



«Ποσοτικές μετρήσεις και ποιοτικές προσ<mark>εγγίσεις</mark> στην υγεία και την ιατρικ<mark>ή περίθαλψη</mark>» 28-30 Σεπτεμβρίου 2018 Ξενοδοχείο Hydrama, Δράμα

Κλινική ιατρική και αποτίμηση επιπτώσεων

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Ιατρική Σχολή Πανεπιστημίου Κρήτης





Ευχαριστίες:

- ✓ σε πολλούς ανώνυμους και επώνυμους που συνέβαλαν στην έμπνευση και στη δημιουργία όσων έχουν επιτευχθεί στην Κλινική Κοινωνικής και Οικογενειακής Ιατρικής
- σε όλους τους συνεργάτες μου που εξακολουθούν να συνεισφέρουν στο κοινό όραμα
- Στον αξέχαστο φίλο και συνάδελφο Α. Κούτη
- Στους δασκάλους μου και στη γυναίκα μου

Περίγραμμα



Sir Karl Raimund Popper (28 July 1902 – 17 September 1994)

- ✓ Κλινική ιατρική: είναι κατάλληλος όρος;
- ✓ Η σύγχυση σε όρους και έννοιες
- ✓ Ιατρική και λήψη της απόφασης
- ✓ Εμπόδια στην ορθή απόφαση και στην αποτίμηση των επιπτώσεων της κλινικής ιατρικής: αναφορά σε μεθοδολογικά θέματα
- Από τη θεωρία στην πράξη και από τα νοσήματα στη συμπεριφορά κινδύνου
- Συζήτηση και εφαρμογές σχετικές με τα μείζονα προβλήματα υγείας
- ✓ Επίλογος

Κλινική ιατρική- Εννοιολογικές αποσαφηνίσεις

- Η διαφορά του care από το cure (το πρώτο συνδέεται με το «είμαι μαζί» και το δεύτερο με την «αλλαγή»)
- Η διαφορά του primary health care (ευρύτερος όρος περιλαμβάνει και υπηρεσίες στα άτομα και λειτουργίες που απευθύνονται στο πληθυσμό, Muldoon, et al 2006) από το primary care
- Η σύγχυση ανάμεσα στο preventive και στο clinical care

Αναζητώντας ένα καθολικά αποδεκτό ορισμό της υγείας

Διασύνδεση ή συχνά εξίσωση ευδαιμονίας με υγεία και ευημερία

Ορισμός υγείας: "Ως υγεία ορίζεται η κατάσταση πλήρους ευημερίας σε επίπεδο φυσικής, ψυχικής και κοινωνικής κατάστασης. Δεν αναφέρεται απλά στην απουσία νόσου ή αναπηρίας." ¹

Ορισμός της ευημερίας (wellbeing):² κατάσταση διαβίωσης με βιοτική άνεση, υγεία και ευτυχία. Χαρακτηρίζει θετικά ή αρνητικά την κατάσταση ενός ατόμου αναφορικά με: οικονομικές, ψυχολογικές, πνευματικές και πτυχές υγείας

 ✓ Υψηλά επίπεδα ευημερίας = θετική όψη επιπέδου ανάπτυξης και διαβίωσης

✓ Κατηγορίες ευημερίας: γνωστική (αλληλεπιδράσεις ενός ατόμου με το περιβάλλον και τους ανθρώπους) και συναισθηματική (συναισθηματικές επιδράσεις που δέχεται κάθε ατόμου από το εξωτερικό περιβάλλον). μεγαλύτερη έμφαση στην ικανότητα προσαρμογής και αυτο-διαχείρισης στο πλαίσιο αντιμετώπισης κοινωνικών, σωματικών και συναισθηματικών προκλήσεων. Η έννοια της 'απόλυτης ευεξίας' δίνει στον ορισμό της υγείας μια ουτοπική, μη ρεαλιστική διάσταση, μειώνοντας τις πιθανότητες για κάποιον να είναι υγιής.

Huber, et al, BMJ 2011

1. Oxford dictionaries. Available at: <u>http://www.oxforddictionaries.com/definition/english/well-being</u> και WHO. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June 1946, and entered into force on 7 April 1948

2. Giboa, Schmeidler, Itzhak, David (2001). "A cognitive model of individual well-being". Social Choice and Welfare 18 (2): 1.

Κλινική ιατρική (οι τρεις διαστάσεις)

- ✓ Η διάσταση της μείωσης του κινδύνου (risk reduction)
- Η διάσταση της μείωσης ή ελαχιστοποίηση της ζημιάς (harm reduction ή minimization)
- Η διάσταση της αποκατάστασης της ζημιάς

Κλινική ιατρική- η επίπτωση στην εμφάνιση της νόσου (outcomes)

✓ Φυσική πορεία
 νόσου

- ✓ Μετάθεση ή αποτροπή της νόσου
- ✓ Εμφάνιση της νόσου (μικρότερη ένταση, απουσία επιπλοκών)
- ✓ Εμφάνιση της νόσου (μεγάλη ένταση, επιπλοκές)

Κλινική ιατρική- η επίπτωση στον ασθενή (συμπτώματα, ευεξία/ευδαιμονία, ποιότητα)

- Συμπτώματα (εκτίμηση της έντασης και της παρουσίας τους)
- Αυτοφροντίδα (συμμόρφωση, προσκόλληση στη θεραπεία, τρόπος ζωής)
- ✓ Ευτυχία, ευδαιμονία
- ✓ Προσδόκιμο επιβίωσης
- ✓ Ποιότητα ζωής

Κλινική ιατρική- η επίπτωση στο νοικοκυριό και στην οικογένεια

✓ Συνοχή
 ✓ Δυναμικά οικογένειας
 ✓ Κόστος

Μεθοδολογικές δυσκολίες στην αποτίμηση των επιπτώσεων του κλινικού έργου

- ✓ Η απαίτηση ενός θεωρητικού υποδείγματος για τους προσδιοριστές του νοσήματος
- Ο ορισμός της νόσου και τα διαγνωστικά/ ταξινομικά κριτήρια
- ✓ Η παρουσία πολλών αιτιών (προσδιοριστών) (αιτιολογικά συμπλέγματα Rothman)
- Το πολύπλευρο υπόβαθρο της συμπεριφοράς (υγείας και νόσου) του ατόμου
- ✓ Η πολλαπλή νοσηρότητα

Η απαίτηση ενός θεωρητικού υποδείγματος

Am J Psychiatry. 1980 May;137(5):535-44.

