Saskatchewan Ministry of Health Appropriateness of Care Network

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Deploying Appropriate Use Criteria into Clinical Workflows to Optimize Care Delivery

Intermountain[®] Healthcare Brent C. James, M.D., M.Stat. Chief Quality Officer and Executive Director Intermountain Institute for Healthcare Leadership



Disclosures

Neither I, Brent C. James, nor any family members, have any relevant financial relationships to be discussed, directly or indirectly, referred to or illustrated with or without recognition within the presentation.

I have no financial relationships beyond my employment at Intermountain Healthcare.



Core idea behind variation research

Apply rigorous measurement tools developed for clinical research

to

routine care delivery performance



Quality, Utilization, and Efficiency (QUE)

• Six clinical areas studied over 2 years:

- transurethral prostatectomy (TURP)
- open cholecystectomy
- total hip arthroplasty
- coronary artery bypass graft surgery (CABG)
- permanent pacemaker implantation
- community-acquired pneumonia

pulled all patients treated over a defined time period

across all Intermountain inpatient facilities - typically 1 year

• identified and staged (relative to changes in expected utilization)

- severity of presenting primary condition
- all comorbidities on admission
- every complication
- measures of long term outcomes

•compared physicians with meaningful # of cases

(low volume physicians included in parallel analysis, as a group)

Intermountain TURP QUE Study

Median Surgery Minutes vs Median Grams Tissue



Intermountain TURP QUE Study

Average true cost to hospital



The opportunity (care falls short of its <u>theoretic</u> potential)

- 1. Massive variation in clinical practices (beyond even the remote possibility that all patients receive good care)
- 2. High rates of inappropriate care (where the risk of harm inherent in the treatment outweighs any potential benefit)
- 3. Unacceptable rates of preventable careassociated patient injury and death
- 4. Striking inability to "do what we know works"

5. Huge amounts of waste, leading to spiraling prices that limit access to care

We know why variation occurs

(1) Continued reliance on the "craft of medicine"

(clinicians as stand-alone experts)

encounters

(2) Complexity; a.k.a. clinical uncertainty

- the fruits of 100 years of clinical discovery

"The complexity of modern medicine exceeds the capacity of the unaided expert mind." Dr. David Eddy, Stanford University -- the father of evidence-based medicine)



The craft of medicine

An individual physician

- placing her patient's health care needs before any other end or goal,
- Drawing on extensive clinical knowledge gained through formal education and experience

can craft

• a unique diagnostic and treatment regimen customized for that particular patient.

Medicine's promise:

This approach guarantees the best result possible for each patient.



Clinical uncertainty (a hundred years of science ... the primary sources of practice variation)

1. Lack of valid clinical knowledge regarding best treatment (poor evidence)

2. Exponentially increasing new medical knowledge

(doubling time has decreased to <8 years; at current rates, a clinician will need to learn, unlearn, then relearn half of her medical knowledge base 5+ times during a typical career)

3. Continued reliance on subjective judgment

(subjective recall is dominated by anecdotes, and notoriously unreliable when estimating results across groups or over time)

4. Limitations of the expert mind when making complex

decisions (Miller, 1956: The magic number 7, plus or minus 2: some limits on our capacity for processing information)

Which, when combined with the craft of medicine, leads to: Enthusiam for unproven methods ... Mark Chassin, MD The maxim, "If it might work, try it" ... David Eddy, MD, PhD Quality means "spare no expense" ... Brent James, MD, MStat



Two methods to manage complexity

Subspecialize (analytic method; reductionism; 'divide and conquer')

An old joke: Know more and more about less and less until you know everything about nothing

Mass customize (a shared baseline: focus on that relatively small subset of factors that are unique for each individual patient [typically 5-15% of all factors], concentrating your most important resource -- the trained human mind -- where it can have the greatest impact)



Dr. Alan Morris, LDS Hospital, 1991

NIH-funded randomized controlled trial

assessing an Italian "artificial lung" vs. standard ventilator management for acute respiratory distress syndrome (ARDS)

 discovered large variations in ventilator settings across and within expert pulmonologists

• created a protocol for ventilator settings in the control arm of the trial

implemented the protocol using Lean principles

(Womack et al., 1990 - The Machine That Changed the World)

