Direct Access Testing

A Physician’s Perspective

Verlin K. Janzen, MD

Overview

- Do physicians have a view on DAT?
- Concerns / Risks
- Benefits – & to whom?
- Recommendations

What do physician's think about DAT?

- Professional Organizations
- 'Study' – AAFP State officer's listserv
  - 18 responses

Copyright © 2002 Creators Syndicate, Inc.

Informal ‘Study’

N = 18

- For (2), Against (7), Neutral (9)
- Aware of: Yes (8), No (7)
- Repeat Test? Yes (6), No (2), Depends (3)
- WB CT in Community: Yes (7), No (5)

Why do patients want DAT?

- First – do they want it?
  - ? Is/will advertising/marketing creating demand?

Why do patients want DAT?

- "Many health conscious individuals wish to have lab testing performed but want to avoid the inconvenience and expense of physician office visit."

  Henry Soloway, MD

- "Public is becoming better informed and are *capable* of taking responsibility for their actions"

  John Halsey, PhD

Why do patients want DAT?

- Patients have *seemingly* simple questions
  - Am I pregnant? Do I have AIDS? Have I taken too much Coumadin? Is my cholesterol too high? Will my drug test be positive?
- Convenience - easy access / rapid TAT
- Access - payor restrictions on testing
- Haven’t learned about / won’t accept EBM
- To verify accuracy of prior testing

Why do patients want DAT?

- "Anonymous is more than confidential"

  Dr. Halsey

  - HIV testing - why not use STD clinic?
    - stigma attached to being seen there
    - not 'anonymous'
  - Drugs of abuse
    - parents checking kids
    - pre-employment, pre-insurance
  - Concerns about insurance database
  - Concerns about employer finding out
  - Privacy for healthcare workers

CONCERNS

Concerns

- Are the tests necessary?
  - Is there any potential benefit?
  - Is there harm w/ unnecessary testing?
- Normal process w/ patient request
  - If necessary / reasonable – order
  - If not recommended – <u>discuss pros/cons</u>
    - Harm ≈ Benefit – probably order
    - Harm > Benefit – probably wouldn’t order

"We can't be absolutely certain until we run some tests, but your initial blood work indicates that you may have a large spear through your right shoulder."

Concerns

- Can clients of DAT lab be smart consumers of diagnostic tests?

"My thigh hurts. Could it be my thyroid?"

Concerns

- Can clients of DAT lab be smart consumers of diagnostic tests?
- Can they reliably interpret the results?
  - Clients are “anxious, educated, somewhat affluent”
  - “The public is becoming better informed”

? Cholesterol of 280 last yr vs 265 this yr
? What does the result mean for THEM?
? Can they understand / will they read handouts
? (-) preg test – could still be pregnant

TC 234 HDL 36 Trig 180 LDL 158

Patient	32 yo white male	52 yo white male	52 yo white male
Known CHD/ASD	No	No	No
Diabetes	No	No	No
Cigarette Use	Yes	No	Yes
Hypertension	Yes – 160 systol	Yes – 160 systol	Yes – 160 systol
… Treatment	No	No	No
FH prem CHD	Yes	Yes	Yes

10-yr CHD Risk	9%	12%	26%
LDL Goal / Rx	< 130 / > 100	< 100 / > 130	< 100 / > 130

TC 234 HDL 36 Trig 180 LDL 158

Patient	32 yo white male	52 yo white male	52 yo white male
Known CHD/ASD	No	No	No
Diabetes	No	No	No
Cigarette Use	Yes	No	Yes
Hypertension	Yes – 160 systol	Yes – 160 systol	Yes – 160 systol
… Treatment	No	No	No
FH prem CHD	Yes	Yes	Yes

10-yr CHD Risk			
LDLGoal / Rx			

Diabetes Screen

Learn ab
Health Con

QuickLook

Price $40.00

Results can provide information on or about your
- Sugar metabolism

This test requires
- Blood sample

Preparation for your visit
- Wear sleeves that roll up easily
- Fasting required 8 hours before your test

QuesTest™ panel includes
- glucose
- hemoglobin A1C, screening

This QuesTest™ panel is available at full service and purchase only locations.

Since when do you *screen* for diabetes with an A1c?

Will patient know what to do with A1c of 6.8 and blood sugar of 188?