The clinical application of the biopsychosocial model.

Engel GL.

Abstract

How physicians approach patients and the problems they present is much influenced by the conceptual models around which their knowledge is organized. In this paper the implications of the biopsychosocial model for the study and care of a patient with an acute myocardial infarction are presented and contrasted with approaches used by adherents of the more traditional biomedical model. A medical rather than psychiatric patient was selected to emphasize the unity of medicine and to help define the place of psychiatrists in the education of physicians of the future.

PMID: 7369396 DOI: 10.1176/ajp.137.5.535



 biopsychosocial framework: an approach to describing and explaining how biological, psychological and social factors combine and interact to influence physical and mental health



Προσδιοριστές της υγείας

About social determinants of health

The social determinants of health are the conditions in which people are born, grow, live, work and age. These circumstances are shaped by the distribution of money. power and resources at global, national and local levels. The social determinants of health are mostly responsible for health inequities - the unfair and avoidable differences in health status seen within and between countries



Measures to clarify how different types of jobs and the threat of unemployment affect workers' health.

Social exclusion The relational processes that lead to the exclusion of particular life Rodriguez

groups of people from engaging fully in community and social

Public health programmes and social determinants

Factors in the design and implementation of programs that increase access to health care for socially and economically disadvantaged groups



WHO /D Rodriguez

Women and gender equity

Employment conditions

Mechanisms, processes and actions that can be taken to reduce gender-based inequities in health by examining different areas.

Globalization

How globalization's dynamics and processes affect health outcomes: trade liberalization, integration of production of goods.



X.

WHO /A. Kari

Health systems

Innovative approaches that effectively incorporate action on social determinants of health.



Measurement and evidence

The development of methodologies and tools for measuring the causes, pathways and health outcomes of policy interventions

About Determinants of Health

The range of personal, social, economic, and environmental factors. that influence health status are known as determinants of health.

Determinants of health fall under several broad categories:

- Policymaking
- Social factors
- Health services
- Individual behavior
- Biology and genetics



FRAMEWORK FOR REACHING HEALTHY PEOPLE 2020 GOALS

DETERMINANTS OF HEALTH

Determinants of Health: A Framewo.

COPHP | Office of Disease Prevention and Health Promotion



provided to young children are cruc

Early child development Well established evidence illustrate

nealth and development status





Urbanization

Broad policy interventions related to healthy urbanization, including close examination of slum upgrading

Η ανάγκη εστίασης στην έννοια του κινδύνου και στη διαχείριση του

< azcentral.

he Difference Between What is Risk?

According to the Insurance Bureau of Canada, 'Risk, in insurance terms, is the possibility of a loss or other adverse event that has the potential to interfere with an organization's ability to fulfil its mandate."

Examples of advense events in health care are unexpected death, failure to diagnose or treat disease, surgical mistakes or accidents. All of those can interfere with a provider's delivery of medical care. Some can result in fligation.

Kinds of Risk Management

The Joint Commission, which accredits and certifies more than 17,000 health care organizations and programs in the United States, defines risk management in health care as '(c)linical and administrative activities undertaken to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itset."

Risk management is proactive or reactive. Proactive is avoiding/preventing risk. Reactive is minimizing loss or damage after an adverse/bad event. Medical care delivery is art based in science. Good results cannot be guaranteed.

Every surgery has the potential for an undesirable outcome. Sometimes, regardless of medica intervention, patients die.

Applying common sense can prevent bad results or accidents. For example, slippery floors in high traffic areas can cause accidents. Washing floors at low traffic times and diverting traffic away from wet floors until dry is a practice means of risk avoidance.

Measuring Risk

Potential for some adverse events can be mathematically measured

Treatment choices for a particular patient with a particular disease depend on the reliability of availat options, the nature of the disease, whether the patient is hospitalized, the ease of care delivery, side effects, cure rates and other factors.

Statistical data, regarding the effectiveness of medications, as well as the kinds and rates of pr side-effects, helps physicians decide what to prescribe.

s/healthyliving accentral com/the definition of risk management in health care 12334511.html

https://healthyliving.azcentra I.com/the-definition-of-riskmanagement-in-health-care-12334511.html Τι είναι διαχείριση κινδύνου;

«Κλινικές και διοικητικές δραστηριότητες που αναλαμβάνονται για τον προσδιορισμό, αξιολόγηση και μείωση της ζημιάς σε πρόσωπα, προσωπικό και επισκέπτες καθώς και κίνδυνος απώλειας στον οργανισμό τον ίδιο» [Joint Commission, J Miller, 2017]



Διαχείριση κινδύνου

-Μπορεί να μετρηθεί -Θεραπευτικές επιλογές "Individuals mentally assess risk in a similar way, but risk perception is shaped by several largely unconscious emotional processes shared by scientists and nonscientists alike".

volume 122 | number 10 | October 2014 • Environmental Health Perspectives

Η έννοια του risk communication

Η κριτική στη δυνατότητα γενίκευσης της θεωρίας ιδιαίτερα στην εφαρμογή της από ένα τόπο σ' ένα άλλο



Στάση απέναντι στη συμπεριφορά-προσδιορίζεται από την αξιολόγηση ενός ατόμου των αποτελεσμάτων που σχετίζονται με τη συμπεριφορά.