- built into clinical workflows automatic unless modified
- clinicians encouraged to vary based on patient need
- variances and patient outcomes fed back in a Lean Learning Loop

Problems with "best care" protocols

Lack of evidence for best practice

- Level 1, 2, or 3 evidence available only about 15-25% of the time

Expert consensus is unreliable

- experts can't accurately estimate rates relying on subjective recall (produce guesses that range from 0 to 100%, with no discernable pattern of response)

- what you get depends on whom you invite (specialty level, individual level)

Guidelines don't guide practice

- systems that rely on human memory execute correctly ~50% of the time (McGlynn: 55% for adults, 46% for children)

• No two patients are the same; therefore, no guideline

perfectly fits any patient (with very rare exception)

Shared Baseline "Lean" protocols (bundles)

- 1. Identify a high-priority clinical process (key process analysis)
- 2. Build an evidence-based best practice protocol (always imperfect: poor evidence, unreliable consensus)
- 3. **Blend it into clinical workflow** (= clinical decision support; don't rely on human memory; make "best care" the lowest energy state, default choice that happens automatically unless someone must modify)
- 4. Embed data systems to track (1) protocol variations and (2) short and long term patient results (intermediate and final clinical, cost, and satisfaction outcomes)
- **5. Demand that clinicians vary based on patient need**

6. Feed those data back (variations, outcomes) in a Lean Learning Loop - constantly update and improve the protocol

Results:

- Survival (for ECMO entry criteria patients) improved from 9.5% to 44%
- Costs fell by ~25% (from ~\$160,000 to ~\$120,000 per case)
- **Physician time fell by ~50%** (a major increase in physician productivity)



Key take-aways

1. No protocol perfectly fits any patient

- solution: Shared Baseline "bundles"

(mass customization = "patient centered care")

2. Serious limitations to protocol development

- solution: a Learning System (embedded variance and outcomes tracking; continuous protocol review and tested improvement)

3. Reliance on human memory (craft of medicine) produces "55% execution"

- solution: tools to embed protocols in workflows

4. Only two differences from traditional practice: It requires (1) coordinated teams with (2) reliable data systems





We count our successes in lives





Most often

(but not always)

better care is cheaper care



The same method – Shared Baseline protocols – works well for "indications" guidelines / appropriate use criteria (AUCs)



CT pulmonary angiography for r/o PE



*Healthy 41 year-old woman w/ atypical chest pain

Risks

- Missed diagnosis
- Over-diagnosis
- Radiation
- Contrast injury
- "Incidentaloma"



Suspected PE in ED CPM (Care Process Model)

Care Process Model

DECEMBER 2011

APPROPRIATE USE GUIDELINES FOR CTPA FOR PULMONARY EMBOLISM

DECEMBER 2011



APPROPRIATE USE GUIDELINES FOR

.....

CT Pulmonary Angiogram for Suspected Pulmonary Embolism

This care process model recommends an evidence-based protocol to evaluate patients suspected of pulmonary embolism (PE). These recommendations represent a collaborative effort including Intermountain's Cardiovascular and Intensive Medicine Clinical Programs, Intermountain's Imaging Service, and Intermountain Medical Center's Thrombosis Clinic, Department of Medicine, and Department of Emergency Medicine.

Key points

Intermountain Healthcare

 Most patients suspected of acute pulmonary embolism (PE) do not have this disease. A prospective study of 7,940 patients presenting with suspected PE to 12 Emergency Departments (EDs) in the United States found that only 7.2% had venous thromboembolism.¹ A study of 3,500 consecutive CTPAs performed at LDS Hospital and Intermountain Medical Center EDs found that 9.7% of these patients had PE.

