Performance improvement intersects analytical integrity: Putting the Lean Mindset to Work to Raise Analytical Quality and Boost Patient Care

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> > THE DARK REPORT Spicewood, Texas

Fourth Annual Lab Quality Confab San Antonio, Texas 2 November 2010 rmichel @darkreport.com ph: 512-264-7103 fax: 512-264-0969

A New Premise In Lab Testing

Medical laboratories must now perform to a higher standard of quality—and that standard is increasing.

How Is "Quality" Changing?

Primary emphasis: increased precision of analytical test results that directly support improved patient outcomes.

◆ Integrity, accuracy, reproducibility, quality

 Secondary emphasis: quality service as experienced by patients.

 Lab appointments, specimen collection, billing, patient service calls, and more

New Quality Mindset for Labs

Perfect timing for labs to use Lean, Six Sigma, and similar methods specifically to improve quality of analytical test results.

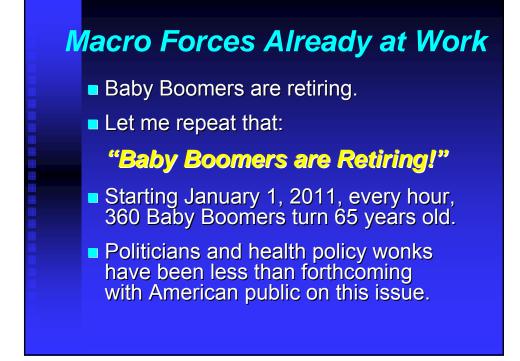
- Assembled at this year's Lab Quality Confab are leaders in this trend.
- Nation's first-ever look at the intersection of process improvement methods with lab test analytical quality.

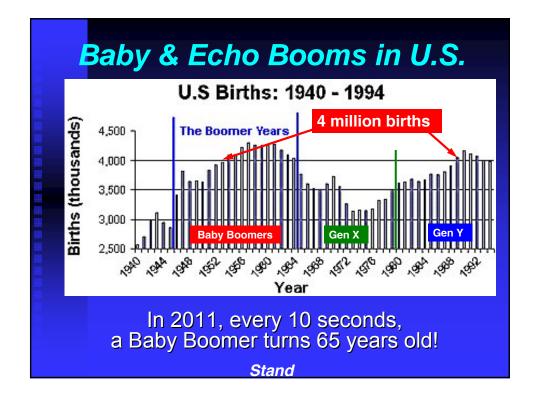
Our discussion Today

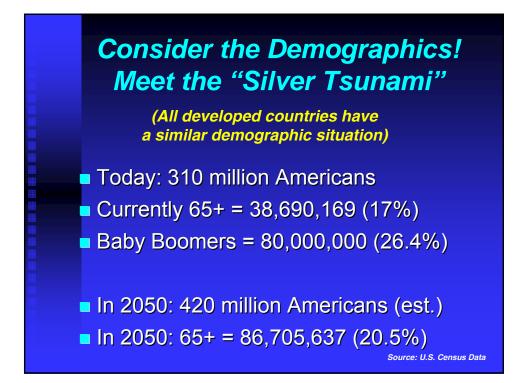
- One: Review industry trends reinforcing need for continuous improvement.
- Two: Discuss soon-to-be urgent gap between primary trends, new healthcare legislation, and needs of laboratories.
- Three: Identify examples of publicized lab failures caused by quality failures.
- Four: Explore how labs can improve analytical quality and overall quality.

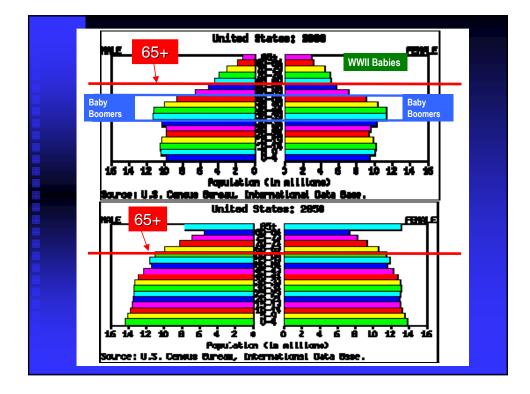


- New Federal health legislation will dramatically change existing healthcare landscape.
- Most mandates happen two to six years down the road—short term impact is uncertain.
- One thing is sure: increased taxes on providers and medical suppliers, as well as less reimbursement.





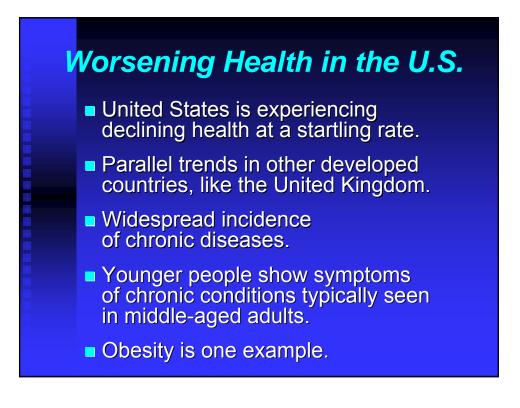




Silver Tsunami's Direct Implications for Lab Medicine

- Utilization of lab tests is about to skyrocket over the next decade!
- Commercial lives (under 65 years), average about 2 lab tests per person per year in the United States.
- Medicare lives (65 or older) average about 9+ lab tests per person per year in the U.S.
- 80 million baby boomers are rapidly advancing into this age cohort.

Do the math: 80 million X 9 tests!