Υποκειμενικοί κανόνες-αναφέρονται στο βαθμό στον οποίο ένα άτομο πιστεύει ότι σημαντικά άτομα ή ομάδες (π.χ. γονείς, σύζυγος, στενός φίλος, συνάδελφοι, γιατρός ή λογιστής) εγκρίνουν ή όχι τη συμπεριφορά τους.

Αντιλαμβανόμενος έλεγχος της συμπεριφοράς-αναφέρεται στο βαθμό στον οποίο το άτομο πιστεύει ότι μπορεί να ελέγξει τη συμπεριφορά του και περιλαμβάνει πεποιθήσεις για παράγοντες που θα επηρεάσουν τη δυσκολία της συμπεριφοράς και την αντιλαμβανόμενη δύναμη αυτών των παραγόντων

Μεθοδολικές δυσκολίες στην καθιέρωση των κλινικών εκβάσεων



Published in final edited form as: Value Health. 2015 September ; 18(6): 741–752. doi:10.1016/j.jval.2015.08.006.

Clinical Outcome Assessments: Conceptual Foundation–Report of the ISPOR Clinical Outcomes Assessment – Emerging Good Practices for Outcomes Research Task Force DOES THIS HAVE TO BE LABLED AS PART 1

Walton, et al, 2015

- «When clinical assessments are used as clinical trial outcomes, they are called clinical outcome assessments (COAs)».
- «COAs include any assessment that may be influenced by human choices, judgment, or motivation, COAs must be well-defined and possess adequate measurement properties in order to demonstrate (directly or indirectly) the benefits of a treatment».
- «A critical element in appraising or developing a COA is to describe the treatment's intended benefit as an effect on a clearly identified aspect of how a patient feels or functions. This aspect must have importance to the patient and be part of their typical life».
- «One of these features is whether judgment can influence the measurement, and if so, whose judgment. This attribute defines four categories of COAs: Patientreported outcomes (PROs), clinician-reported outcomes (ClinROs), observerreported outcomes (ObsROs), and performance outcomes (PerfOs)».

Ο ορισμός των στόχων και εκβάσεων στην αξιολόγηση της απόδοσης στις υπηρεσίες γενικής ιατρικής

Editorial

The NHS: failing to deliver on Beveridge's promise?

Just over 75 years have passed since Sir William Beveridge budgetary addition might seem, it will barely cover the published his report outlining the parameters for a cost of the clinical negligence scheme alone and will not social welfare state for the UK, which crucially included get to the root of the problem or provide a net benefit to "comprehensive health and rehabilitation services for the system. As service needs rise and resources remain prevention and cure of disease". Beveridge's report inspired Labour Minister of Health Aneurin Bevan to establish the National Health Service (NHS). Although the vision of Beveridge and Bevan-to provide free, adequate, and equally accessible health care for all-remains in high and there was near cross-party governmental support is currently falling short, is the UK in danger of losing hard to see the same commitment and enthusiasm for the NHS because the Government is uninterested in or incapable of the effort needed to save it?

time targets continued to be missed, including the have to ignore waiting time limits, stop prescribing arget time between general practitioner referral and some over the counter medications, and would not be Inst cancer treatment, in England, Scotland, and Wales. able to guarantee to act on any new NICE guidance, all of Moreover, and worryingly, in December, 2017, cancer wray diagnostic services came under national review Health Secretary Jeremy Hunt insisted that the NHS by the Care Quality Commission, after the discovery adhere to waiting time limits. This response is unhelpful, that between April 1, 2016, and March 31, 2017, more and does not address the broader picture of ongoing than 20000 x-ray images had not been reviewed by a system-wide failures. radiologist or properly trained clinician. Indeed, a study from the General Medical Council has shown that, due to chronic staff shortages, inexperienced doctors without sufficient training or competence are being left in charge not address infrastructure or treatment requirements. of hospital departments. It is thus hardly surprising that On Dec 11, 2017, King's College Hospital NHS Foundation nearly 1000 patients have received cancer misdiagnosis ettlements totalling £757 million in the past 10 years BBC that he believes "the government and regulator are and that the cost of the NHS clinical negligence scheme as increased from £400 million in 2006-07 to £1-6 billion in 2016-17

difficulties that we highlighted in a previous Editorial in efficiency, safety, and patients. October, 2015. Long-term underfunding, which in turn has led to deficiencies prevalent for decades in staffing, 70 years ago, is still fit for the purposes of our modern training, and infrastructure, has been at least partly responsible for this deficit of care. Perhaps in recognition costly than it was in the mid-20th century, and care of this pressing need, the 2018-19 Government budget expectations higher. It is a paradox that at a time when plans to allocate an extra E1-6 billion to the NHS. more and more countries aspire to universal health care However, analyses indicate that real-term spending on the NHS is decreasing or remaining stagnant, while demand is increasing by up to 7% per year, fuelled by a money and talk. As in 1948, it needs political motivation d chronic comorbidities. Indeed, as high as this I The Loncet Oncology

non-combanology Vol 19 January 2018

the same, services will exceed capacity and become potentially unsafe. In the late 1940s, with a World War in recent m

British society was in favour of a social welfare stat regard today, the execution and delivery of their goal to provide services such as the NHS. By contrast, it is a the success of the NHS from the UK Government today. In response to the provision in the 2017 autumn budget 2017 was a year of great difficulty for the NHS. Waiting NHS England issued a damning statement-it would which would breach the NHS constitution. In response,

In terms of oncology recommendations, Hunt did skisza promise to hire 500 more cancer experts, but this addition Forthe Wat barely covers current critical shortfalls in staffing, and does Trust chairman Lord Robert Kerslake resigned, telling the unrealistic about the scale of the challenge facing the NHS*, Yet NHS governance is not blameless-furthe funding is of no use if smart and judicious decisions Such issues are regrettably reminiscent of NHS are not made to ensure the service is optimised around

It is reasonable to consider whether the NHS, designed society. Health care is both more complex and more that the country that spearheaded the model is moving further from it. To survive, the NHS needs more than just and ageing population with a rising incidence to ensure its success and, in turn, the health of its citizens.

