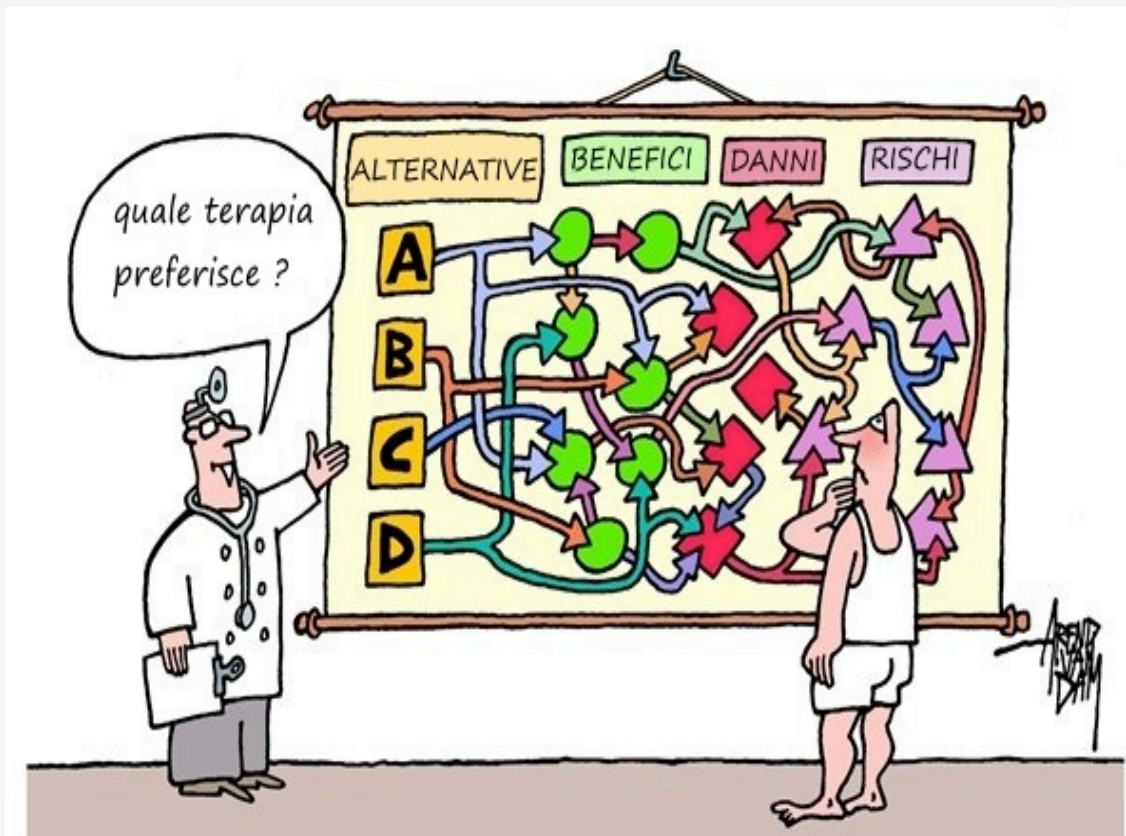




Non solo clinica 2

LA COMUNICAZIONE COL PAZIENTE E IL CONSENSO INFORMATO





CONSENSO INFORMATO E CHIRURGIA DELLA TIROIDE: ieri oggi e ... domani

Vincenzo Giannamarco

- A) il cancro della tiroide ieri e oggi:
epidemia di cancri o abuso di ecografie ed agoaspirati?
- B) il cancro della tiroide ... domani
- è possibile fare marcia in dietro?
 - il consenso informato: una "finzione legale" o una "decisione condivisa" ?

2017 Update on Medical Overuse
Daniel J. Morgan, *JAMA Intern Med.* Published online October 02, 2017

Un esempio è il cancro alla tiroide: è stimato che negli ultimi due decenni 500.000 persone di oltre 12 paesi potrebbero aver ricevuto "overdiagnosis", con conseguenti inutili interventi chirurgici e necessità per molti di assumere medicinali per tutta la vita

cosa é accaduto!



A photograph showing a medical professional in a white lab coat performing a thyroid ultrasound on a patient lying on a table. The patient's head is tilted back, and the doctor is using a probe on their neck. A female assistant in a white lab coat stands by the patient's head, holding a blue water bottle. In the background, an ultrasound machine with a monitor and keyboard is visible on a table. The text "23 anni di ecografie tiroidee" is overlaid in white on the image.

