

MESAFE [EASA.2022.C07]

[D2.1 REPORT ON THE ANALYSIS OF THE AVAILABILITY OF  
DIAGNOSTIC TESTS]

# MESAFE – MEntal health for aviation SAFETy

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# SUMMARY

## Problem area

Mental disorders can influence pilot and air traffic controllers' performance in many detrimental ways. Their effects can bring about incapacitation, which erodes safety margins and might disrupt normal operations. On a more critical level, they can lead to errors, violations, inappropriate automatic hurried actions or biased decision making.

Currently, there are no specific, standard, validated mental health assessment methods for aeromedical use, incorporating the specific operational needs, to address the incapacitation risk due to mental disorders in the framework of the fitness for duty certification process.

MESAFE stands for "MEntal health for aviation SAFETy". It is a research project, funded by EASA under the framework of the European Union's Horizon Europe research and innovation programme. Started in May 2022 and lasting 2 years, the project aims at overcoming challenges preventing the effective implementation of the Aeromedical certification process for pilots and air traffic controllers (ATCOs) with regards to the incapacitation risk associated with mental health conditions. The project will provide evidence-based recommendations for new medical developments for the early diagnosis as well as treatment of mental health conditions which could pose a safety risk for aviation and would consequently lead to pilot and ATCO unfitness or the limitation of their licence privileges for safety purposes.

Two questions are prominent in this light. The first question is: "Can the safety impact of mental disorders be assessed, both in qualitative as well as quantitative terms, given the proposed solutions and mitigations?". It is important to be aware that the total impact may be relatively small, but even then, it may be so that some aspects of the certification process will become less efficient, whereas others will become more efficient. A second question is "what will the impact on regulations be?". To answer this question, it is important to understand, given the proposed changes to aeromedical certification operations, what part of the regulation will be influenced by these changes, so as to be aware of the amount and type of adjustments to regulations that might be expected.

## Description of work

The present document is the D-2.1 REPORT ON THE ANALYSIS OF THE AVAILABILITY OF DIAGNOSTIC TESTS of the MESAFE project and provides a mental incapacitation risk assessment methodology, including psychodiagnostic tools and guidelines for assessing this risk. This represents the reply to one of the research questions of MESAFE: Can the safety impact of mental disorders be assessed, both in qualitative as well as quantitative terms?

In line with these and following the EASA technical requirements, this document provides the following information:

- review of the incapacitation risk levels related to mental disorders, including the definition of little/medium/high incapacitation levels;
- analysis of the ability of the tests identified in task 1 to assess the short-, medium- and long-term evolution of mental pathologies, i.e. risk of recurrence or relapse;
- analysis of the assessment tests and methods identified in task 1 in terms of suitability (taking into consideration operational needs for each class of aeromedical certification and their respective acceptable risk of flight crew incapacitation), frequency of assessment, cost-effectiveness,

comparison with other diagnostic methods used for the respective mental pathology(ies) and availability of state-of-the-art tests at EU Member State level;

- recommendations targeted to AMEs including: (i) how to identify the applicants with mental pathologies who have a higher risk of incapacitation and to quantify that risk and (ii) which diagnostic methods can be used for screening purposes, which for confirmatory purposes, and which for monitoring purposes, according to the class of aeromedical certification.

At the end of Task 2 (planned at T0+12) the Milestone 2 of the project “*Analysis of suitable mental health assessment methods*” is achieved. This output serves as input for the following Task 4 “Validation of the acceptable risk of incapacitation considering the evolution of medical sciences” that runs from T0+9 to T0+15.

## Results and Application

The safety impact of mental disorders can be assessed, both in qualitative as well as quantitative terms, by means of a sound risk assessment methodology. This document proposes a mental incapacitation risk assessment methodology implementing a list of mental incapacitation events and their assessment by a 5x5 risk matrix plotting severity and probability levels.

