AMABEL VIRTUAL SCIENTIFIC SESSION

MARCH 19, 2021

DO WE NEED HARMONIZATION OF THE AEROMEDICAL DECISIONS ?

Olivier MANEN, MD, Prof

G GUIU, J MONIN, C BRESCON, JF OLIVIEZ, S BISCONTE, E PERRIER

Percy Military Hospital, Paris, France

Aeromedical Center

Cardiology and Aviation Medicine Department

French Military Health Service Academy

DISCLOSURE INFORMATION

Olivier MANEN

AMABEL VIRTUAL SCIENTIFIC SESSION
MARCH 19, 2021

I have no financial relationships to disclose

The opinions or assertions expressed here in are the private views of the authors and are not to be considered as official or as reflecting the views of the French Military Health Service, SOFRAMAS or ESAM .

THE AIM OF AEROMEDICAL EXPERTISE

Final objective : decision to practice aviation duties

Binary question : fit or unfit ?

More interestingly : any limitations required ?

Main point of discussion (& possible disagreement) in France

Return to flying duties solo ?

Class 1 with OML : may be incompatible with some jobs

Class 2 with OSL : looks like no feasibility to fly…

AEROMEDICAL EXPERTISE IN PRACTICE

European regulations

Do not cover all situations (good for the AME/AeMC !)

Do not impose a unique decision for each medical issue (same !)

Is the starting point of the discussion

Atrial Fibrillation

AMC1 MED.B.010 Cardiovascular system

(B) For revalidation, applicants may be assessed as fit if cardiological evaluation is satisfactory and the stroke risk is sufficiently low. A fit assessment with an OML may be considered after a period of stable anticoagulation as prophylaxis, after review by the medical assessor of the licensing authority.

AMC and GM (28 January 2019)

AEROMEDICAL EXPERTISE IN PRACTICE

European regulations

Do not cover all situations (good for the AME/AeMC !)

Do not impose a unique decision for each medical issue (same !)

Is the starting point of the discussion

Primary Spontaneous Pneumothorax

AMC1 MED.B.015 Respiratory system

(f) Pneumothorax

(1) Applicants with a spontaneous pneumothorax should be assessed as unfit. A fit assessment may be considered if respiratory evaluation is satisfactory:

(i) 1 year following full recovery from a single spontaneous pneumothorax;

(ii) at revalidation, 6 weeks following full recovery from a single spontaneous pneumothorax, with an OML for at least a year after full recovery;

AMC and GM (28 January 2019)

THE EUROPEAN REGULATIONS

« Should & May » in the **AMC and GM (28 January 2019)**

Flexibility for the AME/AeMC

Why is some leeway important and justified ?

- A same pathology but many different patients
- Not a « simple » annual risk for a same pathology
- Multiple risk to think about and assess for systemic diseases
- Under-estimation of the risk on board with data of patients on the ground
- Consideration for the long-term risk (initial examination)
- Ethical considerations…

Can this 45-yo airline pilot fly in this situation ?

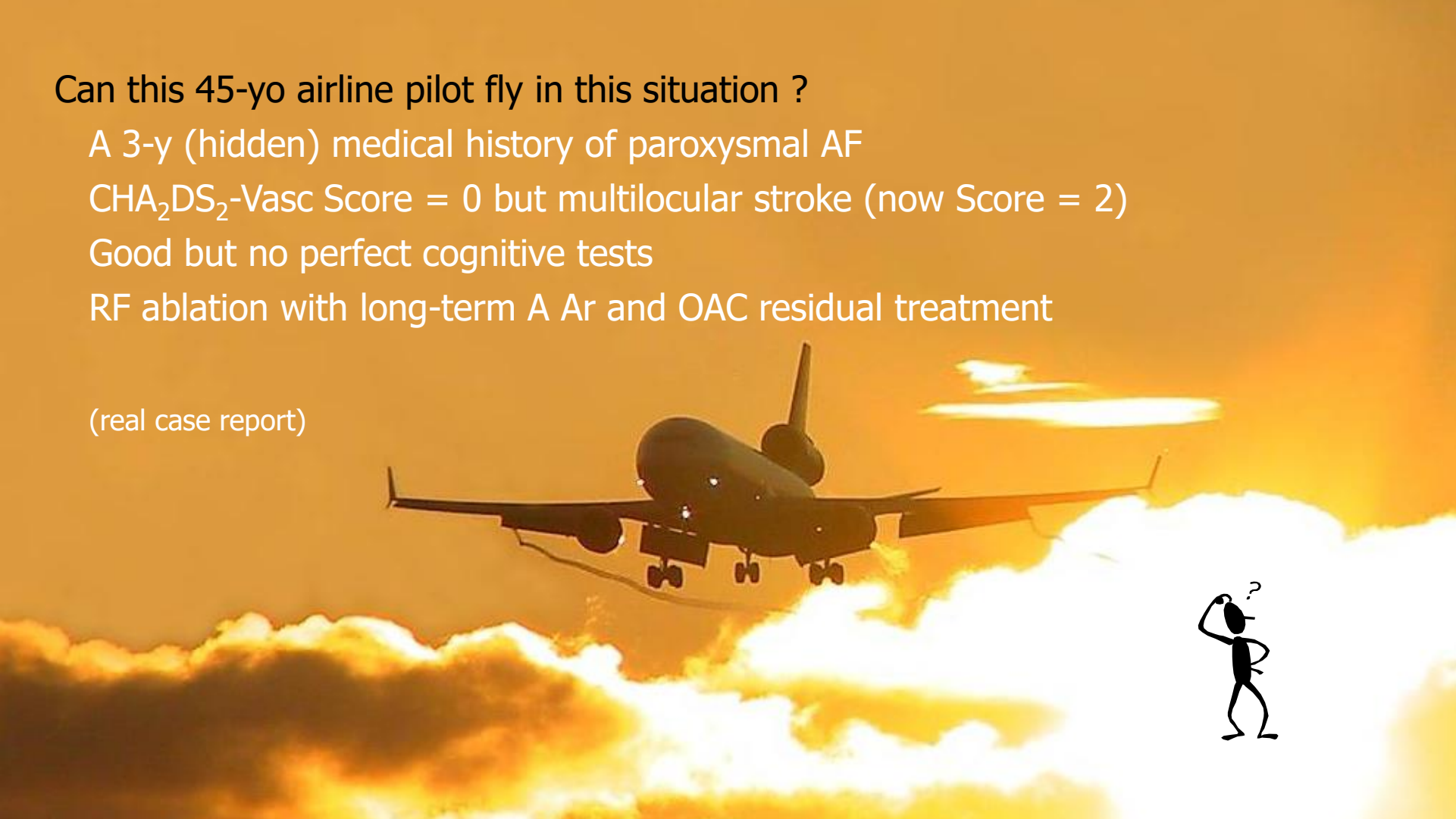
A 3-y (hidden) medical history of paroxysmal AF