23 anni di ecografie tiroidee

alla palpazione



prima 1994

5%

Prevalenza di
"anomalie strutturali"
della tiroide

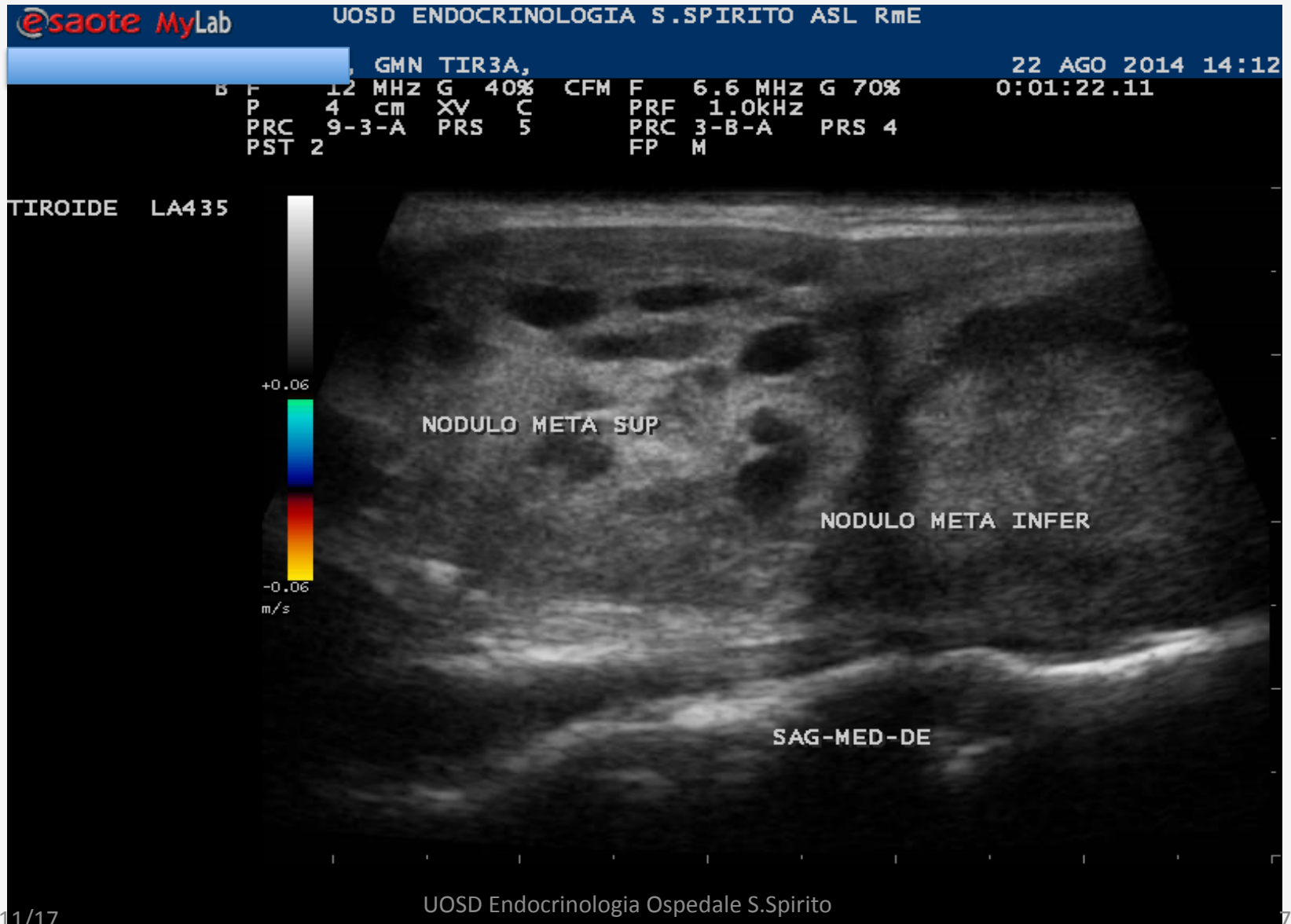
alla ecografia



dopo 1994

60%

abbiamo trovato tanti noduli!





nodulo=tumore?

**abbiamo punto tutti
i noduli e ...
sempre più piccoli!!!**





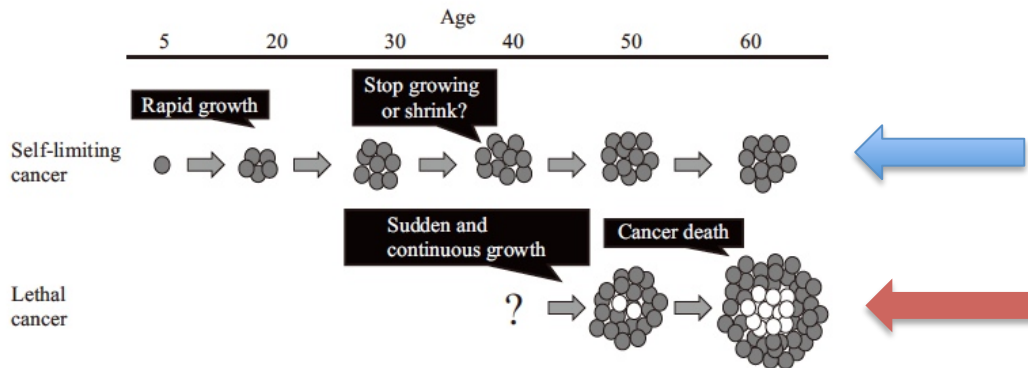
23 anni di ecografie tiroidee
cosa abbiamo imparato



How to Look for Thyroid Cancer

Anne R. Cappola, MD, ScM

- le caratteristiche ecografiche possono essere utilizzate per definire il rischio di malignità
- l'aumento di volume non è prerogativa di malignità
- raramente noduli follicolari benigni diventano maligni
- microcarcinomi papillari (< 1,5cm) - 90% dei tumori operati possono rimanere immutati per tutta la vita



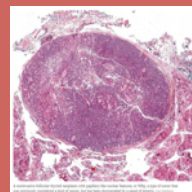
Natural history of thyroid cancer suggested by the thyroid cancer trilogy

Self-limiting cancers arise in the infantile period and then undergo rapid but limited growth. Most of them stop growing, then turn into PMCs. Lethal cancers appear suddenly after middle age and undergo rapid and unlimited proliferation to cause cancer death.

"la storia naturale del cancro della tiroide"

alcuni noduli "maligni" sono stati riclassificati come benigni – NIFTP*

encapsulated follicular variant of papillary thyroid carcinoma



Noninvasive Follicular Thyroid Neoplasm with papillary like nuclear features (NIFTP)

R. Michael Tuttle, MD

Professor of Medicine and Endocrinologist
Memorial Sloan Kettering Cancer Center
New York, NY

"Forse la differenza fra noduli tiroidei che richiedono la chirurgia e quelli che no risiede nelle caratteristiche del paziente, non nelle caratteristiche del tumore"



OSSERVAZIONE nei carcinomi tiroidei a basso rischio

[Thyroid](#). 2017 Apr;27(4):518-523.

Applying Criteria of Active Surveillance to Low-Risk Papillary Thyroid Cancer Over a Decade: How Many Surgeries and Complications Can Be Avoided?

Brito JP, Griffin A, Bahl M, Hoang JK.



"quanti interventi e relative complicazioni possiamo evitare?"



CONSENSO INFORMATO E CHIRURGIA DELLA TIROIDE: ieri oggi e ... domani

Vincenzo Giannamarco

A) il cancro della tiroide ieri e oggi:
epidemia di cancri o abuso di ecografie ed agoaspirati?

B) il cancro della tiroide ... domani

- è possibile invertire la direzione?
- il consenso informato: una "finzione legale" o una "decisione condivisa" ?

OVERTREATMENT di carcinomi differenziati della tiroide

"estimates that over 500.000 people may have received overdiagnoses across 12 countries in the past two decades, leading to unnecessary surgery and lifelong medication for many"

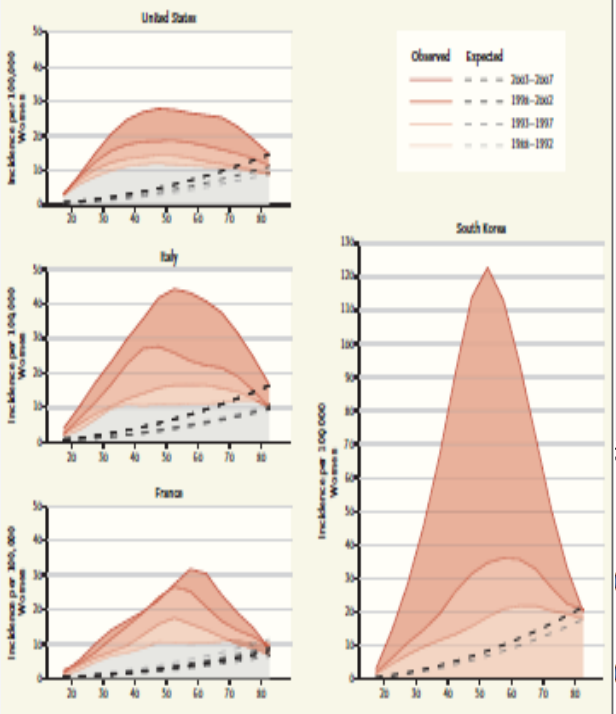
é possibile invertire la direzione?