- The use of pre-test probability assessment (PTP) and sensitive D-dimer can identify patients in whom PE can be excluded without imaging. The American College of Emergency Physicians Clinical Policies Subcommittee states that assessment of pretest probability is essential to evaluate suspected PE.² A low pretest probability coupled with a negative D-dimer result (using a highly sensitive test) identifies patients in whom further testing for PE is not required. The rate of subsequent DVT or PE when anticoagulation is withheld in this group is the same as in patients with a negative CTPA.³⁴ (Note: At Intermountain Healthcare, a second-generation, highly sensitive D-dimer test is used.)
- The Revised Geneva Score (RGS) is suggested to assess PTP.
- Why use the RGS? The RGS is prospectively validated among patients presenting to the ED to safely estimate pretest probability for PE.^{4, 10} Most RGS elements can be found in the electronic medical record. A process is underway to implement computer support for calculation of the RGS for the ED physician.
- Why not use the PERC score? While studied prospectively,^{11, 12} the Pulmonary Embolism Rule-out Criteria (PERC) rule presently lacks prospective validation. A recent study suggests that the PERC rule is inadequately sensitive to safely nule-out suspected PE.¹³
- When the RGS indicates PE is UNLIKELY (RGS 0 to 10) AND the D-dimer is negative (<500 ng/mL), no imaging is needed. Anticoagulants may be withheld; seek an alternate cause for the patient's symptoms. Of note, a recent large study at Intermountain Medical Center and LDSH emergency departments (see sidebar) demonstrated PE in only 1 of 320 patients (0.3%) who had RGS 0–10 and a negative D-dimer test.
- When the RGS score indicates that a PE is LIKELY (RGS >10) OR the RGS score is 0-10 and a D-dimer is positive (>500 ng/mL), imaging with CTPA should be performed unless contraindicated. CTPA has a negative predictive value similar to pulmonary angiography^{3,4} and has replaced pulmonary angiography as the standard imaging modality for suspected PE.¹⁴
- Pregnant patients require a different assessment strategy. Limited data exists to guide evaluation of suspected PE among pregnant women.¹⁵⁻¹⁷ Alternate guidelines focused on evaluating suspected PE in pregnancy will be available in early 2012.

Why Focus on CTPA FOR PULMONARY EMBOLISM?

- The use of CTPA to evaluate suspected PE has increased drastically. More than 3,000 CTPAs are ordered each year at intermountain Medical Center and LDS Hospital.
- While CTPA is generally safe, some risk exists. These include renal injury from contrast; radiation exposure with increased risk for subsequent cancers; and fake positive interpretations leading to unnecessary anticoaquitation of patients.
- While evidence-based guidelines for evaluating suspected PE are available, they are not always followed. A recent study of 3,500 CTPAs performed at intermountain Medical Center and LDS Hospital showed that 54% were not concordant with evidence-based guidelines.

Goals

- To increase the use of pre-test probability assessment before use of CTPA to evaluate suspected PE.
- To improve diagnosis and treatment of adults with suspected PE.

This document presents an evidence-based approach that is appropriate for most patients. It should be adapted to meet the needs of individual patients and situations, and should not replace clinical judgment.



EVALUATING SUSPECTED PULMONARY EMBOLISM

	Patient with Suspected PE									
	CALCULATE REVISED GENEVA SCORE (RGS)									
Fac	tor	Points	Fac	tor	Points					
	Age >65 years	1		Unilateral lower limb pain	3					
	Hemoptysis	2		Previous PE or DVT	3					
	Active malignant condition	2		Pain on lower-limb deep venous palpation and unilateral edema	4					
	Surgery or fracture	2		Heart rate 75–94 beats per min	3					
	within 1 month			Heart rate ≥95 beats per min	5					



REFERENCES

For a numbered list of references used in this document, see the CTPA for suspected PE topic page; this can be found at intermountain.net/clinicalprograms or intermountainphysician.org/clinicalprograms. Find it using the topic page menu in the upper right.

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ALGORITHM NOTES

(a) D-dimer test. The D-dimer test has higher than 95% sensitivity and can decrease probability of PE to about 1% in patients with RGS <3 and less than 5% in patients with RGS 4–10.

(b) Negative D-dimer if RGS is

4–10. An RGS of 4–10 corresponds to an intermediate pretest probability. The ACEP Clinical Policies Subcommittee states with a Level C recommendation that "In patients with an intermediate pretest probability for PE, a negative quantitative D-dimer assay result may be used to exclude PE."²

(c) CT pulmonary anglogram. CTPA has 83-100% sensitivity and 89-98% specificity, and can yield information about alternative diagnoses.² CTPAs are indeterminate 6% to 18% of the time, often due to technical factors or respiratory motion. In these cases further testing should be considered.¹⁸ The radiation dose for CTPA ranges from 3.8 mSv¹⁰ to 15 mSv¹⁹ on average, the equivalent of up to 150 chest x-rays.

