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

“NATIONAL GUIDELINES IN SURGICAL ONCOLOGY”

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SCIENCE

Scale of the Universe

- Parallel Universes?
- Visible Universe
- Milky Way
- Solar System
- Earth
- Human
- Cell
- Atom
- String Theory?

Branches of Science

- Earth & Space
- Social Science
- Life Science
- Physical Science
- Formal Science

Hierarchy of Science

- Sociology
  - law, ethics, economics
- Psychology
  - developmental, cognitive
- Astronomy
  - planetary science, cosmology
- Geoscience
  - climate, geology, oceanography
- Functional Biology
  - physiology, medicine, ecology
- Cellular Biology
  - biochemistry, evolutionary biology
- Chemistry
  - materials, chemical reactions
- Physics
  - particle physics, thermodynamics
- Mathematics
  - computer science, statistics
- Logic
  - reasoning, philosophy
**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

Hierarchy of Research Designs & Levels of Scientific Evidence

- Clinical Practice Guidelines: Secondary, pre-appraised, or filtered Studies
- Meta-Analysis Systematic Reviews
- Randomized Controlled Trial: Prospective, tests treatment
- Cohort Studies: Prospective; cohort has been exposed to a risk. Observe for outcome of interest
- Case Control Studies: Retrospective; subjects have the outcome of interest; looking for risk factor
- Case Report or Case Series: Narrative Reviews, Expert Opinions, Editorials
- Animal and Laboratory Studies: Not involved w/ humans

Based on ability to control for bias and to demonstrate cause and effect in humans
# Evidence Based Medicine

## Size of Treatment Effect

<table>
<thead>
<tr>
<th>Class I</th>
<th>Benefit &gt;&gt; Risk</th>
<th>Procedure/Treatment SHOULD be performed/administered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level A</td>
<td>Multiple populations evaluated*</td>
<td>Recommendation that procedure or treatment is useful/effective</td>
</tr>
<tr>
<td></td>
<td>Data derived from multiple randomized clinical trials or meta-analyses</td>
<td>Sufficient evidence from multiple randomized trials or meta-analyses</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Class IIa</th>
<th>Benefit &gt;&gt; Risk</th>
<th>Additional studies with focused objectives needed</th>
<th>IT IS REASONABLE to perform procedure/administer treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level B</td>
<td>Limited populations evaluated*</td>
<td>Recommendation in favor of treatment or procedure being useful/effective</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Data derived from a single randomized trial or nonrandomized studies</td>
<td>Some conflicting evidence from multiple randomized trials or meta-analyses</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Class IIb</th>
<th>Benefit ≥ Risk</th>
<th>Additional studies with broad objectives needed; additional registry data would be helpful</th>
<th>Procedure/Treatment MAY BE CONSIDERED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level C</td>
<td>Very limited populations evaluated*</td>
<td>Recommendation in favor of treatment or procedure being useful/effective</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Only expert opinion, case studies, or standard of care</td>
<td>Some conflicting evidence from single randomized trials or nonrandomized studies</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Class III</th>
<th>No Benefit or Class III Harm</th>
<th>Procedure/Test</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level</td>
<td>Recommendation’s usefulness/effectiveness less well established</td>
<td>Greater conflicting evidence from multiple randomized trials or meta-analyses</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sufficient evidence from multiple randomized trials or meta-analyses</td>
<td>Evidence from single randomized trial or nonrandomized studies</td>
<td></td>
</tr>
</tbody>
</table>

**Suggested phrases for writing recommendations**

- Should
- Is recommended
- Is indicated
- Is useful/effective/beneficial
- May/might be considered
- May/might be reasonable
- Usefulness/effectiveness is unknown/unclear/uncertain or not well established

**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
- Treatment A is not recommended
- Should not be performed/administered/other
- Is not useful/beneficial/effective
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 programs. 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 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.

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.associationofbreastssurgery.org.uk

- **Australia:** National Health and Medical Research Council www.nhmrc.gov.au/guidelines/index.htm
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 PROPAADEUTIC SURGICAL CLINIC OF
UNIVERSITY OF ATHENS
NATIONAL GUIDELINES IN COLON CANCER SURGERY
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DIRECTOR OF 3rd SURGICAL CLINIC “EVANGELISMOS” HOSPITAL

ΤΕΚΜΗΡΙΩΜΕΝΗ ΑΝΤΙΜΕΤΩΠΙΣΗ
ΤΟΥ ΟΡΘΟΚΟΛΙΚΟΥ ΚΑΡΚΙΝΟΥ
ΚΑΙ ΤΟΥ ΚΑΡΚΙΝΟΥ ΤΟΥ ΠΡΩΧΤΟΥ

Βασίλειος Α. Κομπορόζος
Γεώργιος Ε. Θεοδωρόπουλος
Χρήστος Φ. Γεωργιάδης

Επιμέλεια Έκδοσης:
Βασίλειος Α. Κομπορόζος
Αθήνα 2012
NATIONAL GUIDELINES IN THYROID CANCER SURGERY
NATIONAL GUIDELINES IN THYROID CANCER SURGERY
CONCLUSIONS

- Greece is currently under way of constitution of its own Surgical Oncology Guidelines, where strict scientific criteria are met.

- These Guidelines have yet to be approved from our Central Health Council (Κ.Ε.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.