Nutrition and Vitamin Panel

Lear
Health

QuickLook

Price $95.00

Results can provide information on or about your

- Blood health
- Cardiovascular health
- Immune system
- Iron metabolism
- Sugar metabolism
- Vitamin and mineral levels

This test requires

- Blood sample

Preparation for your visit

- Wear sleeves that roll up easily
- Fasting required 8 hours before your test

QuesTest™ panel includes

- vitamin B12
- folate
- calcium
- iron
- total iron binding capacity
- total cholesterol
- HDL cholesterol
- LDL cholesterol
- triglycerides
- glucose

When the patient receives report with calcium in the normal range, will they assume they don't need to take calcium for their osteoporosis?

Concerns

- Cost – to individual & system
  - Unnecessary tests / Evidence Based Medicine
  - Incidentalomas – false positives
    - Especially with large profiles
    - How will ‘anxious, affluent, educated’ react?
    - Cost ($, anxiety, worry, risk)
  - Frequent re-tests / churning
  - Will insurance eventually be forced to cover?

Concerns

- Bad news result
  - Response – denial, scared, suicidal
- Delayed Diagnosis – False Reassurance
  - False (-)
  - Wrong test
  - Wrong Reason
  - Fad tests

Concerns

- Unproven tests – Commercialism
- Advertising / Marketing
- Unscrupulous providers

- If there is $$ - there will be more labs
  - Competition – low margins – cut corners

http://www.health-tests-direct.com/reasons_for_blood_tests.htm

BLOOD TESTS? *WHY* GET BLOOD TESTS? *Here are FOUR very good reasons...*

Very good reason #1: "You have SYMPTOMS of an illness." Weight loss that is sudden, headaches that are constant, continued low energy levels, skin sores that do not heal or heal too slowly...any one of these symptoms is a strong signal that your body gives you to let you know "something" is wrong with you physically. A blood test can tell you "what" is wrong! **It's *easy* to order your test by toll-free phone: 1-800-456-4647 x 207.**

Very good reason #2: "You have *NO* SYMPTOMS of an illness." Many diseases such as AIDS, and other *life-threatening* maladies like **heart disease**, **liver and kidney disorders** and numerous quite serious illnesses will often exist in your body *without* ANY symptoms for many *weeks* - and even exist for many *months* - long *BEFORE* symptoms become obvious to you...*or to your doctor!* Why on earth should you *wait* for "symptoms"? Check your body's health *today*...with a simple, inexpensive blood test. **Call us toll-free!**

Very good reason #3: "You want to know if you are PREGNANT." A *laboratory* test of a woman's blood can accurately determine pregnancy as early as 7 days after *conception*- and that is *as much as two weeks earlier* than a *urine* test (e.g., an "over the counter" home-test you get from a drug store) can reveal! Why wonder? Find out *sooner* and *more accurately* if you are pregnant...with a simple, low-cost blood test. **Call us!**

Very good reason #4: "PREVENTION. You just want peace of mind!" A *laboratory* can test your blood for *more than 5,600* different diseases, maladies, and your personal levels of very important and critically important vitals. Many individuals choose to routinely test their blood one to three times *annually* to ensure that their body is healthy and disease-free. *At the very least*, you should want to catch a potentially life-threatening illness well *BEFORE* it becomes an irreversible health *crisis* for you! A blood test may do just that (it's called PREVENTION). **Call us *toll-free*: 1-800-456-4647 x 207.**

Which are some of the more popular tests?
Our most popular test for first-time clients is the VIP PLUS. This test establishes a comprehensive foundation of all aspects of your health, upon which future tests can be measured. Once this baseline has been established, many clients use the SuperChemistry as a regular check of progress, and to monitor the effects of a change in diet, exercise, or lifestyle.
Back to Top

Why do I need a Complete Blood Count (CBC)?
A CBC is the most frequently performed lab test. It provides a great deal of information about the three kinds of cells in the blood - red blood cells, white blood cells, and platelets. It is most frequently used as a screening test, as an anemia check, and as a test for infection, but it is also used to aid in the diagnosis and treatment of a large number of other conditions. Included in the CBC are hematocrit, hemoglobin, red blood cell count, red blood cell indices, white blood cell count, white blood cell differential, and platelet count.
Back to Top

Why do I need a Thyroid Profile?
The thyroid is one of the most important glands in the body. This hormone regulates the metabolism of the body by increasing the rate of the reactions taking place in the body's cells. The test is used to evaluate the symptoms of excess (hyperthyroidism) such as unexplained weight loss, tremor, nervousness, rapid heart rate, diarrhea, or the sensation of always being too hot. Symptoms of too little thyroid hormone (hypothyroidism) are unexplained weight gain, tiredness, dry skin, or the sensation of always being too cold.
Back to Top

AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS
MEDICAL GUIDELINES FOR CLINICAL PRACTICE FOR THE EVALUATION AND TREATMENT OF HYPERTHYROIDISM AND HYPOTHYROIDISM

"The sensitive thyroid stimulating hormone (TSH or thyrotropin) assay has become the single best screening test for hyperthyroidism and hypothyroidism, and in most outpatient clinical situations, the serum TSH is the most sensitive test for detecting mild thyroid hormone excess or deficiency."