(d) VQ scan or, in patients with normal chest x-ray, Q-only scan. Recent studies

suggest that a VQ scan or a Q scan has similar diagnostic accuracy as CTPA.²⁰ Radiation exposure, especially to the breast, is significantly less with VQ and Q scans when compared with CTPAs. (Note: **Duplex ultrasonography** is useful when it is positive, as it rules in VTE. If negative, perform VQ scan.)

(f) Negative CTPA with RGS ≥11. If the CTPA is negative but RGS is ≥11, the ACEP Clinical Policies Subcommittee recommends additional testing (Level C recommendation) before excluding VTE disease.² Consider evaluating the D-dimer if ordered; if D-dimer is positive, consider bilateral lower extremity venous duplex and/or VQ scan and/or conventional pulmonary angiography.

EVALUATING PE IN PREGNANCY

The best approach to the pregnant patient suspected of PE is unclear. Recommendations from varying guidelines differ on the use of d-dimer, pre-test probability tools, and imaging.¹⁵⁻¹⁷

The consensus of this team is to begin with bilateral LE Doppler in patients with DVT signs, and otherwise begin with a CXR. Results of the CXR then guide the choice of Q scan or CTPA. Watch for guidelines on this topic in early 2012.

Order Form: CTPA for Suspected PE

Patient Name:	Patient Age:	Weight:	kg	🗆 Male 🛛 Famale
Other factors that need to be on the form not	t sure what else should g	go here, separate	from w	vhat's on the regular ED

order form. Will the two forms be used together, or ...?

Likelihood of PE

Revised Geneva Score (RGS)	:	IF RGS 0-10, D-dime	: 🗆 Positive	Negative	
RGS Factor	Points	RGS Factor	Points		
□ Age >65 years	1	Unilateral lower limb pain	3		
Hemoptysis	2	Previous PE or DVT	3		
□ Active malignant condition	2	Pain on lower-limb deep venous palpation and unilateral edema	4		
□ Surgery or fracture within 1 mon	th 2	Heart rate 75–94 bpm	3		
		Heart rate <u>></u> 95 bpm	5		

Contrast risk factors

- YES NO
- □ □ Contrast allergy
- □ □ Diabetes (if yes, provide sCr and eGFR below)
- \Box Age >60 (if yes, provide sCr and eGFR below)
- □ □ History of kidney disease (if yes, provide sCr and eGFR below)

Kidney function: sCr: ______eGFR: _____

Contraindications to CTPA

- □ RGS 0-10 with negative D-dimer
- □ Contrast allergy

Intermountain Healthcare \Box eGFR <30 with diabetes, age >60, or kidney disease history

In one year, we will:

- Increase the % of patients with RGS measured <u>before</u> undergoing tests to investigate suspected pulmonary embolism from 0% to > 50%
- Reduce the number and % of CTPAs performed when RGS is 0-3 and D-dimer is negative to < 2%.











ED MD

Capture and evaluate initial clinical information



Resident provides ED MD with RGS and algorithm using checklist pad

ED MD

HUC enters D-dimer order and F scans RGS checklist into record h Lab tech selects tubes Lab measures and reports D-dimer

ED MD

Resident and ED MD huddle to review data and decide for or against CTPA





Radiologist reads scan

PE?

CT tech does scan



Revised Geneva Score (RGS) checklist

	Yes	No	Points
Age > 65 yrs			1
Hemoptysis			2
Active cancer			2
Surgery or fracture within 1 month			2
Unilateral leg pain			3
Prior PE or DVT			3
Pain on leg deep vein palpation and edema			4
Heart rate 75-94 > 94			3 5



Pretest probability (RGS) documented



% patients w RGS < 11 who received D-dimer test



% CTPA w RGS < 3 and normal D-dimer



Jan-11 Feb-11 Mar-11 Apr-11 May-11 Jun-11 Jul-11 Aug-11 Sep-11 Oct-11 Nov-11 Dec-11 Jan-12 Feb-12 Mar-12 Apr-12 May-12 Jun-12 Jul-12 Aug-11

CTPA rates among all ED admissions



CTPAs Performed 2014-2015



Financial impact

Direct CTPA costs 2014: Direct CTPA costs 2015:

\$312,238.78 75,963.57

Annual cost savings:

\$236,275.23



Only one pertinent question:

Assume that front-line clinicians are

- as smart you are
- as dedicated to patients as you are
- as hard-working as you are
- as motivated as you are
- are the only ones with fundamental knowledge of how the front-line process actually works;

but they don't control the systems that set the context within which they work ...