Mental incapacitation events are hazardous behaviours due to mental issues. Events to be taken into account include:

- Suicide
- Murder-suicide
- Aggressive behaviour
- Agitation
- Intrusive thoughts - compulsions
- Depersonalization - derealisation
- Reduced alertness
- Panic attack
- Somatic symptoms (not caused by an unrelated physical disease)
- Hallucinations
- Delusions

The probability that a mental incapacitation event would happen depends on:

- presence of one mental disorder or more (comorbidities) and their degree of dangerousness, violation of society standards, statistical deviance, social discomfort, subjective distress, maladaptiveness, irrationality and unpredictability (the 7 mental illness indicators)
- risk of recurrence/relapse
- psychoactive substance abuse
- risks related to biological treatment
- life stressors
- physical health (somatic comorbidity)
- recent incidents/accidents
- risk of lack of self-declaration
- successful treatment and protective factors

The determination of the acceptability of the risk, and with that the colour associated with each cell of the matrix, requires careful consideration taking into account the type of operation for which the risk is assessed (civil multi-crew ops, civil single pilot ops, ATC ops).

From a mental incapacitation risk perspective, single pilots have a higher attributable risk than Captains/First Officers working in a multicrew operational environment. Controllers are considered to have an attributable risk equivalent to professional pilots.

The risk matrix can act as an important communication tool to be discussed with the applicant, because it is focused on incapacitation events rather than on diagnoses of mental disorders.

For the aeromedical assessment of mental health, no psychodiagnostic test and/or questionnaire can be used to replace the clinical interview. For the detection of mental disorders, the clinical interview combined with the mental status examination can be considered the backbone of the assessment.

For both class 1 and class 3 initial and revalidation/renewal, it is recommended to address mental wellbeing and mental complaints during the interview, that can be supported by a questionnaire.

One important way to get around possible underreporting is to have access to previous history as well as previous reports by AMEs, other practitioners and MHSs, if any. Such information should be sought in understanding and collaboration with the pilot/ATCO herself to avoid a breach of trust. There are no scientific arguments for applying different diagnostic procedures in case of class 1 and 3 examinations, mental disorders can be equally troublesome for both commercial air pilots, air traffic controllers and RPA-operators, so detecting mental disorders is equally important. As the onset of mental disorders can be at any point during one's lifetime it seems not logical to follow a largely different diagnostic approach in the interview for initial or renewal examinations. It is recommended that AME's develop interviewing skills regarding mental health that yields relevant information on the one side, but that also create a nonthreatening and trusted atmosphere on the other side.

To implement the aforementioned guidelines, a close collaboration with MHSs is recommended. This is important:

- to properly address the mental incapacitation risk (severity and probability of mental incapacitation events)
- because the presence of biological/psychotherapeutic treatment in between two aeromedical examinations and/or in a given current timeframe is included among the measures to mitigate the mental incapacitation risk
- to train AMEs on interviewing skills
- to support the decision-making process on the mental fitness certification especially when data collected are unclear or discrepant.

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# ABBREVIATIONS

ACRONYM	DESCRIPTION
ACC	Area Control Centre
ADHD	Attention deficit hyperactivity disorder
AeMC	Aero-medical centre
AME	Aviation Medical Examiner
ASSIST	Alcohol, Smoking and Substance Involvement Screening Test
ATC	Air Traffic Control
ATCO	Air Traffic Controller Operator
AUDIT	Alcohol Use Disorders Identification Test
BAC	Blood alcohol level concentration
BAI	Beck Anxiety Inventory
BD	Butanediol
BDI-II	Beck Depression Inventory – II
BZD	Benzodiazepines
CAA	Civil Aviation Authority
CAGE	Cut, Annoyed, Guilty, Eye questionnaire
CPI	California Psychological Inventory
CRM	Crew resource management
DAST	Drug Abuse Screening Test
DISC	Dominance, Influence, Steadiness and Conscientiousness Test
DMT	Dimethyltryptamine
DSM-5	The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
DUDIT	Drug Use Disorders Identification Test
EASA	European Union Aviation Safety Agency
ECG	Electrocardiogram
ECT	Electro-convulsive therapy
EU	European Union
FAA	Federal Aviation Administration
FDA	US Food and Drug Administration
FFPM	Five Factors Personality Model
FINISH	Flu-like symptoms, Insomnia, Nausea, Imbalance, Sensory, Hyperarousal
GBL	Gamma butyrolactone
GHB	Gamma hydroxybutyrate
HAM-S	Hamilton Anxiety Rating Scale
HDR-S	Hamilton Depression Rating Scale
HPPD	Hallucinogen-persisting perception disorder
ICAO	International Civil Aviation Organization
LPC	License Proficiency Checks
LSD	Lysergic acid diethylamide
MAO-inhibitors	Monoamine oxidase inhibitors

