

UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES (U.E.M.S.)



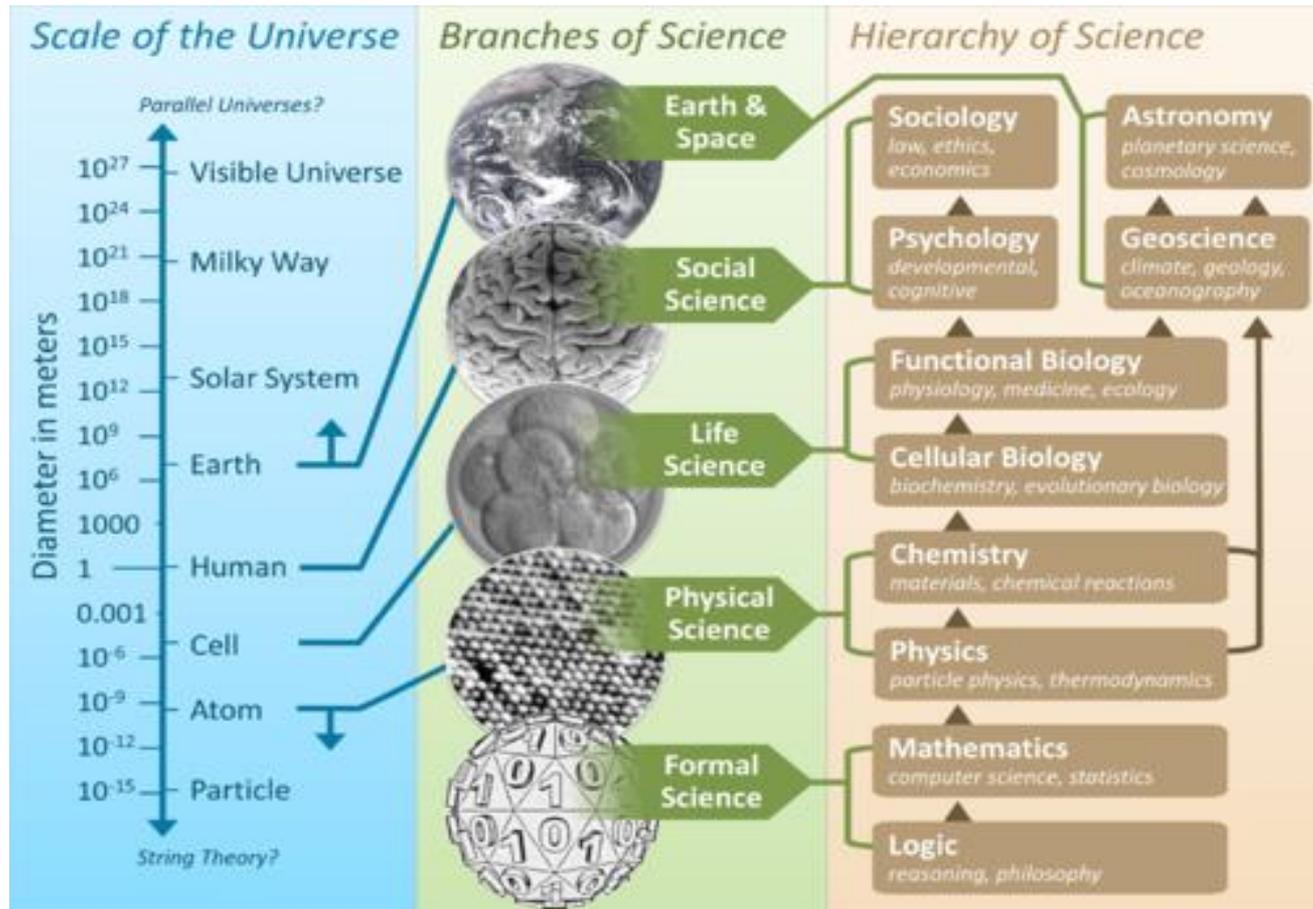
“NATIONAL GUIDELINES IN SURGICAL ONCOLOGY”

