ESC Guidelines – Where Are We Going?

Prof. Dan Atar, FESC
Vice-President National Affairs

Courtesy Prof. JL. Zamorano, Chair of the ESC Guideline Committee,

Mrs. Catherine Despres & Veronica Dean
ESC Guidelines Department

Prof. Jeroen J. Bax, President-elect, ESC

Zürich 10.6.2015
1. How are the ESC guidelines generated?

2. How do guidelines work?

3. The ESC scoring system: Class of recommendations, level of evidence

4. How is this scoring system different from the US?

5. Which topics have been covered in guidelines over the years?

6. How do the topics relate with the core syllabus?

7. Which topics will be covered in 2015 and 2016?

8. What is the impact of guidelines - how many are endorsed, how many are downloaded, how many are translated?

9. How does the GL-App work?
ESC Guidelines = Evidence + expertise for clinicians

- Evidence-based recommendations developed by Task Forces of leading European experts
- Help physicians weigh benefits & risks of particular diagnostic & therapeutic procedures
- Formats include: full texts, executive summaries, pocket guidelines, slide-sets, books, mobile application...

www.escardio.org
The CPG was created in 1994 by the ESC in order to deal with the process of guidelines development.

The CPG has the responsibility of selecting the topics for the documents.

The CPG is responsible for administrative supervision and co-ordination of Task Forces (TF).
# ESC Committee for Practice Guidelines (CPG) 2014 - 2016

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Country</th>
<th>Representing</th>
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<tbody>
<tr>
<td>Jose Luis</td>
<td>Zamorano</td>
<td>Spain</td>
<td>CPG Chairperson/ESC Board Mbr</td>
</tr>
<tr>
<td>Victor</td>
<td>Aboyans</td>
<td>France</td>
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<tr>
<td>Stephan</td>
<td>Achenbach</td>
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<tr>
<td>Stefan</td>
<td>Agewall</td>
<td>Norway</td>
<td>WG CV Pharmacotherapy</td>
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<tr>
<td>Lina</td>
<td>Badimon</td>
<td>Spain</td>
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<td>Gonzalo</td>
<td>Baron Esquivias</td>
<td>Spain</td>
<td>CCP</td>
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<tr>
<td>Helmut</td>
<td>Baumgartner</td>
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<td>Jeroen</td>
<td>Bax</td>
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<td>Héctor</td>
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<td>Scipione</td>
<td>Carerj</td>
<td>Italy</td>
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<tr>
<td>Veronica</td>
<td>Dean</td>
<td>France</td>
<td>ESC staff</td>
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<td>Cetin</td>
<td>Erol</td>
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<tr>
<td>Donna</td>
<td>Fitzimons</td>
<td>UK</td>
<td>CCNAP</td>
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<tr>
<td>Oliver Gaemperli</td>
<td>Switzerland</td>
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<tr>
<td>Paulus Kirchhof</td>
<td>Germany/UK</td>
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<td>Philippe Kolh</td>
<td>Belgium</td>
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<td>Patrizio Lancellotti</td>
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<td>EACVI</td>
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<td>Gregory Lip</td>
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<td>Petros Nihoyannopoulos</td>
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<td>Massimo F. Piepoli</td>
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<td>Poland</td>
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<td>Adam Torbicki</td>
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<td>Antonio Vaz Carneiro</td>
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<tr>
<td>Stephan Windecker</td>
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European Association for Cardiovascular Prevention & Rehabilitation (EACPR)
European Association of Cardiovascular Imaging (EACVI)
European Association of Percutaneous Cardiovascular Interventions (EAPCI)
European Heart Rhythm Association (EHRA)

Acute Cardiovascular Care Association (ACCA)
Council on Cardiovascular Nursing and Allied Professions (CCNAP)
Council for Cardiology Practice (CCP)
Heart Failure Association (HFA)

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Dan Atar, FESC
Vice President National Affairs
Guidelines Production: a 2 year-process

Goals and team Definitions
(3 months)

Document elaboration:
2 phases: writing + review
(12–18 months)

Publication
(3 months)

Details available on the ESC Web Site at:
http://www.escardio.org/guidelines-surveys/esc-guidelines/about/Pages/rules-writing.aspx
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Goals & Team Definitions (3 months)