ENDOCRINE PRACTICE Vol 8 No. 6 November/December 2002 457

Address http://www.directlabs.com/CancerSafe.php

CancerSafe epMARKERS (back) $529

Why test with CancerSafe® MARKERS

In order to cover a large range of cancers,the CancerSafe test incorporates the main tumor markers that are available worldwide. Utilization of materials and reagents from experts Roche-Boehringer and Abbott laboratories, this test can look for breast, ovarian, lung, uterine, prostate, testicle, colorectal, pancreas, liver, stomach, and thyroid cancers.

The Pathologies and their tumor markers

Breast	CA-15-3; CEA; CYFRA 21-1
Ovary	CEA; CA 125; CA 19-9; AFP; BHCG
Uterine	SCC; CYFRA 21-1; CEA; CA 19-9; CA 125
Prostate	PSA; FPSA and ratio
Testicle	BHCG; AFP
Colorectal	CEA; CA 19-9; CA 125
Pancreas	CEA, CA 19-9; CA 72-4
Liver	AFP; CEA
Stomach	CA 72-4; CEA; CA 19-9
Esophagus	CEA; CYFRA 21-1
Thyroid	CEA; NSE
Lung	NSE; CYFRA 21-1; CEA; CA 125; CA 19-9
Bladder	TPA; CEA; CYFRA 21-1

Address http://www.directlabs.com/CancerSafe.php

Disclaimer

The "epMARKERS"® (CancerSafe) blood test is a screening for evidence of cancer in the bloodstream. By participating in this screening exam, you acknowledge that it is a prevention exam, the result of which does not in any way constitute a medical diagnosis. It is understood that this test is NOT a replacement for routinely recommended screening tests, including, but not limited to, mammography, colonoscopy/fecal blood testing, PAP smear/bimanual pelvic exam, or any physical exam. It is understood that a positive test result or results should be discussed with your physician as soon as possible, because this may be an indication of an underlying cancer. Positive results may occur with benign conditions, also, at times and further evaluation by a physician would be necessary to determine the significance of a positive result(s). A negative result does not in any circumstance mean that there is no cancer present, just that it is not indicated by the Cancersafe testing at this time. If any warning signs of cancer are present, including, but not limited to the signs/symptoms listed below, you understand that consultation with a physician immediately is necessary and that the CancerSafe testing would not take the place of such consultation

Testimonial

"Thank you DLS for saving my life. I took advantage of your valuable program and learned that I had prostate cancer. I am now cancer free and owe my life to early detection."

Tommy Wells, retired employee of the La. Dept. of Insurance

Address http://www.directlabs.com/CancerSafe.php

Who should perform the test?

Everyone over 50 should perform it once a year, or more if required, building your baseline and data for the future, as years pass your report will include graphs, demonstrating the evolution of the markers to assist in treatment and prognosis.

What is the Cost?

The cost of the entire panel is $529, which includes shipping of your specimen to the laboratory that processes the epMARKERS CancerSafe tests. If positive results are indicated, you will receive a follow-up test at no cost.