How will your proposed intervention make it easier for them to do it right?



Evidence-based use of cardiac interventions

- Nuclear Stress Testing
- Angioplasty and Stents (PCI)
- Implantation of Permanent Pacemakers
- Implantation of Defibrillators





Nuclear stress testing



Fax:

Phone:

Patient Name:	Gender:	DOB:	Age:				
Patient Phone #: Pt. Addres		dress:					
Referring Physician:		Fax:					
NUCLEAR CARDIAC STRESS TEST							
(Prep—Nothing by mouth >6 hours and no meds, PLUS no caffeine 12-24 hours, wear comfortable exercise clothing)							
(If patient is diabetic have patient hold medications in fasting status or as otherwise directed by you)							

Check a box to identify indication (women under 50 years and men under 40 years old should only have nuclear testing if higher risk or other stress testing modalities are not adequate)

COMMON INDICATIONS

- □ Anginal "chest pain" that is likely to be ischemic (N1)
- Anginal "chest pain" with diabetes, carotid artery disease, abdominal aortic aneurysm, or significant peripheral arterial disease (N2)
- □ Anginal "chest pain" with 3 or more of the coronary heart disease risk factors‡ listed below (N3)
- Anginal "chest pain" AND left bundle branch block, pacemaker, or ICD (N4)
- Anginal equivalent such as exertional dyspnea, jaw pain or arm pain etc. that is likely to be ischemic (N5)
- □ New onset atrial fibrillation (N6)
- □ New onset heart failure with LV systolic dysfunction (N7)
- □ Patient with known coronary heart disease with new or worsening cardiac symptoms (N8)
- \square Asymptomatic with CABG \geq 5 years ago or stent \geq 2 years ago and 3 or more of the coronary heart disease risk



Angioplasty & Stents

Date Patient Name EMPI Date of Birth Clinical Information on this page should be completed before the procedure. □ Patient has Acute Coronary Syndrome (no further documentation beyond medical record is needed) Elective PCI Table A2: Noninvasive Risk Stratification Anginal / Ischemic Symptoms □ CCS 0 (asymptomatic) High-Risk (greater than 3% annual mortality rate) 1. Severe resting left ventricular dysfunction (LVEF less than 35%) CCS III-IV 2. High-risk treadmill score (score less than or equal to -11) 3. Severe exercise left ventricular dysfunction (exercise LVEF less than 35%) Results of Noninvasive Testing (see Table A2) 4. Stress-induced large perfusion defect (particularly if anterior) Not Available 5. Stress-induced multiple perfusion defects of moderate size Normal / Equivocal 6. Large, fixed perfusion defect with LV dilation or increased lung uptake (thallium-201) Low Risk 7. Stress-induced moderate perfusion defect with LV dilation or increased lung uptake (thallium-201) Intermediate Risk 8. Echocardiographic wall motion abnormality (involving greater than two segments) □ High Risk developing at low dose of dobutamine (less than or equal to 10 mg/kg/min) or at a Heart Failure Symptoms low heart rate (less than 120 beats/min) □ Asymptomatic 9. Stress echocardiographic evidence of extensive ischemia Intermediate-Risk (1% to 3% annual mortality rate) □ NYHA Class I 1. Mild / moderate resting left ventricular dysfunction (LVEF 35% to 49%) □ NYHA Class II 2. Intermediate-risk treadmill score (score between -11 and less than 5) □ NYHA Class III Stress-induced moderate perfusion defect without LV dilation or increased lung NYHA Class IV intake (thallium-201) 4. Limited stress echocardiographic ischemia with a wall motion abnormality only at · Left Ventricular Systolic Function higher doses of dobutamine involving less than or equal to 2 segments □ Normal (greater than or equal to 55%) Low-Risk (less than 1% annual mortality rate) 45 - 55% Low-risk treadmill score (score greater than or equal to 5) 35 11%



Implantable pacemakers

Intermountain Permanent Pacemaker Indications

Patient Name:	Date of Service:	EMPI Number:	
V. A. SANDAR STANDAR MANAGEMENT AND A STANDARD MADE	La forma de la constante de la c		

Before performing the pacemaker procedure, the implanting physician must complete the form below and sign this document along with assuring that medical record documentation supports the selected indication. If the physician believes a pacemaker is warranted outside the guidelines below, please check category I and carefully document the specific justifications and be sure they are well documented in the patient's records. These exceptions must be approved by the chief of cardiology or his/her appointee.