CHA_2DS_2-Vasc Score = 0 but multilocular stroke (now Score = 2)

Good but no perfect cognitive tests

RF ablation with long-term A Ar and OAC residual treatment

(real case report)



Would you let these pilots fly solo…

… 6 weeks after a first PSP (Class 2 + aerobatics) ?

… 1 year after a first PSP (Class 1 but real fighter pilot) ?

Can this 48-yo airline pilot fly with this long medical history of coronary artery disease, with no ischaemia but… 8 stents ?

(real case report)

Box 1 Derivation of the 1% rule

- 1 year ≈ 10 000 hours
- A 1% cardiovascular mortality of 1%/annum is ≈ 1 in 10 000 hours x 0.01=1 event in 10^6 hours
- However, in dual crew operations the risk is only critical in take -off and landing phases (≈ 10% of total flight time)—an event rate of $1\times10^6\times10=1\times10^7$ hours
- Simulator data suggest that the second co-pilot successfully takes control 99 times out of 100, therefore the probability of a fatal accident at a critical point is $1\times10^7\times100=10^9$ hours

Level 1 Medical Event	Level 2 Medical Event	Level 3 Medical Event	Level 4 Medical Event
Minimal impact on mission	May result in a mission abort or compromised effectiveness	Likely to result in a flight safety hazard or compromise	Likely to result in a flight safety critical event
May result in a deleterious effect on the health of the individual aircrew but minimal effect on performance	Aircrew able to continue duties with minor to moderate performance compromise.	Major decrement in performance	Total acute incapacitation (may include sudden death)
Requires routine periodic medical follow-up	Requires medical attention	May require immediate medical attention	Requires immediate advanced medical care

PILOTS, COPILOTS				
Likely >2%/yr				
Possible 1-2%/yr				
Unlikely 0.5-1%/yr				
Highly unlikely <0.5%/yr				
NAVIGATORS, FLIGHT ENGINEER, FLIGHT CONTROLLERS				
Likely >2%/yr				
Possible 1-2%/yr				
Unlikely 0.5-1%/yr				
Highly unlikely <0.5%/yr				
FLIGHT ATTENDANTS LOADMASTERS				
Likely >2%/yr				
Possible 1-2%/yr				
Unlikely 0.5-1%/yr				
Highly unlikely <0.5%/yr				

AEROMEDICAL DECISIONS

Final product of a way of thinking which includes

- Medical data & statistics
- The real patient
- Flying specificities
- Experience of the pilot
- Trust & ethical elements

In an official context of regulations

Regulations - Part-MED (19 December 2018)

(e) Aero-medical assessment

(1) Applicants for a class 1 medical certificate with any of the medical conditions specified in point (d) shall be referred to the medical assessor of the licensing authority.

(2) Applicants for a class 2 medical certificate with any of the medical conditions specified in point (d) shall be assessed in consultation with the medical assessor of the licensing authority.

CAN THE AME/AeMC DECIDE « ALONE » ?

Examples for Class 1 pilots

Coronary artery disease
Atrial fibrillation
Left bundle branch block
WPW syndrom
Sleep apnea syndrom
Sarcoidosis
Cancer
Urinary calculi
Mood disorder
Epilepsy
Disturbance of vestibular function

Right bundle branch block
Isolated ectopic complexes
Low degree AV block
Diabetes (no treatment)
Crohn's disease (Class 2)
Pregnancy
Musculoskeletal disorder
Benign head trauma
Keratoconus (Class 2)
Eye surgery
Sinus dysfunction

MEDICAL ASSESSOR OF

THE LICENSING AUTHORITY

PRESENT ISSUE

Homogeneity of the fitness decisions is necessary to increase

- Legitimacy of medical thought
- Acceptability by the aircrew

Many opportunities for a pilot to fly in one country : the French example

- Class 1, 2 or LAPL EASA - French license
- Class 1, 2 or LAPL EASA - license of another country
- Class 1, 2 or 3 FAA - US license - US aircraft
- Others ?