Results Example

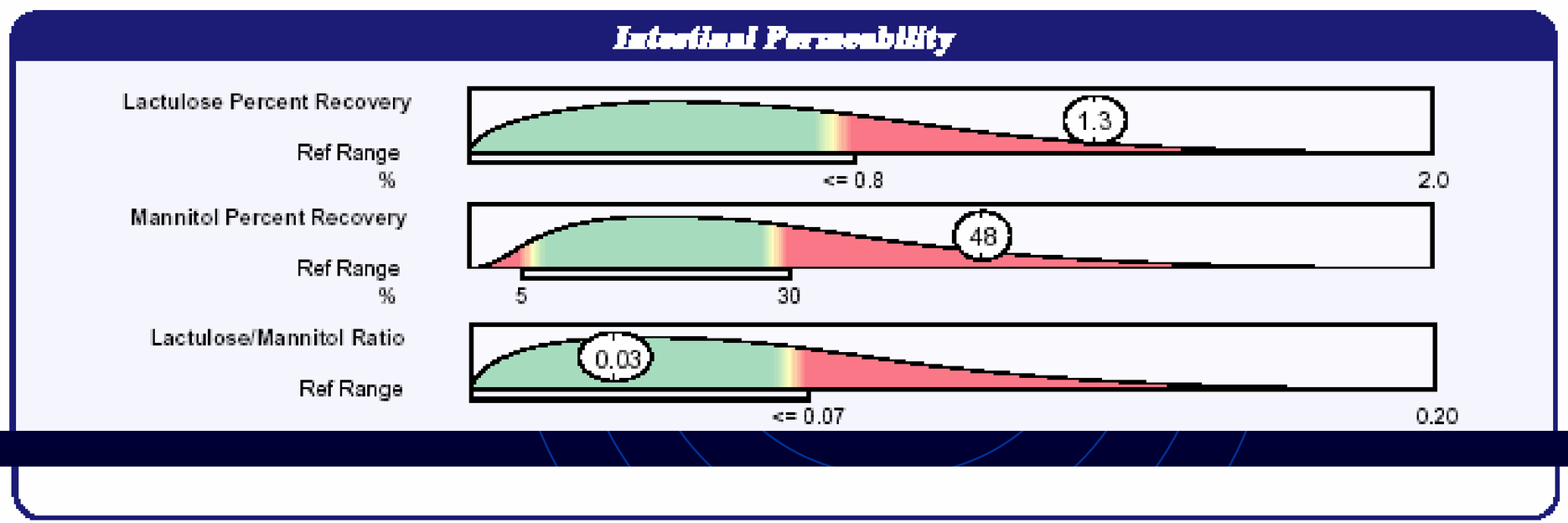
MARKER	RESULT	REFERENCE RANGE
CA 15-3	15.5 U/ml	< 40.0
CA 19-9	12.7 U/ml	< 35.0
CA 125	32.0 U/ml	< 35.0
CA 72-4	0.8 U/ml	< 5.2
AFP	1.7 ng/ml	< 15.0

Date: Tue, 18 Feb 2003 00:28:33 -0500
From: MWS <MWS@a1offerstoyou.com>
Reply-to: Reply@a1offerstoyou.com
Subject: US doctors and meds without a doctor visit!

Intestinal Permeability

Age: 38
Sex: F
MRN:

Completed:
Received:
Collected:



© GSDL · College of American Pathologists #31722-01 · CLIA Lic. #34D0655571 · Medicare Lic. #34-8475

Comprehensive Digestive Stool Analysis

Digestion

		Reference Range
Triglycerides	<dl	<= 3.1 mg/g
Chymotrypsin	44.9	1.4-36.8 U/g
Valerate, Iso-Butyrate	4.9	0.8-20.1 umol/g

	Inside	Outside	Ref. Range
Meat Fibers	None		None
Vegetable Fibers	Rare		None - Few

Absorption

		Reference Range
Long Chain Fatty Acids	4.4	<= 15.0 mg/g
Cholesterol	0.6	<= 3.2 mg/g
Total Fecal Fat	NR	<= 16.6 mg/g
Total SCFAs	70.9	23.8-165.4 umol/g

Microbiology

Bacteriology

Beneficial Bacteria

Lactobacillus species	I	*NG
Escherichia coli	N	4+
Bifidobacterium	N	4+

Additional Bacteria

alpha haemolytic Streptococcus	N	4+
gamma haemolytic Streptococcus	N	4+
Citrobacter freundii	P	3+
Klebsiella pneumoniae	P	3+

Metabolic Markers

		Reference Range
n-Butyrate	22.6	2.4-39.4 umol/g
Beta-Glucuronidase	3,683	937-4,500 U/g
pH	6.1	6.0-7.2