MCI	Mild cognitive impairment
MCMI-IV	Millon Clinical Multiaxial Inventory IV
MDMA	3,4-methylmethamphetamine
MHS	Mental Health Specialist
MMPI-2	Minnesota Multiphasic Personality Inventory - 2
NASA	National Aeronautics and Space Administration
NEO-PI-R	NEO Personality Inventory Revised
NIDA	National Institute on Drug Abuse
NIMH	National Institute of Mental Health
N2O	Nitrous oxide
OPC	Operator Proficiency Checks
OSA	Obstructive sleep apnea
PHQ-4	Patient Health Questionnaire-4
PHQ-9	Patient Health Questionnaire-9
PTSD	Posttraumatic Stress Disorder
REM-sleep	Rapid eye movement sleep
rTMS	Repetitive Transcranial Magnetic Stimulation
Rtower	Remote tower
SCRA	Synthetic cannabinoid receptor agonists
SNRI	Selective Norepinephrine Reuptake Inhibitor
SQ-48	Symptom Questionnaire – 48
SSRI	Selective Serotonin Reuptake Inhibitor
TAT	Thematic Apperception Test
TCA	Tri-cyclic antidepressants
THC	Delta9-tetrahydrocannabinol
TMA	Terminal Manoeuvring Area
XTC	Ecstasy
16PF	16 Personality factors

# 1. Introduction

The present document is the D-2.1 REPORT ON THE AVAILABILITY OF DIAGNOSTIC TESTS of the MESAFE project. The document provides up to date methods and procedures to assess and monitor the mental incapacitation risk of pilots and ATCOs.

MESAFE stands for “MEntal health for aviation SAFETy”. It is a research project, funded by EASA under the framework of the European Union's Horizon Europe research and innovation programme. Started in May 2022 and lasting 2 years, the project aims at overcoming challenges preventing the effective implementation of the Aeromedical certification process for pilots and air traffic controllers (ATCOs) with regards to the incapacitation risk associated with mental health conditions.

Detailed background information about MESAFE and expected results by the project can be found in the MESAFE deliverable D1.1 Report on the review of diagnostic measures, which is available at <https://www.easa.europa.eu/en/research-projects/mesafe-mental-health#group-downloads>.

## 1.1 Scope of the document

The present document is the deliverable of the Task 2 of the project and includes the output of subtasks 2.1, 2.2 and 2.3.

Task 2 “*Identify mental health diagnostic tests suitable for use in aeromedical fitness assessments*” lasts 6 months. The objective of this Task is to produce evidence-based recommendations for mental health assessment methods suitable for aeromedical fitness assessments. As expected output, this task has produced an overview of recommended diagnostic methods both for mental disorders’ screening, confirmatory and monitoring purposes, based on an assessment of the applicants’ incapacitation risk, as well as a cost-effectiveness analysis of those methods. These recommendations are targeted to Aeromedical Examiners (AMEs) and assessors as supporting materials.

Subtask 2.1, “*Review incapacitation risk levels and analyse the diagnostic tests in terms of suitability and availability of state-of-the-art tests at EU Member State level*”, provides a review of the incapacitation risk levels related to mental disorders. Such risk assessment includes: (i) a list of mental conditions related to little/medium/high incapacitation levels; (ii) a method to quantify that risk for aviation safety; (iii) a proposal of diagnostic options for incapacitation risk detection. The diagnostic tests will be described on the basis of the availability, the required frequency of the assessment and the class of aeromedical certification they can be applied to.