The Lancet, 2018, Editorial

 Οι στόχοι για τους χρόνους αναμονής των ασθενών εξακολουθούν να μην προσεγγίζονται.

- Συμπεριλαμβάνεται και ο χρόνος από την παραπομπή από το γενικό γιατρό μέχρι την πρώτη θεραπεία για καρκίνο
- ✓ Σ'ένα έτος πάνω από 20,000. ακτινογραφίες δε διαβάστηκαν από ακτινολόγο ή κατάλληλα εκπαιδευμένο γιατρό.
- Περίπου 1,000 ασθενείς έλαβαν κακή διάγνωση για καρκίνο.



Το θέμα των στόχων και εκβάσεων στην τεκμηριωμένη πολιτική υγείας-Ι

Quality and Outcomes Framework: what have we learnt?

BMJ 2016 ; 354 doi: https://doi.org/10.1136/bmj.i4060 (Published 04 August 2016) Cite this as: *BMJ* 2016;354:i4060

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Examples of indicators that went wrong	
Indicator	Problem
Patient survey reports of whether patients could get appointments	Insufficient survey numbers and a poorly constructed formula linking survey scores to payment resulted in substantial random variation in payments (introduced in 2008, dropped in 2011)
Using a validated instrument (PHQ9) to assess the severity of depression within 28 days of a new diagnosis, repeating the assessment 2-12 weeks following diagnosis	Poor alignment with professional beliefs prompted substantial criticism about lack of supporting evidence (although other indicators with similar levels of evidence that GPs did believe in were not criticised in the same way). It was also easily "gamed" by GPs using free text description of the patient's problem rather than coding "depression" in electronic records (introduced in 2006 dropped in 2013)
Practices should develop a register of patients with obesity	Practices could effectively claim payments by including a register with one obese patient. The indicator does not encourage regular weighing to create a more comprehensive obesity register or any strategy for tackling the problems of obesity (introduced in 2006, still current)
Opportunistic screening of elderly and at- risk patients for dementia (technically an "enhanced service" rather than part of QOF)	Little professional support, substantial concern about harms resulting from false positive results, lack of services for specialist diagnosis and management (introduced in 2014, dropped in 2015)

- «The Quality and Outcomes Framework επιτάχυνε προηγούμενες χρήσεις των ηλεκτρονικών εγγράφων και της διεπαγγελματικής διαχείρισης των χρόνιων νοσημάτων»
- «Γενικά είχε <u>περιορισμένη</u> επιπρόσθετη <u>βελτίωση</u> της ποιότητας αλλά μείωσε τις κοινωνικοοικονομικές ανισότητες <u>στην παροχή της φροντίδας»</u>
- «Διάφοροι δείκτες αποσύρθηκαν αφού δεν έτυχαν επαγγελματικής υποστήριξης ή παρουσίασαν προβλήματα στην εφαρμογή»

Roland and Guthrie, BMJ 2016

Το θέμα των δεικτών και εκβάσεων στην τεκμηριωμένη πολιτική υγείας-ll

Page 1 of 19

BMJ 2015;350:h904 doi: 10.1136/bmj.h904 (Published 2 March 2015)

RESEARCH

Investigating the relationship between quality of primary care and premature mortality in England: a spatial whole-population study

OPEN ACCESS

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Abstract

Objectives To quantify the relationship between a national primary care pay-tor-performance programme, the UK's Quality and Outcomes Framework (QOF), and all-cause and cause-specific premature mortality linked closely with conditions included in the framework.

Design Longitudinal spatial study, at the level of the 'lower layer super output area" (LSOA).

Setting 32482 LSOAs (neighbourhoods of 1500 people on average), covering the whole population of England (approximately 53.5 million), from 2007 to 2012.

Participants 8647 English general practices participating in the QOF for at least one year of the study period, including over 99% of patients registered with primary care.

Intervention National pay-for-performance programme incentivising performance on over 100 quality-of-care indicators.

Main outcome measures All-cause and cause-specific mortality rates for six chronic conditions: dabetes, heart failure, hypertension, ischaemic heart disease, stroke, and chronic kidney disease. We used multiple linear regressions to investigate the relationship between spatially estimated recorded quality of care and mortality.

Results All-cause and cause-specific mortality rates declined over the study period. Higher mortality was associated with greater area deprivation, urban location, and higher proportion of a non-white population. In general, there was no significant relationship between practice performance on quality indicators included in the QOF and all-cause or cause-specific mortality rates in the practice locality. Conclusions Higher reported achievement of activities incentivised under a major, nationwide pay-for-performance programme did not seem to result in reduced incidence of premature death in the population.

