

# CAA Update for AMEs

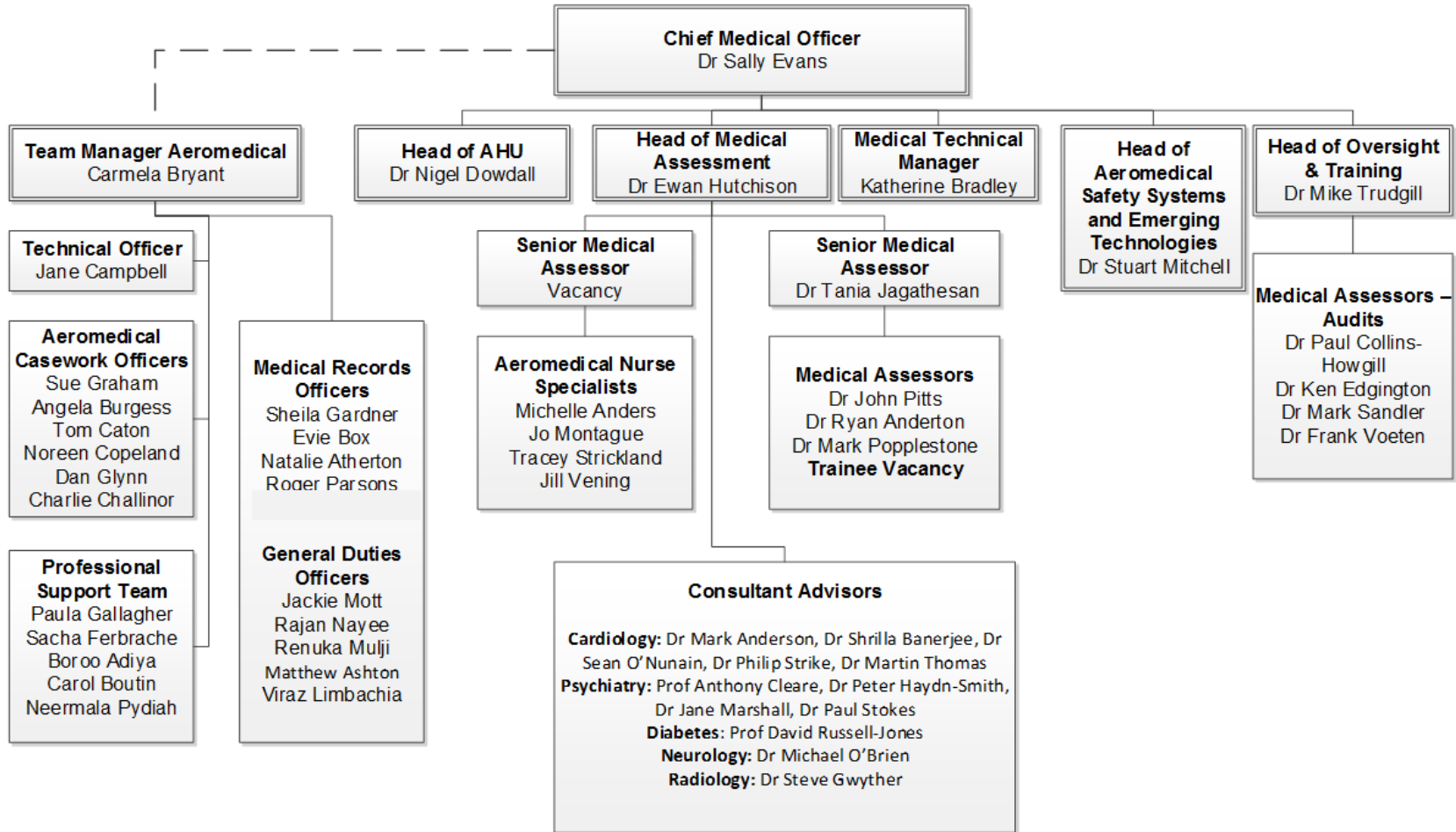


Dr Sally Evans  
Chief Medical Officer  
UK CAA

17 March 2018, AAME

# Medical Department Structure

CAA Medical Department  
February 2018



# Medical IT System Replacement Project



- Project on track for 'Go Live' by end March 2019 latest
- 'Off-the-shelf' solution requiring configuration but minimal bespoke development
- Web-based solution, Cloud based data storage, access via CAA portal
- Single applicant record – AMEs will see the same system as users at the CAA
- GDPR compliant
- Penultimate stage of supplier selection – 3 potential suppliers currently being evaluated
- Decision on successful bid due mid-April
- Subsequent work to include data migration, configuration, UAT and training