SCFA distribution

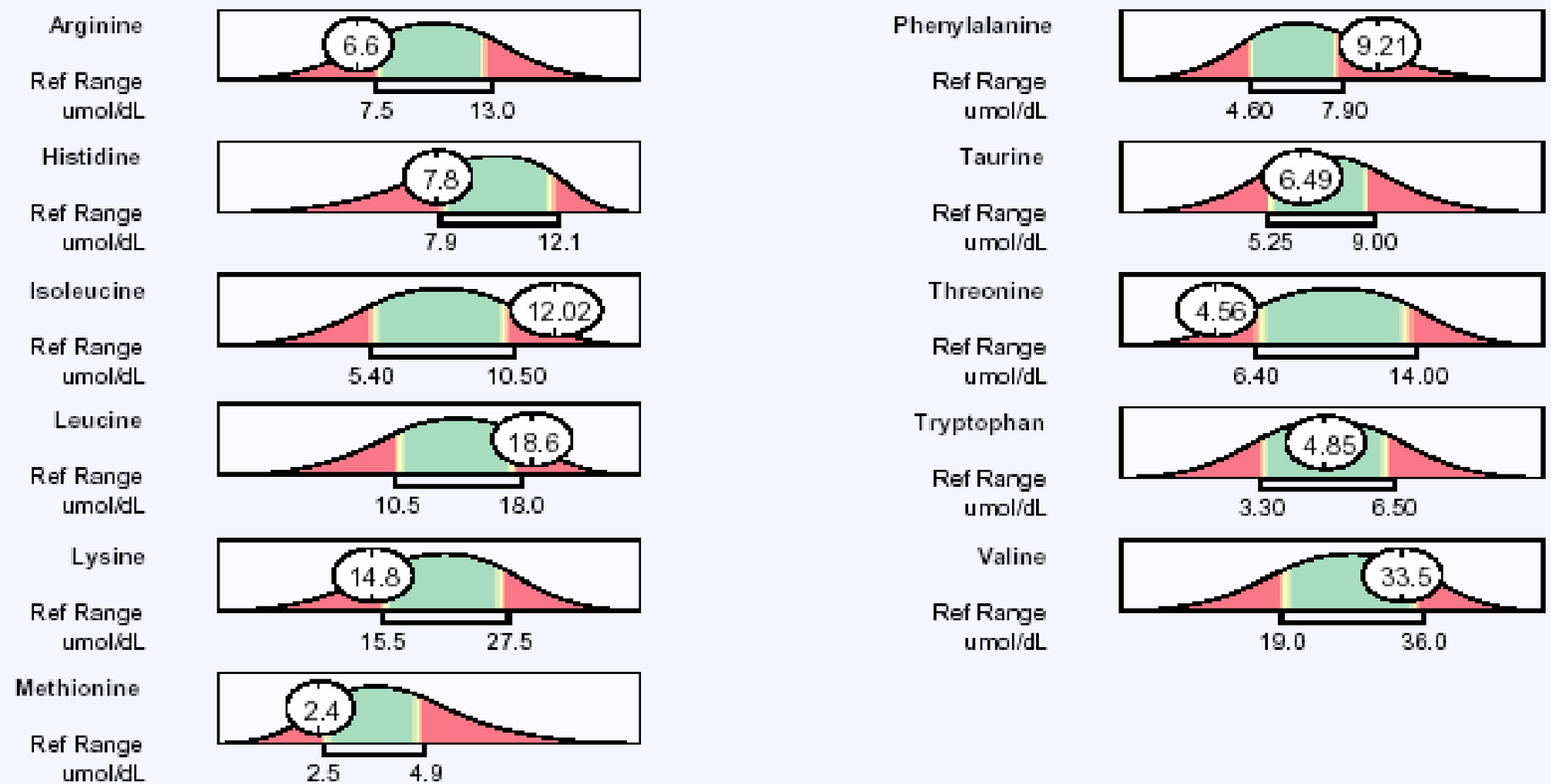
Acetate	44	46-72 %
Propionate	24	12-34 %
n-Butyrate	32	10-32 %

Immunology

	Inside	Outside	Reference Range

Amino Acid Analysis (Plasma)

Nutritionally Essential and Semi-Essential Amino Acids



© GSDL · College of American Pathologists #31722-01 · CLIA Lic. #34D0655571 · Medicare Lic. #34-8475