Subtask 2.2, “*Analyse the tests’ cost-effectiveness, including the tests’ ability to assess the short-, medium- and long-term evolution of mental pathologies, i.e. risk of recurrence or relapse*”, has engaged in a qualitative cost-effectiveness analysis of the psychodiagnostic options identified in subtask 2.1. Such analysis has taken into account the balance between the cost of the tests and their ability to address the safety risk related to incapacitation in the short, medium and long term. The analysis of the costs has taken into account, for each option: (i) its cost; (ii) the time required for its use (data collection and analysis); (iii) the human resources needed (i.e. Aeromedical examiners, Aviation psychologists); (iv) the administration method (online/face to face); (v) its sensitivity to the incapacitation risks; (vi) its ability to detect the risks of incapacitation recurrence or relapse; (vii) the validity time-frame (short-, medium- and long-term); (viii) the comparison with other diagnostic methods used for the respective mental pathology(ies), i.e. interviews. Basically, this task provides a general assessment of different diagnostic options, including questionnaires, measures and “tools” commonly used by mental health professionals, transferable to application by aeromedical examiners, including those used by AMEs. This topic is crucial as it would pave the way to the following key questions: (i) to what extent are there relevant scales or formalised/validated tools which may be used? (ii) what training would be needed to give a basic competency in doing such evaluations? (iii) to what extent can we train AMEs to perform such examinations? To address it, the task has taken onboard the results of the survey targeted to AMEs about specific tests/interviews they are required to use as part of the examination of applicants (see

the MESAFE deliverable D1.1 Report on the review of diagnostic measures), to validate or investigate their effects. The scope and expected results of the training for the AMEs will be addressed in the next stages of the project, instead.

Subtask 2.3, “Analyse the suitability of readily available test options taking into consideration operational needs for each class of aeromedical certification and their respective acceptable risk of flight crew incapacitation”, provides a list of psychodiagnostic guidelines that can be recommended to assess the mental fitness of applicants in the aviation domain.

Task 2 takes input from Task 1 “Review and critique of the state-of-the-art in the diagnosis and care of mental health conditions” and Task 3 “Identify screening and confirmation tests for psychoactive substances suitable for use in aeromedical fitness assessment”. Tables 1, 2, and 3 provide a list of the take-home messages from D1.1, D1.2 and D3.1 that are followed-up in this document.

D1.1 REPORT ON THE REVIEW OF DIAGNOSTIC MEASURES					
TAKE HOME MESSAGE		FOLLOW-UP IN THIS DOCUMENT		STATUS	FOLLOW-UP IN NEXT TASKS
ID	Description	Output	Section		
2.1	Mental health problems can lead to total and subtle incapacitation	Description of the mental functions’ alterations due to mental disorders and consequent list of mental incapacitation events	The mental status examination risk of recurrence/relapse of mental disorders the MESAFE risk matrix list of mental disorders who have a higher risk of incapacitation	CLOSED	-
3.2	Not all mental disorders are long-term. Many of them are short-term.	Description of the differences among mental disorders and highlight of the opportunity to address their risks specifically	Mental disorders that have a higher risk of incapacitation Risk of recurrence/relapse of mental disorders	CLOSED	-
3.4	Life changing events and work-related stressors have an impact on mental health	Evaluation of life stressors and recent incidents/accidents included in the mental incapacitation risk assessment methodology	Mental issues after an incident/accident Clinical interview History taking, including stressors and life-changing events	CLOSED	-
3.6	Many mental disorders impede the ability to concentrate and cause sleeping difficulties, which is much more frequent than suicidal behaviour, and also an important risk for flight safety.	Description of the mental functions’ alterations due to mental disorders and consequent list of mental incapacitation events	The mental status examination the mental incapacitation events	OPEN	overview of the mental health conditions that are eligible for aeromedical certification according to their severity and the class of aeromedical