# AME Requests – Records Management

- Automated response for documents to be scanned set up
- Transfer of large files: new method of transmission of information using Huddle being introduced.
- General Data Protection Regulation (GDPR) information for AMEs
- Naming protocols for documents – await new IT system
- Removal of limitations by AMEs – await new IT system

# Regulatory Activities

- EASA Standardisation
  - Audit Findings
  
- EASA Rulemaking
  - Update of Part MED
  - Drugs and alcohol testing
  - Peer support programmes
  - EAMR
  - Age research
  
- UK Exemption for Self Declaration

# EASA Standardisation

- UK CAA Participation in EASA Audits of other States
  - 2017
    - TJ Switzerland
    - SE Denmark (cancelled)
  - 2018
    - EH Netherlands
    - SM Greece
  
- Full (Aircrew and ATCO) EASA MEST Inspection Audit July 2017

# UK MEST Audit Findings & Actions (1)

Code	Title	Description	Proposed Action	Start Date	Due Date
EASA – 20505/1	Non-submission of reports/certificated.	<p>The compliance monitoring process established by the competent authority does not ensure systematic, regular and complete monitoring of the compliance of its management system with the applicable requirements in the medical domain. As a result, it failed to detect following non-compliances:</p> <p>After completion of aero-medical examinations AeMCs, AMEs and GMPs do not regularly submit full reports and copies of the issued medical certificates.</p>	<p>Root Cause The UK CAA electronic medical records system was developed to include a free text box where AMEs could include relevant information rather than ticking multiple boxes. All AMEs are required to keep copies of the application forms. All medical certificates are printed from the electronic system with an audit trail.</p> <p>Proposed Action All AMEs shall submit all required documentation to the CAA. This will be communicated by e-mail to all AMEs. Additional resource will be required to support the intake of the additional data and the recruitment process will take <u>a period of time</u>.</p>	14-Aug-2017	31-Mar-2018
EASA – 20505/2	Non-compliant codes of limitations	<p>The compliance monitoring process established by the competent authority does not ensure systematic, regular and complete monitoring of the compliance of its management system with the applicable requirements in the medical domain. As a result, it failed to detect following non-compliances:</p> <p>2. Non-compliant codes of limitations established by the competent authority are imposed on the holders of the medical certificates.</p> <p>Note: Identical finding #16614 has been raised during the standardisation inspection MED.UK.07.2013 and closed in November 2013 based on the UK-CAA statement that this practice would be discontinued.</p>	<p>Root Cause For ease of reference, codes had been created for all SSL limitations. Amending the template has proved problematic.</p> <p>Proposed Action An IT solution has now been found and the additional codes will not be printed on the medical certificates once the solution has been implemented.</p>	14-Aug-2017	30-Nov-17

# UK MEST Audit Findings & Actions (2)

Code	Title	Description	Proposed Action	Start Date	Due Date
EASA – 20505/3	Lack of detailed procedures	The compliance monitoring process established by the competent authority does not ensure systematic, regular and complete monitoring of the compliance of its management system with the applicable requirements in the medical domain. As a result, it failed to detect following non-compliances: Some procedures (e.g., AME certification, secondary review, referral) are presented as a flowchart without a description of the process. <u>As a consequence</u> , they do not serve as the basic working documents for the related tasks.	Root Cause Historically, procedures have been developed within the CAA Medical Department as flowcharts.  Proposed Action A project has been initiated to rewrite all flowcharts with a written description of the process. A sample of the completed procedures will be submitted for evidence of the closure of the finding.	14-Aug- 2017	31-Mar- 2018
EASA – 20505/4	Lack of legal reference in procedures	The compliance monitoring process established by the competent authority does not ensure systematic, regular and complete monitoring of the compliance of its management system with the applicable requirements in the medical domain. As a result, it failed to detect following non-compliances: Some procedures and related documents concerning both ACW and ATCO medical domains (e.g., application for AeMC certification, AME certificate <u>format...</u> ) do not contain legal references to the Reg. (EU) 2015/340 where it is applicable.	Root Cause Historically the CAA Medical Department has not included legal references on all documentation.  Proposed Action A review of all applicable documentation will be carried out and amendments made as required. A sample of the completed documentation will be submitted for evidence of the closure of the finding.	14-Aug- 2017	30-April- 2018