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Athens 2015

SCIENCE



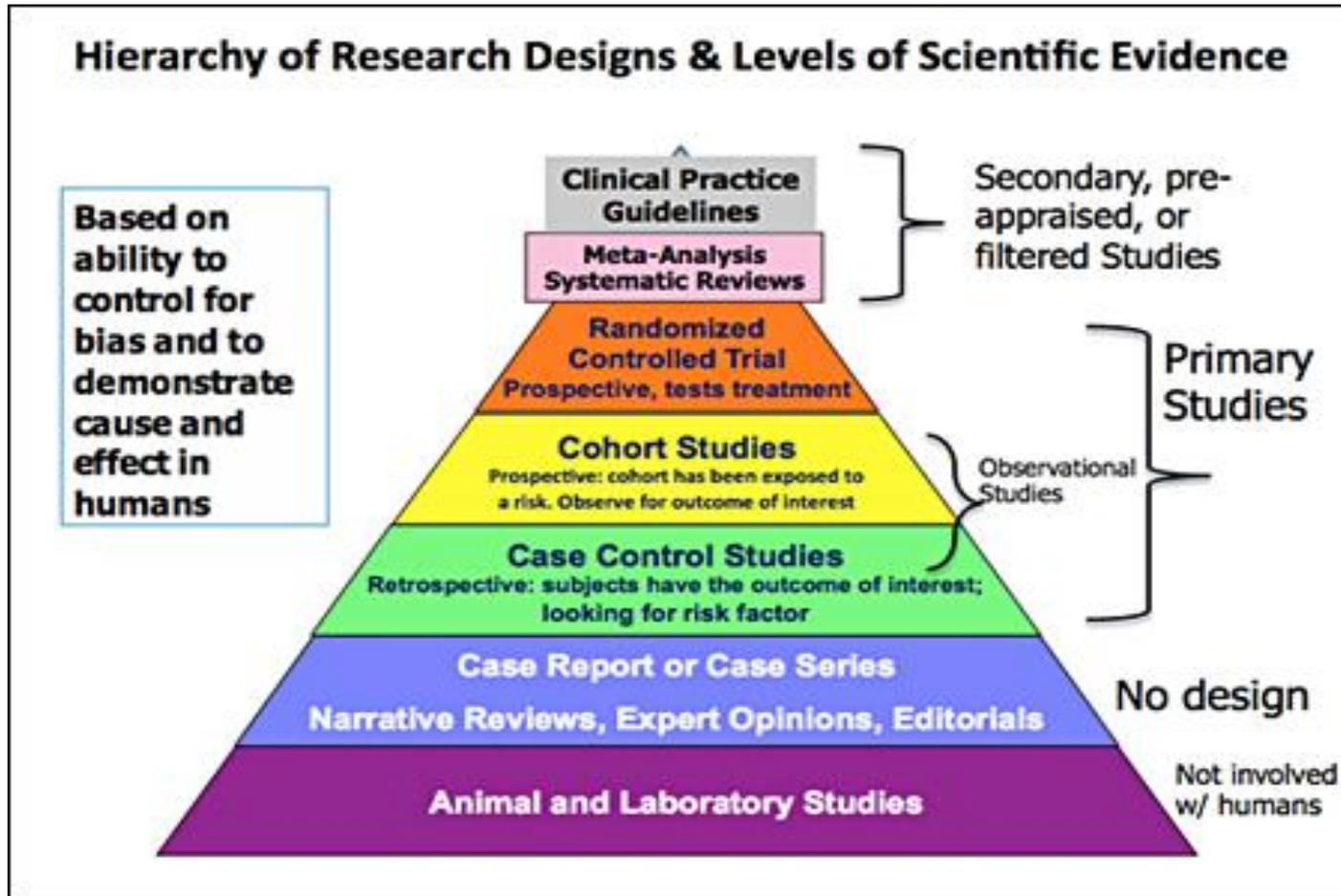
MEDICINE

- **Definition:**

the science and art of diagnosing, treating, curing, and preventing disease, relieving pain, improving and preserving health

