CONSIDERATIONS FOR A EUROPEAN HARMONIZED EXEMPTION CONCEPT OF SINGLE COMMERCIAL HELICOPTER PILOTS AGED 60-65 YEARS

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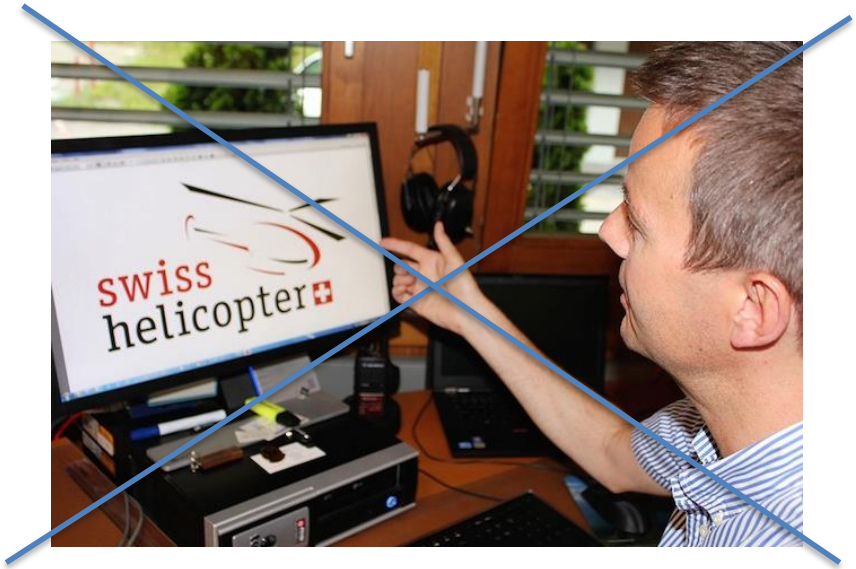
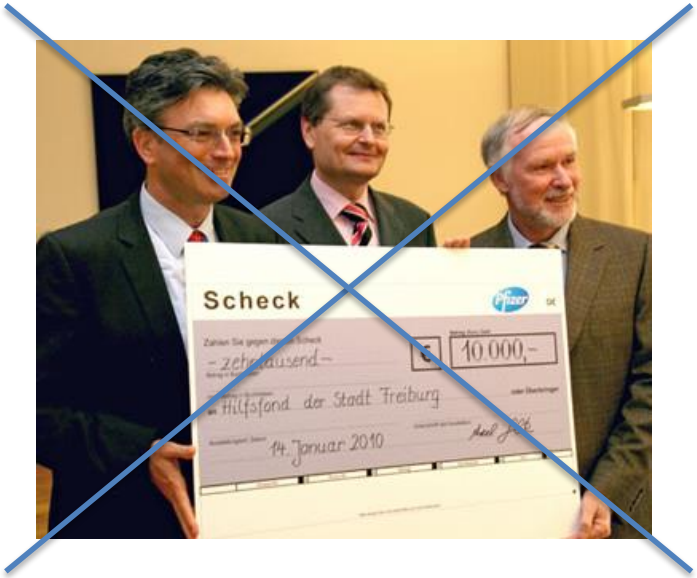
- Stefan Drechsel — *Cardiological Expert of FOCA, Division of Cardiology, Hospital Davos, Switzerland*
- Severin Muff — *Former Chief Medical Officer, Federal Office of Civil Aviation (FOCA), Switzerland*

SPITAL DAVOS

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra



Disclosures: No conflicts of interest



EASA
European Aviation Safety Agency

Should Class 1 pilots be allowed to fly single pilot CAT operations up to the age of 65?

MEG meeting - 18 April 2016

Your safety is our mission.