					certification (Task 5)
3.7	The safety assumption according to which an applicant suffering from a mental health disorder will seek help and self-declare her/his condition might fail. Indeed, for many mental disorders denial in a relatively frequent symptom leading to a reduced rate of self-declaration. Feelings of shame and guilt can also reduce the rate of self-declaration.	Building trust, history taking, access to previous AMEs records, access to medical records, access to psychological/psychiatric records, access to other relevant documentation	Risk of lack of self-declaration Psychodiagnostic guidelines	OPEN	Training modules on interviewing skills and history taking targeted to AMEs (Task 6) Rules and procedures enabling the access to previous records and relevant documentation (Task 5)
3.8	The cultural and organizational environment which individuals belong to have an impact on their possibility and willingness to self-declare mental health issues. A supportive and just-culture oriented environment towards mental health and psychological discomfort might help self-declaration of possible mental issues before they escalate into negative effects for safety and for the health of people suffering from them.	Focus on symptoms rather than disorders Highlight of the importance of getting the content by pilots/ATCOs to access relevant documentation Highlight of the importance of interviewing skills of AMEs	The MESAFE risk matrix Clinical interview Building trust and psychodiagnostic guidelines	OPEN	Safety promotion material (task 6) Training modules on interviewing skills targeted to AMEs (Task 6)
4.1	Psychodiagnostic tests taken as standalone assessment measures do not enable a psychological diagnosis. Still tests and questionnaires might be useful to support the part of the interview addressing mental complaints.	Description of the advantages and shortcomings of tests	Psychodiagnostic options for mental incapacitation risk assessment	OPEN	Cooperation processes between MHS and AMEs (task 4) Standardized Procedures for mental health assessment (task 5) Training modules on clinical interview targeted to AMEs (Task 6)

4.2	Very few dedicated and validated tests and questionnaires for pilots, ATCO's and other aviation professionals exist. Valid pilot and ATCS norms are available for the MMPI-2.	Analysis of tests' usability, suitability and acceptability	Review of psychodiagnostic tests and options	OPEN	Training modules on psychodiagnostic options targeted to AMEs (Task 6)
4.3	Personality tests cannot be used for diagnosing mental disorders	Explanation of the scope of personality tests	Personality tests	CLOSED	-
4.4	Tests and questionnaires hardly predict the mental health status in between two medical examinations.	Description of the advantages and shortcomings of tests	Review of psychodiagnostic tests and options	CLOSED	-
4.5	Assessing the risk of suicide and other risky behaviours is generally assumed to be based on two major principles: the clinical impression and quality of the contact with the patient, and epidemiological risk factors.	Guidelines to address the suicide risk	The mental status examination The mental incapacitation risk assessment	OPEN	Cooperation processes between MHS and AMEs (task 4) Mitigation measures (task 4)
4.6	It is not possible to assess the mild cognitive decline solely on the basis of the score achieved in a neuropsychological test, but the results of such a test or battery of tests can provide useful background information in the process of deciding on the medical certification of an individual who has been referred by the AME/AeMC for a specialist evaluation.	Description of the scope of cognitive tests	Cognitive tests Review of psychodiagnostic tests and options	CLOSED	-
4.7	To detect possible neurocognitive shortcomings the recommended aeromedical examination should be based on the two most important pillars: 1) the AME interview (history taking), and 2) Operational information: occupational history and functioning of the pilot or ATCO in the event of incidents and	Guidelines to address cognitive decline	Cognitive tests	OPEN	Training modules on cognitive decline assessment targeted to AMEs (Task 6)

	accidents and during simulator sessions, proficiency checks and training courses.				
5.1	There is little international guidance on how the screening examinations may be done in an environment where non-reporting of symptoms is probable.	Mitigation measures to override underreporting of mental issues and discomfort	Risk of lack of self-declaration Psychodiagnostic guidelines	CLOSED	-
	<p>The key challenges reported by AMEs with respect to the current procedures for the aeromedical mental fitness assessment, both for initial applicants and revalidation/renewal, are summarized as follows:</p> <ul style="list-style-type: none"> <li>• Applicants' opposing attitudes to disclose information</li> <li>• Difficulties in identifying symptoms</li> <li>• Insufficient training on mental health</li> <li>• Lack of legal definition or basis of implementation Mental Health Assessment in the different CAA</li> <li>• Absence of clear, robust, and validated questionnaires and interviews</li> <li>• Impossibility to access the applicant psychosocial and medical history; no access to earlier AME's record</li> <li>• Insufficient cooperation among AMEs and mental health specialists</li> </ul>		The mental incapacitation risk assessment Psychodiagnostic guidelines	OPEN	The mental fitness certification process (task 4) Task 5 guidelines Task 6 training