Introduction

Primary care has enormous potential to improve population health outcomes—including mortality from common chronic conditions—through early intervention in the disease process^{1,2} and coordinated provision of care. Effective primary care is associated with reduced morbidity, increased longevity, and more equitable health outcomes,^{1,4} but quality of primary care varies widely between providers.^{1,4} Traditional physician payment systems have facilitated this variation, with fee-for-service systems potentially incentivising over-investigation and over-treatment, and capitation systems potentially incentivising under-utilisation. Neither approach directly rewards high quality care or investment in quality improvement.^{2,8}

In order to improve patient outcomes, policymakers worldwide have attempted to link remuneration for providers to quality of care through pay-for-performance programmes. Multiple programmes have been implemented across a range of settings, but clear evidence for improved patient outcomes is yet to emerge.⁴¹³ In the United Kingdom a national primary care incentive scheme was introduced in 2004. The Quality and Outcomes Framework (QOF), one of largest

pay-for-performance programmes in the world, links up to 25% of family practitioners' income to performance on over 100

Kontopantelis, et al BMJ 2015

- Η συνολική ποιότητα της φροντίδας που δόθηκε από τα ιατρεία, όπως μετρήθηκε από τους δείκτες ποιότητας δε συσχετίστηκε με τους ρυθμούς θνησιμότητας στις ζώνες ευθύνης τους για τα νοσήματα στόχους
- Διάφορες εξηγήσεις όπως η ταχύτητα μεταβολής τα δυο πρώτα χρόνια
- Αρκετές συνέπειες; η επανεξέταση των δεικτών κάτω από το φως της καινούργιας τεκμηρίωσης και το φαινόμενο της Ushapped συσχέτισης μεταβλητών ρύθμισης με την έκβαση
- Μελέτη παραγόντων όπως η κοινωνική απομόνωση και αγροτικές vs αστικές περιοχές φαίνεται να επηρεάζουν περισσότερο από ότι η ποιότητα στις υπηρεσίες ΠΦΥ
- Ο ρόλος των παραγόντων εκτός υπηρεσιών ΠΦΥ

Lionis et al. BHC Health Services Research (2017) 17255 DOI 16.1186/612913-017-01840

BMC Health Services Research

Δείκτες υγείας και προσδοκίες των ασθενών

Informing primary care reform in Greece: patient expectations and experiences (the QUALICOPC study)

hristos Lienis¹⁴, Sochia Papadakis¹², Chrysanthi Tats¹, Antonis Bertsias¹, G als⁸, Wenke Boerna⁴, Willemijn Schäfer⁴ and on behalf of Creek OLISUICORC save

nties with similar context and ords: Primary care, Quality, Patient-centered care,

Παράγοντες εκτιμούμενοι ως πολύ σημαντικοί από τους ασθενείς κατά τη διάρκεια της επίσκεψης στον ιατρό



19

Μεθοδολογικές δυσκολίες στην ανάγνωση των παρατηρούμενων αποτελεσμάτων



Figure 2. How biases operate in relation to observa

English

- <u>Systematic Reviews</u> Critical Appraisal Sheet
- <u>Diagnostics</u> Critical Appraisal Sheet
- <u>Prognosis</u> Critical Appraisal Sheet
- Randomised Controlled Trials (RCT) Critical Appraisal Sheet

https://www.cebm.net/2014/06/critical-appraisal/

Η κριτική στο ιεραρχικό μοντέλο της ΕΒΜ

Context

SCIENCE PAST AND PRESENT TOM SIEGFRIED

CONTEXT SCIENCE & SOCIETY, CLINICAL TRIALS, BIOMEDICINE

Philosophical critique exposes flaws in medical evidence hierarchies

Rankings of research reliability are logically untenable, an in-depth analysis concludes BY TOM SIEGFRIED 2:30PM, NOVEMBER 13, 2017



Αναφορά στην κριτική του Christofer Blunt που δημοσιεύτηκε στη δ.δ. το 2015 πάνω στα ιεραρχικά μοντέλα της EBM.

•Εισάγει την αμφισβητήση σε ποιο βαθμό οι «καλύτερες» ιεραρχικά μέθοδοι προσφέρουν ανώτερη τεκμηρίωση

Εστιάζεται στο βαθμό που η υψηλότερη από πλευράς
 τεκμηρίωση είναι συναφής με τον πληθυσμό που χρειάζεται τη θεραπεία αλλά και στην τυχαιοποίηση όλων μεταβλητών που
 τυχόν επιδρούν στο αποτέλεσμα αλλά και σε θέματα που
 αφορούν την εγκυρότητα της τεκμηρίωσης

«There is convincing evidence for the claim that hierarchical appraisal improves practice»

Chris J Blunt

Hierarchies of Evidence

Hierarchies of Evidence are a tool employed by many advocates of Evidence-Based Medicine. They are used to appraise evidence from a range of sources, as well as to teach medical students about evidence and evidence appraisal. My PPD thesis concerns the variation in hierarchies defended, and the range of philosophical interpretations of those hierarchies. In order to complete this project, it is necessary to create and maintain a database of hierarchies of evidence. This database is available here for the benefit of other researchers interested in Evidence-Based Medicine



T. TIBBI

https://www.sciencenews.org/blog/context/critique-medical-evidencehierarchies?tgt=nr

Η κριτική στην τεκμηριωμένη ιατρική



Evidence-based CARDIOVASCULAR MEDICINE www.elsevier.com/locate/ebcm

GUEST EDITORIAL

Criticisms of Evidence–Based Medicine

More than twenty years after its conception, 'evidence-based medicine' (EBM) continues to invoke polarised debate. There are several areas of disagreement between EBM supporters and detractors as well as unanswered questions about the role of EBM in modern healthcare. Proponents suggest that the goal of EBM is to rescue medicine from many of its major ills, including wide variations in clinical practice, use of unproven interventions, and failure to apply consistent practice guidelines. Opponents disagree that EBM adequately addresses these issues, and dismiss EBM on the grounds of philosophical and practical flaws. This editorial briefly summarises the criticisms of EBM under five main themes, to provide a starting point for more focused discussion.