Turning the Tide

South Korea's Thyroid-Cancer "Epidemic" — Turning the Tide

NEJM 373;24-2015



screening ecografico

March 2014
physician coalition
call to stop
screening

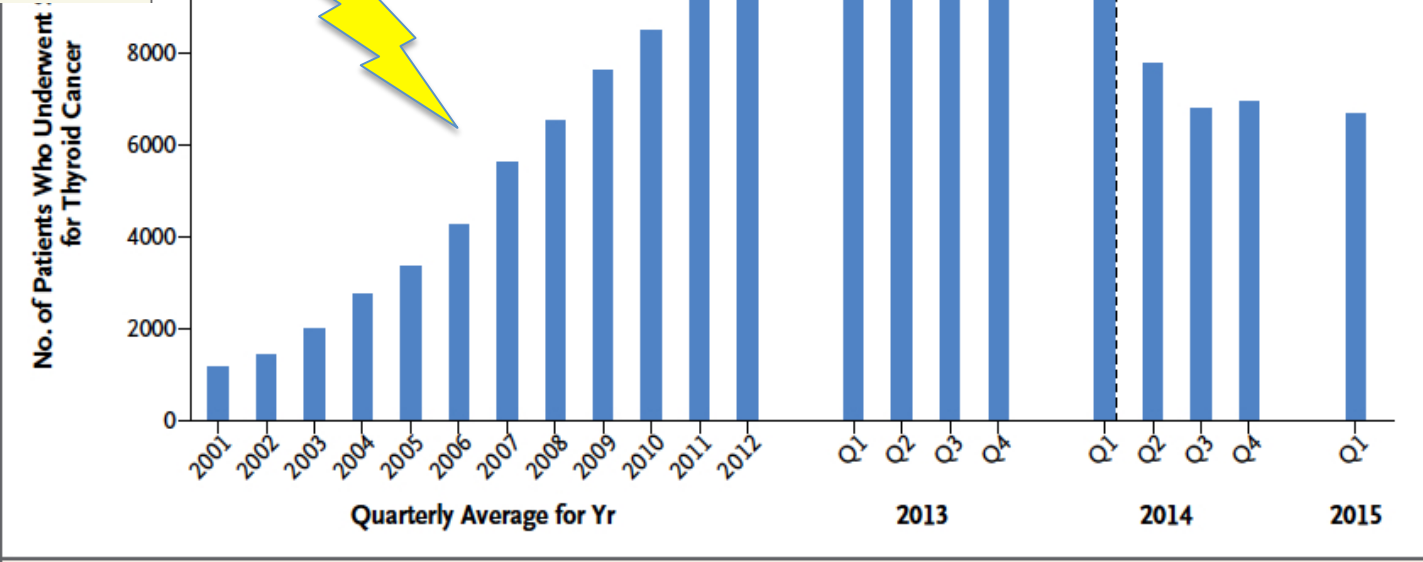


Figure 1. Trend in the Number of Operations for Thyroid Cancer in South Korea, 2001–2015.

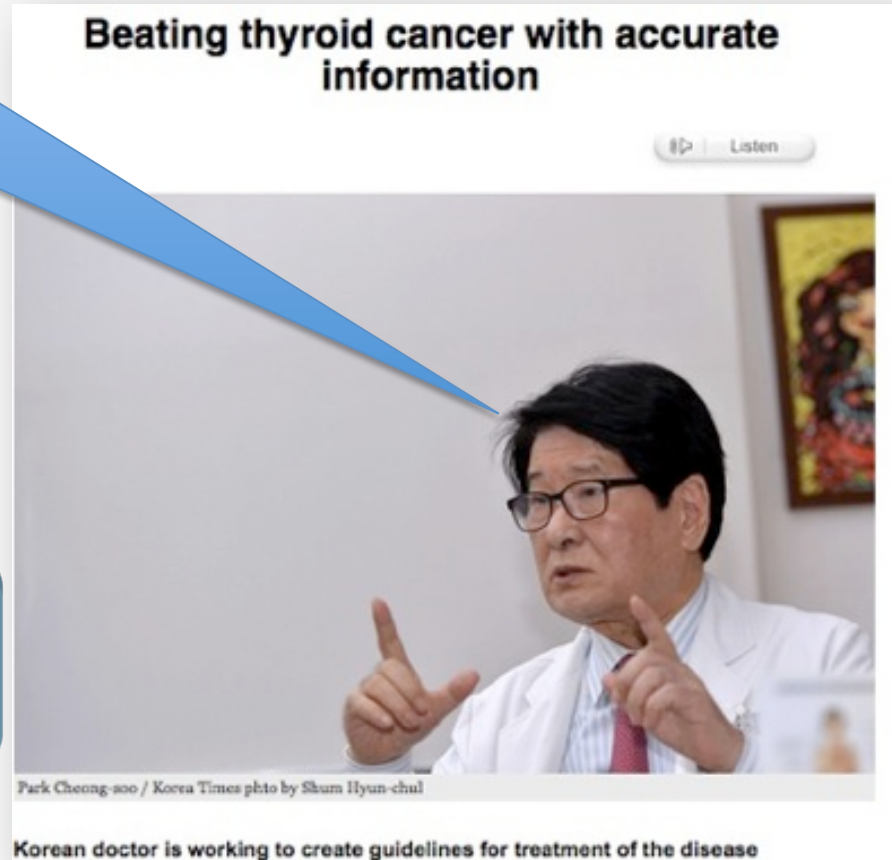
Data are from the Health Insurance Review and Assessment Service, South Korea.