	<ul style="list-style-type: none"> <li>• Too little time allocated to assess mental fitness of applicants</li> </ul>				
5.3	<p>Suggested recommendations to improve the mental fitness assessment process, both for initial applicants and revalidation/renewal, by AMEs:</p> <ul style="list-style-type: none"> <li>• Multidisciplinary collaboration with mental health specialists and peer support groups</li> <li>• Standardized questionnaires and interviews</li> <li>• Possibility to access the applicant psychosocial and medical history</li> <li>• Shared procedures among Member States</li> <li>• Especially through EASA guidelines on how to perform the assessment</li> <li>• Periodical evaluation performed by mental health specialists</li> <li>• Trainings and educational material both for AMEs and mental health specialists on their collaboration</li> </ul>		The mental incapacitation risk assessment Psychodiagnostic guidelines	OPEN	<p>The mental fitness certification process (task 4)</p> <p>Task 5 guidelines</p> <p>Task 6 training</p>

Table 1 - D1.1 take-home messages and follow-up

D1.2 REPORT ON THE REVIEW OF TREATMENT OPTIONS				
TAKE HOME MESSAGE		FOLLOW-UP IN THIS DOCUMENT		STATUS
ID	Description	Output	Section	
				FOLLOW-UP IN NEXT TASKS



2.1	There are several effective biological and psychotherapeutic treatment options for mental disorders.	Highlights on the protective value of treatment options for mental disorders and the possibility to include it among the mental incapacitation risk mitigation measures	The acceptable risk level	OPEN	Mitigation measures (task 4) Recommendation to refer to psychotherapists and psychiatrists (task 5) Training modules for AMEs and PSGs on psychosocial interventions and biological treatment for mental disorders (task 6)
2.3	The presence of psychotherapeutic treatment in between two aeromedical examinations and/or in a given current timeframe should be evaluated carefully before being considered as disqualifying, as it works as a safety net to prevent relapses. It would be beneficial if the AME could consult the psychotherapist and obtain information regarding the evolution of the applicant	Highlights on the protective value of treatment options for mental disorders	Risk of recurrence/relapse of mental disorders	OPEN	Definition of cooperation processes between the psychotherapist and the AMEs within the mental health risk assessment process (task 4) Recommendation to involve psychotherapists (task 5) Information for AMEs and PSGs on effectiveness of psychosocial interventions
3.2	The compatibility of biological treatment options for mental Health with aviation duties depends on the duties, the disorder, the effects of the treatment, and the side-effects of the treatment. As a general rule, such evaluation must be made on an individual basis by a psychiatrist.	Review of biological treatment options according to the class of medication and definition of safety periods respectively after initiation of the treatment, after changing doses and after the end of the treatment in which most of the side effects should be gone	Mental incapacitation risk related to biological treatment Mental incapacitation risk assessment	OPEN	Definition of cooperation processes between the psychiatrist and the AMEs within the mental health risk assessment process (task 4) Recommendation to involve psychiatrists (task 5) Information for AMEs and PSGs on effectiveness and side-effects of biological treatment
3.3	The following equation can be used as a basis for evaluation of compatibility with aviation duties: <i>Total compatibility with flight duties = compatibility of the underlying disorder x</i>	Review of biological treatment options for mental disorders	Risks related to biological treatment	OPEN	List of compatible and non compatible biological treatment options (task 5 and 6)

	<i>compatibility of the biological treatment (risks and side-effects) x benefits of the biological treatment.</i>				
4.3	AMEs should work closely with mental health specialists and peer support groups.	Relevance of PSGs in promoting self-awareness and declaration of mental discomfort	Barriers to mitigate the risk of lack of self-declaration	OPEN	Definition of cooperation processes among PSGs, AMEs and MHSs in the framework of the mental health risk assessment process (task 4)

