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How often should we renew clinical guidelines?

Disclosures

Member of ESVS AAA Guidelines Committee
2011, 2019, 2024

What & why clinical practice guidelines?

- **“systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” Institute of Medicine**
- **Designed to improve the quality of care**

Emerging responsibilities of guidelines & guideline committees

- Identification of new roles in research & healthcare
- Development of new targets to be addressed & the strategies to achieve them.
- Organise guidelines & recommendations by selected groups to improve clinical practice & to support research activities.
- Establishment and monitoring of inventories and registries

The establishment moves in to research too: taken from ESC statements

Who sits on guideline committees

- SVS – vascular surgeons
- ESVS - >90% vascular surgeons, with other clinicians
- ESC – clinicians – mainly cardiologists
- NICE – clinicians, nurses, patients & others
- Different guidelines may not be aligned

Guidelines for guidelines: how are they made?

Minimum of 2.5 years for development

- time lines (m)
- 0
 - 3
 - 6
 - 10
 - 12
 - 15
 - 15
 - 18
 - 19
 - 22
 - 28
 - 30
- Established authority or organisation appoints & trains a guideline (gl0 committee
 - Identify programme of themes for guideline development
 - Identify chairperson(s) for specific guideline eg AAA
 - Chairpersons select committee of ~12-16 members
 - Kick off meeting to identify topics to be covered & chapters
 - Small groups assigned to systematically review evidence for each chapter
 - Draft chapters prepared along with recommendations & tables of evidence
 - Consensus meeting to discuss & agree recommendations
 - Chairmen prepare first draft of guidelines
 - First draft sent for review to GL committee who also seek external reviewers
 - First reviews received
 - Second draft of new G: prepared and sent out for further review
 - Third, final draft to GL committee for approval
 - GL sent for typesetting, followed by proofing before on-line publication



Benefits & harms of clinical guidelines

Positive

- Quality of care
- Consistency of care
- Information & empowerment of patients
- Influence public policy
- Identify knowledge gaps

Negative

- Lack of evidence with misleading guidance
- Poor design studies with flawed evidence
- Outdated guidance
- Influenced by experience of guideline group
- Often do not consider patient needs
- Provide legal cover for sometimes poor advice



Lack of evidence with misleading guidance: threshold for iliac aneurysm repair

Editor's Choice — European Society for Vascular Surgery (ESVS) 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms

Recommendation 102

The threshold for elective repair of isolated iliac artery aneurysm (common iliac artery, internal iliac artery and external iliac artery, or combination thereof) may be considered at a minimum of 3.5 cm diameter

Class	Level	References
IIb	C	[665,671-673,659,658]

Experience of the guideline committee

- In the absence of evidence this was decided by majority vote of the guideline committee

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A systematic review on endovascular repair of isolated common iliac artery aneurysms and suggestions regarding diameter thresholds for intervention

Nektarios Charisis, MD,^a Vasileios Bouris, MD,^b Alexander Rakic, MD,^a David Landau, MD,^a and Nicos Labropoulos, PhD,^a *Stony Brook and New York, NY*

Journal of Vascular Surgery November 2021

Rupture rate of aneurysms <4 cm diameter is extremely rare (0.2%)

Minimum threshold of 4 cm diameter suggested

Guidelines causing harm

- “The repair of CIAA <4.0 cm may present greater risks to patients than observation because the rupture rates of these aneurysms seem to be exceedingly low. Overtreatment may lead to patient harm, wasted re-sources and unnecessary costs.”



Further evidence indicates that thresholds should be morphology dependent, since CiAAs after an acute iliac bend never rupture *Parker et al EJVES 2019*

Studies with flawed evidence

- ESVS 2017 descending thoracic aortic guidelines for sub-acute/chronic type B dissection
- It has been demonstrated that TEVAR, in addition to optimal medical treatment, was associated with improved 5 year aorta specific survival and delayed disease progression.^{INSTEAD}