CASE REPORT 01

UK private pilot, French home + house in Canada

UK license : would be Fit to fly (no limitation including duration)

Canadian license : would be Fit to fly (same)

Flying activities : aeroplane, seaplane, aerobatics (CAP10)

French (EASA) license : Unfit, expertise asked in Percy AeMC

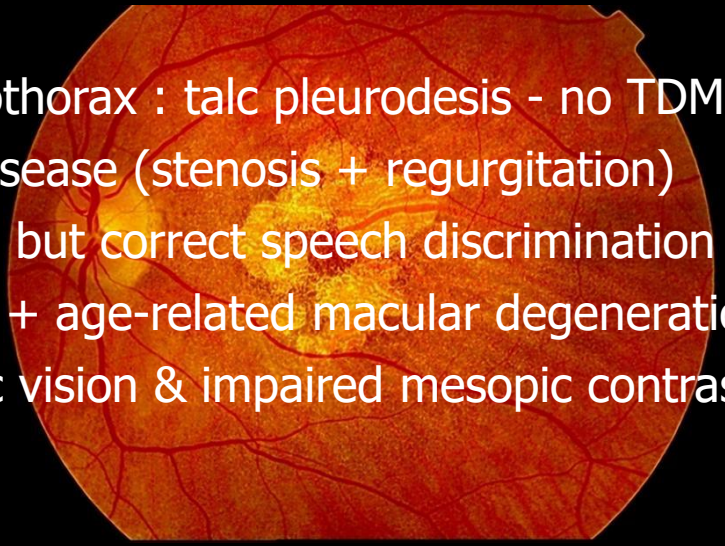
CASE REPORT 01

Past and present medical history

- Common surgeries (appendix, inguinal hernia)
- Prosthesis (both knees)
- Complete RBBB (negative stress echocardiography)

and

- Recent recurrent pneumothorax : talc pleurodesis - no TDM available
- Not severe aortic valve disease (stenosis + regurgitation)
- Important loss of hearing but correct speech discrimination test
- Bilateral cataract surgery + age-related macular degeneration :
  - Impaired stereoscopic vision & impaired mesopic contrast sensitivity



CASE REPORT 01

What is the medical problem ?

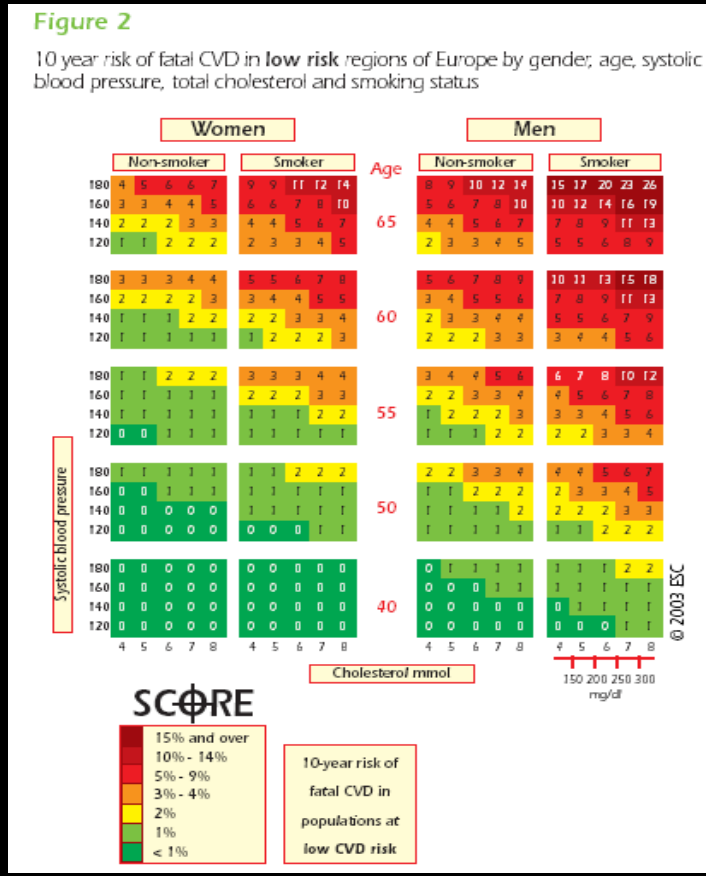
Last detail… 93 yo !

Flying activity since 80 yo : ~ 800 flying hours

French decision : Fit

Limitations : OSL, SSL No aerobatics,
VML, VCL, TML 6 mo, RXO

Interestingly : he understood our arguments,
but would have preferred to
have progressive limitations…



CASE REPORT 02

Very experienced private pilot

> 15,000 flying hours

Periodical examination in Percy AeMC for a Class 2 license

Past medical history (no medical record !)