Obesity Trends Among U.S. Adults between 1985 and 2009

Definitions:

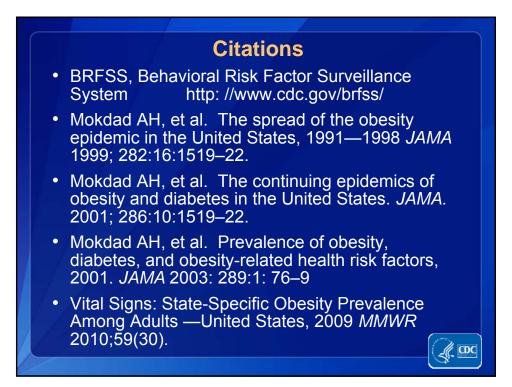
- Obesity: Body Mass Index (BMI) of 30 or higher.
- Body Mass Index (BMI): A measure of an adult's weight in relation to his or her height, specifically the adult's weight in kilograms divided by the square of his or her height in meters.

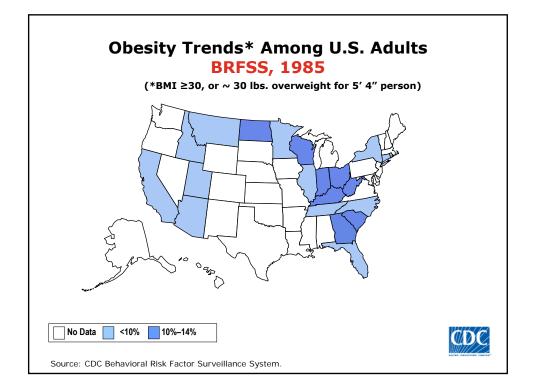
🥼 CDC

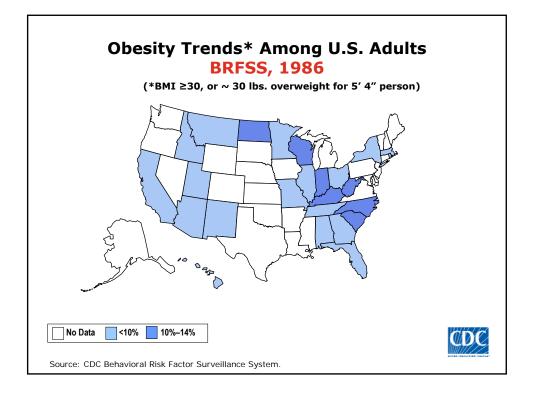
Obesity Trends Among U.S. Adults between 1985 and 2009

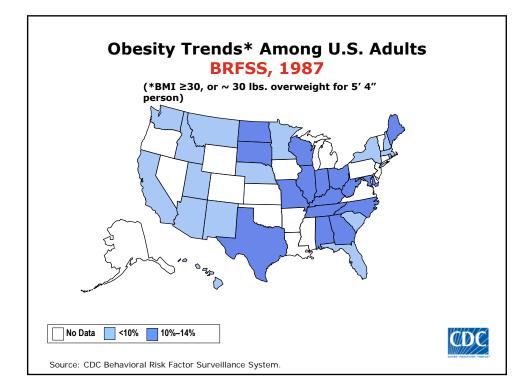
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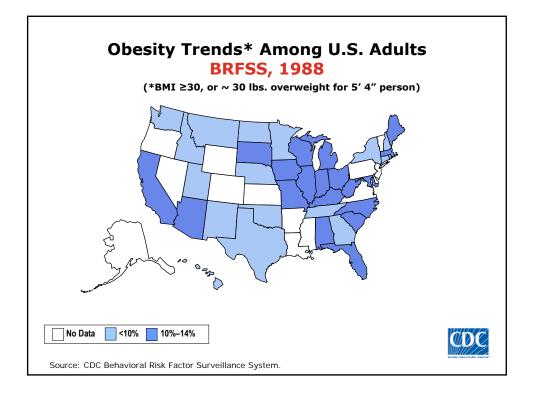
- The data shown in these maps were collected through CDC's Behavioral Risk Factor Surveillance System (BRFSS). Each year, state health departments use standard procedures to collect data through a series of telephone interviews with U.S. adults.
- Prevalence estimates generated for the maps may vary slightly from those generated for the states by BRFSS (http://aps.nccd.cdc.gov/brfss) as slightly different analytic methods are used.