Translated into guideline 39

ESVS 2017 descending thoracic aorta

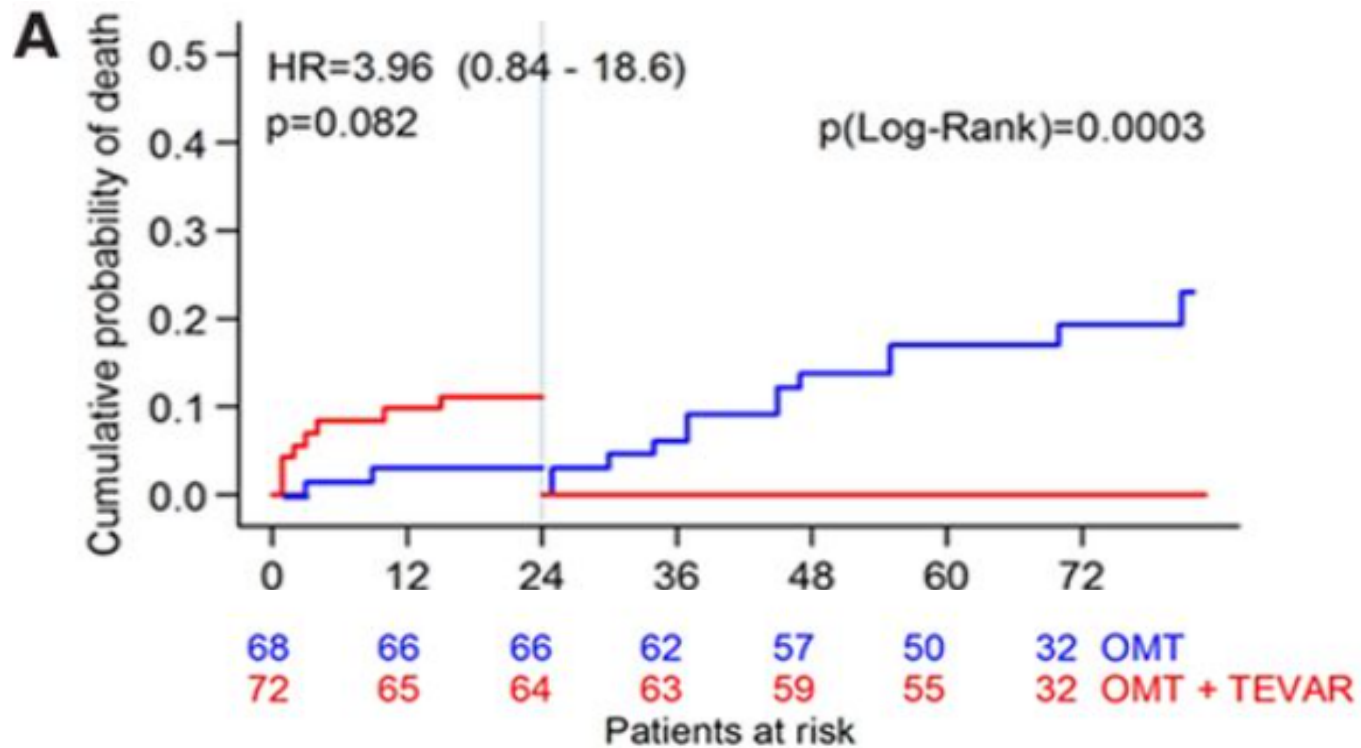
Recommendation 39			
In patients at risk of further aortic complications with suitable anatomy for endografting, endovascular repair of uncomplicated chronic type B aortic dissections should be considered in the sub-acute phase, in dedicated centres	Ila	B	190

INSTEAD trial

- RCT of TEVAR vs no intervention with best medical therapy in both arms.
- 2 year results: TEVAR failed to improve 2-year survival and adverse event rates despite favorable aortic remodeling. Circulation 2009: **great paper**
- 5 year results: TEVAR in addition to optimal medical treatment is associated with improved 5-year aorta-specific survival and delayed disease progression. In stable type B dissection with suitable anatomy, preemptive TEVAR should be considered to improve late outcome. Circ Cardiovasc Intervent 2013
- This was based on a landmark analysis including only patients alive at 2 years after randomisation