Crash (aeroplane) 5y before

Badly burnt person (50% of BS) - head trauma

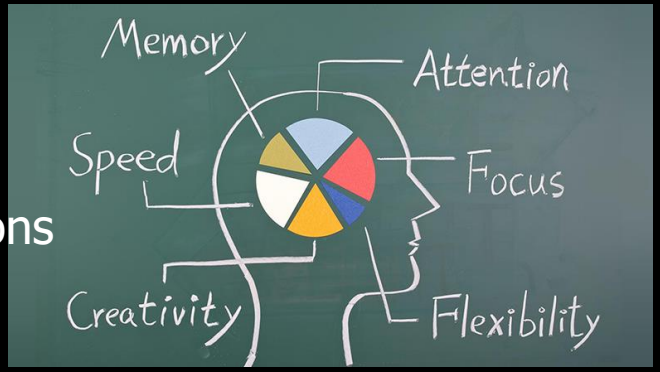
Many periods of sedation for clean dressing of wounds

Physiotherapy several years

No significant functional sequela

No psychological sequela

CASE REPORT 02



What is the medical problem ?

Neurocognitive assessment : significant sequelae

Impairment of planning, attention, executive functions

But > 70 yo…

Critics of these tests by the pilot

Has returned flying with a FI

Would be fit to fly solo (FAA) with his own US aeroplane

French proposal : Medical flight test (passed)

then Fit OSL

CASE REPORT 02

Epilogue

Next examination

New medical event : pacemaker

Not spontanously confessed…

However required 2 mo before the medical flight test !

« *very common, said the cardiologist* »

« *no problem, said someone of the FAA* »

dgac

Final French decision : Fit OSL

A few words of a friend flying with him…

« However, for LAPL medical certificate, if satisfactory « cardiological assessment », a standard AME may declare you fit to fly without any concertation with the licensing authority… You only have to change your PPL to LAPL (definitly) and so you may fly on any aircrafts < 2 t with 4 seats maximum in Europe only »

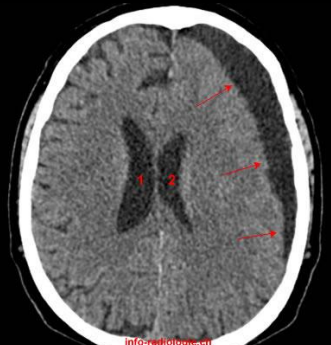
CASE REPORT 03

Very experienced professional helicopter pilot

- 65 yo, > 12,000 flying hours
- The only pilot of his own helicopter society

Past medical history

- Car crash (30 yo) with facial trauma
- Helico crash (45 yo) with spine trauma (Fit to fly)
- Bike crash with banal fractures but severe head trauma
  - Subdural hematoma and cerebral (temporal) hemorrhage
  - Regular TDM : good evolution



CASE REPORT 03

What is the medical problem ?

« *I feel better so that I can fly* »…

No visible sequela : head trauma confessed after 6 mo (2nd examination !)

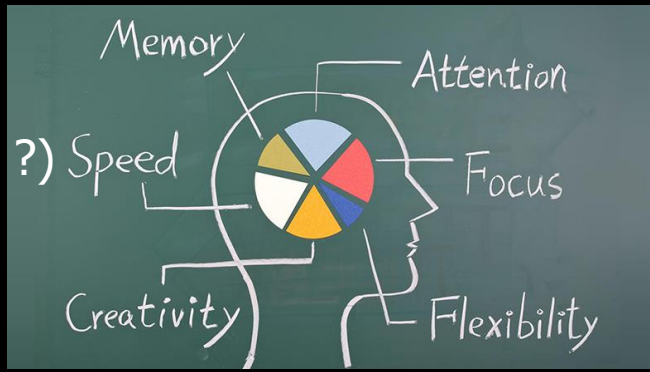
No clinical sequela but on cerebral MRI

Normal EEG including after sleep deprivation

Abnormal neurocognitive tests (permanent sequelae ?)

Memory + attention + executive functions +

Way of thinking + data integration…



dgac

Initial French decision : Unfit, new examination in 1 y

CASE REPORT 03

Epilogue

Examination at 1 y : no change in the neurocognitive assessment

but *« I am training for US PPL »* !

dgac Final French decision : Unfit

New examination asked by the pilot 3 y later

Would have FAA medical certificate…

Would fly in France with US aircrafts !

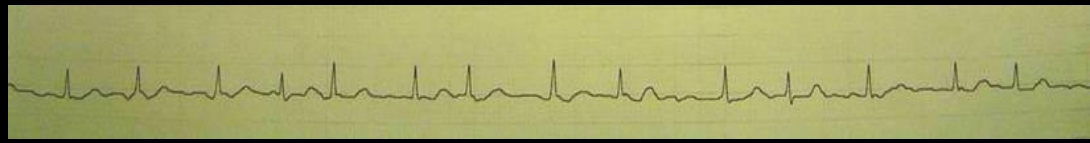
Psychological assessment : pathological motivation, mood disorder, denial…