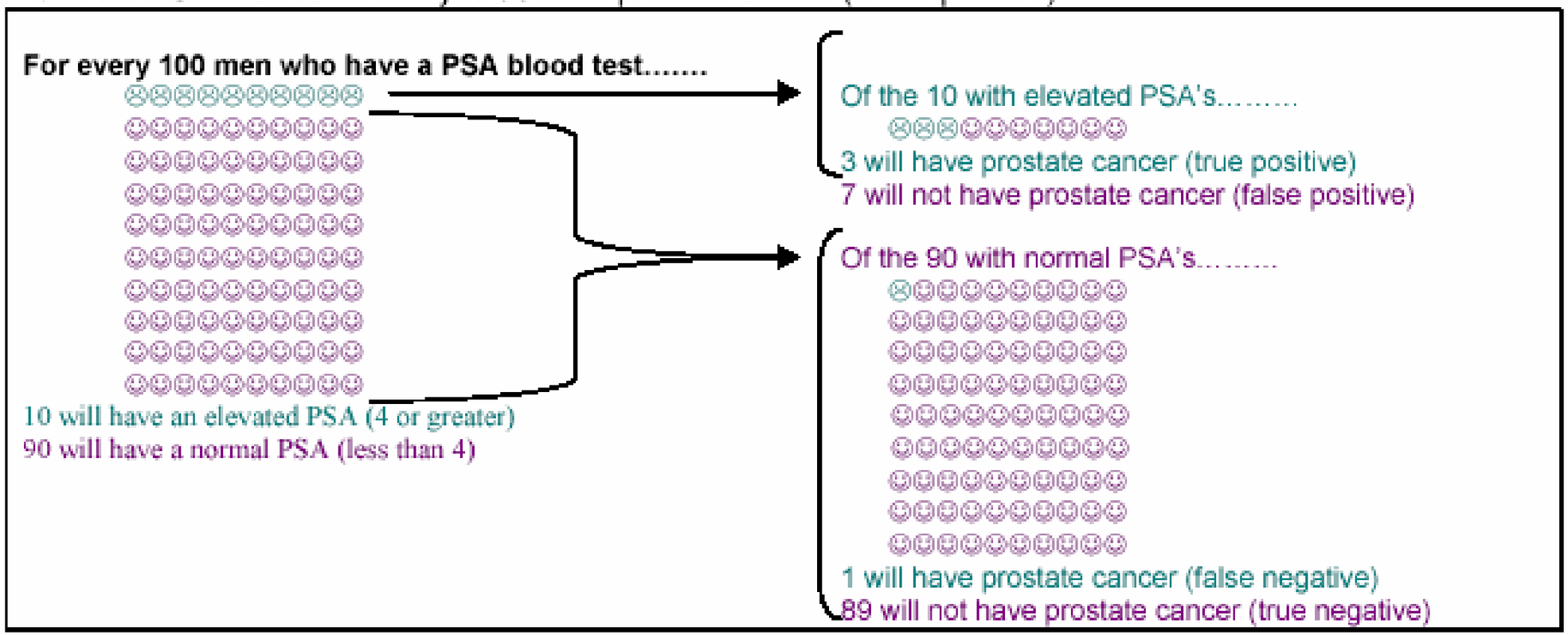
Concerns

- Improper preparation / collection
  - Hemoccult, fasting, TDM, urine cultures
- Lack of informed consent
  - PSA, HIV, genetic tests

PSA Testing

There are 4 possible outcomes to a PSA test:

1. Your PSA is normal and you *do not* have prostate cancer (a true negative)
2. Your PSA is normal but you *do* have prostate cancer (a false negative)
3. Your PSA is elevated but you *do not* have prostate cancer (a false positive)
4. Your PSA is elevated and you *do* have prostate cancer (a true positive)



Copyright © 2001 American Academy of Family Physicians. Permission is granted to reproduce this material for nonprofit educational uses. Written permission is required for all other uses, including electronic uses.

PSA Testing

If you have prostate cancer you must make a tough decision of whether or not to treat it. Most treatments can have bad side effects. It is not known whether treatment or no treatment results in better quality of life. It is not known whether treatment prolongs life. Here are some of the things that can happen after treatment:

Possible Outcomes of Treatment

	Radiation	Surgery
Improved survival	Unknown	Unknown
Death from treatment	2 in 1000	1 in 200 younger men 1 to 3 in 100 older men
Impotence *(difficulty with erection)*	40 in 100	30* to 90 in 100 *nerve sparing surgery
Any Incontinence *(loss of urine control)*	60 in 100	32 in 100
Complete Incontinence (*lose complete control of urine)*	1 in 100	7 in 100
Urinary Stricture *(makes if difficult to urinate)*	5 in 100	12-20 in 100
Any rectal Injury *(discomfort/trouble with bowel movements)*	11 in 100	30 in 100

Copyright © 2001 American Academy of Family Physicians. Permission is granted to reproduce this material for nonprofit educational uses. Written permission is required for all other uses, including electronic uses.

PSA Testing

It is up to you and your doctor to decide whether you should have a PSA. The correct decision is the informed decision. Talk to your doctor and decide what factors are important to you. Here are some Pros and Cons to consider:

Possible advantages to having a PSA test:	Possible disadvantages to having a PSA test:
• **It may give reassurance if it's normal** • **It can find many cancers earlier than is possible by a digital rectal exam** • **Treatment at early stages *may* help men live longer and avoid cancer complications**	It may miss cancer and give a false reassurance that there is no cancer It may lead to a biopsy and anxiety when a man has no cancer Treatment at early stages *may not* help men live longer and treatment has risks of side effects

Copyright © 2001 American Academy of Family Physicians. Permission is granted to reproduce this material for nonprofit educational uses. Written permission is required for all other uses, including electronic uses.