- **CPG**: Choice of titles and timelines
- **Board**: Validation of titles and timelines
- **CPG**: Choice of Chairs with Board validation pending DOI review by Board VPs
- **CPG**: Choice of TF Members with call on specific expertise from specialty center and others
- Invitations to TF members and check of their DOIs for final composition of TF
Document Elaboration (12–18 months)

Kick-off meeting
Laying out of writing rules + table of contents + assignments + timelines + document search (literature + systematic reviews)

TF - writing phase
2-3 face to face meetings and Task Force review phases (2-3)

CPG - Choice of Review Coordinators with Board validation pending DOI review by Board VPs

CPG - Choice of Peer Reviewers with call on specific expertise from specialty center and others

External peer review
2-3 rounds of peer review are necessary to obtain a final document

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Dear National Cardiac Society President,
Dear National Cardiac Society Secretary,
Dear ESC Guidelines Coordinator,

Our new review process aiming at increasing diversity of reviews and global readability of the Guidelines is now well in place and we would like to take this opportunity to thank you for your support.

As mentioned by Prof. Jose Luis Zamorano, Chairperson of the ESC Committee for Practice Guidelines (CPG), during the ESC Guidelines Coordinators Meeting in January 2015, we are pleased to involve ALL National Societies in the review of ALL 2016 ESC Guidelines again this year.

The CPG is therefore calling upon ALL National Cardiac Societies to nominate ONE reviewer, expert in the field, for EACH of the below-mentioned 2016 ESC Guidelines:

1. ESC/EAS Guidelines on the management of dyslipidaemias
2. European Guidelines on cardiovascular disease prevention in clinical practice
3. ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS
4. ESC Guidelines on acute and chronic heart failure

As in previous years, to keep the manageable and a good quality of review, the CPG is asking the National Cardiac Societies’ reviewers to focus specifically on reviewing Class I and III recommendations.

The National Cardiac Societies’ reviewers having been involved in the review process will be listed in the document in an Appendix in order to acknowledge their time and effort. They will be indexed in PubMed.

Please send us the name and full contact details of your selected reviewer for each of the above-mentioned Guidelines: ONE name per Guidelines, by Friday 26 June 2015. Beyond this date the reviewers’ lists will be closed.
Publication Phase (3 months)

CPG + TF → Endorsement phase → EHJ (in specific cases) → EHJ → Devlp of derivative products

Publication approval from all TF and CPG Members (as well as partner associations in the case of joint guidelines)

Systematic submission to EHJ via a fast track process + to specialty and partner society journals when appropriate + in specialty and partner society journals when appropriate

CME questions
Pocket Guidelines
Guidelines App
Slide-sets
Essential messages
Summary cards
Mobile App ...
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# Table 1: Classes of Recommendations

<table>
<thead>
<tr>
<th>Classes of recommendations</th>
<th>Definition</th>
<th>Suggested wording to use</th>
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</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.</td>
<td>Is recommended/is indicated</td>
</tr>
<tr>
<td>Class II</td>
<td>Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.</td>
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</tr>
<tr>
<td>Class IIa</td>
<td>Weight of evidence/opinion is in favour of usefulness/efficacy.</td>
<td>Should be considered</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Usefulness/efficacy is less well established by evidence/opinion.</td>
<td>May be considered</td>
</tr>
<tr>
<td>Class III</td>
<td>Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.</td>
<td>Is not recommended</td>
</tr>
</tbody>
</table>
# Levels of Evidence

<table>
<thead>
<tr>
<th>Level of evidence A</th>
<th>Data derived from multiple randomized clinical trials or meta-analyses.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of evidence B</td>
<td>Data derived from a single randomized clinical trial or large non-randomized studies.</td>
</tr>
<tr>
<td>Level of evidence C</td>
<td>Consensus of opinion of the experts and/or small studies, retrospective studies, registries.</td>
</tr>
</tbody>
</table>
Guidelines for the management of atrial fibrillation

The Task Force for the Management of Atrial Fibrillation of the European Society of Cardiology (ESC)

Developed with the special contribution of the European Heart Rhythm Association (EHRA)†

Endorsed by the European Association for Cardio-Thoracic Surgery (EACTS)
Recommendations
Total = 210

Class of Recommendation
- I: is recommended
- IIa: should be considered
- IIb: may be considered
- III: should not...