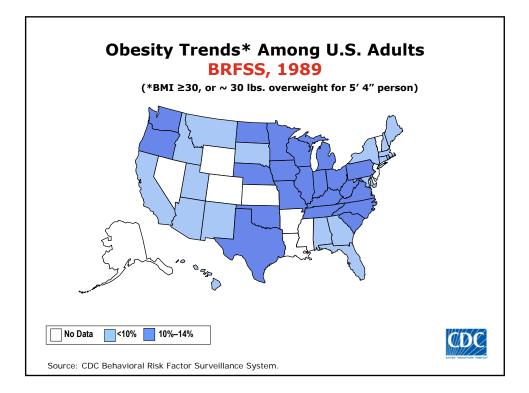


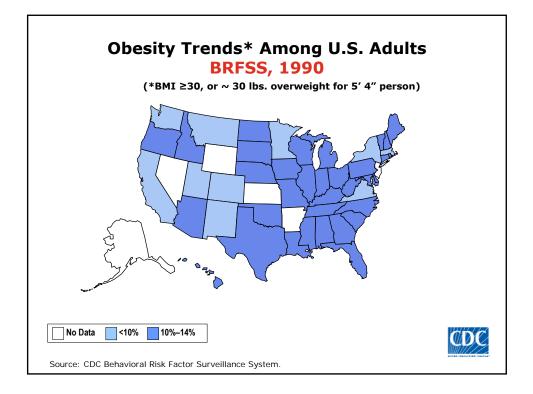


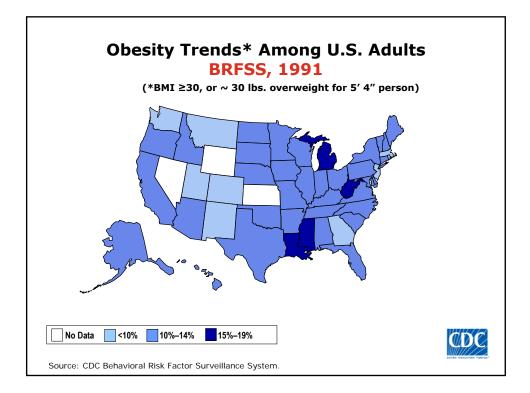


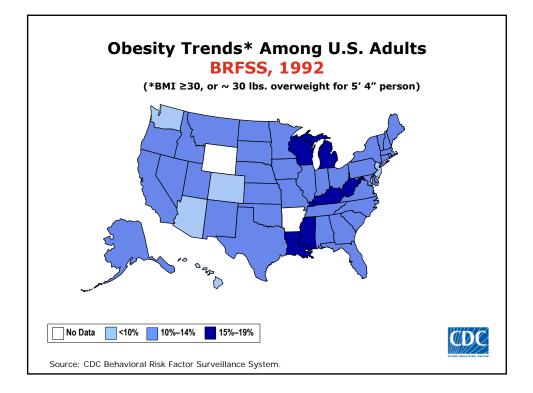


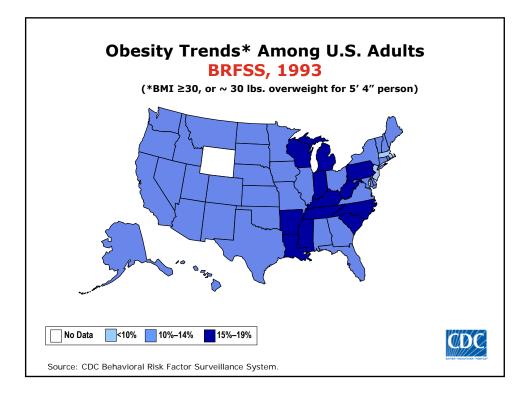


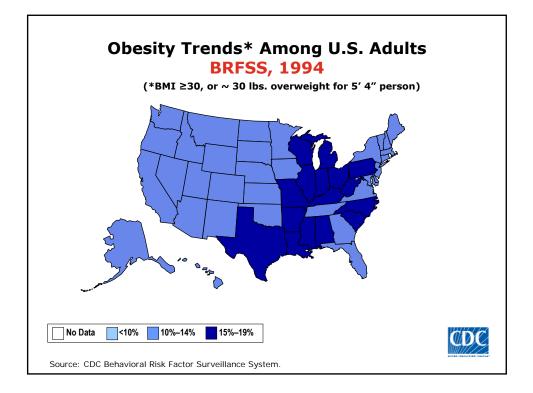


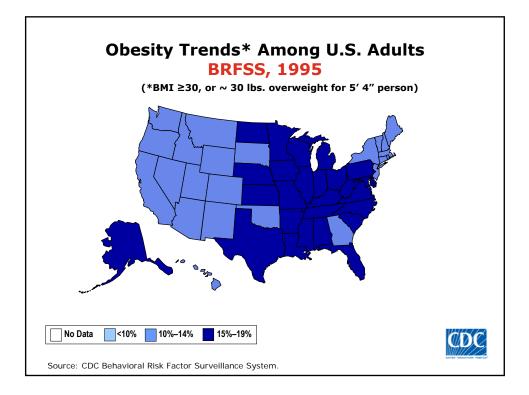


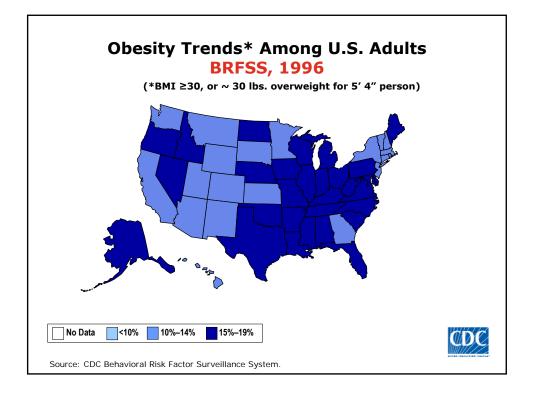


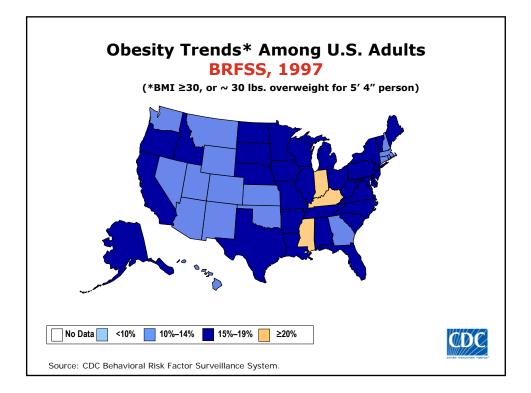


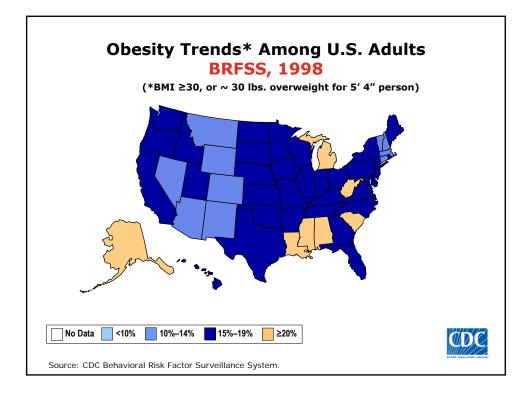


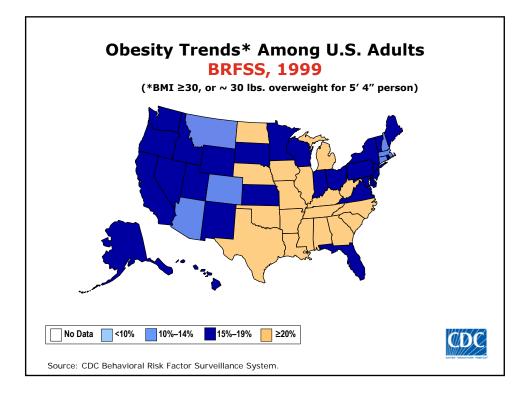


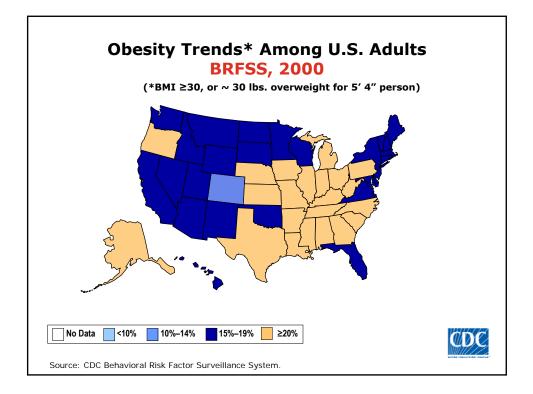


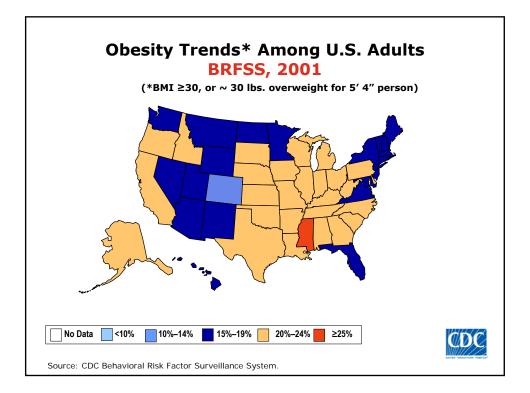


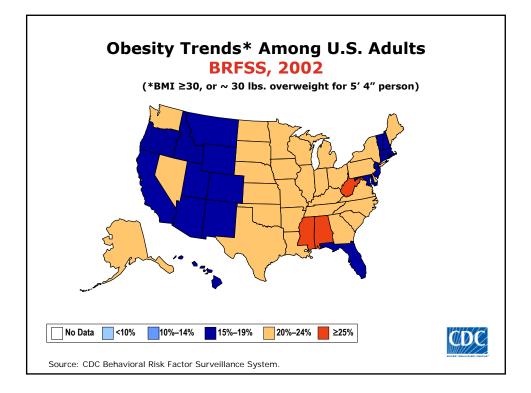


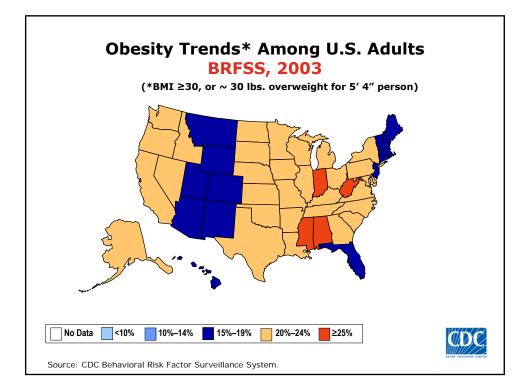


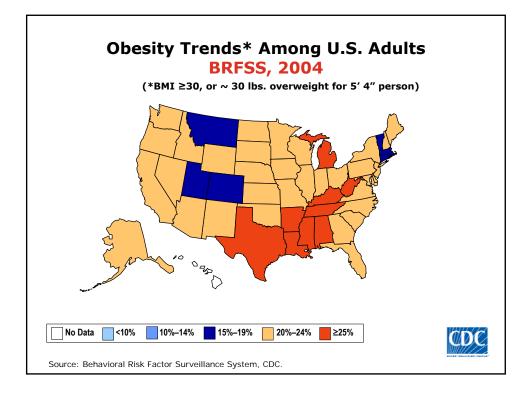


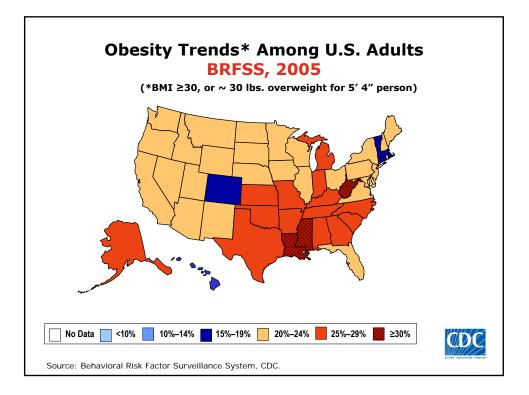


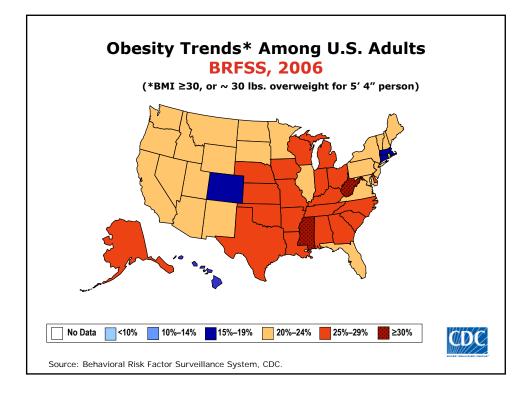


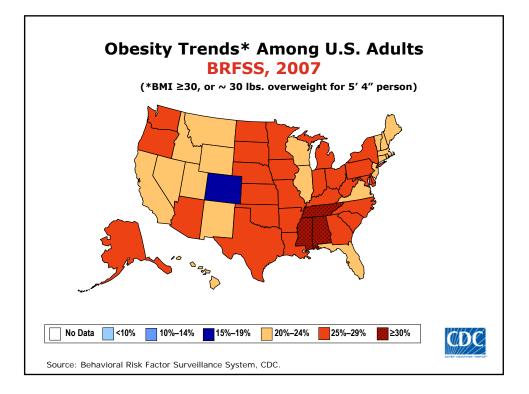


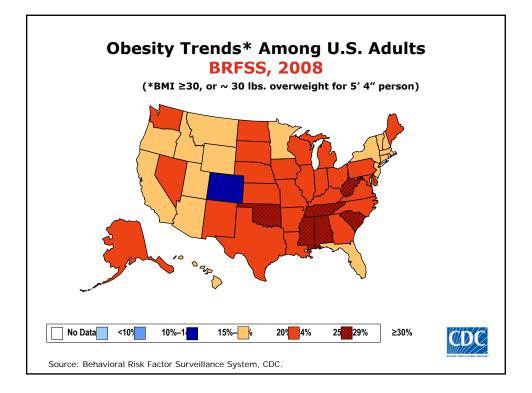


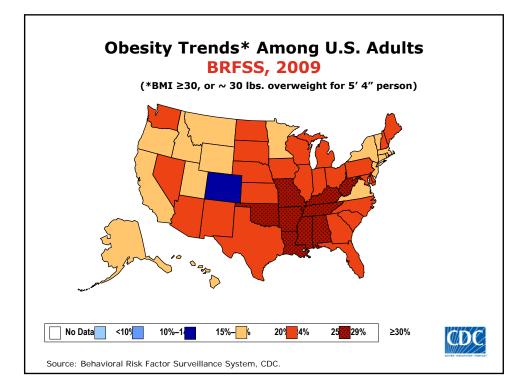


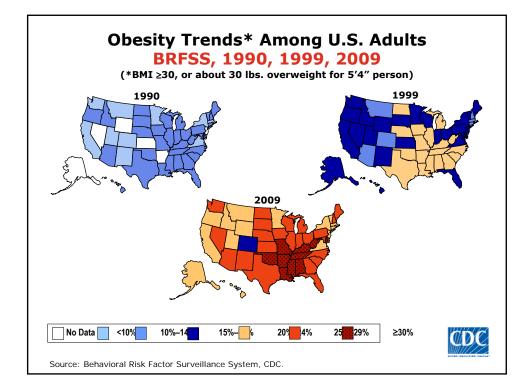