# PART MED Changes – approx. Sep 2018



- PART MED
  - Drugs and alcohol testing at initial Class 1
  - Comprehensive mental health assessment
  - Mental Health Section will be amalgamation of Psychology and Psychiatry
  - Tidying up of AME responsibilities around non-disclosure
  - Suspension and Revocation of certificates
  - Thoracic aneurysms after surgery
  - CAD test
  
- Text has been requested
  
- EAMR has been included in the Part MED changes

# PART OPS Changes approx. 2019-2021



- PART OPS
  - Pilot support programme (National P-PAN)
  - Psychological 'assessment' pre-line training
  - Random drugs and alcohol testing
  - 2 year transition

# EAMR key points – Why?

## European Aero-Medical Repository

- Recommended by Germanwings Taskforce: National Authorities to collaborate and exchange information
- Designed to eliminate medical tourism; reduces reliance on pilot self-declaration
- Makes some key information available online
- Pilots can check their own information

# EAMR key points – What?

- Web based system (Class 1 pilots only?)
- Currently 14 fields to be populated
- A few minutes per person input
- Each information change will be notified direct to the pilot by email (helps data integrity)
- Responsibility for the creation of initial record, and subsequently data entry, maintenance and quality lies with each NAA and its AMEs.
- Training material will be provided; delivery is NAA responsibility
- Unclear what the rate of data refresh at outset will be, target is real time.
- GDPR compliant

# EAMR key points – When?

- Entry into force with update of PART MED (EASA expect full data capture to be complete in 12- 15 months)
- The initial record is created as each pilot is revalidated or recertificated (UK - 25,500 records 12 month cycle)
- 2 phases; no historic data in Phase 1; no assurances on historic data given for phase 2
- NAA engagement with the database likely to be audited (UK MEST Nov 2018)
- Interface with individual NAA IT systems being discussed but not planned until phase 2 (requirements not yet written so timescales unknown)

# EAMR – Risks and issues for CAA and AMEs

- Resource impact to set up systems
- Increased AME and CAA workload challenge
- Running two databases side by side (MARS, EAMR) presents a data integrity risk
- Diverse (European) AME community with vastly differing IT skills represents a real risk to compliance and data integrity
- Phase 2 feeds from NAA systems likely to cause significant problems
- Will need to be designed into oversight system and will require resource to monitor and oversee

# Future EASA Rulemaking

- NPA 2017-22 Update of Parts ARA.MED and ORA.MED
- RMT .0424 Regular update of Part MED
- RMT .0707 Merging Parts MED and ATCO MED
- EASA Age 60 Research Project

# GA Medical Self-declaration

- Proposal by GA industry / stakeholders to extend self-declaration for Pilots flying EASA aircraft after 8<sup>th</sup> April 2018
- <2000kg see AME for LAPL if taking medication for psychiatric illness
- 2000 – 5700 kg see AME for LAPL if have any of the specified conditions
- UK airspace only
- Exemption from 8 April 2018 announced to General Aviation Partnership 13 March. Due to be published in next few days. Commission will be notified and will consider response.