dgac Unfit

CASE REPORT 04

68-yo private pilot

~ 1,000 flying hours



Past medical history

Permanent idiopathic AF

CHA_2DS_2-Vasc Score = 1 (age) and so AC

1rst AME (France) : VKA then Unfit 6 mo

Not happy then 2nd AME (other European country)…

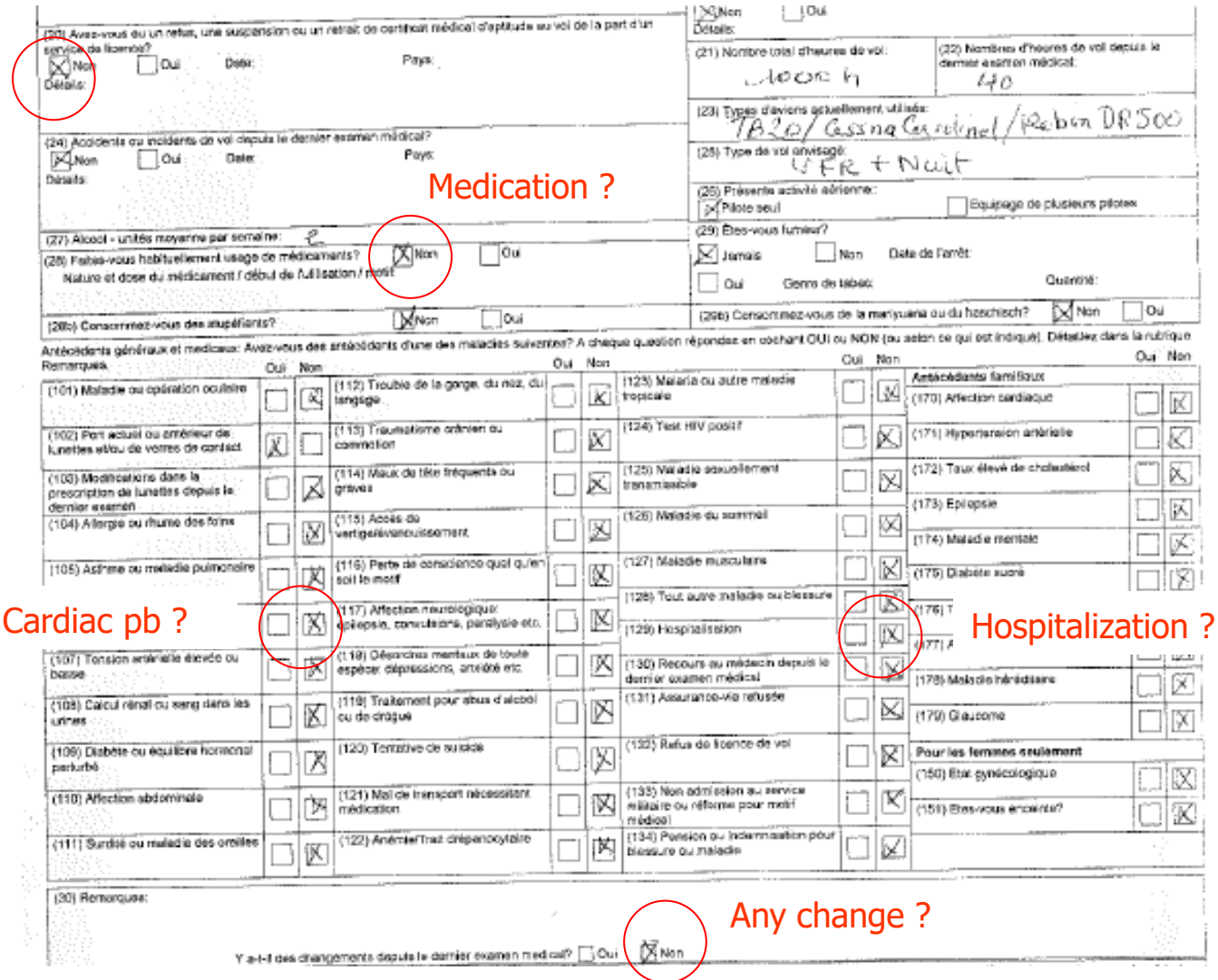
Previously unfit ?

Medication ?

Cardiac pb ?

Hospitalization ?

Any change ?



(22) Avez-vous eu un refus, une suspension ou un retrait de certificat médical d'aptitude au vol de la part d'un service de licence?
☒ Non ☐ Oui Date: Pays:
Détails:

(21) Nombre total d'heures de vol: 1000 h

(22) Nombres d'heures de vol depuis le dernier examen médical: 40

(23) Types d'aéronefs actuellement utilisés: TB20 / Cessna Cardinal / Robin DR500

(24) Accidents ou incidents de vol depuis le dernier examen médical?
☒ Non ☐ Oui Date: Pays:
Détails:

(25) Type de vol envisagé: VFR + Nuit

(26) Présente activité aérienne:
☒ Pilote seul ☐ Equipage de plusieurs pilotes

(27) Alcool - unités moyenne par semaine: 2

(28) Faites-vous habituellement usage de médicaments? ☒ Non ☐ Oui
Nature et dose du médicament / début de l'utilisation / motif:

(29) Êtes-vous fumeur?
☒ Jamais ☐ Non Date de l'arrêt:
☐ Oui Genre de tabac: Quantité:

(28b) Consommez-vous des stupéfiants? ☒ Non ☐ Oui

(29b) Consommez-vous de la marijuana ou du haschisch? ☒ Non ☐ Oui

Antécédents généraux et médicaux: Avez-vous des antécédents d'une des maladies suivantes? A chaque question répondez en cochant OUI ou NON (ou selon ce qui est indiqué). Détaillez dans la rubrique Remarques.