INSTEAD 5-year landmark analysis

Aorta specific mortality



INSTEAD 5-year landmark analysis: statistician error – resurrected patients

Table 2. Aorta specific mortality

	OMT (n=68)	OMT+TEVAR (n=72)	
Outcome	n/Total n (Rate/100 Person-y)	n/Total n (Rate/100 Person-y)	P Value
Aorta-specific mortality			
All patients			
Time since randomization			
0–12 mo	2/68 (3.0)	5/72 (7.5)	0.44
12–24 mo	0/66 (0)	0/65 (0)	...
24–60 mo	11/66 (3.6)	0/64 (0)	0.001
>60 mo	1/50 (0.3)	0/55 (0)	0.48

Surgical Innovation New T... pdf



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Show all

68
72

66
65

66
64

62
63

57
59

50
55

32

OMT

32 OMT + TEVAR

Patients at risk

Poor design studies with lack of patient input

- Guidelines are heavily dependent on systematic reviews as providing good quality evidence
- Systematic reviews are only as good as the contributed studies
- Systematic reviews are only useful if they ask the important questions

What outcomes are most valued by patients facing elective AAA repair?

- Mid-term survival, next 3 years or so
- Physical, social & mental functioning

From focus groups in Germany, Sweden, UK in collaboration with Anders Wanhainen & Christian Behrendt

Systematic review & meta-analysis of factors influencing survival after AAA repair

DOI:<https://doi.org/10.1016/j.ejvs.2015.09.007>

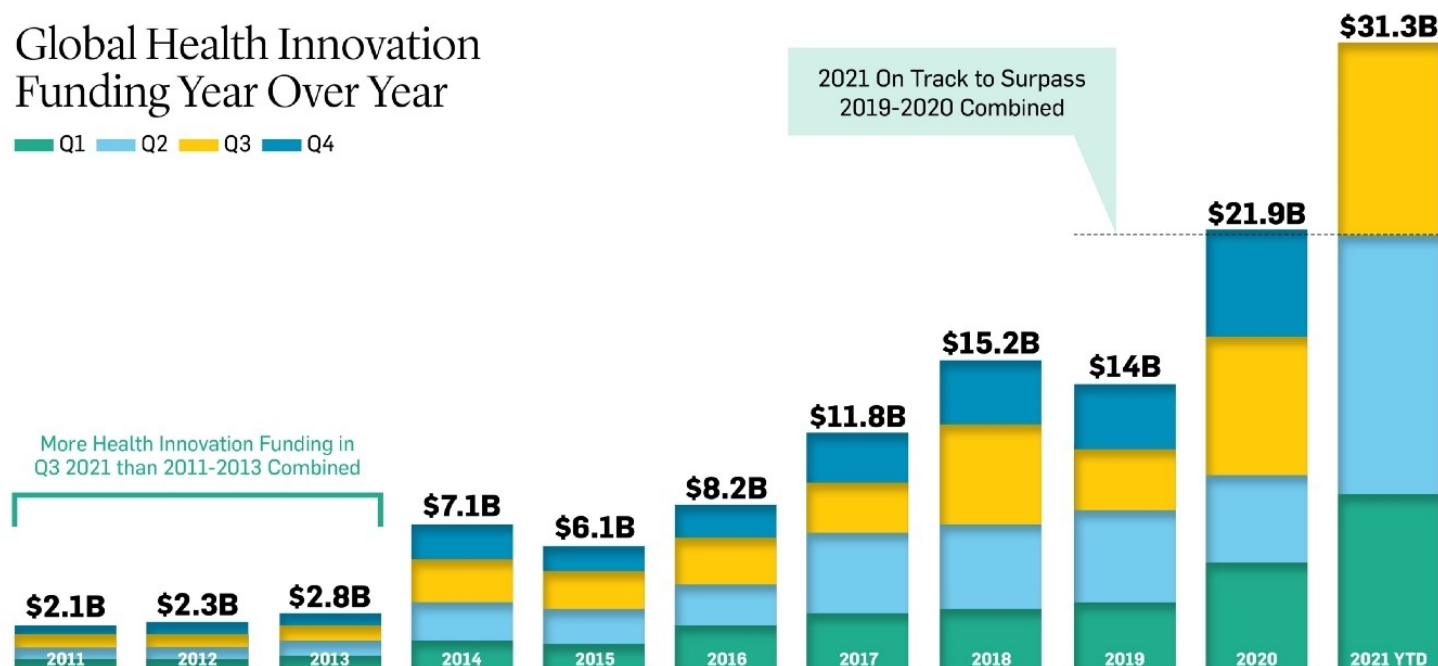
- Predicting long-term survival following repair is essential to clinical decision making when offering abdominal aortic aneurysm (AAA) treatment.
- Articles reporting risk factors influencing long-term survival (≥ 1 year) following OAR and EVAR
- 49/51 studies were observational, follow up time and patients lost to follow up were not reported
- How can this be used to formulate meaningful guidelines?
- ,