From Webster's New World College Dictionary

EVIDENCE BASED MEDICINE



EVIDENCE BASED MEDICINE

		SIZE OF TREATMENT EFFECT				
		CLASS I <i>Benefit >>> Risk</i> Procedure/Treatment SHOULD be performed/administered	CLASS IIa <i>Benefit >> Risk</i> Additional studies with <i>focused objectives needed</i> IT IS REASONABLE to perform procedure/administer treatment	CLASS IIb <i>Benefit ≥ Risk</i> Additional studies with <i>broad objectives needed; additional registry data would be helpful</i> Procedure/Treatment MAY BE CONSIDERED	CLASS III <i>No Benefit or CLASS III Harm</i>	
				Procedure/ Test	Treatment	
				COR III: No benefit Not Helpful	No Proven Benefit	
				COR III: Harm Excess Cost w/o Benefit or Harmful	Harmful to Patients	
ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	<ul style="list-style-type: none"> Recommendation that procedure or treatment is useful/effective Sufficient evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> Recommendation in favor of treatment or procedure being useful/effective Some conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> Recommendation's usefulness/efficacy less well established Greater conflicting evidence from multiple randomized trials or meta-analyses 	<ul style="list-style-type: none"> Recommendation that procedure or treatment is not useful/effective and may be harmful Sufficient evidence from multiple randomized trials or meta-analyses 	
	LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	<ul style="list-style-type: none"> Recommendation that procedure or treatment is useful/effective Evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> Recommendation in favor of treatment or procedure being useful/effective Some conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> Recommendation's usefulness/efficacy less well established Greater conflicting evidence from single randomized trial or nonrandomized studies 	<ul style="list-style-type: none"> Recommendation that procedure or treatment is not useful/effective and may be harmful Evidence from single randomized trial or nonrandomized studies 	
	LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	<ul style="list-style-type: none"> Recommendation that procedure or treatment is useful/effective Only expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> Recommendation in favor of treatment or procedure being useful/effective Only diverging expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> Recommendation's usefulness/efficacy less well established Only diverging expert opinion, case studies, or standard of care 	<ul style="list-style-type: none"> Recommendation that procedure or treatment is not useful/effective and may be harmful Only expert opinion, case studies, or standard of care 	
Suggested phrases for writing recommendations		should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit is not recommended is not indicated should not be performed/administered/ other is not useful/ beneficial/ effective	COR III: Harm potentially harmful causes harm associated with excess morbidity/mortality should not be performed/ administered/ other
Comparative effectiveness phrases†		treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B			

GUIDELINES DEFINITION

- Plato (*4th Century BC*) was the first to mention that “doctors would be stripped of their clinical freedom and no longer allowed unchecked authority”
- The 28th Bethesda Conference (*Maryland U.S.A.*) provided specific definitions for a variety of guidelines: Healthcare Guidelines; Clinical Practices Guidelines; CarePlan; Care Module; Clinical Pathway. Guidelines were defined as *‘a related set of generalizations derived from past experience arranged in a coherent structure to facilitate appropriate responses to specific situations’*. Clinical Practice Guideline was defined as *‘a guideline developed to aid practitioner and patient pursuit of the most appropriate healthcare responses to specific clinical circumstances’*
- Prof Hurwitz Br (*King’s College London*) wrote: *Guidelines* (compared to text books) *are more concerned with specifying treatment strategies for certain patient types, with healthcare quality, and the reduction of unjustifiable clinical variability and costs’*

THE GENERAL LEGAL ASPECT (I)

- Due to the complexity of medical subject matters, national legislators (Governments & Parliaments) tend to turn to learned and independent bodies to carry the responsibility for preparing the detailed technical documentation underpinning legislation in these areas.
- Generally, the creation of medical guidelines should follow specific criteria (“guidelines for creation of guidelines”), which are:
 1. Face Credibility
 2. Validity
 3. Reproducibility
 4. Representativeness
 5. Clinical Applicability & Flexibility
 6. Clarity
 7. Reliability
 8. Transparency
 9. Scheduled Review

(European Heart Journal(1999)20,1152–1157)

THE GENERAL LEGAL ASPECT (II)

- 4 examples of European countries:
 1. **Netherlands:** Very strict guidelines on physician assisted death have been drawn up by the Royal Dutch Medical Association and incorporated in a legislative directive, allowing doctors intentionally to terminate the lives of their patients only if this is done in accordance with these strict guidelines.
 2. **U.K:** In 1990, the Parliament established a special Authority, called the Human Fertilization and Embryology Authority, to develop and enforce in vitro fertilization (IVF) techniques. This designated Body proposed a carefully researched and drafted 'Code of Practice', regulating both the ethical and clinical parameters of this treatment. The Authority's decision to restrict to three the number of fertilized eggs which can be placed in a woman's uterus during treatment by IVF is a clear example of a guideline emanating from ethical, scientific, safety and cost considerations

THE GENERAL LEGAL ASPECT (III)

3. **France:** Since 1993, many practice 'Guidelines' have been introduced and developed under the responsibility of an independent agency for the development of medical evaluation. It's worth noting that these guidelines which cover investigation, prescribing and certain medical procedures, were developed by an independent body and are backed up by fines for non-compliance.
4. **Germany:** The second Health Care Reform Law (Zweiten GKV-Neueordnungsgesetz) states in paragraph 137a Abs. 2 that for medical activities of which the quality should be ascertained, the Federal Chamber of Physicians should determine the necessary quality assurance programmes. However, guidelines issued by professional medical and/or scientific organizations do not have a direct legal status in Germany, but they may easily gain an indirect legal character (mittelbare Verrechtlichung) if the courts determine that they represent standards of care for medical practice. This would mean that if a physician does not follow such guidelines in a specific situation, there might be a strong requirement to justify any deviation from the established standard.