Level of Evidence
- LoE A
- LoE B
- LoE C
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### Class I (Strong)

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Risk</th>
</tr>
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<tbody>
<tr>
<td>Suggested phrases for writing recommendations:</td>
<td>Benefit &gt;&gt;&gt; Risk</td>
</tr>
<tr>
<td>- Is recommended</td>
<td></td>
</tr>
<tr>
<td>- Is indicated/useful/effective/beneficial</td>
<td></td>
</tr>
<tr>
<td>- Should be performed/administered/other</td>
<td></td>
</tr>
<tr>
<td>- Comparative-Effectiveness Phrases‡:</td>
<td></td>
</tr>
<tr>
<td>- Treatment/strategy A is recommended/indicated in preference to treatment B</td>
<td></td>
</tr>
<tr>
<td>- Treatment A should be chosen over treatment B</td>
<td></td>
</tr>
</tbody>
</table>
For comparative-effectiveness recommendations (COR I and IIa; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

<table>
<thead>
<tr>
<th>CLASS IIa (MODERATE)</th>
<th>Benefit &gt;&gt; Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Suggested phrases for writing recommendations:</strong></td>
<td></td>
</tr>
<tr>
<td>▪ Is reasonable</td>
<td></td>
</tr>
<tr>
<td>▪ Can be useful/effective/beneficial</td>
<td></td>
</tr>
<tr>
<td>▪ Comparative-Effectiveness Phrases‡:</td>
<td></td>
</tr>
<tr>
<td>▪ Treatment/strategy A is probably recommended/indicated in preference to treatment B</td>
<td></td>
</tr>
<tr>
<td>▪ It is reasonable to choose treatment A over treatment B</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CLASS IIb (WEAK)</th>
<th>Benefit ≥ Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Suggested phrases for writing recommendations:</strong></td>
<td></td>
</tr>
<tr>
<td>▪ May/might be reasonable</td>
<td></td>
</tr>
<tr>
<td>▪ May/might be considered</td>
<td></td>
</tr>
<tr>
<td>▪ Usefulness/effectiveness is unknown/unclear/uncertain or not well established</td>
<td></td>
</tr>
</tbody>
</table>

‡ For comparative-effectiveness recommendations (COR I and IIa; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.
## CLASS III: No Benefit (MODERATE)

**Benefit = Risk**

*(Generally, LOE A or B use only)*

Suggested phrases for writing recommendations:

- Is not recommended
- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

## CLASS III: Harm (STRONG)

**Risk > Benefit**

Suggested phrases for writing recommendations:

- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

**ACC/AHA**

CLASS (STRENGTH) OF RECOMMENDATION

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LEVEL A

- High-quality evidence from (more than 1)† RCTs
- Meta-analyses of high-quality trials
- One or more RCTs corroborated by high-quality registry studies

† The method of assessing quality is evolving, including the application of standardized, validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.
<table>
<thead>
<tr>
<th>LEVEL B-R</th>
<th>(randomized)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate-quality evidence from (1 or more)‡ RCTs</td>
<td></td>
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<tr>
<td>Meta-analyses of moderate-quality RCTs</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LEVEL B-NR</th>
<th>(nonrandomized)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate-quality evidence from (1 or more)‡ well-designed, well-executed nonrandomized studies, observational studies, or registry studies</td>
<td></td>
</tr>
<tr>
<td>Meta-analyses of such studies</td>
<td></td>
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</tbody>
</table>

† The method of assessing quality is evolving, including the application of standardized, validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

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A recommendation with LOE C or E does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

### LEVEL (QUALITY) OF EVIDENCE†

<table>
<thead>
<tr>
<th>LEVEL C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized or nonrandomized observational or registry studies with limitations of design or execution</td>
</tr>
<tr>
<td>Meta-analyses of such studies</td>
</tr>
<tr>
<td>Physiological or mechanistic studies in human subjects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LEVEL E</th>
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</thead>
<tbody>
<tr>
<td>Consensus of expert opinion based on clinical experience when evidence is insufficient, vague, or conflicting</td>
</tr>
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</table>
Who Applies GRADE?