" Our findings suggest that a small group of physicians can change the direction of medical care through public discourse.."

come



inversione di corrente
con corretta
comunicazione
scientifica sui media



raccomandazioni per la chirurgia dei carcinomi differenziati della tiroide (Linee Guida ATA / AME-AACE)

- sorveglianza può essere praticabile per microcarcinomi (< 1,5 cm) papillari **(diagnosi citologica)** a basso rischio.
(markers tumorali possono supportare questa decisione)
la lobectomia può essere una valida alternativa
- tiroidectomia totale dovrebbe essere riservata ad una minoranza di casi a medio alto potenziale aggressivo

overdiagnosis



overtreatment

METTERE IN PRATICA

ASL ROMA 1 **UOSD ENDOCRINOLOGIA** **REGIONE LAZIO**

Responsabile dott Vincenzo Giammarco
 Tel 066835 2265/7126 FAX 0668352162
 vincenzo.giammarco@aslroma1.it
 cell 3476530630
 giammarcov@mdlink.it

PER PRENOTARE
 con ricetta rosa del medico curante
 RECUP 803333 ORE 8-18
 visita intramoenia 06-77307447
 lunedì-venerdì ore 8-18

20/09/2017 **MMG** RICHIESTA FNA MEDICO PRESCRIVENTE AGOASPIRATO APPROPRIATEZZA RICHIESTA AGOASPIRATO

relazione medica data di nascita 28/09/1965 tel 3389484908

1-3-2013: esegue eco tiroide per cardiopalmo (!!!) con riscontro di nodulo misto a dx di dimensioni non precisate nel referto(!?). Nel 2014>2016: mastectomia sinistra in due tempi per K seguita da chemioterapia (attualmente assume Femara). Assume inoltre Cardicor 2.5 per extrasistolia; Eutimil. Ha eseguito nuovamente eco tiroide (stesso operatore diplomato SIUMB) il 7-4-2017 con riscontro di incremento dimensionale del nodulo con vascolarizzazione peri ed intra. Consigliato FNAB

referto ecocolor Doppler tiroide/collo 20/09/2017
 volume nei limiti con ecostruttura di fondo regolare ed omogenea. In sede medio lobare destra formazione ovoidale 6,3x8,5x11,2, moderatamente ipoecogena, disomogenea, con margini netti leggermente irregolari, con rinforzo posteriore, vascolarizzazione peri e intranodulare.
 Non linfoadenopatia LC di aspetto patologico

% INDICE NEOPLASTICO ECOGRAFICO tiroide
5-10 sospetto basso

controlli ECO

20/09/2017 data 1° relazione
 iperplasia nodulare a basso rischio neoplastico. Spiegato alla paziente le indicazioni diagnostiche terapeutiche secondo LG accreditate (AME/AACE) e le relative proiezioni prognostiche si decide di soprassedere all'esecuzione dell'agoaspirato e rivalutare fra 6 mesi.

Indicatore AGOASPIRATO? **NO**

INTERVENTO istologia T N

4th Thyroid Ultrasound 2016
 Lines Guida vs Pratica Clinica: consenso e controversie

High Suspicion 70-90%
 Microcalcifications, hypoechoic nodule, irregular margin; Hypoechoic, irregular margins; Hypoechoic, taller-than-wide; Hypoechoic, irregular margins, extracapsular extension; Hypoechoic, intranodular calcification with soft tissue extension; Nodule with irregular margins, suspicious hilar lymph node

Intermediate Suspicion 10-20%
 Hypoechoic solid regular margin; Hypoechoic solid regular margin

Low Suspicion 5-10%
 Hyperechoic solid regular margin; Isoechoic, taller-than-wide; Partly cystic with eccentric solid area; Partly cystic with eccentric solid areas

Very low Suspicion <3%
 Spongiform; Partly cystic no suspicious features; Partly cystic no suspicious features

Benign <1%
 Cyst

Risk of malignancy ↑

AMERICAN THYROID ASSOCIATION
 DEDICATED TO SCIENTIFIC INQUIRY, CLINICAL EXCELLENCE, PUBLIC SERVICE, EDUCATION, AND COLLABORATION.

adottare l'indice di sospetto neoplastico nella refertazione ecografica

ULTIMO CONTROLLO **Indice di attenzione**

appropriatezza prescrittiva e gestionale da parte del MMG

Medico *[Signature]*

METTERE IN PRATICA

raccomandazioni per agoaspirato ecoguidato
Linee Guida ATA / AME-AACE



noduli inferiori a 10-15 mm

limitare l'agoaspirato a quelli con
caratteristiche "particolari"

CDT Carcinomi Differenziati Tiroide

The Optimal Practice of Evidence-Based Medicine Incorporating Patient Preferences in Practice Guidelines

Victor M. Montori,
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Rochester, Minnesota,
Department of
Medicine, Mayo Clinic,
Rochester, Minnesota,
and Center for the
Science of Healthcare
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jama.com

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jama.com

Research evidence is necessary but insufficient for making patient care decisions. An effective but toxic chemotherapeutic regimen is the treatment one patient with cancer can and will take, another patient can take but will not, and yet another patient could not take even if wanted. Careful attention to the biopsychosocial context of patients and to their informed preferences when crafting treatments requires expertise and practical wisdom. This represents the optimal practice of evidence-based medicine.

Patient preferences refer to patient personal beliefs, expectations, and goals for health care, and to the processes that individuals use to weigh the potential benefits and risks of health care in light of their preferences of the self and others. Patient preferences and expertise may hinder the development of evidence-based medicine. Patient preferences or only produce patient involvement, false inclusion, and devalued input.³

These challenges could be considered opportunities to develop new and better methods. This optimism is somewhat tempered by the stubbornly poor quality of contemporary guidelines. Getting the evidence right—the right options, outcomes, and outcome data—is an obligatory prerequisite for considering informed patient preferences. For instance, in a survey of more than 2000 patients with diabetes living in Minnesota, 1 in 4 respondents considered hemoglobin A_{1c}, a measure of glycemic control, to be as important as death or major morbidity.⁶ For decades, experts, diabetes organizations, and industry have indoctrinated patients and physicians to believe that hemoglobin A_{1c} captures the beneficial effects of diabetes care, a view not supported by large randomized trials. If panels were to consider the preferences from these patients, in this context of inaccurate information, guidelines would probably look just like the ones produced by similarly misguided diabetes experts.

Getting the evidence right—the right options, outcomes, and outcome data—is an obligatory prerequisite for considering informed patient preferences.

receiving information about the small absolute reduction in coronary risk statins could afford them than patients receiving guideline-directed care.² Where the use of statins in patients with diabetes is linked to quality measures or performance incentives, clinicians face the conflict of following either the guideline or the informed patient.

Challenges in the Incorporation of Preferences in Guidelines

Access to patients' preferences is complex. Individuals form their preferences when they have to make a decision, in a context replete with emotional and social influences.³ This context is often absent when volunteers, not facing a decision, report preferences.

Hindsight bias, cognitive dissonance, and regret can reduce the validity of surveys of preferences in patients who are living with the consequences of a prior decision. Indeed, a systematic review of patient preference literature for the antithrombotic guidelines of the American College of Chest Physicians found only heterogeneous evidence.⁴ Direct patient involvement, false inclusion, and devalued input.³

These challenges could be considered opportunities to develop new and better methods. This optimism is somewhat tempered by the stubbornly poor quality of contemporary guidelines. Getting the evidence right—the right options, outcomes, and outcome data—is an obligatory prerequisite for considering informed patient preferences. For instance, in a survey of more than 2000 patients with diabetes living in Minnesota, 1 in 4 respondents considered hemoglobin A_{1c}, a measure of glycemic control, to be as important as death or major morbidity.⁶ For decades, experts, diabetes organizations, and industry have indoctrinated patients and physicians to believe that hemoglobin A_{1c} captures the beneficial effects of diabetes care, a view not supported by large randomized trials. If panels were to consider the preferences from these patients, in this context of inaccurate information, guidelines would probably look just like the ones produced by similarly misguided diabetes experts.