The first type of criticism involves the philosophical underpinnings of EBM, which is based on empiricism. In its rawest form, EBM elevates experimental evidence to primary importance over pathophysiological and other forms of knowledge, and implicitly assumes that scientific observations can be made independent of the theories and biases of the observer. However, since the late 19th century, philosophers and scientists have been aware that making theory-free, objective observation is impossible. All observations are affected by the world view of the observer.1 In fact, the preferred situation is for "clinical trials to provide evidence in support of theory".2 Clearer observations allow for theory to be challenged and eventually replaced by better theory. Better theory allows for more specific, more detailed, and ultimately more useful observations. EBM ignores this essential interplay between observation and theory, disregarding the history and philosophy of science.

Science. The second theme is that the definition of evidence within EBM is narrow and excludes information important to clinicians.^{4,3} EBM grades evidence according to the methods used to collect it. Certain types of studies, such as randomised

trials, are thought to be less vulnerable to bias and therefore 'better' evidence.^{3,6} However, randomised trials and meta-analysis have not been found to be more reliable than other research methods.^{3,7,8} The EBM definition of high quality evidence excludes information necessary to address many kinds of medically relevant questions.⁹ In addition, EBM does not provide a means to integrate other, non statistical, forms of medical information, such as professional experience and patient specific factors.^{3,4,10}

Third, EBM is not 'evidence-based' because it does not meet its own empirical tests for efficacy.^{3,11,12} Considering that EBM proposes that patient care can be improved by basing clinical decision-making on information from statistically valid clinical trials, it is somewhat ironic to find there is no evidence (as defined by EBM) that this is actually the case.⁴

Fourth, the usefulness of applying EBM to individual patients is limited. Because individual circumstances and values vary, and because there are so many uncommon diseases and variants, for "an increasing number of subgroups of patients we will never have higher levels of evidence".⁹ Clinicians must balance general rules, empirical data, theory, principles, and patient values and apply them to individual people.^{3,5} This requires a great deal of clinical judgment.¹³

Lastly, EBM has been criticised for reducing the autonomy of the doctor-patient relationship by limiting the patient's right to choose what is best in their individual circumstances. EBM could be used as a cost-cutting tool to deny treatment where interventions are not 'proven' effective. On the other hand, EBM could also increase costs by 'proving' the efficacy of some expensive interventions. Currently, the net effect of EBM is unknown.^{5, 14-16}

None of the critics of EBM suggest that highquality evidence obtained by clinical epidemiological methods should be ignored in the context of

Cohen and Hersh, Evidence-based Cardiovascular Medicine, 2004 <u>Πέντε βασικές κριτικές εστιασμένες πάνω στα</u> <u>παρακάτω:</u>

- Το φιλοσοφικό υπόβαθρο της EBM που βασίζεται στον εμπειρισμό
- Ο ορισμός είναι στενός και αποκλείει σημαντική πληροφορία για τους κλινικούς
- Δεν είναι βασισμένη στην τεκμηρίωση μια και δεν ικανοποεί τα δικά της εμπειρικά κριτήρια για την απόδοση
- Η χρησιμότητα της εφαρμογής της στους ασθενείς είναι περιορισμένη
- Περιορίζει την αυτονομία στη σχέση γιατρούασθενή

<u>Το άρθρο καταλήγει</u> ότι καμμία από τις παραπάνω κριτικές δεν προτείνει η υψηλής ποιότητας τεκμηρίωση να αγνοείται στη φροντίδα του ασθενή. <u>Αλλά τονίζει</u> ότι αυτός είναι ένας μόνο παράγοντας σε ένα περίπλοκο πλαίσιο.

^{1361-2611/5 -} see front matter © 2004 Elsevier Ltd. All rights reserved.

Πόση αλήθεια μας λένε οι τυχαιοποιημένες και ελεγχόμενες δοκιμές (I);

	Sacial Science & Hodanie 210 (2010) 2-21	
ELSEVIER	Contents fors available at formations Social Science & Medicine Journal homopage: www.stervier.com/tocate/bocstmad	
Understanding and a Angus Deaton ^{1,0,1,1,2} , Nancy ¹ Patase Discrete, DM ¹ Dataset Research, DM ¹ Dataset Research, DM ¹ Dataset, DM ¹ Dataset, DM ¹ Dataset, DM ¹ Dataset, DM		
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1. Introduction

Randomized controlled stials (RCTs) are widely encouraged as the ideal methodology for causal inference. This has long been true in medicine (s.g. for drug triak by the FDA. A sutable exception is the mont paper by Friedes (2017), ex-director of the U.S. Centers for Disease Control and Prevention, who lists key limitations of RCTs as well as a range of connexts where RCIs, even when feasible, are dominated by other methods. Karlier critiques in medicine include Feinstein and Skowitz (1997). Consisto et al. (2000). Raieting (2000). and Contato (2013)1. It is also increasingly true in other health sciences. and across the notal sciences, including psychology, economics, education, political urisace, and sociology. Among both researchers and the general public, RCTs are perceived to yield causal inferences and setimanes of average treatment effects (ATEs) that are more reliable and ore credible than those from any other empirical method. They are taken to be largely ecompt from the myriad problems that characterise observational studies, to require minimal substantive assumptions, little or no prior information, and to be largely independent of 'experitionorledge that is often regreded an manipabable, goldically baland, or otherweise mapset. They are also remotions for to be more resistant to meansther and publisher disgons of theodeum (for scample through phocking, attentive analysis, or publication bial) than non-remotinguized studies given that trial negativation and pus-specified analysis plans are manducory or as its into more.

halt apor, not disturbed. hClin can play a rain in building extended intervelope and northel predictions but they can only do so as part of a summittree program, combining with other morbiols, including conceptual and theoretical discretionents, to discrete net what work?, hot why things work?.