- American College of Physicians
- American Thoracic Society
- Publishers – BMJ
- Publications – UpToDate
- Cochrane Collaboration
The GRADE Process for developing recommendations

1. **Health Care Question (PICO)**
   - Systematic review

2. **Studies**
   - S1
   - S2
   - S3
   - S4
   - S5

3. **Outcomes**
   - OC1
   - OC2
   - OC3
   - OC4
   - Important outcomes
   - Critical outcomes

4. **Generate an estimate of effect for each outcome**

5. **Rate the quality of evidence for each outcome, across studies**
   - RCTs start with a high rating, observational studies with a low rating
   - Rating is modified downward:
     - Study limitations
     - Imprecision
     - Inconsistency of results
     - Indirectness of evidence
     - Publication bias likely
   - Rating is modified upward:
     - Large magnitude of effect
     - Dose response
     - Confounders likely minimize the effect

6. **Final rating of quality for each outcome:** high, moderate, low, or very low

7. **Rate overall quality of evidence**
   - (lowest quality among critical outcomes)

8. **Decide on the direction (for/against) and grade strength (strong/weak) of the recommendation considering:**
   - Quality of the evidence
   - Balance of desirable/undesirable outcomes
   - Values and preferences

9. **Decide if any revision of direction or strength is necessary considering:** Resource use
<table>
<thead>
<tr>
<th>Study Design</th>
<th>Quality of Evidence</th>
<th>Lower if</th>
<th>Higher if</th>
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<tbody>
<tr>
<td>Randomized trial</td>
<td>High</td>
<td>Risk of bias</td>
<td>Large effect</td>
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<td></td>
<td></td>
<td>-1 Serious</td>
<td>+1 Large</td>
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<td></td>
<td></td>
<td>-2 Very serious</td>
<td>+2 Very large</td>
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<tr>
<td>Observational study</td>
<td>Moderate</td>
<td>Inconsistency</td>
<td>Dose response</td>
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<td></td>
<td></td>
<td>-1 Serious</td>
<td>+1 Evidence of a gradient</td>
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<tr>
<td></td>
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<td>-2 Very serious</td>
<td>All plausible confounding</td>
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<td></td>
<td>Low</td>
<td>Indirectness</td>
<td>+1 Would reduce a demonstrated effect or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1 Serious</td>
<td>+1 Would suggest a spurious effect when results show no effect</td>
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<td></td>
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<td>-2 Very serious</td>
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<td></td>
<td>Very low</td>
<td>Imprecision</td>
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<td></td>
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<td>-1 Serious</td>
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<td></td>
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<td>-2 Very serious</td>
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<td>Publication bias</td>
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<td></td>
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<td>-1 Likely</td>
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<td>-2 Very likely</td>
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Next steps:

• JOIN ACC/AHA?

• Simultaneous ESC / GRADE in some GL’s (same as US)
## Recommendations regarding risk estimation

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
<th>GRADE</th>
<th>Ref[^c]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total risk estimation using multiple risk factors (such as SCORE) is recommended for asymptomatic adults without evidence of CVD.</td>
<td>I</td>
<td>C</td>
<td>Strong</td>
<td>36</td>
</tr>
<tr>
<td>High-risk individuals can be detected on the basis of established CVD, diabetes mellitus, moderate to severe renal disease, very high levels of individual risk factors, or a high SCORE risk, and are a high priority for intensive advice about all risk factors.</td>
<td>I</td>
<td>C</td>
<td>Strong</td>
<td>36,37</td>
</tr>
</tbody>
</table>

[^c]: European Society of Cardiology
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<td>Peripheral Artery Disease</td>
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</table>
1. How are the ESC guidelines generated?
2. How do guidelines work?
3. The ESC scoring system: Class of recommendations, level of evidence
4. How is this scoring system different from the US?
5. Which topics have been covered in guidelines over the years?
6. How do the topics relate with the core syllabus?
7. Which topics will be covered in 2015 and 2016?
8. What is the impact of guidelines - how many are endorsed, how many are downloaded, how many are translated?
9. How does the GL-App work?
### Core Curriculum 2013 Topics