An Agency of the European Union

CONSIDERATIONS FOR A EUROPEAN HARMONIZED EXEMPTION CONCEPT OF SINGLE COMMERCIAL HELICOPTER PILOTS AGED 60-65 YEARS

- Single pilot commercial air transport operations by pilots aged > 60 years are prohibited by EASA in line with ICAO.
- The age 60-rule has been discussed in an international, interdisciplinary workshop in Vienna, 16./17.03.2017.

austro CONTROL

AGE 60 - RULE WORKSHOP

16.-17. March 2017

Hotel NH Danube City, Wagramer Strasse 21, 1220 Vienna / AUSTRIA

AGENDA 16/03/2017		
TIME	**AGENDA ITEM**	**SPEAKER**
09:30 – 10:00	**REGISTRATION**	
10:00 – 10:10	WELCOME PRESENTATION OF AGENDA	J. EIDHER & T. PINK CAA AUT
10:10 – 10:20	WELCOME – HISTORY AGE 60 RULE – MAB DISCUSSIONS OVERVIEW	F. GRASER CAA AUT
10:20 – 10:30	WELCOME AGE 60 RULE – EU COMMISSION's PERSPECTIVE	J. WOELDGEN EU COMMISSION
10:30 – 10:55	AGE 60 RULE – ICAO's POINT OF VIEW	A. JORDAAN

AGE-60-Rule Workshop (16th-17th March 2017) Vienna, Austria

SUMMARY / FINAL NOTE

…

The reason to dedicate this topic a separate event was a decision in the MAB committee (Member States' Advisory Body) of the European Aviation Safety Agency (EASA) as some Member States have already been granted exemptions under Article 14.4 of Regulation (EC) No 216/2008 for commercial single pilot operations for pilots over 60 in HEMS operation.

…

…

Favored solutions:

The majority was of the opinion that a change of the current situation/rule change is inevitable. Furthermore there an immediate/intermediate solution, in order to have time to develop the amendment, would be necessary.

- No individual national Art. 14/4 exemptions in the future
- Change of rule (delete or change FCL.065, regulation in another Part)

Only the minority intended to continue with the current system of individual national Art. 14/4 exemptions.

…

Summary, main results & next steps?

The uniform tenor of the workshop was the demand for a harmonized solution in Europe (in coordination with ICAO) and a departure from different national individual exemptions. It was also clear for all stakeholder groups that a change in the provisions of the EU Regulation

Aging

- Which functions of the human body decline with increasing age?
- Which diseases are related with an increased sudden incapacitation in the age > 60 years?

Answers

- Many functions decline with increasing age.
- The cardiovascular diseases are of significance for the issue of sudden incapacitation in the age > 60 years, this is a fact!
- Do other organ functions have a significant higher risk in this age group?

European Heart Journal (2004) **25**, 1197–1207

Review

Atherothrombosis: A widespread disease with unpredictable and life-threatening consequences☆

Juan F. Viles-Gonzalez, Valentin Fuster, Juan J. Badimon*

Cardiovascular Biology Research Laboratory, Zena and Michael A Wiener Cardiovascular Institute, Mount Sinai School of Medicine, New York, NY 10029, USA

Received 17 December 2003; revised 5 February 2004; accepted 4 March 2004
Available online 27 April 2004

Atherothrombosis, characterised by atherosclerotic lesion disruption with superimposed thrombus formation, is the major cause of acute coronary syndromes (ACS) and cardiovascular death. It is the leading cause of mortality in the industrialised world. Atherosclerosis is a diffuse process that starts early in childhood and progresses asymptomatically through adult life. Later in life, it is clinically manifested as coronary artery disease, stroke, transient ischaemic attack, and peripheral arterial disease.

The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

Edward W. Campion, M.D., *Editor*

Acute Myocardial Infarction

Jeffrey L. Anderson, M.D., and David A. Morrow, M.D.

N Engl J Med 2017;376:2053-64.
DOI: 10.1056/NEJMra1606915

...

The epidemiologic characteristics of acute myocardial infarction have changed dramatically over the past three to four decades ...

...

Globally, ischemic heart disease has become the leading contributor to the burden of disease as assessed on the basis of disability-adjusted life-years.[3]

...

Neue Zürcher Zeitung Donnerstag, 18. Mai 2017

Senioren am Steuer sind nicht häufiger für Unfälle verantwortlich als jüngere Verkehrsteilnehmer. GAETAN BALLY / KEYSTONE

Ärztliche Kontrollen für Autofahrer erst ab 75

Bundesrat will verkehrsmedizinische Untersuchungen hinausschieben

Statt wie bisher mit 70 Jahren sollen autofahrende Senioren erst fünf Jahre später zum Arzt. Den Anstoss dazu gegeben hat der 75-jährige SVP-Mann Maximilian Reimann.