Investment in & pace of health technology since 2011

StartUp Health Insights | 2021 Q3 REPORT

Global Health Innovation Funding Year Over Year

Q1 Q2 Q3 Q4



Source: StartUp Health Insights | startupehealth.com/insights. Note: Report based on publicly available data through 9/30/21 on seed (incl. accelerator), venture, corporate venture, and private equity funding only. Companies tracked in StartUp Health Insights may fall under multiple moonshots and therefore will be represented throughout the report.

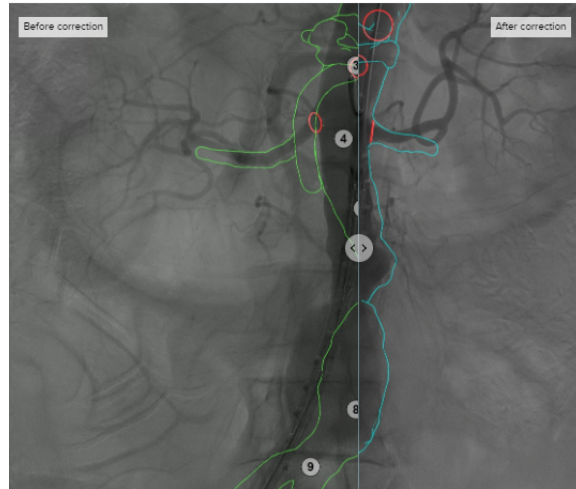
Surgical technology moves faster & faster

- New devices only need 1-year IDE follow up for licensing
- Sophisticated campaigns to get new devices into the marketplace and on hospital shelves rapidly



The pace of surgical technology

- ARIA trial for AI assisted positioning of endovascular grafts (Cydar)



- Delayed because new product for AI assisted selection of endovascular graft

The pace of research & research priorities

- 1980s Confocal microscopy study of single cells
- 2016 Single cell genomics comes of age
- 2018 Wellcome sponsor 1st annual single cell conference including imaging aspects
- 2019 Single cell proteomics comes of age
- 2021 Single cell biology enters the multi 'omics age

Ideal for vascular research? Does this feature in guidelines?

Outdated information

- The Nellix (endovascular aneurysm sealing technology) saga

Guidelines & the Nellix saga

Editor's Choice — European Society for Vascular Surgery (ESVS) 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms

- “Currently, EVAS should only be used within studies approved by research ethics committees until adequately evaluated.”

New guidelines due in 2024

NICE National Institute for
Health and Care Excellence

March 2019: We have withdrawn the guidance because the CE mark for the Nellix Endovascular Aneurysm Sealing (EVAS) System has been withdrawn. Endologix is recalling unused stock. The MHRA recommends [enhanced patient surveillance](#) (see MDA/2019/002) because of a high risk of the graft failing beyond 2 years after implantation.

Then gentlemen it is the consensus of this meeting that we do nothing, say nothing and hope it all blows over before our next meeting



Guidelines are good for journal impact factor

- Guidelines usually are heavily cited in research literature
- Schedule of guideline renewal is used as a tactic to maintain or accelerate journal impact factor
- Every 5 years for ESVS

Update tagging as a solution for published guidelines

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Via pop up
for text
history

Clinical guidelines need to be living documents continuously updated & available on the internet

- The technology to do this exists
- The management process does not & needs to be reformed
- To serve our patients we need to develop continuous updating, with complete renewal triggered by number of updates added
- Suggest guideline renewal is needed after 5 updates have been added

In the future
clinical guidelines
risk being ignored
unless we move
to continuous
updating



**Guidelines say that we need 5 nurses on the ward,
so this is Alice, Brenda, Chris & Daphne**