THE GENERAL LEGAL ASPECT (IV)

- **General Conclusion:**

1) The trend to issue guidelines based on statute law directly or on delegated legislation developed via State Agencies can be expected to continue and increase in Europe. In many ways, such guidelines have better credibility with the public in that they are generally well researched and based on all available expert opinion. However, the same challenge remains with quasi legal guidelines as with other guidelines; namely, keeping these up to date and current with both modern and evolving science and public opinion.

2) Guidelines could be introduced to a court by an expert witness as evidence of accepted and customary standards of care, but they cannot be introduced as a substitute for expert testimony. Courts are unlikely to adopt standards of care advocated in clinical guidelines as legal “gold standards” because the mere fact that a guideline exists does not of itself establish that compliance with it is reasonable in the circumstances, or that non-compliance is negligent.

Hurwitz Br. Legal and political considerations of clinical practice guidelines BMJ. 1999 Mar 6; 318(7184): 661–664.

SURGICAL ONCOLOGY GUIDELINES WORLDWIDE

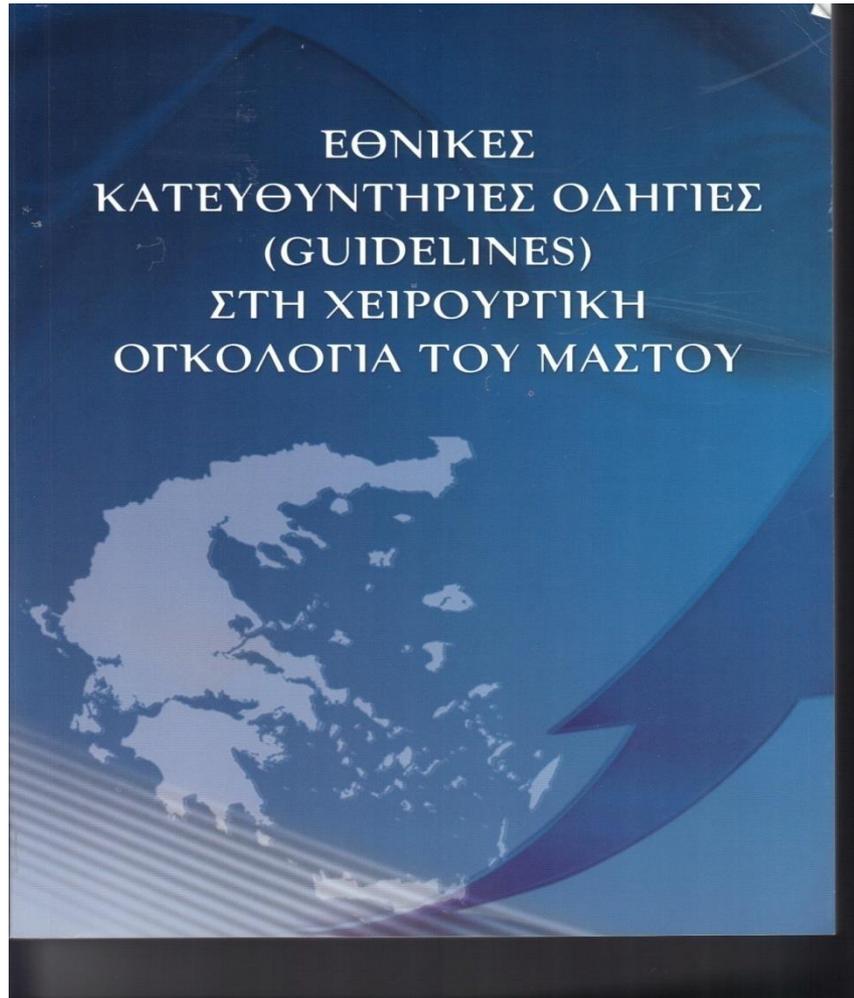
- Europe: - General: ESMO, ESTRO & ESSO Guidelines.
www.esmo.org/Guidelines
- USA: Society of Surgical Oncology (SSO) Guidelines
National Guideline Clearinghouse – www.guideline.gov
- UK: British Association of Surgical Oncology Guidelines
www.associationofbreastsurgery.org.uk
- Australia: National Health and Medical Research Council
www.nhmrc.gov.au/guidelines/index.htm