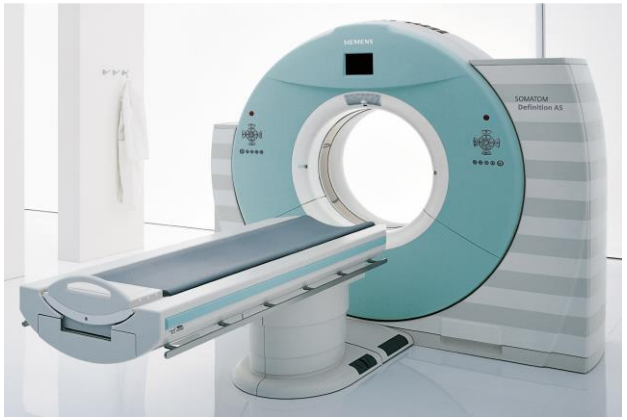
nahmen soll vermieden werden, dass sich der spätere Beginn der medizinischen Kontrolluntersuchung negativ auf die Verkehrssicherheit auswirkt. Die Informations- und Sensibilisierungsmassnahmen des Bundes zielen darauf ab, dass sich Senioren weiterhin ab 70 Jahren mit der Frage befassen, ob sie dem stellen. Dieses müsse aber ebenfalls in Eigenverantwortung vorgenommen werden – oder könnte in Zweifelsfällen ab 75 Jahren auch vom Strassenverkehrsamt angeordnet werden.

Auch Hausärzte sind dafür

Risk stratification

- The highest risk for sudden incapacitation in the age group 60-65 years form cardiovascular diseases.
- Therefore a cardiovascular risk evaluation has priority when checking pilots in this age group for fitness to fly.
- Single commercial pilots aged 60+ can be classified in different risk categories, as we are used to do so with patients.