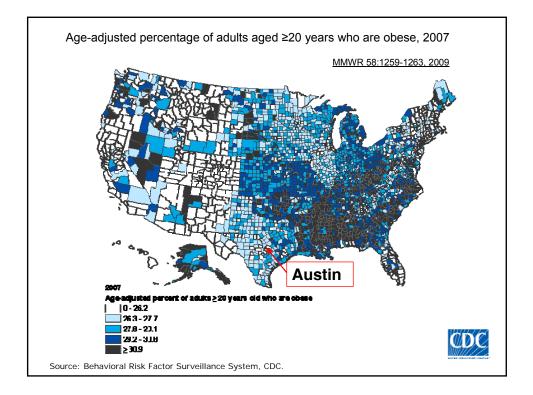


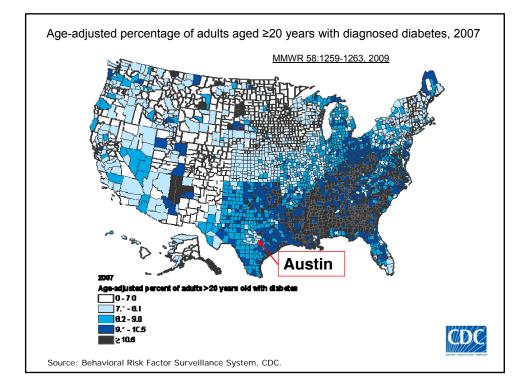


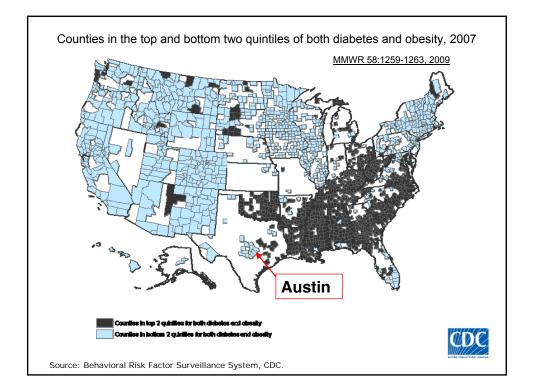


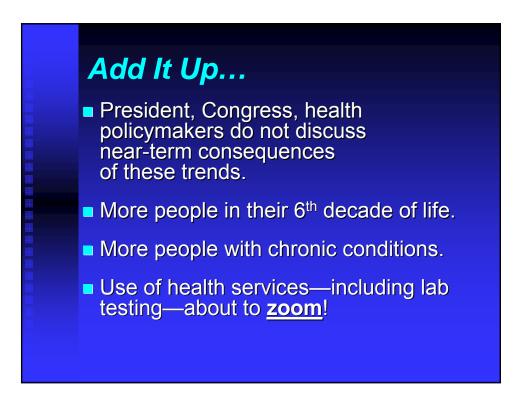


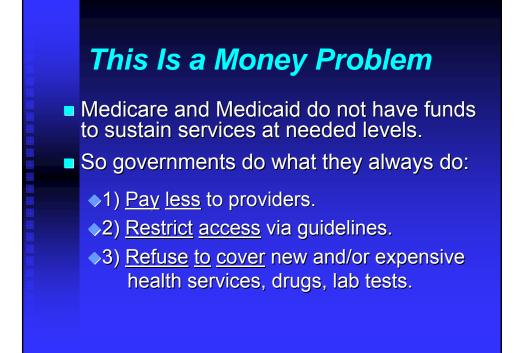


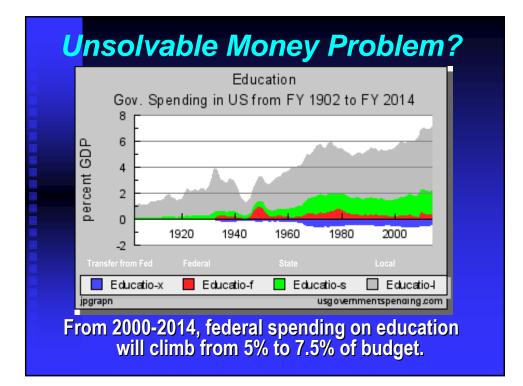


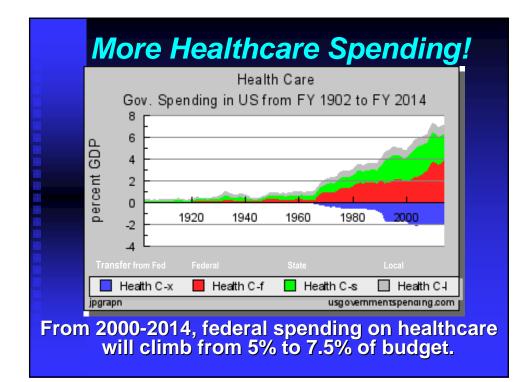


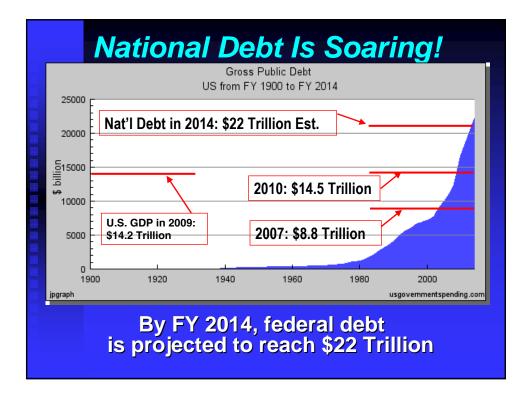












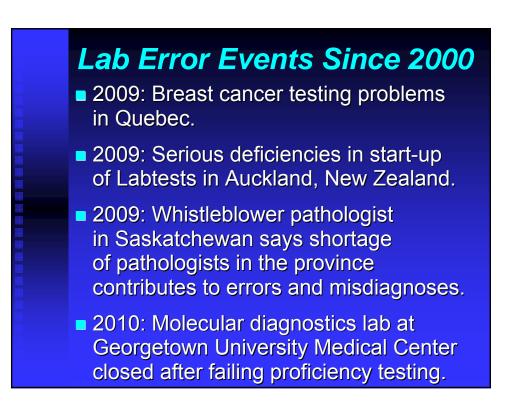


- Government at federal, state, local levels will not be able to adequately fund healthcare system.
- Healthcare needs solutions that improve outcomes while lowering cost of care.
- This strikes to the sweet spot of laboratory medicine.



Lab Error Events Since 2000

- 2007-2008: Inaccurate Vitamin D results at Quest Diagnostics Incorporated (Estimated that as many as 500,000 patients affected over 18 months).
- In 2009, Quest Diagnostics and its subsidiary Nichols Institute Diagnostics entered into \$302 million settlement with U.S. Department of Justice related to problems with certain types of lab tests.