	Oui	Non
(101) Maladie ou opération oculaire	☐	☒
(102) Port actuel ou antérieur de lunettes et/ou de verres de contact	☒	☐
(103) Modifications dans la prescription de lunettes depuis le dernier examen	☐	☒
(104) Allergie ou rhume des foins	☐	☒
(105) Asthme ou maladie pulmonaire	☐	☒
(107) Tension artérielle élevée ou basse	☐	☒
(108) Calcul rénal ou sang dans les urines	☐	☒
(109) Diabète ou équilibre hormonal perturbé	☐	☒
(110) Affection abdominale	☐	☒
(111) Surdité ou maladie des oreilles	☐	☒
(112) Trouble de la gorge, du nez, du langage	☐	☒
(113) Traumatisme crânien ou commotion	☐	☒
(114) Maux de tête fréquents ou graves	☐	☒
(115) Accès de vertiges/étourdissement	☐	☒
(116) Perte de conscience quel qu'en soit le motif	☐	☒
(117) Affection neurologique: épilepsie, convulsions, paralysie etc.	☐	☒
(118) Désordres mentaux de toute espèce: dépressions, anxiété etc.	☐	☒
(119) Traitement pour abus d'alcool ou de drogue	☐	☒
(120) Tentative de suicide	☐	☒
(121) Mal de transport nécessitant médication	☐	☒
(122) Anémie/Trait drépanocytaire	☐	☒
(123) Malaria ou autre maladie tropicale	☐	☒
(124) Test HIV positif	☐	☒
(125) Maladie sexuellement transmissible	☐	☒
(126) Maladie du sommeil	☐	☒
(127) Maladie musculaire	☐	☒
(128) Tout autre maladie ou blessure	☐	☒
(129) Hospitalisation	☐	☒
(130) Recours au médecin depuis le dernier examen médical	☐	☒
(131) Assurance-vie refusée	☐	☒
(132) Refus de licence de vol	☐	☒
(133) Non admission au service militaire ou réforme pour motif médical	☐	☒
(134) Pension ou indemnisation pour blessure ou maladie	☐	☒

Antécédents familiaux	Oui	Non
(170) Affection cardiaque	☐	☒
(171) Hypertension artérielle	☐	☒
(172) Taux élevé de cholestérol	☐	☒
(173) Epilepsie	☐	☒
(174) Maladie mentale	☐	☒
(175) Diabète sucré	☐	☒
(176) T		
(177) A		
(178) Maladie héréditaire	☐	☒
(179) Glaucome	☐	☒
Pour les femmes seulement		
(150) Etat gynécologique	☐	☒
(151) Etes-vous enceinte?	☐	☒

(30) Remarques:

Y a-t-il des changements depuis le dernier examen médical? ☐ Oui ☒ Non

Interprétation (non confirmée)
026 Fibrillation auriculaire
131 Compatibilité avec un bloc de branche droite

Commentaires :

Poids : 0 kg

Axe P, QRS, T : -, 46°, 22°

(201) Catégorie d'examen	(202) Taille	(203) Poids	(204) Yeux couleur	(205) Cheveux couleur	(206) Tension artérielle (sassis) mm Hg		(207) Pouls au repos	
Initial					Systolique	Diastolique	Pulsations min	Rythme
Revalidation								X régulier
X Renouvellement 2								irrégulier
Examen spécial	182.0 cm	92.0 kg	bleu-vert	gris	132	82	76	

Regular rhythm !

Examen médical (chaque point doit être traité)

	Normal	Anormal		Normal	Anormal
(208) Tête, face, cou, cuir chevelu	X		(218) Abdomen, hernie, foie, rate	X	
(209) Bouche, gorge, dents	X		(219) Système gastro-intestinal	X	
(210) Nez, sinus	X		(220) Système génito-urinaire	X	
(211) Oreilles, tympans, mobilité tympanique	X		(221) Système endocrinien	X	
(212) Yeux - orbites et annexes, champs visuels	X		(222) Membres supérieurs et inférieurs, articulations	X	
(213) Yeux - pupilles et fond de l'œil	X		(223) Colonne vertébrale et appareil musculosquelettique	X	
(214) Yeux - mobilité oculaire, nystagmus	X		(224) Neurologie - réflexes etc.	X	
(215) Poumons, thorax, seins	X		(225) Psychiatrie	X	
(216) Cœur	X		(226) Peau, marque d'identification, syst. lymphatique	X	
(217) Système vasculaire	X		(227) Etat général systémique	X	

(228) **Notes:** Décrivez chaque constatation d'anomalies. Notez le numéro du point concerné avant chaque commentaire.

