorstman's passion and dedication is to help men and their spouses/partners understand fully their particular prostate cancer as well as the minimally invasive treatment options such as hifu and cryoablation for selected men with localized prostate cancer along with radiation/proton beam options for others with prostate cancer. In that regard he has developed a Center for Minimally Invasive Treatment Options for localized prostate cancer.
Dr. Vorstman has also developed a leading urology practice, Florida Urological Associates pa, was instrumental in developing the Coral Springs Surgical Center, www.coralasc.com as well as developing websites highlighting prostate cancer issues such as www.hifurx.com and www.urologyweb.com