Let's Take a Quick Look

- Recent publicized episodes in Canada can be instructive.
- Key details about specific problems have not been made public in every case of systemic or unacceptable rates of errors in laboratory test results.
- What follows are "snapshots" and public comments made about discoveries of laboratory errors.

Newfoundland, Labrador 2005

- In May 2005 Eastern Health discovered errors in hormone receptor breast cancer test results from a histology lab in St. Johns, Newfoundland.
- Affected patients had been tested between 1997 and 2005.
- Up to 1,500 patients authorized for retesting based on indications of errors in original test result report.

Newfoundland, Labrador 2005

- After retesting, Eastern Health concluded that 383 patients had received erroneous results, of whom 117 required a change to their treatment programs.
- More than 100 of the women whose lab results were reviewed had died prior to this review.

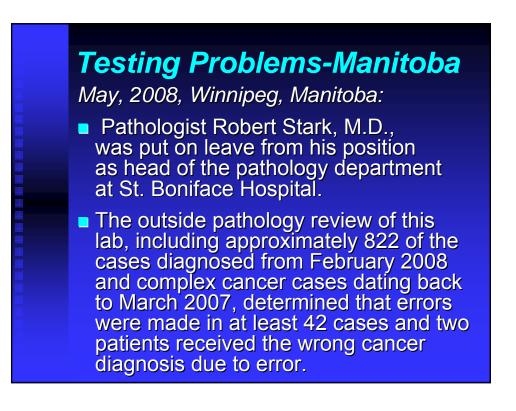
Newfoundland, Labrador 2005

A judicial enquiry, on Tuesday [March 2, 2009], reported that the protocols and procedures at the health authority at the centre of a breast-cancer-testing scandal in Newfoundland and Labrador were "so deficient as to be practically non-existent."

Pathology Testing-Ontario

May, 2008, Owen Sound, Ontario:

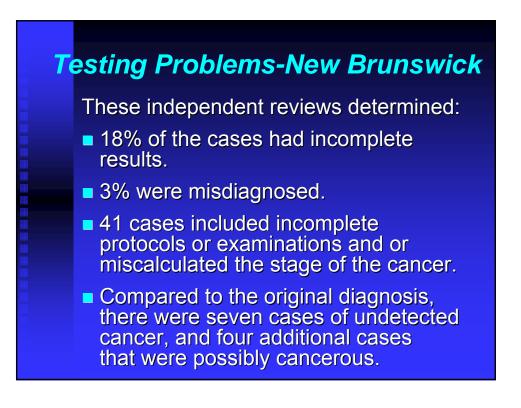
- After routine quality control testing identified an error by pathologist Barry Sawka, M.D., at Owen Sound Hospital, a more detailed review of 600 of his cases was launched.
- Grey Bruce Health Services, the local health authority, determined that the error rate was 6%, which health officials stated was six times the "the normal error rate for pathologists." These misdiagnoses lead to errors in treating patients.