Risk stratification



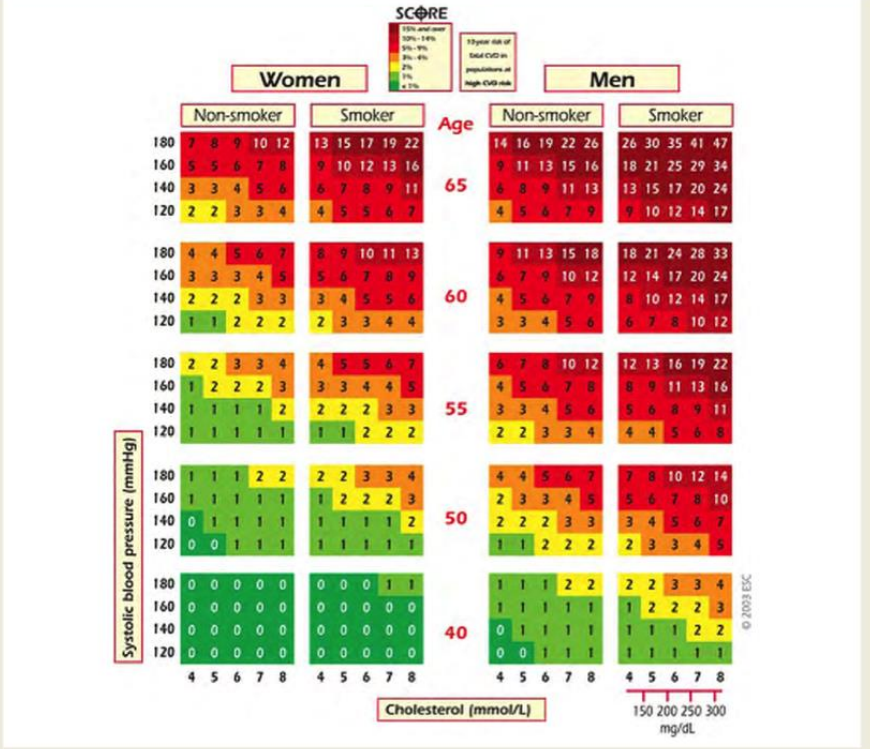


Figure 1 SCORE chart: 10 year risk of fatal cardiovascular disease (CVD) in populations at **high CVD risk** based on the following risk factors: age, gender, smoking, systolic blood pressure, and total cholesterol. To convert the risk of fatal CVD to risk of total (fatal + non-fatal) hard CVD, multiply by 3 in men and 4 in women, and slightly less in old people. Note: the SCORE chart is for use in people without overt CVD, diabetes, chronic kidney disease, or very high levels of individual risk factors because such people are already at high risk and need intensive risk factor advice.

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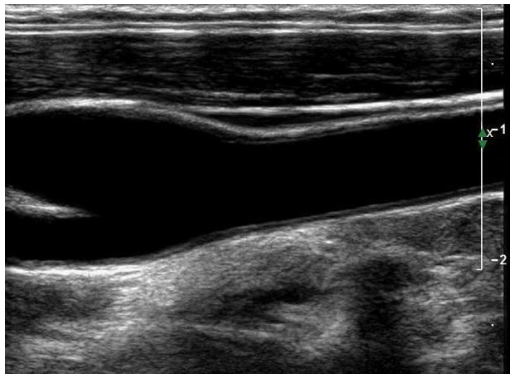
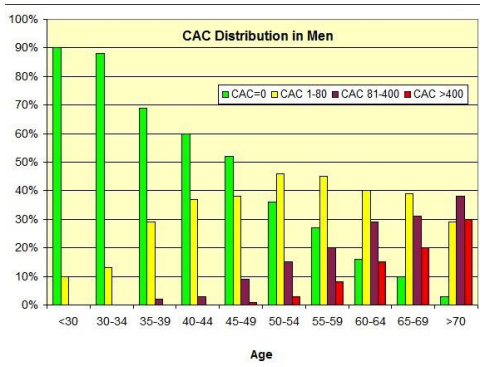
Today ...

... in addition to the cardiovascular score systems there are techniques, which allow a more precise estimation of the cardiovascular risk, like ...



- Carotid ultrasound imaging
- Coronary artery calcium testing
- Coronary artery CT-Scanning



Literature Coronary artery CT Scanning

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Coronary Calcium as a Predictor of Coronary Events in Four Racial or Ethnic Groups

Robert Detrano, M.D., Ph.D., Alan D. Guerci, M.D., J. Jeffrey Carr, M.D., M.S.C.E., Diane E. Bild, M.D., M.P.H., Gregory Burke, M.D., Ph.D., Aaron R. Folsom, M.D., Kiang Liu, Ph.D., Steven Shea, M.D., Moyses Szklo, M.D., Dr.P.H., David A. Bluemke, M.D., Ph.D., Daniel H. O'Leary, M.D., Russell Tracy, Ph.D., Karol Watson, M.D., Ph.D., Nathan D. Wong, Ph.D., and Richard A. Kronmal, Ph.D.

ABSTRACT

N Engl J Med 2008;358:1336-45

European Heart Journal (2009) **30**, 2622–2629
doi:10.1093/eurheartj/ehp272

CLINICAL RESEARCH
Imaging

Incremental prognostic value of multi-slice computed tomography coronary angiography over coronary artery calcium scoring in patients with suspected coronary artery disease

Jacob M. van Werkhoven[1,2], Joanne D. Schuijf[1], Oliver Gaemperli[3,4], J. Wouter Jukema[1,2], Lucia J. Kroft[5], Eric Boersma[6], Aju Pazhenkottil[3,4], Ines Valenta[4], Gabija Pundziute[1], Albert de Roos[5], Ernst E. van der Wall[1,2], Philipp A. Kaufmann[4,7], and Jeroen J. Bax[1]*