Acuité visuelle Birkhäuser

(229) de loin (à 5m/6m)			Lunettes	Lentilles de contact
Oeil droit non corr.	1.00	corrigée à		
Oeil gauche non corr.	1.00	corrigée à		
Vision binoc. non corr.	1.00	corrigée à		

(230) intermédiaire	non corrigée		corrigée	
N14 à 100 cm	Oui	Non	Oui	Non
Oeil droit	X		X	
Oeil gauche	X		X	
Vision binoculaire	X		X	

(231) de près	non corrigée		corrigée	
N5 à 30 - 50 cm	Oui	Non	Oui	Non
Oeil droit		X	X	
Oeil gauche		X	X	
Vision binoculaire		X	X	

(232) Lunettes (233) Lentilles de contact

(234) Fonction respiratoire — (237) Hémoglobine

FEV1/FVC	%	g/dl
X Normal	Anormal	Normal / Anormal

(235) Analyse d'urine

X Normal Anormal

Glucose	Protéines	Sang	Autres
NIL	NIL	NIL	NIL

Rapports annexés	Non effectué	Normal	Anormal
(238) ECG		X	
(239) Audiogramme	X		
(240) Ophtalmologie	X		
(241) ORL	X		
(242) Lipides sanguins	X		

Normal ECG !!

Medical class issued **2 / LAPL**

IX Expiry date of this certificate

class 1 (CPL/ATPL)	----
comm. single-pilot with pax *	----
class 2 (PPL)	17.04.2015
LAPL	17.04.2016

Fit !!!

* single-pilot commercial air transpot operation carrying passengers (EASA Part-MED. A. 045a)

X Date of issue / valid after **17.04.2014**

CASE REPORT 04

Epilogue

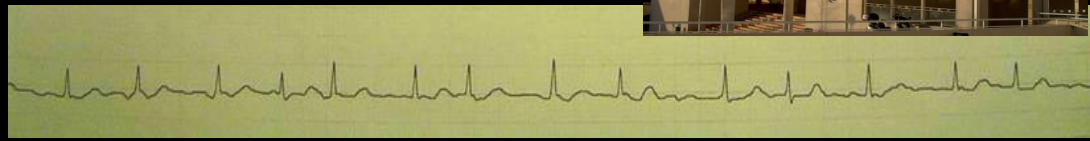
Conflict between two different/opposite decisions

French license…

Expertise asked by the French licensing authority in Percy AeMC

Permanent AF + VKA

Final French decision : Fit OSL



4 years later…

Has managed to be off treatment (73 yo) to be Fit without OSL (unsuccessfully)

Has presented impaired visual field during 3 w : anticoagulation again

(not reported during the next examination !)

My opinion : permanently Unfit

SYNTHESIS : WHAT'S GOING ON ?

No homogeneity in the decisions between the civil aviation aeromedical authorities ?

EASA, FAA, UKCAA, Transport Canada, others…

No homogeneity in the decisions within EASA countries ?

Attempt to explain

- Different access or use of medical data ?
- Different interpretation of regulations ?
- Unability to say « No » ?
- Wish to let everybody fly ?
- Defence of freedom ?
- Fight against discrimination ?

European Aviation Safety Agency

Notice of Proposed Amendment 2017-22

Updating Part-MED and related AMC and GM
RMT.0287(b) (MED.001)

ARA.MED.330 Special medical circumstances

« Aircrafts registered in the Member States involved in the medical certification protocol… »

SYNTHESIS : WHAT'S GOING ON ?

No homogeneity in the decisions between Class 2 and LAPL pilots ?

LAPL not very much used in France (not yet !)

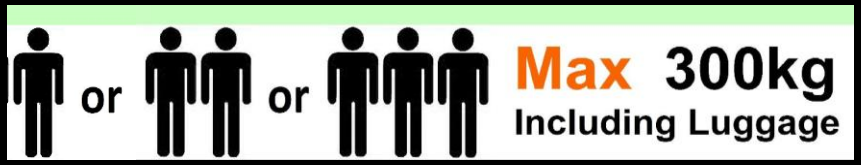
Medical distinction with Class 2 requirements created by EASA

IR : very poor (< 1 page)

AMC/GM : 13 pages but key formula is « satisfactory evaluation »

3 passengers maximum

« The price of the fourth life »



EPILEPSY

AMC2 MED.B.065 Neurology

(a) Epilepsy

Applicants may be assessed as fit if:

(2) there has been no recurrence after at least 10 years off treatment;

Class 2

AMC12 MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates

NEUROLOGY

(a) Epilepsy and seizures

(2) Applicants may be assessed as fit if:

(ii) there has been no recurrence after at least 5 years off treatment;

LAPL

AMC12 MED.C.025 Content of aero-medical assessments

NEUROLOGY

(b) Cabin crew members with an established history or clinical diagnosis of:

(1) epilepsy without recurrence after 5 years of age and without treatment for more than 10 years;

should undergo further evaluation before a fit assessment may be considered.

Cabin crew

European Aviation Safety Agency

DIABETES REQUIRING INSULIN

Medically justifiable ?

YES

NO

120 min before take-off

30 min before take-off

No take-off if Gly > 15 mmol/l

Every 60 min

30 min before landing

10-15 g sugar if Gly < 4.5 mmol/l + re-test within 30 min

LAPL

Pilot with 3 frequent passengers and 100 flying hours / year

FIT

Class 2

Pilot with no passenger at all and 20 flying hours / year

UNFIT

SYNTHESIS : WHAT'S GOING ON ?

No homogeneity in the decisions between GP or specialists and AME ?