Testing Problems-New Brunswick

February 2008, Miramichi, New Brunswick:

Pathologist Rajgopal Menon, M.D., left his position as head of pathology at Miramichi Regional Hospital following a review of 227 cases of prostate and breast cancer biopsies from 2004-2005.



Testing Problems-New Brunswick

- Health officials announced they would review as many as 24,000 cases.
- Menon characterized this review as "unjustified and unfair."
- He filed a civil suit against the regional health authority.

Testing Problems-Quebec

May/June, 2009: Montreal, Quebec:

The province's health department has ordered 2,100 new tests after a tiny pathology study exploded on the Quebec scene last week, suggesting that 15 to 30 per cent of breast-cancer tests were botched, throwing patients into a panic about the reliability of their tests and health status.

Montreal Gazette, June 6, 2009

Testing Problems-Quebec

- "Not only are Quebec's ill-equipped, underfunded and short-staffed laboratories under a microscope, but the government was forced to revise its standards and is now setting up a universal quality control program.
- "Effective immediately, all provincial labs will be required to have external audits of their tests. Some labs are already doing that."

Montreal Gazette, June 6, 2009

Testing Problems-Quebec

 "Gaetan Barrette, head of Quebec's federation of medical specialists, said problems in the labs are long-term and systemic. It's not just breast cancer tests that are at risk, but all cancer testing, Barrette said."

Testing Problems-Quebec

"St. Mary's Hospital Centre is the only Quebec facility to have a CAP accreditation, and it took a decade to achieve, said chief pathologist Ron Onerheim. Having no quality control program is a red flag, he said."

Montreal Gazette, June 6, 2009

Findings from Review Canadian Press, December 17, 2009: Out of 2,856 exams reviewed, 87 errors were found in the test results. The new provincial study, released Wednesday, confirms 39 cancer sufferers failed to receive the proper care (of which five have died). PhenoPath of Seattle, Washington conducted the outside review.

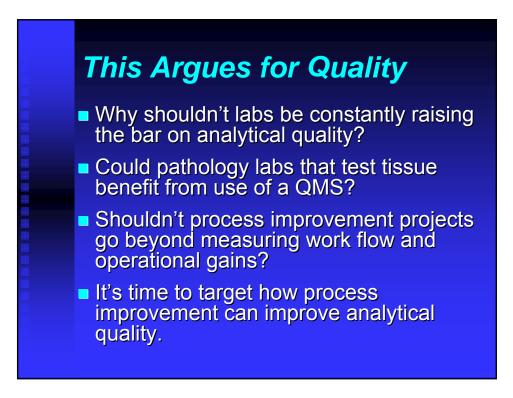
Quebec Specialists Speak

December 17, 2009 Press Conference

"The FMSQ is, however, disappointed that the detection threshold selected was so high that that one wonders why it was even considered.

In fact, the great majority of patients whose [estrogen receptor] results ranged from 1% of positive cells to the 10% threshold stated at this morning's press conference by the Minister and his experts, Drs Bernard Têtu and André Robidoux, could benefit from an adjustment to their treatment in the same way as the 87 patients identified so far."

Gaétan Barrette, MD, President, Quebec Association of Medical Specialists (FMSQ).



More on Newfoundland

CBC News, May 23, 2008:

"A new wage package for Newfoundland and Labrador's struggling pathologists moves the province to the top of the heap for compensation, Premier Danny Williams says. Williams announced the package — which includes a \$73,000 annual wage increase for pathologists for this year alone — late Thursday..."

Inadequate Lab Resources?

CBC News, May 23, 2008:

"The raise comes amid testimony at the Cameron inquiry on flawed breast cancer tests, in which workload, understaffing, and pay for pathologists have frequently been identified as perennial problems in the province's hospitals."



- During past decade, in provinces such as Ontario and British Columbia, histopathology costs were scrutinized.
- New contracts with pathologists contributed to reduced rate of spending on anatomic pathology testing services.
- Year-to-year budgeted funding for laboratory testing services in some provinces has not kept pace with inflation, test utilization, and acquisition of new diagnostic technology.

It Can't Happen in USA?

The Washington Post

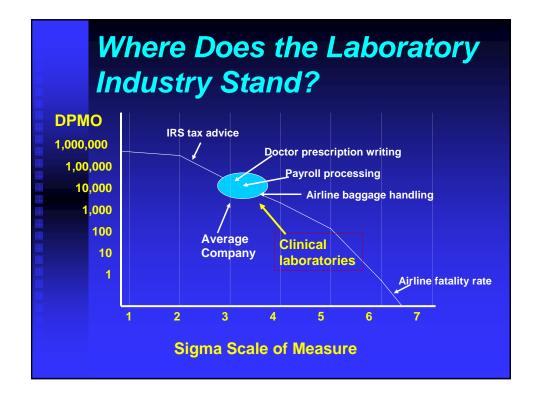
Georgetown U. Hospital closes lab after problems with breast cancer tests

By Lena H. Sun and Carol D. Leonnig Washington Post Staff Writer Friday, August 6, 2010; A01 ent to outside labs, Stephen Evans, the hospital's chief medical officer, said this week. He said the suspension was unprecedented. Federal officials are

Reported on Friday, August 6, 2010

Understanding Six Sigma Quality

Sigma Level	Defects per Million Opportunities	Yield
6	3.4	99.9997%
5	233	99.977%
4	6,210	99.379%
3	66,807	93.32%
2	308,537	69.2%
1	690,000	31%