This example illustrates a key insight: the challenges intrinsic to incorporating patient preferences are the same as those involved in incorporating expert views into guidelines. These include advocacy and activism of a particular position; lack of appreciation for evidence-based medicine and its methods for the selection, appraisal, summary, and presentation of the evidence; complicated power, language, goal,⁷ and experience differences across panelists; and lack of respect for the rigorous methods of guideline formulation.

This example illustrates a key insight: the challenges intrinsic to incorporating patient preferences are the same as those involved in incorporating expert views into guidelines. These include advocacy and activism of a particular position; lack of appreciation for evidence-based medicine and its methods for the selection, appraisal, summary, and presentation of the evidence; complicated power, language, goal,⁷ and experience differences across panelists; and lack of respect for the rigorous methods of guideline formulation.

INCORPORARE LE PREFERENZE DEL PAZIENTE IN LINEE GUIDA "PRATICHE"

disseminare

LG ai pazienti: è possibile?

Schipper et al. *Implementation Science* (2016) 11:82
DOI 10.1186/s13012-016-0447-x

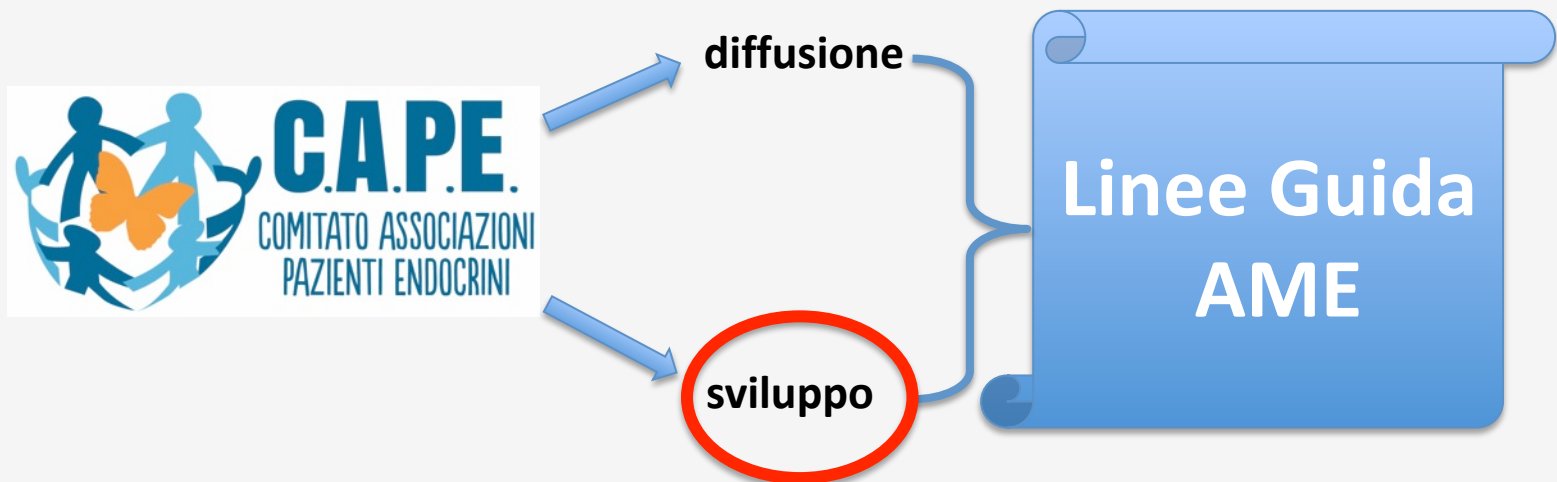
Implementation Science

SYSTEMATIC REVIEW

Open Access



Strategies for disseminating
recommendations or guidelines
to patients: a systematic review




J. BRITO alla Mayo Clinic

ClinicalTrials.gov ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

[Home](#) > Study Record Detail

Shared Decision Making in Patients With Thyroid Nodules

This study is currently recruiting participants. 

See [▶ Contacts and Locations](#)

Verified October 2017 by [Juan P. Brito Campana, MBBS, Mayo Clinic](#)

Sponsor:
Mayo Clinic

"MEDICINA CONDIVISA" JAMA 2017

Opinion

VIEWPOINT

SHARING MEDICINE

Sharing as the Future of Medicine

Sharing Medicine—A *JAMA Internal Medicine* Series

Robert Steinbrook, MD; Rita F. Redberg, MD, MSc

In this issue of *JAMA Internal Medicine*, we launch a series on “Sharing Medicine.” Encompassing the mutual decisions by physicians and patients that are often referred to as “shared decision making,” sharing medicine describes a broader ecology of the sharing of knowledge, data, skills, and experiences within the medical profession, with patients, and with the public and society.

The Sharing Medicine series begins with 7 Viewpoints, starting in this online issue¹ and continuing weekly online. These articles will consider such topics as the importance of understanding the goals and preferences of individual patients, the sharing of medical knowledge among physicians, and the sharing of experiences of illness and care.

The articles have been commissioned and developed for publication in collaboration with Richard Lehman, BM, BCH, MRCPG, the guest editor for the series. In the first article,

 Viewpoint
 Related article

Lehman¹ offers a vision for sharing, writ large, as the future of medicine. Sharing medicine begins with shared decision making, which, as Lehman notes, is not a “single act of choice,” but “something more wide-ranging and complex.”¹¹ It is part of an ongoing dialogue between clinicians and patients, which elicits goals and preferences and continues with an exchange of knowledge that is relevant and understandable to the patient.

Also in this issue is a Special Communication from Tulskey and colleagues² that proposes research approaches to

improving the quality of communication between physicians and patients in serious illness. Starting from the premise that poor communication has a central role in the suffering of patients living with serious illness, the article considers shared decision making, advance care planning, communication about prognosis, and related topics. That improvements in the quality of communication in serious illness can help to ease the suffering of patients is a powerful concept and closely aligned with the themes of the Sharing Medicine series.

Individual patients will vary in the extent to which they wish to make shared decisions with physicians and in their ability to make them. Nonetheless, the days of paternalism and the view that “the experts” alone know best are behind us. A recent article focused attention on shared decision making, and noted that “informed patients often choose more conservative and hence less expensive medical options.”^{3(p1309)} The article also summarized what was needed for successful implementation, including “common definitions, trusted certified decision aids, clinician engagement, strategies to enable successful implementation into practice, and a commitment to rigorous evaluation and improvement.”^{3(p1310)}

This series aims to enable sharing medicine as the future direction of medicine. The driving forces are improving medical care and making it more patient centered. We hope you find the series informative and thought provoking and a stimulus to move forward.