Concerns

- Improper preparation / collection
  - Hemoccult, fasting, TDM, urine cultures
- Lack of informed consent
  - PSA, HIV, genetic tests
- Drugs of Abuse – to pass pre-employment or insurance physical

Concerns

- What do we do with positive tests & requests for phone treatment?
  - Strep
  - UTI
  - Protime

Concerns

- Teachable moment - opportunity to educate patients may be lost
  - time to address preventive medicine
  - address *patient-specific* issues / risks
  - encourage healthy lifestyle

We're dealing with *real* people

39 y/o lady called requesting blood sugar because she was having urinary frequency like a friend recently diagnosed with diabetes. Didn't want appointment - last checkup was 8 years ago after last child.

? not concerned about UTI ??

Results of office visit

Blood sugar	91
Cholesterol	290
Triglycerides	220
HDL	29
LDL	217
Breast exam	Normal
Pap smear	Abnormal, probably cured with in-office procedure

What if . . .

She'd gone to DAT lab for blood sugar?

How long before she would have had pap smear?

What would have been outcome?

We're dealing with *real* people

- Male on chronic steroids for COPD. Dr requested DEXA – showed osteoporosis.
- Went to DAT for 'heel DEXA' – was normal – so refused treatment.
- Finally – repeated DEXA at another facility, again positive – consented to treatment

We're dealing with *real* people

- 27 y/o with (+) FH for diabetes. Presents for complaints of thirst & urinary frequency.
- Has been doing blood sugars on his mother's machine x 9 months. Brings log – frequently over 300
- He's sure he doesn't have diabetes because some have been normal.

Why do patients want DAT?

- "Many health conscious individuals wish to have lab testing performed but want to avoid the inconvenience and expense of physician office visit."

  Henry Soloway, MD

- "Public is becoming better informed and are *capable* of taking responsibility for their actions"