> We argue that any special extent for BCTs is unvertrated. Which methad is most large to pickl a good casual informers depends on what we are trying to discover as well as on what is already howers. When infer pick hanceledge is a scalable, no method is Windy to yield sufmposed conclusion. This paper is not a criticism of BCTs in and of farmatoless, nor does it propose any hierarchy of widewice, nor attempt o identify good and had endow. Instand, we will sugge that, depending as what we scart to discover, why we scart to discover it, and what we sharedly alows: then will distant to support or invest of investigation and, for a good many quantizes when BCTs can help, a good dual of other work--empiric, theoretical, and conceptual-models to be fourse of these

⁶ Corresponding author: 127 Julis Roma Rationantic Building, Primitian Tationsky, Primitian, NJ 08544, URA E-mail address: Social Systematics via UK, Desired).

https://doi.org/18.1826/j.antinineri.2017.12.005

Reserved 3 Database 2017; Reserved to revised how 4 December 2017; Ascepted 6 December 2017 Available unline 25 December 2017

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Deaton et al, 2018

- Η πρακτική αξία τους
- Το θέμα της εξωτερικής
 εγκυρότητας
- Χρειάζονται minimal assumptions και συνήθως λειτουργούν στη βάση μικρής προ υπάρχουσας πληροφορίας

 Εξαιρετικές για να πείσουν δύσπιστους ακροατές αλλά έχουν το μειονέκτημα της συσσώρευσης της επιστημονικής προόδου

Πόση αλήθεια μας λένε οι τυχαιοποιημένες και ελεγχόμενες δοκιμές (II);

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Education And Debate

Inappropriate use of randomised trials to evaluate complex phenomena: case study of vaginal breech delivery

BMJ 2004; 329 doi: https://doi.org/10.1136/bmj.329.7473.1039 (Published 28 October 2004) Cite this as: BMJ 2004;329:1039

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Another reason why randomised controlled trials do not necessarily tell the whole truth in clinical medicine

The randomised controlled trial (RCT) is considered to be the gold standard (or at least the silver standard, Simon, 2001) in clinical research and by far superior to all other forms of study design. There are good reasons to accept this. Non-randomised trials may generate all kinds of bias. Observed outcomes may be caused by differences among the patients given the two treatments, rather than the treatments alone (Barton, 2000). The only way to avoid known differences (selection bias) as well as concealed differences (confounding bias) between treatment and control groups, is to let fate determine to which group a given patient will be allocated (Grimes and Schultz, 2002), Blinding furthermore precludes information bias. One can expect that, if the sample size is large enough, the play of chance will conduct to similar groups, in which possible confounding factors are equally distributed. Any result in outcome may then be attributed to the intervention under study. If no significant differences in outcome are detected, either the intervention is not effective, or the power of the trial is not sufficiently large to detect a real difference. Of course, in the latter case one may guestion the clinical relevance of a possible small difference.

https://www.bmj.com/rapid-response/2011/10/30/another-rea...-why-randomised-controlled-trials-do-not-necessarily-tell-wh

Αποτίμηση του ωφέλους ή και της ζημιάς; Medical error (the third leading cause of death in the US)

Martin Makary and Michael Daniel

BMJ 2016; 353 doi: <u>https://doi.org/10.1136/bmj.i2139</u> (Publ ished o3 May 2016)Cite this as: *BMJ* 2016;353:i2139

Δείκτες έκβασης ή δείκτες διαδικασίας

Seven Countries Study¹: Μελέτη – ορόσημο που ανέδειξε τα οφέλη της μεσογειακής διατροφής και κατέταξε τον πληθυσμό της Κρήτης ως «χαμηλού κινδύνου» για καρδιομεταβολικά.

ΟΜΩΣ:

Αλλαγή διατροφής και τρόπου ζωής τα τελευταία χρόνια αύξηση στους παράγοντες κινδύνου.²

Πρόσφατη μελέτη σε επισκέπτες ΠΦΥ στην Κρήτη: Υψηλος επιπολασμός μεταβολικού συνδρόμου και σημαντικά ποσοστά ατόμων στις υψηλότερες κατηγορίες καρδιαγγειακού κινδύνου.

Επιπολασμός Μεταβολικού Συνδρόμου σε 815 επισκέπτες ΠΦΥ άν	ω
των 40 ετών	

Total	Males	Females		
	P-value b			
34 (4.2)	7 (1.9)	27 (5.9)	0.028	
72 (8.8)	29 (8.0)	43 (9.5)		
109 (13.4)	52 (14.4)	57 (12.6)		
600 (73.6)	273 (75.6)	327 (72.0)		
	34 (4.2) 72 (8.8) 109 (13.4)	n (%) 34 (4.2) 7 (1.9) 72 (8.8) 29 (8.0) 109 (13.4) 52 (14.4)	n (%) 34 (4.2) 7 (1.9) 27 (5.9) 72 (8.8) 29 (8.0) 43 (9.5) 109 (13.4) 52 (14.4) 57 (12.6)	

^a According to the National Cholesterol Education Program's Adult Treatment Panel III (NCEP ATP III – revision 2005) guidelines for metabolic syndrome (MetS).