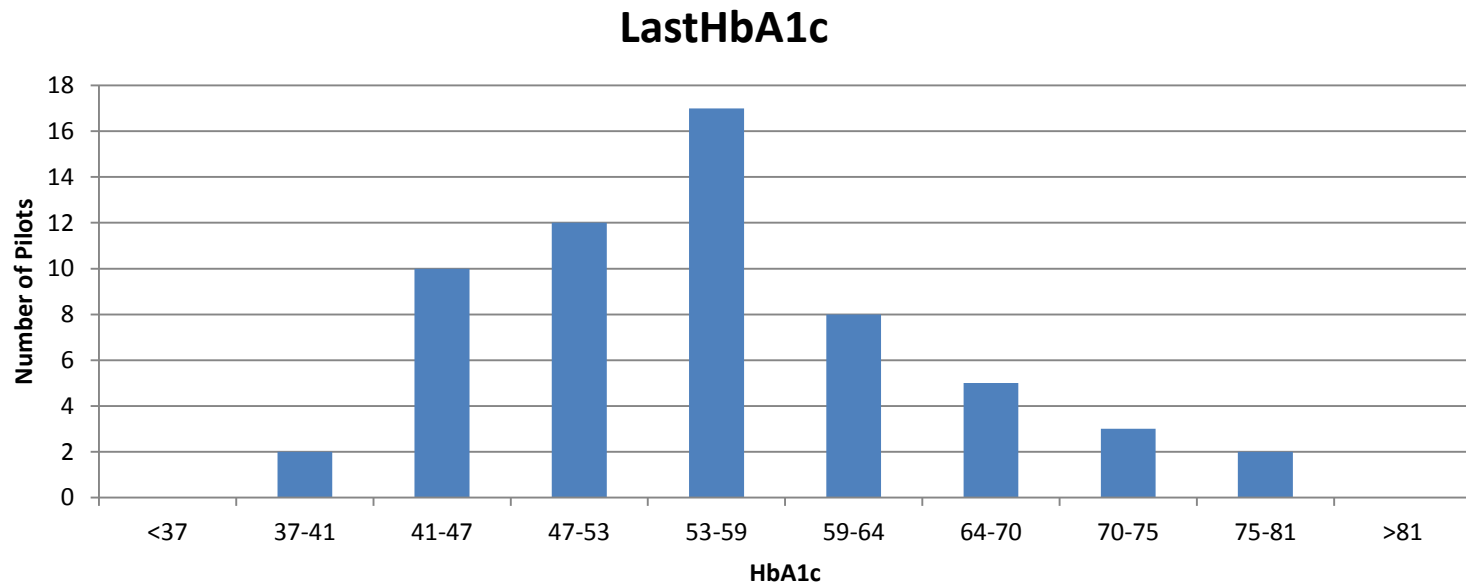
# Class 1 and 3 Casework

- Part MED and Part ATCO.MED have implementing rules that permit AMEs to make fit/unfit assessments and indicate which cases should be referred to the licensing authority.
- Adjustments to MARS/AME On Line
- Workshops in August/September 2017 for AMEs (92) and e-Learning Platform training course (37)
- AMEs now able to make fit/unfit assessments on specified Class 1 and 3 cases following periods of unfitness and record these on MARS

# Initial Class 1 OML and HIV

- **HIV**
- Recent case in media about initial applicant with HIV infection; current IRs/AMCs do not permit unrestricted certification with HIV.
- CAA working with HIV specialists to consider mitigations for unrestricted certification
  
- **Class 1/OML**
- Issue around **initial issue** of a Class 1 medical certificate with OML.
- IR currently states that OML can only be added to medical certificate of existing CPL/ATPL/MPL holder.
- CAA has submitted an Article 14(4) exemption to notify the EC of the issue of initial Class 1 medical certificates with OML whilst encouraging EASA to commission research to consider initial Class 1 with OML rule change.

# Insulin Treated Diabetes Mellitus



Male	58	Average Age	44	Avge HbA1c	55		Diabetes Type
Female	1	Minimum Age	18	Min HbA1c	37	Type 1	45
Total	59	Maximum Age	75	Max HbA1c	79	Type 2	14

# Guidance Material Project

- Various documents requiring revision, partially revised, awaiting publication on website.
  
- Recent activity:
  - Process written for producing and publishing guidance material
  - Collation of all material, stage of completion, authors etc
  - Central repository for developing material on CAA Sharepoint site

# Oversight

- 4 AeMCs, 165 Active AMEs (135 UK Class 1, 30 UK Class 2).
- 4 AMEs currently suspended (2.5%)
- Approaching end of first 3 year audit cycle
- 90 site audits in 2017 (on target to meet EASA requirement), 16 so far in 2018.
- Findings and observations at most audits (2-3 average) – continuous improvement is the aim