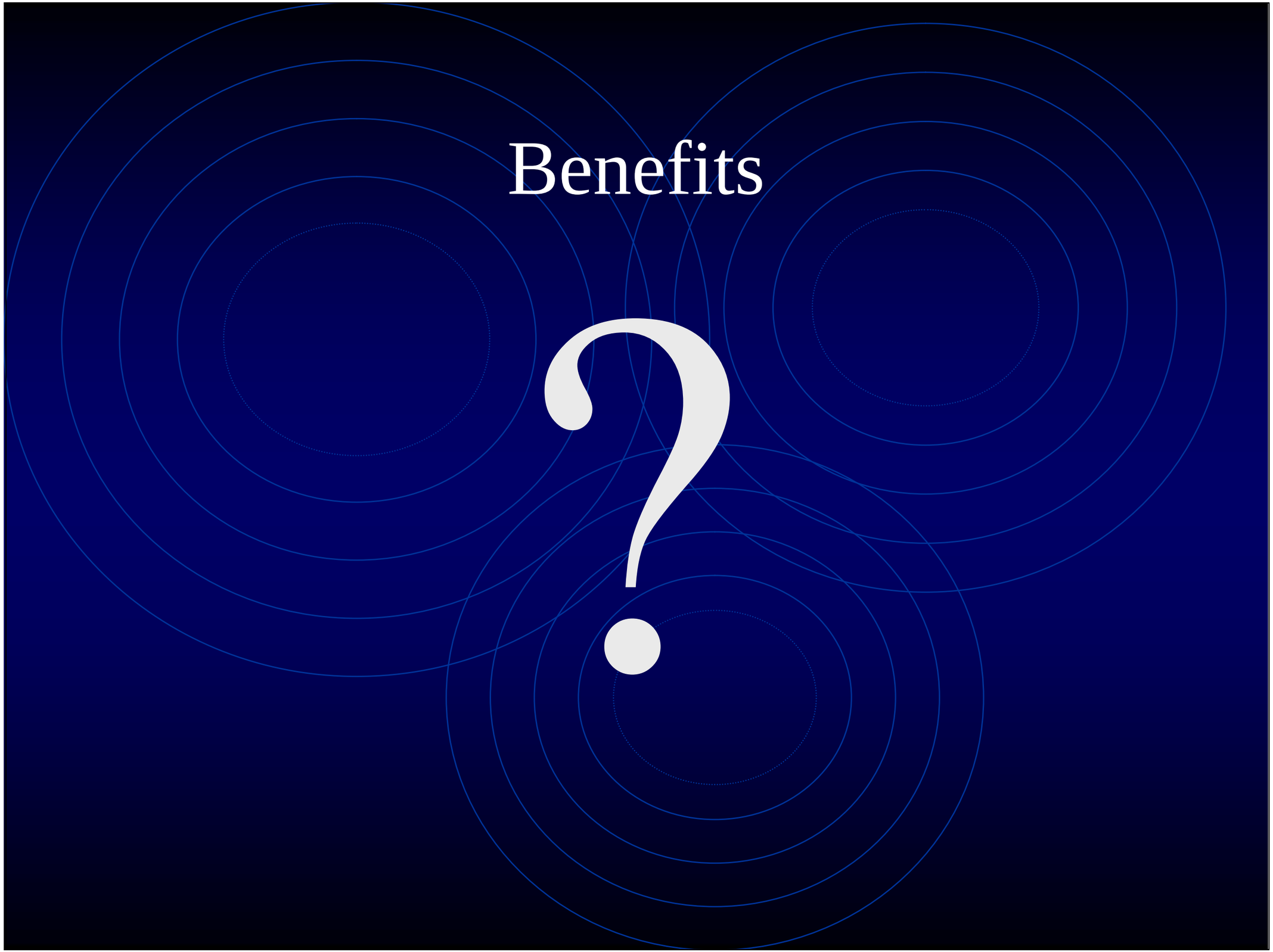
  John Halsey, PhD

Janzen says ...

"Patients often don't want to see their doctor, but sometimes it is for the best."

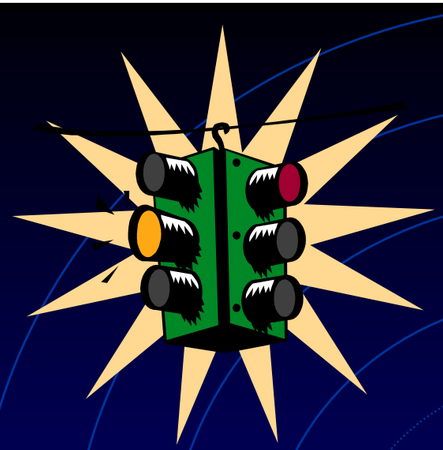
"Patients come in for darnedest reasons and we must be ready to educate when they do."

Benefits



Benefits

- Early detection
- Convenience – ‘snow-birds’
- **Anonymous**
- *Income stream for labs*



Recommendations

- Limited menu
- Limit/restrict advertisement/marketing
- No reimbursement by insurance
- No reports sent to physicians
- Lab responsible for
  pre & post counseling
- Anonymous vs confidential

Consider

- Why are we here?
- Why is there demand?
- What have we done wrong?
- More coming – CT, MRI, PET etc etc

Food for thought …

Does *'taking active role in your health' mean …*

- Ordering your own tests, prescribing your own medications, or should it mean
- Being aware of information – learning to be your own advocate – learning about your health conditions – making lifestyle changes to improve your health/condition

déjà vu

- If there is any truth to the old proverb that "one who is his own lawyer has a fool for a client," the Court … now bestows a constitutional right on one to make a fool of himself.

ATTRIBUTION: Dissenting opinion in 6-3 ruling that allowed a defendant to refuse counsel, 30 Jun 75

Caveat Emptor

“Let the Buyer Beware”

Fall foliage at Table Rock Lake – Ozark Mountains

"Our philosophy is if someone wants the information, it should not be denied to them, *particularly if they're willing to pay for it.*"

Henry Soloway, MD

Comments

- Don’t send results to me - don’t hold me liable
- Envision your whole community getting 'screening' CEA's and CA-125's
- As an entrepreneurial enterprise, those running the lab have incentive to encourage more testing, no matter what the down sides, especially as they bear no responsibility for the complexity and/or complications of follow-up.

Comments

- The clinical evaluation of the patient using labs includes the responsibility for proper collection, specimen handling, receipt and review of the information, evaluation of the results in light of the other patient problems/information, notification and education of the patient about the results, liability for the correctness of the results and management of the data and storage of that information often for the life of the patient. It is NOT JUST the chemical analysis or taking of pictures.

Comments

- Family physicians and pediatricians should be well-informed as to which tests are of some screening value and which are not.
- Why do we then want to have patients spend money getting tests which are not recommended?
- What have we, as a medical society, done or failed to do that has made this attractive?
- What do we need to do to fight this trend, to ensure our patients spend their money where it will serve their health?

Comments

- I have been asked about CT scans for cardiac disease. This is now being perceived as more important & more accurate than BP checks, cholesterol & glucose screening, and diet & exercise!!
- It is often a rip-off. The studies, if interpreted, are so full of hedges as to be useless

Comments

- We will either have low risk people getting normal tests (? is this really reassuring), or
- symptomatic people getting inapprop tests (carotid duplex for chronic cervical muscle pain), or
- high risk people reaffirming the presence of disease which is already getting max medical Rx (coronary calcium index in people on statins, beta/ca blockers nitrates and ASA...and who still smoke).