ARTICLE INFORMATION

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Conflict of Interest Disclosures: None reported.

REFERENCES

1. Lehman R. Sharing as the future of medicine [published online July 3, 2017]. *JAMA Intern Med*. doi:10.1001/jamainternmed.2017.2371
2. Tulskey JA, Beach MC, Butow PN, et al. A research agenda for communication between health care

professionals and patients living with serious illness [published online July 3, 2017]. *JAMA Intern Med*. doi:10.1001/jamainternmed.2017.2005

3. Spatz ES, Krumholz HM, Moulton BW. Prime time for shared decision making. *JAMA*. 2017;317(13):1309-1310.

Informare

responsabilizzare

condividere

BMJ 2014;349:g5811 doi: 10.1136/bmj.g5811 (Published 25 September 2014)

Page 1 of 2

EDITORIALS

Decision aids, empowerment, and shared decision making

Each works or fails to work in patient-clinician conversations

Ian Hargraves lead designer, Victor M Montori professor of medicine

Knowledge and Evaluation Research Unit, Mayo Clinic, Rochester, MN 55905, USA

[Cancer](#). 2013 Jan 1;119(1):189-200

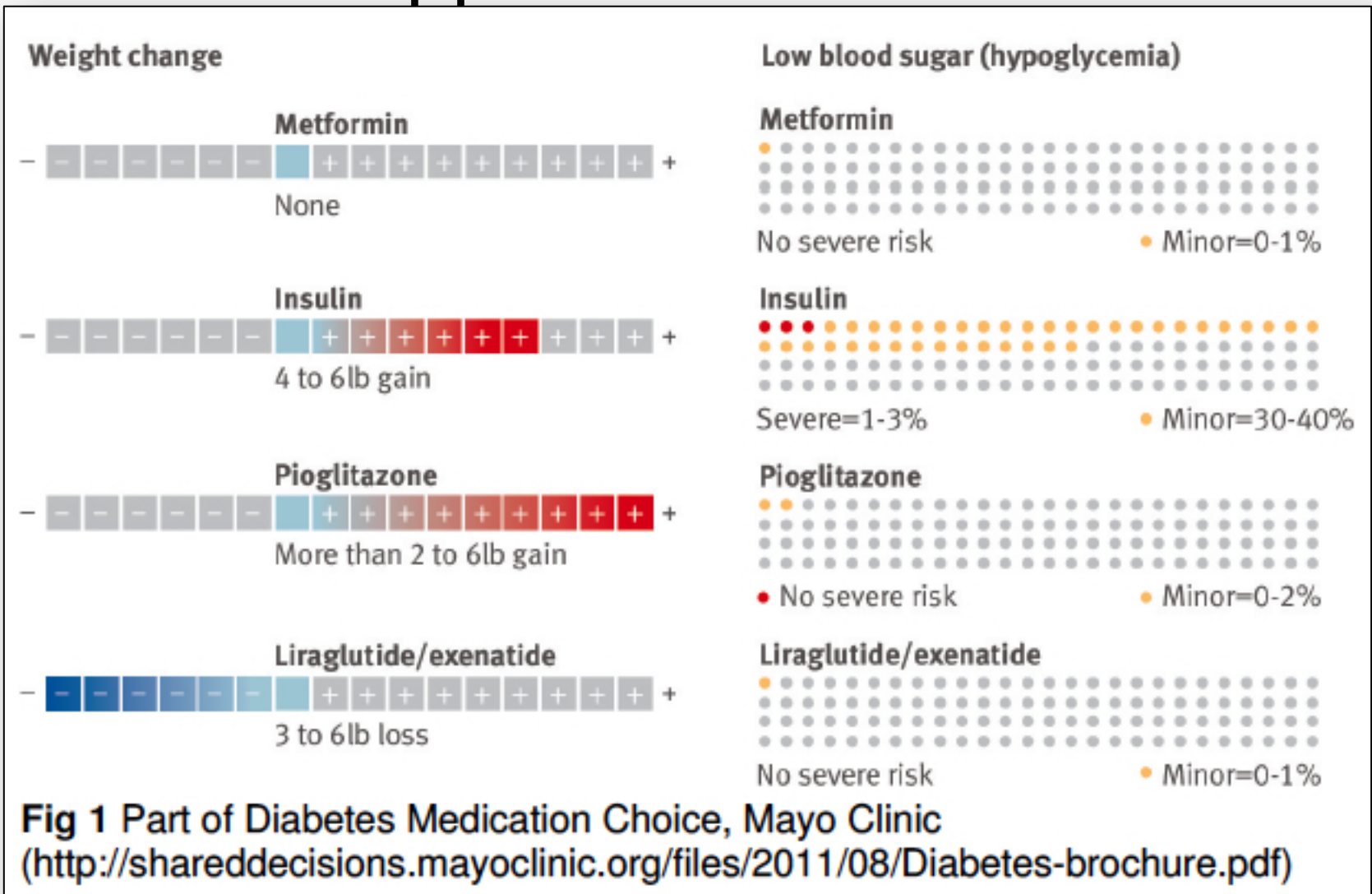
Patient decision aids for cancer treatment: are there any alternatives?

[Spiegle G](#)

aiuti decisionali comprendono

- registrazioni audio,
- schede decisionali,
- interventi computerizzati,
- interviste e opuscoli,
- diverse combinazioni di questi

"supporto decisionale"



responsabilizzare

«Una buona pratica clinica richiede di prospettare al paziente le soluzioni alternative e navigare con accortezza nei diversi contesti INDIVIDUALI

YSIS



CrossMark
click for updates

Clinical encounters in the post-guidelines era

Glyn Elwyn and colleagues highlight the potential benefits of fast and frugal knowledge tools

condividere

bmj.com

Narrative based medicine: Narrative based medicine in an evidence based world

Trisha Greenhalgh

BMJ 1999;318;323-325



... condividere veramente le decisioni non significa mettere il paziente davanti a una serie di opzioni, ma trovare cosa interessa al paziente, cosa è in gioco per lui e ... chiedersi qual è il miglior piano d'azione per questo paziente, in queste circostanze, a questo punto della sua malattia?"

ridurre i costi

VIEWPOINT

Erica S. Spatz, MD, MHS
Section of Cardiovascular Medicine, Yale School of Medicine, New Haven, Connecticut; and Center for Outcomes Research and Evaluation.

Prime Time for Shared Decision Making

JAMA April 4, 2017 Volume 317, Number 13

The recognition that informed patients often choose more conservative and hence less expensive medical options has made shared decision making a focus of value-based care.¹ In 2007, Washington State passed legislation incentivizing shared decision making as an alternative to traditional informed consent procedures and forms for preference-based treatment decisions that include an elective procedure, such as joint replacement for hip or

i pazienti informati spesso scelgono opzioni conservative e quindi meno costose

to guide the implementation of high-quality and achievable shared decision making, policy makers and health systems may consider the following key steps.