Table 2 - D1.2 Take home messages and follow-up

<b>D3.1 Report on the analysis of the suitability of screening and confirmation tests for misuse of alcohol and drugs</b>					
<b>TAKE HOME MESSAGE</b>		<b>FOLLOW-UP IN THIS DOCUMENT</b>		<b>STATUS</b>	<b>FOLLOW-UP IN NEXT TASKS</b>
<b>ID</b>	<b>Description</b>	<b>Output</b>	<b>Section</b>		
3.1	EASA guidelines specifically mention alcohol, opioids, cannabinoids, sedatives and hypnotics, cocaine, other psychostimulants, hallucinogens, and volatile solvents as psychoactive substances of concern because all these substances have acute, prolonged, or residual effects, and/or withdrawal symptoms that are incompatible with flying or ATC duties. The use of so-called 'party drugs' is presently widespread among the general population, and is not limited to specific sub-cultures anymore. Simultaneous use of different substances, including alcohol, is popular. The acute and hangover effects of alcohol are detrimental to flight safety. Residual or hangover effects represent a major threat to flight safety, as the consequent degradation of performance may be insidious and may not be recognised by the other crewmembers.	Description of the effects of psychoactive substances on operational safety	Mental incapacitation risk related to substance abuse	OPEN	List of psychoactive substances (task 5) Training modules for AMEs and PSGs (task 6)
3.2	All aeromedical licence examinations of pilots and ATCOs should include physical examination and extensive history taking by the AME in which several dedicated questions concerning psychoactive substance use should be included in the interview. In addition, screening test methods for identification of psychoactive substance (mis)use are considered important additional tools to support AMEs/AeMCs in their	Options to address the risk of psychoactive substances abuse	Questionnaires for substance abuse Psychodiagnostic guidelines	OPEN	Training modules for AMEs and PSGs (task 6)

	considerations about an applicant's fitness to function in a safety-sensitive aviation job.				
3.3	Hair analysis appears best suited for initial Class 1 /Class 3 psychoactive substance testing because it can provide a 30-90 days alcohol/ drugs/ medication history of the applicant.	Options to address the risk of psychoactive substances abuse	Questionnaires for substance abuse	OPEN	Task 5 guidelines
3.4	For renewal of Class 1, Class 3, and all Class 2 examinations a Urine Drugs Screen (if positive, followed by a confirmation analysis) is suitable to demonstrate the use of opioids, cannabinoids, amphetamines, cocaine, hallucinogens, and sedative hypnotics over a time period covering at approximately 2 to 4 days (for most drugs) before the test is taken.	Options to address the risk of psychoactive substances abuse	Questionnaires for substance abuse	OPEN	Task 5 guidelines
3.5	When evidence has to be found for chronic excessive alcohol use, the combination of serum levels of Gamma Glutamyl Transferase (GGT) and Carbohydrate Deficient Transferrin (CDT) appears the most suitable method to be used for screening. This combination covers excessive alcohol use in the 2-3 weeks prior to the examination. For recent excessive use of alcohol, Ethyl glucuronide (EtG) in urine is suitable to demonstrate excessive alcohol use at least within 24 hours prior to the examination.	Options to address the risk of psychoactive substances abuse	Questionnaires for substance abuse	OPEN	Task 5 guidelines

Table 3 - D3.1 Take home messages and follow-up

In line with these and following the EASA technical requirements, this document provides the following information:

- review of the incapacitation risk levels related to mental disorders, including the definition of low/medium/high incapacitation levels;
- analysis of the ability of the tests identified in task 1 to assess the short-, medium- and long-term evolution of mental pathologies, i.e. risk of recurrence or relapse;
- analysis of the assessment tests and methods identified in task 1 in terms of suitability (taking into consideration operational needs for each class of aeromedical certification and their respective acceptable risk of flight crew incapacitation), frequency of assessment, cost-effectiveness, comparison with other diagnostic methods used for the respective mental pathology(ies) and availability of state-of-the-art tests at EU Member State level;
- recommendations targeted to AMEs including: (i) how to identify the applicants with mental pathologies who have a higher risk of incapacitation and to quantify that risk and (ii) which diagnostic methods can be used for screening purposes, which for confirmatory purposes, and which for monitoring purposes, according to the class of aeromedical certification.