# Head of Aeromedical Safety Systems and Emerging Technologies



## Overall Purpose

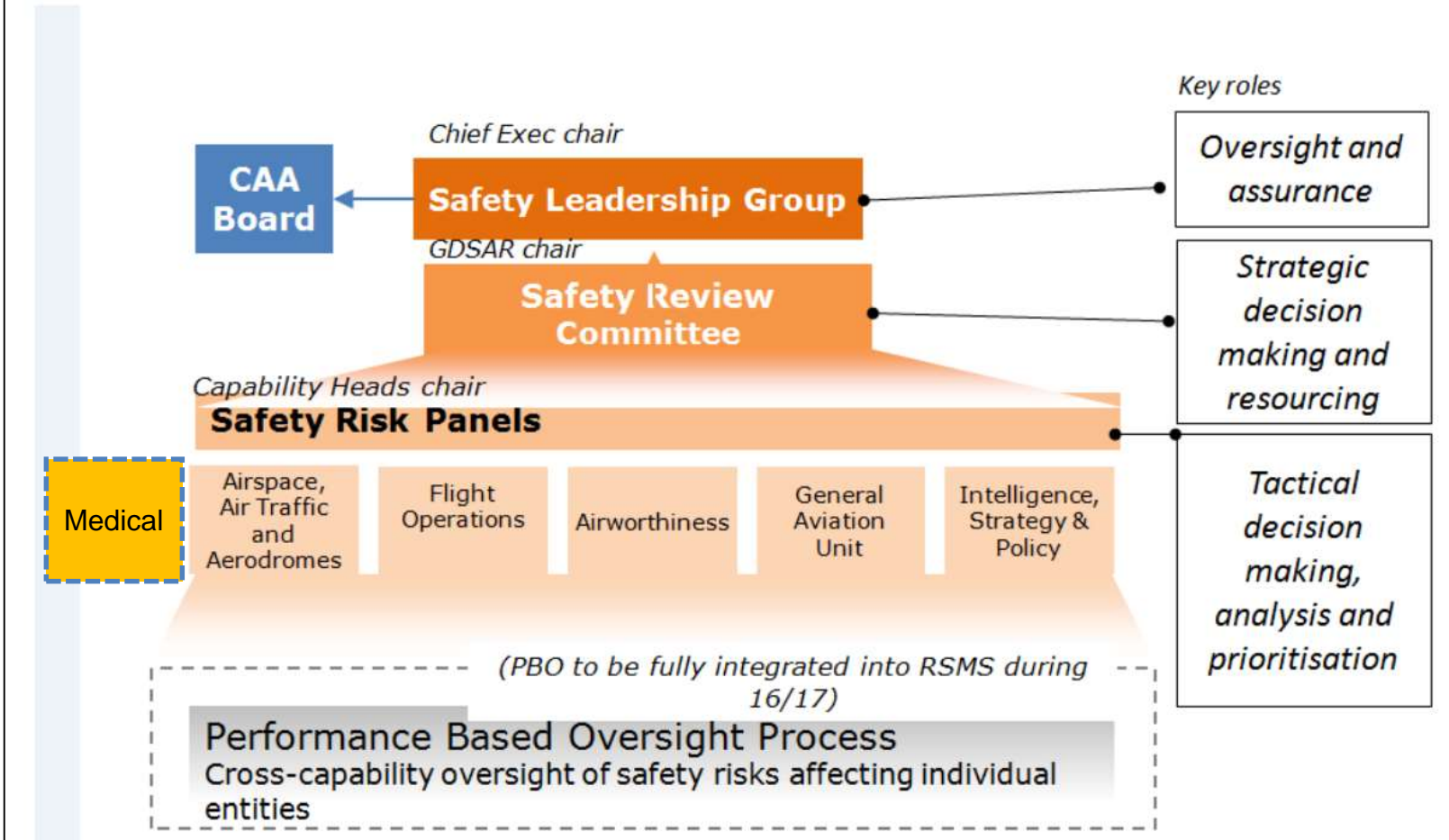
- To act as the lead for Medical on aeromedical safety systems, compliance and risk management.
- To provide expert advice on new technologies and innovations in Aviation and Space Medicine to the CAA and external stakeholders.
- To systematise and oversee departmental research activities.
- Other projects and pop-ups

# Aeromedical Safety Systems, Compliance and Risk Management.

- Set up Medical Safety Risk Panel
  
- Systematise Safety Risk Data collection and reporting eg accidents, oversight information, Mandatory Occurrence Reports
  
- Horizon Scanning
  
- 'Pop-ups'
  - Balloon CAT review
  - GA medical self-declaration proposals
  - Spaceplanes secondary legislation

# CAA regulatory SMS

## The Regulatory SMS Governance Structure





# Aviation & Space Medicine Meetings

- ASMA Dallas 7-11 May 2018
- RAeS Spring lecture 24 May 2018 (provisional)
- ECAM Prague 20-23 September 2018
- AMDA Aviation Health Conference 25-26 September 2018
- ICASM Bangkok 11-15 November 2018

# Contact us

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