[1]Department of Cardiology, Leiden University Medical Center, Albinusdreef 2, 2333 ZA Leiden, The Netherlands; [2]The Interuniversity Cardiology Institute of the Netherlands, Utrecht, The Netherlands; [3]Department of Cardiology, University Hospital Zurich, Zurich, Switzerland; [4]Department of Nuclear Medicine, University Hospital Zurich, Zurich, Switzerland; [5]Department of Radiology, Leiden University Medical Center, Leiden, The Netherlands; [6]Department of Cardiology, Erasmus Medical Center, Rotterdam, The Netherlands; and [7]Zurich Integrative Human Physiology, University of Zurich, Zurich, Switzerland

Received 26 November 2008; revised 25 May 2009; accepted 11 June 2009; online publish-ahead-of-print 29 June 2009

Eur Heart J 2009;30:2622-9

ORIGINAL INVESTIGATIONS

Use of Coronary Computed Tomographic Angiography to Guide Management of Patients With Coronary Disease

Michelle C. Williams, MD,[a] Amanda Hunter, MD,[a] Anoop S.V. Shah, MD,[a] Valentina Assi, PhD,[b] Stephanie Lewis, PhD,[b] Joel Smith, PhD,[c] Colin Berry, MD,[d] Nicholas A. Boon, MD,[a] Elizabeth Clark,[a] Marcus Flather, MD,[e] John Forbes, PhD,[f] Scott McLean, PhD,[g] Giles Roditi, MD,[d] Edwin J.R. van Beek, MD,[a] Adam D. Timmis, MD,[h] David E. Newby, MD,[a] on behalf of the SCOT-HEART Investigators

J Am Coll Cardiol 2016;67:1759-68

Journal of the American College of Cardiology
© 2010 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 56, No. 22, 2010
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2010.07.005

APPROPRIATE USE CRITERIA

ACCF/SCCT/ACR/AHA/ASE/ASNC/NASCI/SCAI/SCMR 2010 Appropriate Use Criteria for Cardiac Computed Tomography

A Report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, the Society of Cardiovascular Computed Tomography, the American College of Radiology, the American Heart Association, the American Society of Echocardiography, the American Society of Nuclear Cardiology, the North American Society for Cardiovascular Imaging, the Society for Cardiovascular Angiography and Interventions, and the Society for Cardiovascular Magnetic Resonance

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J Am Coll Cardiol 2010;56:1864-94

Int J Cardiovasc Imaging (2011) 27:413–420
DOI 10.1007/s10554-010-9652-x

REVIEW

Prognostic value of absence or presence of coronary artery disease determined by 64-slice computed tomography coronary angiography A systematic review and meta-analysis

Jawdat Abdulla · Camilla Asferg · Klaus Fuglsang Kofoed

Received: 15 April 2010 / Accepted: 29 May 2010 / Published online: 12 June 2010

Int J Cardiovasc Imaging 2011;27:413-20

CONSIDERATIONS FOR A EUROPEAN HARMONIZED EXEMPTION CONCEPT OF SINGLE COMMERCIAL HELICOPTER PILOTS AGED 60-65 YEARS

Journal of the American College of Cardiology
© 2013 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 61, No. 12, 2013
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2012.12.035

Cardiovascular Risk

Progression of Coronary Calcium and Incident Coronary Heart Disease Events

MESA (Multi-Ethnic Study of Atherosclerosis)

Matthew J. Budoff, MD,* Rebekah Young, PHD,† Victor A. Lopez, MS,‡ Richard A. Kronmal, PHD,† Khurram Nasir, MD, MPH,*§‖¶# Roger S. Blumenthal, MD,§ Robert C. Detrano, MD, PHD,‡ Diane E. Bild, MD, MPH,** Alan D. Guerci, MD,†† Kiang Liu, PHD,‡‡ Steven Shea, MD,§§ Moyses Szklo, MD,‖‖ Wendy Post, MD,§ Joao Lima, MD,§ Alain Bertoni, MD, MPH,¶¶ Nathan D. Wong, PHD, MPH‡

Los Angeles and Irvine, California; Seattle, Washington; Baltimore and Bethesda, Maryland; Miami, Florida; Roslyn and New York, New York; Chicago, Illinois; Winston-Salem, North Carolina

Conclusions Progression of CAC is associated with an increased risk for future hard and total CHD events. (J Am Coll Cardiol 2013;61:1231–9) © 2013 by the American College of Cardiology Foundation

- We analyzed the medical parts of the different national concepts („mitigation measures”) which led to a derogation of the age limit by EASA and compared them with the Swiss concept.
- Seven EASA Member States (including Switzerland) have been granted an exemption by EASA.
- All concepts include operational and medical mitigation measures.
- There is a huge variety of the medical concepts, some with numerous medical requirements, partly lacking scientifc basis and causing high costs.