- Care medicine : to treat (remission, stabilization, recovery)
- Return to professional / physical / recreational / social / flying activities
  - Not the first objective of the medical team
  - But easily recommended when everything is all right

Attempt to explain

- Psychological impact
- No specific training
- No knowledge of the 3 foundations in Aviation medicine

THE 3 FOUNDATIONS IN AVIATION MEDICINE

1. They aircrew can carry out all actions required by his function on board in normal and impaired conditions

« Easy » for AME, « may be considered » by GP

2. There is no significant risk of in-flight sudden or subtle incapacitation

« Difficult » for AME, « hardly not imagined » by GP

3. The flying activity must not make the health of the aircrew worse

Not a universal foundation

+Gz accelerations !

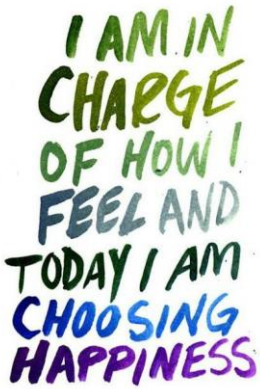
THE 3 FOUNDATIONS IN AVIATION MEDICINE

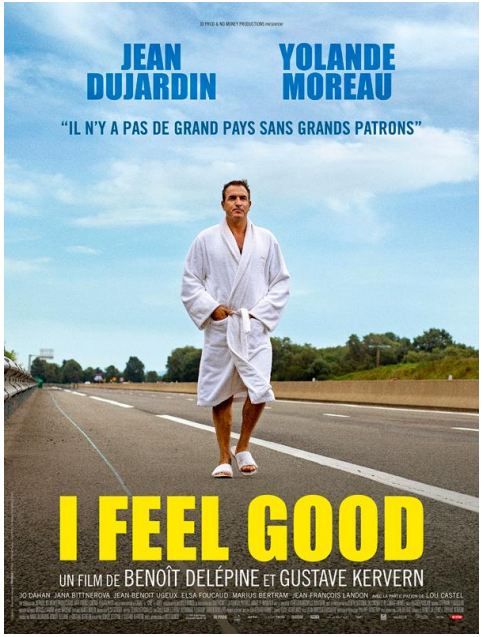
AME vs GP ? A study to be carried out by ESAM

SYNTHESIS : WHAT'S GOING ON ?

No homogeneity in the feeling of good health between pilots and AME ?

So obvious in France… and yet no culture for Unfit sanction





CONCLUSION

Do we need harmonization of the aeromedical decisions ?

Definitely yes ! (I personnally think)

We are not experts to push everyone in cockpits (same)

Dangerous side effects of heterogeneity between AME/AeMC/Authorities

No trust in AME

No understanding of the role & usefulness of AME

Direct impact

Bad atmosphere of aeromedical expertise

Crash ?

CONCLUSION

62-yo private pilot, little experience

CVRF : Family history + tobacco + obesity

Faintness with LOC

Scenario 1

The best one…

Phone call to the AME

Cardiological investigations

CAD diagnosis

Wait before flying

Long life with his wife

CONCLUSION

62-yo private pilot, little experience

CVRF : Family history + tobacco + obesity

Faintness with LOC

Scenario 2

The real one !

Phone call to nobody including the AME

Flight 1 mo later

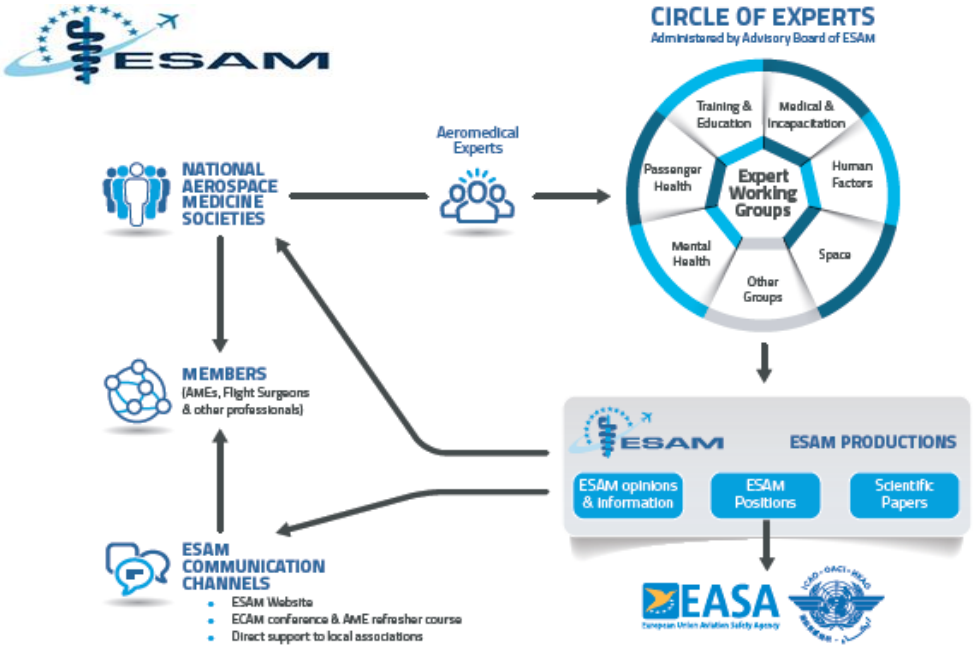
Crash

Death

Autopsy : acute MI

How to work together better ?

Some ideas…



Contact: olivier.manen@intradef.gouv.fr