Shared Decision Making to Improve Care and Reduce Costs

Emily Oshima Lee, M.A., and Ezekiel J. Emanuel, M.D., Ph.D.

NEJM 368;1 nejm.6 org january 3, 2013

A sleeper provision of the Affordable Care Act (ACA) encourages greater use of shared decision making in health care. For many health situations in which there's not one clearly superior course of treatment, shared decision making can ensure that medical care better aligns with patients' preferences and values. One way to implement this ap-

However, more than 2 years after enactment of the ACA, little has been done to encourage shared decision making. Medicare should begin working to achieve three important goals: promote an ideal approach to clinician-patient decision making,

Obama Care

than 1000 office visits in which more than 3500 medical decisions were made, less than 10% of decisions met the minimum standards for informed decision making.¹ Similarly, a study showed that only 41% of Medicare patients believed that their treatment reflected their preference for palliative care over more aggressive interventions.²

- **knowledge**
 - Evidence Based Medicine
- **skills**
 - capacità di ascolto
 - diagnosi razionale
 - comunicazione efficace con il paziente
- **experiences**
 - condividere l'esperienza del paziente

la conoscenza
non basta!



NEJM 375;18 November 3, 2016

BECOMING A PHYSICIAN

Tolerating Uncertainty — The Next Medical Revolution?

Arabella L. Simpkin, B.M., B.Ch., M.M.Sc, and Richard M. Schwartzstein, M.D.

iatrogenic injury and withholding of information from patients.³ In addition, by attempting to achieve a sense of certainty too soon, we risk premature closure in our decision-making process, thereby allowing our hidden assumptions and unconscious biases to have more weight than they should, with increased potential for diagnostic error.

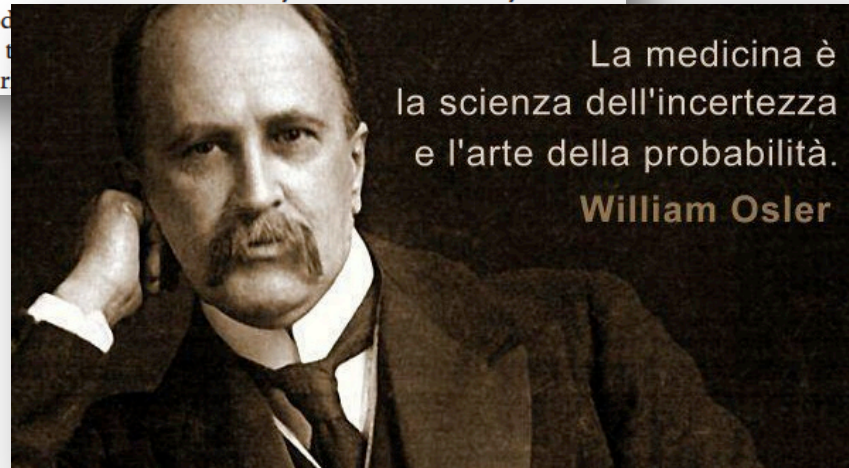
Our need to tolerate uncertainty has never been more urgent. Technology is advancing at lightning speed, and we are now able,

need to thrive in 21st-century medicine.

We believe that cultivating a tolerance of uncertainty, and addressing the barriers to this goal for physicians, patients, and the health care system, will require a revolutionary change in medicine's cultural attitude and approach to uncertainty. Our curricula (formal, informal, and hidden), assessments, and evaluations will need to be modified to accommodate size reasoning, and to embrace more than one

tivity in the illness narrative, diagnostic sensitivity and specificity, unpredictability of treatment outcomes, and our own hidden assumptions and unconscious biases, to name a few. We can then teach physicians specifically how to communicate scientific uncertainty, which is essential if patients are to truly share in decision making, and we can reduce everyone's discomfort by refram-

medici,
pazienti,
amministratori



il consenso informato

una "finzione legale" o una
"decisione condivisa" ?

Se ...



SHARING MEDICINE

Sharing as the Future of Medicine

vecchio e nuovo

"richiedere la firma di un consenso scritto potrebbe insospettire il paziente e provocare la richiesta di spiegazioni per chiarire la ragione di tanta formalità "

il vicepresidente della facoltà di Medicina di Harvard 1974

"è necessario ricercare la cooperazione del paziente per combattere meglio la malattia"

Ippocrate di Cos, 460 ac

rapporto medico/paziente

il medico = missionario

- guida
- decide
- sceglie

il paziente = suddito

- obbedisce



cultura paternalistica

The New Era of Informed Consent

Getting to a Reasonable-Patient Standard Through Shared Decision Making

JAMA May 17, 2016 Volume 315, Number 19

Erica S. Spatz, MD, MHS
Section of Cardiovascular Medicine, Yale University School of Medicine, New Haven, Connecticut; and Center for Outcomes Research and Evaluation, Yale-New Haven Hospital, New Haven, Connecticut.

Harlan M. Krumholz, MD, SM
Section of Cardiovascular Medicine, Yale University School of Medicine, New Haven, Connecticut; and Center for Outcomes Research and Evaluation, Yale-New Haven Hospital, New Haven, Connecticut.

Benjamin W. Moulton, JD, MPH
Informed Medical Decisions Foundation, Healthwise Research and Advocacy, Adjunct Harvard School of Public Health, Boston, Massachusetts.

The rights of patients to be informed about care decisions in clinical practice is yet again under scrutiny, both in the United States and around the world. The well-ingrained ethical-legal process of informed consent, so fundamental to patient autonomy—or the patient's right to self-determination—was the subject of a 2015 UK Supreme Court case (*Montgomery v Lanarkshire Health Board*).¹ In that case, a woman with insulin-dependent diabetes, claimed that her obstetrician failed to communicate the risk of shoulder dystocia during vaginal delivery (a complication associated with fetal macrosomia) that ultimately resulted in severe fetal brain anoxia. She claimed that had she received full information about the risks, she would have opted for a cesarean delivery. Yet the treating obstetrician (and other expert physicians called to trial) claimed that the ensuing risk was very small and thus appropriately not communicated because a cesarean delivery is not in the maternal interest. The obstetrician reported that "...had I raised it [the risks of shoulder dystocia] with her then yes, she would have no doubt requested a caesarean section, as would any diabetic today."¹

In its final decision, the UK Supreme Court ruled that the standard for what physicians should inform patients about the risks, benefits, and alternatives of treatment will no longer be determined by what a responsible body of physicians deems important but rather by what a reasonable patient deems important. **In rendering this decision, the court swept away decades of medical paternalism in the United Kingdom to embrace a new patient-centered standard.** Perhaps more compelling, the head of the Royal College of Surgeons urged that the only way to operationalize such a substantial and needed change is through shared decision making, a collaborative communication process between clinicians and patients that integrates the best evidence available with the patients' values and preferences, to promote high-quality health care decisions.

are critical to meaningful patient decision making. Informed consent documents for procedures, surgery, and medical treatments with material risks (eg, radiation therapy) tend to be generic, containing information intended to protect the physician or hospital from litigation. These documents are often written at a high reading level and sometimes presented in nonlegible print, putting a premium on health literacy and proactive information-seeking behavior.³ Moreover, informed consent documents are often read minutes before the start of a procedure, a time when patients are most vulnerable and least able to understand. This is hardly consistent with what we would expect of a process deemed acceptable. In the United States, the state of Washington, that has adopted a shared decision making as an alternative to the traditional consent process,⁴ the law that truly supports a reasonable patient standard through shared decision making.