1. History taking and clinical examination
2. The electrocardiogram (standard & exercise ECG, ambulatory,CPX)
3. Non-invasive imaging
4. Invasive imaging: cardiac catheterization & angiography
5. Genetics
6. Clinical pharmacology
7. Cardiovascular prevention
8. Acute coronary syndromes
9. Chronic ischaemic heart disease
10. Myocardial diseases
11. Pericardial diseases
12. Oncology and the heart
13. Congenital heart disease in adult patients
14. Pregnancy & heart disease
15. Valvular heart disease
16. Infective endocarditis
17. Heart failure
18. Pulmonary arterial hypertension
19. Physical activity & sport in primary & secondary prevention
20. Arrhythmias
21. Atrial fibrillation & flutter
22. Syncope
23. Sudden cardiac death & resuscitation
24. Diseases of the aorta & trauma to the aorta & heart
25. Peripheral artery diseases.
26. Thrombo-embolic venous disease
27. Acute cardiovascular care
28. The cardiac consult

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**22/28**

Core Curriculum topics covered by ESC Guidelines
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2015: 5 Guidelines, 1 Position paper to be published

**Pulmonary Hypertension**
Chairs: Marc Humbert, Nazzareno Galie

**Acute Coronary Syndromes in Patients presenting without persistent ST Segment elevation - (ACS – NSTE)**
Chairs: Marco Roffi, Carlo Patrono

**Pericardial Diseases**
Chairs: Philippe Charron, Yehuda Adler

**Infective Endocarditis**
Chairs: Gilbert Habib, Patrizio Lancellotti

**Ventricular Arrhythmia & Sudden Cardiac Death**
Chairs: Silvia Priori, Carina Blomstrom Lundqvist

**Cardio-Oncology Position Paper**
Chairs: Pepe Zamorano, Patrizio Lancellotti

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4 Guidelines in writing phase
For publication in 2016

Dyslipidaemias
Chairs: Ian Graham, Alberico Catapano

CVD Prevention
Chairs: Massimo Piepoli, Arno W. Hoes

Atrial Fibrillation
Chairs: Paulus Kirchhof, Stefano Benussi

Heart Failure
Chairs: Piotr Ponikowski, Adriaan Voors
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ESC Publications – Massive dissemination

Talking millions

<table>
<thead>
<tr>
<th>Year</th>
<th>Total ESC Journal Downloads</th>
<th>Total ESC Guidelines Downloads</th>
<th>Total ESC GL Download Contribution (%)</th>
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<td>1 472 524</td>
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<td>11</td>
<td>10 753 135</td>
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www.escardio.org
Endorsements per NCS countries (2009 to January 2015)

Dan Atar, FESC
Vice President National Affairs
Translations of Pocket Guidelines/titles
2010-2014 (Dec 2014)

Published in Barcelona Congress
Translation of Some Pocket Guidelines Available

The translations are done by the NCS
1. How are the ESC guidelines generated?

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3. The ESC scoring system: Class of recommendations, level of evidence

4. How is this scoring system different from the US?

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9. How does the GL-App work?
ESC POCKET GUIDELINES APPLICATION
Over 90 practical tools linked to the 2011, 2012, 2013 and 2014 ESC Guidelines

http://www.escardio.org/guidelines
Example of interactive tools in the App: CHA2DS2-VASc Score

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<td>1</td>
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<td>Hypertension</td>
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<td>Age ≥ 75</td>
<td>0</td>
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<td>Diabetes mellitus</td>
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<td>Age 65-74</td>
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Risk factor scores:

- Cong. HF/LV dysfunction: 0
- Hypertension: 0
- Age ≥ 75: 0
- Diabetes mellitus: 0
- Stroke/TIA/TE: 0
- Vascular disease<sup>a</sup>: 0
- Age 65-74: 0
- Sex category (i.e., female gender): 0

Score: Stroke and thromboembolism event rate at 1 year follow-up (%): 0

Treatment recommendation:

- iPad version
- Smartphone version
Example of interactive tools in the App: Choice of anticoagulant

iPad version

www.escardio.org
Conclusions

• The ESC Guidelines: highly visible / used world wide

• Quality the primary feature

• Regular updates required for every topic covered

• GLs assist physicians in decision making, however do not replace individual clinical judgement

• Guidelines are not meant to be the law

• Future developments: GRADE, while keeping the simple and accepted system of recommendations
Thank you for your attention