Country:	**State 1**
Organisation(s) affected:	**2 HEMS operators**
Number of HEMS Pilots affected (currently):	**1**
Reasons/Justification for granting the exemption:	• State 1 already had an exemption from JAR-FCL for domestig CAT-flights • Regular age for retirement 65 • No higher risk (statistically proven) • Average duration of HEMS-mission only 26 minutes • Operation close to surface, emergency landing can be performed
Mitigating Measures:	
Administrative:	• Inform staff • Notify pilots names to CAA (6 months before a pilot reaches the age of 60) • Inform the pilots of all requirements and procedures
Licence:	• Remark: "Art. 14.4 age 60-exemption: approval for single HEMS operations with an adapted medical certificate (SSL)"
Medical:	
First examination (at the age of 60):	• Laboratory report • Extended ophtalmological examination by eye specialist • Neurological status examination by specialist • Extended psychological test incl. cognitive skills
Each examination:	• Laboratory report, Spirometry
Every year	• Laboratory report
Every two years:	• Extended ophtalmological examination by eye specialist • Extended ENT examination by ENT-specialist • Extended cardiovascular/internal examination by specialist • Neurological status evaluated by a specialist
Further examinations:	• Further examinations can be determined
Medical issued:	• By CAA, including limitations
Limitations on Medical:	• "SIC" and "SSL"
Operational:	• Limited operation time (fives days a week, max. of three consecutived days) • Limit of the duty time to 12 hours (within 24 hours) • Avoid or limit the operation in case of extraordinary physical situations • Risk profile (risk assessment) of pilot to be considered • Documented review on the quality of line operation performed by the pilot (every 6 months)
Reporting:	• Report to CAA (at least every 3 months) – Statistics and incidents occuring with pilots older than 60 • Management review on the exemption process – Report to CAA once in 6 months • Documentation in the operating manual • Audit plan (must include the exemption process)

Country:	**State 2**
Organisation(s) affected:	**17 HEMS operators**
Number of HEMS Pilots affected (currently):	**7**
Reasons/Justification for granting the exemption:	• Unforeseen urgent operational circumstances/ operational needs • Potential shortage of qualified pilots • Retirement age 64-65
Mitigating Measures:	
Administrative:	
Medical:	
First examination (at the age of 60):	• Comprehensive examination of the cardiovascular system (cardiovascular assessment) • Cardiovascular risk assessment – calculated risk must be below 10 percent
Medical issued:	
Limitations on Medical:	• Determined by the Medical Assessor of the CAA
Operational:	• Proficiency check (according to provisions, min. every 6 months)
Reporting:	• Results of Proficiency check to CAA • Audit inspection / Stringent oversight programme by the CAA (successful application of mitigating measures must be prooved)

Country:	**State 4**
Organisation(s) affected:	**6 HEMS operators**
Number of HEMS Pilots affected (currently):	**20**
Reasons/Justification for granting the exemption:	• Guarantee an acceptable coverage of available HEMS pilots in Germany
Mitigating Measures:	
Administrative:	
Medical:	
First examination (at the age of 60):	• Comprehensive examination of the cardiovascular system (cardiovascular assessment) • Cardiovascular risk – calculated risk must be below 10 percent • Laboratory report • Comprehensive eye examination by an ophtalmologist • Assessment of cognitive abilities (assessed by psychiatrist in cooperation with a clinical pychologist) • Neurological/psychiatric status by a specialist • Risk assessment
Every 1,5 year:	• Assessment of cognitive abilities (assessed by psychiatrist in cooperation with a clinical pychologist)
Every 2,5 years:	• Laboratory report • Comprehensive eye examination by an ophtalmologist • Neurological/psychiatric status by a specialist
Medical issued:	• By CAA
Limitations on Medical:	• No issuing of Medical with limitation "OML" and "OSL"
Operational:	• Proficiency check (according to provisions) • Line check every 6 months
Reporting:	• Notification to LBA of occurrences in flight operations involving a pilot aged 60 or older • Operational documentation of mitigating measures

Harmonisation of exemption

- Risk that there will be a compromise (political instead of scientific decision).
- Each demand for a specific additional medical examination (besides the routine aero-medical checking) must have a scientific justification.
- For additional medical examinations …
- ... decision and practicability criteria must be set up …
- ... as well its cost efficiency.