	του SCORE της Ευρωπαϊκής Καρδιολογικής Εταιρείας					
	10-year Cardiovascular Risk – SCORE					
			Low-to- moderate risk persons (<5%)	High-risk persons (5-9%)	Very high-risk persons (≥10%)	
		n		n (%)		p-value ^c
Total		803 ^b	313 (39.0)	382 (47.6)	108 (13.4)	< 0.001
Gender	males	355	89 (25.1)	167 (47.0)	99 (27.9)	<0.001
	females	448	224 (50.0)	215 (48.0)	9 (2.0)	<0.001
Age, years	40-59	266	239 (89.8)	24 (9.0)	3 (1.1)	
	60-79	452	69 (15.3)	296 (65.5)	87 (19.2)	< 0.001
	80+	85	5 (5.9)	62 (72.9)	18 (21.2)	

10-ετής καρδιαγγειακός 815 επισκεπτών ΠΦΥ άνω των 40 ετών βάσει

The overall mean 10-year cardiovascular risk score was 5.7 (stand. dev.±3.6; median=5.0).

^a SCORE: European Society's 10-year Systematic Coronary Risk Estimation.

^b Analysis based on patients with or without any cardiovascular disease.

1. Keys A, et al. Coronary heart disease in seven countries. Circulation. 1970

2. 2. Vassilaki M, et al. Burden of heart disease in Greece: time to act. Public Health. Elsevier; 2014

Η αδυναμία της περιγραφικής έρευνας στη μέτρηση της επίπτωσης-το παράδειγμα του καρκίνου πνεύμονα



Εικόνα: Γεωγραφική κατανομή θνησιμότητας (Age-Standardized Mortality Rates/100,000/year) και ποσοστού αποδιδόμενων στο κάπνισμα θανάτων από KN πνεύμονα (PAFs, %)

Οι καπνιστές είχαν υψηλότερη επίπτωση και θνησιμότητα σε σύγκριση με τους πρώην καπνιστές (p = 0,02) και τους μη καπνιστές (p < 0,001)</p>

Το ποσοστό των θανάτων από KN πνεύμονα (Population Attributable Fraction, PAF%) που ήταν αποδοτέο στο κάπνισμα ήταν 86% και για τα δύο φύλα (άνδρες: 89%, γυναίκες: 78%)

Οι Δήμοι με την ισχυρότερη συσχέτιση καπνίσματος και θνησιμότητας από καρκίνο του πνεύμονα ήταν οι: Ηρακλείου, Χερσονήσου, Ιεράπετρας, Ρεθύμνου, Χανίων και Αποκορώνου

Αλλαγή της συμπεριφοράς και κάπνισμα-Ι

5As (Ask, Advise, Assess, Assist, Arrange) tobacco treatment delivery in primary care settings in Greece



Η αλλαγή της συμπεριφοράς ως εκτιμητής της απόδοσης στις υπηρεσίες υγείας και η συμπεριφορά υγείας ως έκβαση υγείας

Το χαμηλό ποσοστό εμπλοκής των ιατρών ΠΦΥ στην υποστήριξη διακοπής του καπνίσματος

UNIVERSITY OF OTTAWA HEAT INSTITUTE INSTITUTE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA



Aπό ένα ερευνητικό πρόγραμμα**Tobacco treatment TrAining Network in Crete (TiTAN Crete)** του ΠK/ http://titan.uoc.gr/index_en.html

Αλλαγή της συμπεριφοράς και τρόπος ζωής-ΙΙ



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http://titan.uoc.gr/index_en.html

Training General Practitioners in Evidence-Based Tobacco Treatment: An Evaluation of the Tobacco Treatment Training Network in Crete (TiTAN-Crete) Intervention

Charis Girvalaki, MPH¹, Sophia Papadakis, PHD, MHA^{1,2,3}, Constantine Vardavas, MD, PhD¹, Andrew L. Pipe, MD, PhD^{2,3}, Eleni Petridou, MD, PhD⁴, Ioanna Tsiligianni, MD, PhD¹, and Christos Lionis, MD, PhD, FRCGP¹, on behalf of the TiTAN Crete Partners



Follow-up Visit (2-weeks)

Quit Plan Visit (ACT)



 Table 4. General Practitioners' Performance in 4As Delivery Following Exposure to the TiTAN Intervention Compared With That of the Control Group.

Parameter			TiTAN vs. control	
	Control (n = 317), n (%)	TiTAN (n = 460), n (%)	AOR [95% CI] ^a	Þ ^a
Ask	166 (52.5)	381 (82.8)	4.12 [1.31, 13.0]	.0158
Advise: Quit smoking	149 (47.2)	375 (81.5)	5.03 [1.87, 13.6]	.0014
Advise: Health hazards	94 (29.8)	306 (66.8)	5.43 [2.94, 10.0]	<.001
Assist: General ^c	13 (4.1)	298 (64.8)	45.45 [18.24, 113.3]	<.001
Assist: Set quit date ^c	2 (0.6)	57 (12.6)	19.13 [3.57, 102.5]	.0006
Assist: Self-help materials ^c	3 (0.9)	120 (26.1)	37.51 [9.27, 151.8]	<.0001
Assist: Discuss medications	7 (2.2)	152 (33.0)	23.40 [10.08, 54.4]	<.0001
Assist: Prescribe medications ^d	0 (0.0)	7 (1.6)		_
Arrange ^c	3 (1.0)	70 (15.2)	15.07 [3.49, 65.1]	.0003

Επίλογος

- Η εισήγηση αυτή ως σύνολο προτάσεων για συμφωνία.
- Πολλές έννοιες και όροι που χρειάζεται να αποδοθούν με συμφωνία στα ελληνικά.
- Η συζήτηση για τα μεθοδολογικά θέματα που αντιμετωπίζει η αποτίμηση της κλινικής ιατρικής.
- Η ανάγκη συμπερίληψης της έννοιας της συμπεριφοράς και του κινδύνου.
- Για μια άλλη φορά υπογραμμίζεται η ανάγκη σύνταξης ενός κειμένου θέσεων με αναφορά και στην πολιτική υγείας.

Πολλές ευχαριστίες για την προσοχή σας