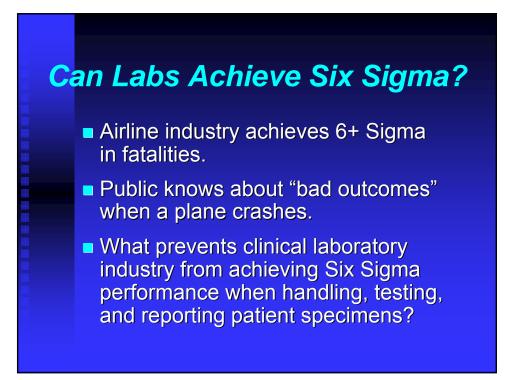
Q-Probe QUALITY INDICATOR	% ERROR	DPM	SIGMA
TDM timing errors	24.4	244,000	2
Cytology specimen adequacy	7.32	73,700	2.
Surgical pathology specimen accessioning	g 3.4	34,000	3
PAP smear rescreening false negatives	2.4	24,000	3.
Order accuracy	1.8	18,000	3
Surg path froz sect diagnostic discordanc	e 1.7	17,000	3
Duplicate test orders	1.52	15,200	3.
Laboratory proficiency testing	0.9	9,000	3.
Wristband errors (not banded)	0.65	6,500	
Hematology specimen acceptability	0.38	3,800	4.
Chemistry specimen acceptability	0.3	3,000	4.
Reporting errors	0.0477	477	4

The following Sigma metrics are drawn from Nevalainen D, Berte L, Kraft C, Leigh E, Morgan T.: "Evaluating Laboratory Performance on Quality Indicators with the Six Sigma scale." *Arch Pathol Lab Med 2000*,124:516-519.



ISO 15189 is Global QMS

- More countries use ISO 15819 for laboratory accreditation and/or licensing.
- In the U.S., CAP and A2LA offer ISO 15189 accreditation services.
- Today and tomorrow, you can hear about ISO 15189 from CAP, A2LA, QMP-LS accrediting bodies.
- ISO 15189 provides laboratories with an appropriate QMS



Tackling Analytical Quality

- This Lab Quality Confab recognizes the opportunity for labs to use performance improvement methods to improve analytical quality.
- Visionaries and First-Movers are here to share their knowledge.
- This is the next frontier for QA/QC and QMS in medical laboratory management.



- Luci Berte on QMS
- Chinu Jani to discuss ISO 15189 adoption at Specta Laboratories.
- Chris Christopher to lay out his vision of the "virtual laboratory" of tomorrow.
- Challenge your thinking! Move beyond the ordinary to the extraordinary.
- Your patients will thank you.

Each Afternoon on QMS

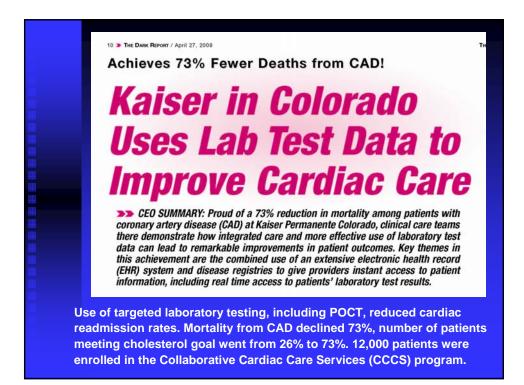
- Georgene Cook on ISO 15189 "Do's and Don'ts".
- Julie Coffey of QMP-LS on Ontario's eight years of ISO 15189 accreditation.
- Dan Tholen on of A2LA on QMS and its role with ISO 9001 and ISO 15189.
- Panel Discussion today on shifting the lab management paradigm with quality management systems.

Tomorrow's General Session Raising Analytical Quality

- Michael Astion, MD, PhD, on using industrial engineering methods in preand post-analytical stages to improve analytical quality.
- Michael Noble, MD., PhD, on how performance improvement techniques can simultaneously improve analytical quality.
- Curtis Parvin, MD, specific ways to use QA/QC to manage analytical accuracy.

First-Time these Experts Are Together at the Same Time

- It's the first-ever event when these experts come together and speak.
- Gives you an unprecedented opportunity to view the next goals in quality management.
- Provides you with a head start to put your lab in front of the competition, and...
- A head start on contributing to better patient outcomes through more accurate analytical quality.



THE DARK REPORT / March 29, 2010

>>> CEO Summary: In a thinly-populated region the size of Texas and New Mexico combined, an integrated clinical care program based on point-of-care testing (POCT) has delivered impressive gains in health outcomes. For rural residents, mortality rates from cardiovascular disease have fallen by 50%. There were comparable declines in hospital length of stay and the rate of readmissions. A reli-able test result and speed to answer from POC testing is a major factor in these improved outcome

added. Faced with waiting for the once-day tropomir run, most physicians contin-lood specimens 200 kilometers (124 mil) or nore--sometimes a lot nore," recall a the same time that Tideman was pon-Tidemin, by the most the wirks to stropomis porting a simple as mach as 1,000 kilom at this Addide hospital, in an effort or overlated by bus, tax, or private acar. "If the specimens arrived at a periphe-ter an individual bush rules on the set of the specimens arrived at a periphe-man individual bash rules on the set."

uld have to be called in

THE DARK REPORT / www.darkre

Use of Point-of-Care Testing Reduces Mortality by 50%

In the Australian state of South Australia, mortality rates in rural ares were twice that of Adelaide, the state's capital. POCT was deployed in rural clinics as part of iCCnet SA, or Integrated Cardiovascular Clinical Network for South Australia.

Soon, mortality rates in rural areas declined to the same level as Adelaide. POCT allowed improved triaging of patients, so needless visits to hospital ERs were avoid. Savings were substantial and the program continues today.