NATIONAL GUIDELINES

Greece:

- Medical guidelines are introduced from abroad (Europe and USA)
- In Surgical Oncology, ESSO & SSO Guidelines, are adopted
- Constitution of national guidelines has not yet formally established

NATIONAL GUIDELINES IN BREAST CANCER SURGERY
PROF. G.K. ZOGRAFOS M.D. Ph.D. F.A.C.S
DIRECTOR OF FIRST PROPAEDEUTIC SURGICAL CLINIC OF
UNIVERSITY OF ATHENS



NATIONAL GUIDELINES IN COLON CANCER SURGERY
V.A.KOMPOROZOS M.D. Ph.D. F.A.C.S
DIRECTOR OF 3rd SURGICAL CLINIC “EVANGELISMOS” HOSPITAL

Υπό την Αιγίδα της Ελληνικής Χειρουργικής Εταιρείας

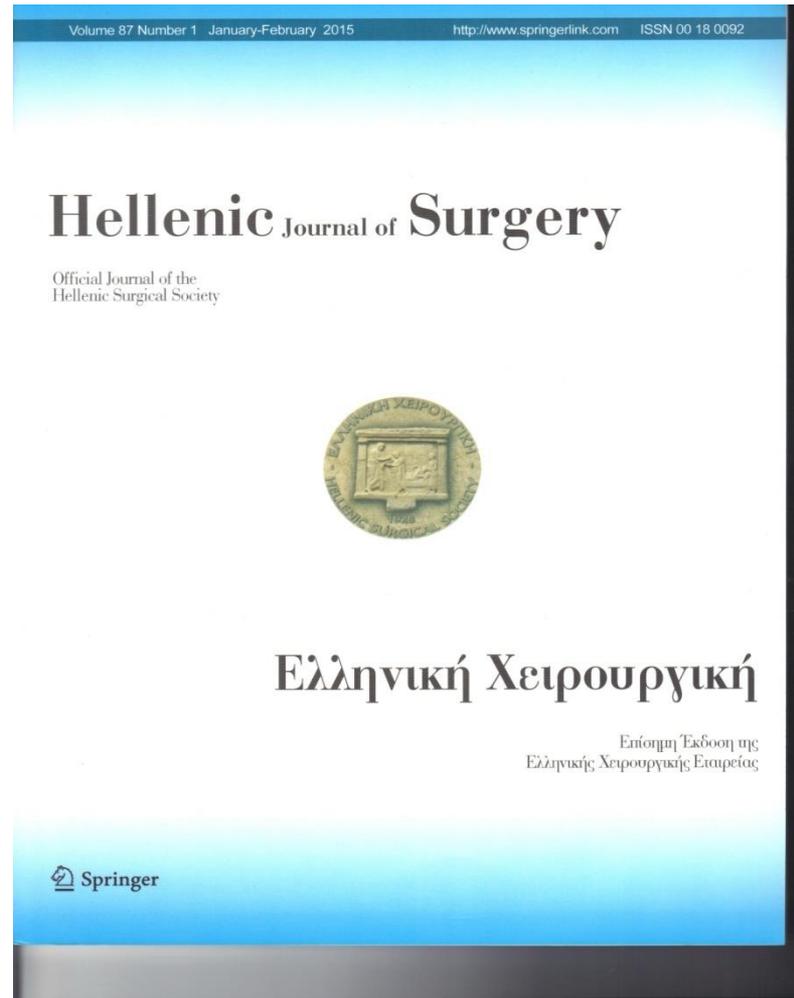
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ΚΑΙ ΤΟΥ ΚΑΡΚΙΝΟΥ ΤΟΥ ΠΡΩΚΤΟΥ

Βασίλειος Α. Κομπορόζος
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Χρίστος Φ. Γεωργιάδης

Επιμέλεια Έκδοσης:
Βασίλειος Α. Κομπορόζος

Αθήνα 2012

NATIONAL GUIDELINES IN THYROID CANCER SURGERY



NATIONAL GUIDELINES IN THYROID CANCER SURGERY

	
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CONCLUSIONS

- Greece is currently under way of constitution of it's own Surgical Oncology Guidelines, where strict scientific criteria are met
- These Guidelines have yet to be approved from our Central Health Council (K.E.Σ.Υ.) and our Ministry of Health, in order to gain legislation and formality
- Nationwide adoption of these Guidelines by all our Healthcare Institutions is the ultimate Purpose, so that the best level of Care for every Cancer Patient is achieved

THANK YOU