Informed Consent and Patient-Centered Care

According to the US Center for Disease Control and Prevention, more than 50 million inpatient procedures are performed annually on patients, informed consent is a critical part of the patient-physician relationship. Communicating information about attendant risks, benefits, and alternatives, patients have an opportunity to reflect on their preferences, values, and goals; to learn more about their prognosis; and to signal concerns about safety and rehabilitation. Reasonably, patients may request more information, a second opinion, or support from a family member or friend in the decision-making process. **What would a high-value, patient-centered process for informed consent look like? A comprehensive, trans-**



"Con questa decisione la Suprema Corte inglese ha spazzato via decenni di paternalismo per avviare un nuovo modello di rapporto medico/paziente"

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Constant conflict rolls the health care landscape, including issues related to the Affordable Care Act, electronic health records, payment changes, and consolidation of hospitals and health plans. The morale of physicians and other clinicians is in jeopardy.¹

One foundational cause of the discord is an epic collision of 2 eras with incompatible beliefs.

Era 1

Era 1 was the ascendancy of the profession, with roots millennia deep—back to Hippocrates. Its norms include these: the profession of medicine is noble; it has special knowledge, inaccessible to lay; it is beneficent; and it will self-regulate. In return, society conceded to the medical profession a privilege most other work groups do not get: the authority to judge the quality of its own work.²

However, the idealism of era 1 was shaken when researchers examining the system of care found problems, such as enormous unexplained variation in practice, rates of injury from errors in care high enough to make health care a public health menace, indignities, injustice related to race and social class, and profiteering. They also reported that some of the soaring costs of care were wasteful—not producing better outcomes.

These findings made a pure reliance on trusted professionalism seem naive. If medical professionals were scientific, why was there so much variation? If they were beneficent, how could they permit so much harm? If they self-regulate, how could they waste so much?

Era 2

The inconsistency helped birth era 2, which dominates the present. Exponents of era 1 believe in professional trust and prerogative; those of era 2 believe in accountability, scrutiny, measurement, incentives, and markets. The machinery of era 2 is the manipulation of contingencies: rewards, punishments, and pay for performance.

The collision of norms from these 2 eras—between the romance of professional autonomy on the one hand, and the various tools of external accountability on the other—leads to discomfort and self-protective reactions. Physicians, other clinicians, and many health care managers feel angry, misunderstood, and overcontrolled. Payers, governments, and consumer groups feel suspicious, resisted, and often helpless. Champions of era 1 circle the wagons to defend professional prerogatives. Champions of era 2 invest in more and more rigorous inspection and control.

This conflict impedes the pursuit of the social goals of fundamentally better care, better health, and lower cost. The best route to these goals is the continual design and redesign of health care as a system. When the ethos of professionalism clashes with the ethos of markets and accountability, immense resources get diverted from the crucial and difficult enterprise of re-creating care.

The tactics of eras 1 and 2 reflect deeply held beliefs. The clash will continue unless and until those beliefs change and stakeholders act differently as a result.

Era 3

It is time for era 3—guided by updated beliefs that reject both the protectionism of era 1 and the reductionism of era 2. Era 3 requires 9 changes, at least.

First, Reduce Mandatory Measurement

Era 2 has brought with it excessive measurement, much of which is useless but nonetheless mandated. Intemperate measurement is as unwise and irresponsible as is intemperate health care. Purveyors of measurement, including the Centers for Medicare & Medicaid Services (CMS), commercial insurers, and regulators, working with the National Quality Forum, should commit to reducing (by 50% in 3 years and by 75% in 6 years) the volume and total cost of measurements currently being used and enforced in health care. The aim should be to measure only what matters, and mainly for learning.

With that focus, all health care stakeholders could know what they need to know with 25% of the cost and burden of today's measurements enterprise. The CMS has, to its credit, removed many process measures from programs, but progress toward a much smaller set of outcome measures needs to be faster. Such discipline would restore to care providers an enormous amount of time wasted now on generating and responding to reports that help no one at all.

Second, Stop Complex Individual Incentives

Aligning payment systems and incentives with triple aim goals for organizations makes sense, but payers and health care executives should declare a moratorium on complex incentive programs for individual clinicians, which are confusing, unstable, and invite gaming. The CMS should confine value-based payment models for clinicians to large groups. A moratorium would require placing more trust in the intrinsic motivation of the health care workforce and putting more effort into learning and less into managing carrots and sticks. For many, if not all, clinicians, the best form of individual payment to support a focus on need is, simply, salaried practice in patient-focused organizations.

Third, Shift the Business Strategy From Revenue to Quality

Maximizing revenue continues too much to dominate the business models of health care organizations. That reflects short-term thinking. A better, more sustainable route to financial success is improving quality. This requires mastering the theory and methods of improvement as a core competence for health care leaders. It also requires that the CMS and other payers continue to un-

Le 3 ere di Berwick

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ERA 1 paternalismo professionale

ERA 2 controllo contabile e legale

ERA 3 sia l'era MORALE

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beneficio e rispetto

VIEWPOINT

The Ethics of Disclosure and Counseling of Patients With Thyroid Cancer



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The ethical basis for the interactions between physicians and patients is primarily grounded in the principles of beneficence and respect for persons. Beneficence emphasizes the importance of acting in such a way that patients will benefit from the interaction. The principle of beneficence is central to patients' expectations of their physicians. Patients expect that their physicians will make recommendations that are in the patient's best interests rather than primarily in the physicians' best interests. In previous generations, physicians were given wide latitude to make choices on behalf of their patients because, based on their education and ex-

naturalness, but most physicians will be com-
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status of a known lesion can be distressing and may be a driving force to perform a biopsy.²

beneficio e rispetto
alla persona: le basi
etiche del rapporto
medico/paziente

Arcispedale di S. Spirito in Saxia

*Un ritorno al passato sulle orme di
Giovanni Maria Lancisi*

a cura del Dott. Vincenzo Giammarco



grazie