Specific additional medical examination for cardiovascular diseases

- It is evidence based medicine that the risk of cardiovascular events is increasing in the age 60+.
- Definition of accepted risk: for example annual 1% risk for sudden incapacitation.
- A risk analysis is possible: Clinical examination by a cardiologist, exercise test, using score systems, if necessary in addition Coronary artery calcium testing or Coronary artery CT-Scanning.
- The costs for these examinations are acceptable.

Call for tenders' details

Title:	Research Study: age limitations for commercial air transport pilots.		
Contracting authority:	European Aviation Safety Agency (EASA)		
TED publication date:	14/06/2017		
Time limit for receipt of tenders:	21/08/2017	Status:	Closed

EASA.2017.HVP.12.

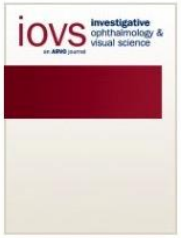
Research Study: age limitations for commercial air transport pilots.

The study aims at assessing the need for a regulatory pilot age limit in order to mitigate the risk to flight safety resulting from the potential increasing cases of sudden incapacitation for pilots aged over 60. Furthermore, considering the different types of CAT operations the study should determine whether the aforementioned risk of incapacitation can be mitigated by specific health screening or shortened screening intervals rather than by an arbitrary age limit. In the case of a positive answer, the study should also propose a battery of tests (medical, physiological, psychological etc.) to support aero-medical decision on the applicant's fitness on an individual basis.

Visual attention problems as a predictor of vehicle crashes in older drivers.

K Ball; C Owsley; M E Sloane; D L Roenker; J R Bruni

+ Author Affiliations



The NEW ENGLAND JOURNAL of MEDICINE

CLINICAL PRACTICE

Mild Cognitive Impairment

Ronald C. Petersen, M.D., Ph.D.

This Journal feature begins with a case vignette highlighting a common clinical problem. Evidence supporting various strategies is then presented, followed by a review of formal guidelines, when they exist. The article ends with the author's clinical recommendations.

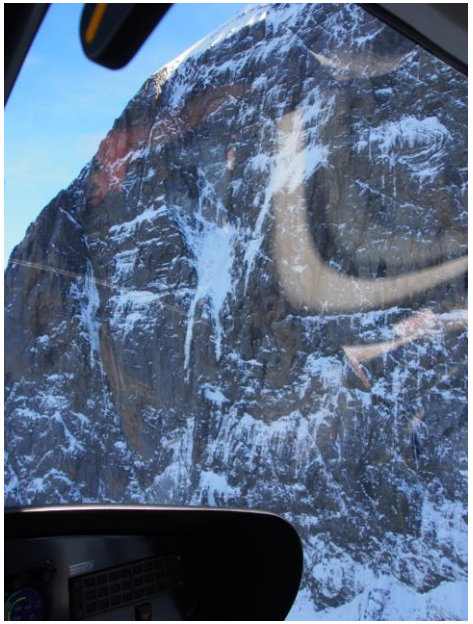
N Engl J Med 2011;364:2227-34.

Conclusions

- A harmonized solution for an exemption of the age 60-rule must be based on scientific level and include considerations about its decison criteria, its practicability and its cost efficiency.
- The Swiss model with its focus on the cardiovascular field would fulfill these criteria.

Conclusions - continued

- The result of the working group winning the EASA-tender „Research Study: Age limitations for commercial air transport pilots“ might define other important medical fields besides the cardiovascular one which have to be checked specifically when increasing the age limit.



Thank you for your attention!