ALL APPLICABLE SECTIONS MUST BE COMPLETED BEFORE PROCEEDING WITH PACEMAKER IMPLANTATION

- Section 1—Permanent Pacemaker Indications
- Section 2—Dual Chamber Indication
- Section 3—Biventricular Indication

Section 1—Pacemaker Indication

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- (P-1) Acquired complete (also referred to as third-degree) AV heart block.
- (P-2) Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms due to the bradycardia.
- (P-3) Second-degree AV heart block of Type II (i.e., no progressive prolongation of P-R interval prior to each blocked beat. P-R interval indicates the time taken for an impulse to travel from the atria to the ventricles on an electrocardiogram).
- (P-4) Second-degree AV heart block of Type I (i.e., progressive prolongation of P-R interval prior to each blocked beat) with significant symptoms due to hemodynamic instability associated with the heart block.
- (P-5) Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, congestive heart failure); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

(P-6) In selected and few patients, sinus bradycardia of lesser severity (heart rate 50-59) with dizziness or confusion

Implementation Appropriate Use Criteria

	Use of AUC forms Q1 2016, Q2 2016, Q3 2016													
Ţ		ICD			Pacemaker			PCI			G	Grand Total		
		Form Present	Num. of Records	AUC Co mplete										
Dixie	Q1 2016	24	24	100.0%	61	65	93.8%	129	130	99.2%	214	219	97.7%	
	Q2 2016	16	16	100.0%	75	78	96.2%	102	104	98.1%	193	198	97.5%	
	Q3 2016	17	17	100.0%	42	42	100.0%	80	81	98.8%	139	140	99.3%	
	Total	57	57	100.0%	178	185	96.2%	311	315	98.7%	546	557	98.0%	
IMC	Q1 2016	61	62	98.4%	105	110	95.5%	124	138	89.9%	290	310	93.5%	
	Q2 2016	47	48	97.9%	124	124	100.0%	157	168	93.5%	328	340	96.5%	
	Q3 2016	47	47	100.0%	82	82	100.0%	95	103	92.2%	224	232	96.6%	
	Total	155	157	98.7%	311	316	98.4%	376	409	91.9%	842	882	95.5%	
Logan	Q1 2016				7	7	100.0%	6	6	100.0%	13	13	100.0%	
	Q2 2016				12	14	85.7%	3	3	100.0%	15	17	88.2%	
	Q3 2016				11	11	100.0%	6	7	85.7%	17	18	94.4%	
	Total				30	32	93.8%	15	16	93.8%	45	48	93.8%	
McKay	Q1 2016	15	15	100.0%	49	52	94.2%	79	84	94.0%	143	151	94.7%	
	Q2 2016	29	30	96.7%	40	40	100.0%	84	88	95.5%	153	158	96.8%	
	Q3 2016	13	13	100.0%	35	37	94.6%	83	86	96.5%	131	136	96.3%	~



All Cath Lab procedures (system-wide)



Nuclear Medicine procedures (system-wide)



Results in cardiac procedures

Clinical Outcomes:

Remained Excellent

2014 Costs to Community:

	Decrease in Variable Cost
Echo	\$161,634
Nuclear Medicine	\$1,644,344
Cath Lab	\$17,112,541
Total	\$18,918,519





Process management is the key

- better clinical results produces lower costs
- more than half of all cost savings will take the form of unused capacity (fixed costs: empty hospital beds, empty clinic patient appointments, reduced procedure, imaging, and testing rates)

balanced by increasing demand:

- demographic shifts (Baby Boom);
- population growth;
- behavioral epidemics (e.g., obesity);
- technological advances



Better has no limit ...

an old Yiddish proverb