At the end of Task 2 (planned at T0+12) the Milestone 2 of the project “*Analysis of suitable mental health assessment methods*” is achieved. This output serves as input for the following Task 4 “Validation of the acceptable risk of incapacitation considering the evolution of medical sciences” that runs from T0+9 to T0+15.

## 1.2 Structure of the document

This deliverable is structured as follows:

- Section 1 is the present section, introducing the document in the framework of the project and its research ambition and scope.
- Section 2 addresses mental health and safety, providing information about the signs and symptoms of mental disorders in terms of psychological functions and their alterations; those mental disorders that have a higher risk of incapacitation; the risk of recurrence/relapse of mental disorders; the risk of lack of self-declaration; the mental incapacitation risk related to biological treatments and to substance abuse; the mental issues emerging from incidents/accidents.
- Section 3 provides the MESAFE mental incapacitation risk assessment methodology
- Section 4 provides a detailed description of the psychodiagnostic options to detect mental incapacitation risks.
- Section 5 describes conclusions and next steps.
- Section 6 is the list of the references

All the sections of this document end with a list of take-away messages, based on scientific evidence, which summarize the main findings that will be followed-up in the next tasks of the MESAFE project. Indeed the take-aways will be collected and translated into recommendations to be discussed with EASA and relevant stakeholders in the next phases of MESAFE.

## 2. Mental health and aviation safety

This section provides a comprehensive overview of the relationship between mental health and safety, providing a framework that describes the mental disorders' issues and challenges for the safety of flight and air traffic control operations.

This framework is a way to address the questions: (i) "What is the safety impact of mental disorders?" and (ii) "how can the safety impact of mental disorders be assessed in qualitative terms?", which are included in the EASA technical specifications of the project.

### 2.1 Brief summary of mental disorders

As extensively described in the MESAFE deliverable D1.1 Report on the review of diagnostic measures, mental disorders refer to a broad range of conditions that affect, among other, an individual's thinking, mood, behavior, and overall psychological functioning. They can range from mild to severe and can be caused by various factors, including genetics, environment, and life experiences.

The current version of the DSM, the DSM-5-TR (Diagnostic and Statistical Manual of Mental Disorders 5 text revised), which collects the latest scientific thinking in criteria, content, and organizational structure of mental disorders, clusters mental disorders into 20 different categories: Neurodevelopmental disorders; Schizophrenia Spectrum and Other Psychotic disorders, Bipolar and Related disorders, Depressive disorders; Anxiety disorders; Obsessive-Compulsive and related disorders; Trauma- and Stressor-related disorders; Dissociative disorders; Somatic symptoms and related disorders; Feeding and Eating disorders; Elimination disorders; Sleep-wake disorders; Sexual dysfunctions; Gender dysphoria; Disruptive, Impulse-control, and Conduct disorders; Substance-related and Addictive disorders; Neurocognitive disorders; Personality disorders; Paraphilic disorders; and Other mental disorders that do not meet diagnostic requirements for any of the mental disorders.

A detailed description of the 20 categories, with specific insights for certain safety-critical mental disorders, can be found in the aforementioned MESAFE deliverable: "MESAFE - D-1.1 - Report on the review of diagnostic measures" accompanied by a table crossing the categories with 7 mental illness indicators (i.e., dangerousness, violation of society standards, statistical deviance, social discomfort, subjective distress, maladaptiveness, irrationality and unpredictability) to measure the disabling potential associated with each category of mental disorders. In fact, mental disorders can potentially incapacitate individuals by impairing their ability to think, feel, and behave in ways that are necessary for everyday functioning. However, not all mental disorders result in a loss of medical fitness certification. The degree and nature of the incapacitation can vary depending on the specific disorder and the severity of its symptoms.

Coexistence of more than one mental disorder in the same patient at the same time is common. Consequently, diagnosing mental disorders is much more than just checking whether a patient fulfils all the DSM or ICD diagnostic criteria, it is a matter of clinical experience to judge whether symptoms should be attributed to one disorder, or to two comorbid disorders. Recognizing comorbid disorders is important but recognizing underlying traits of other disorders or recognizing underlying personality features, even if no formal diagnosis of another disorder can be established, is even more important, as it may influence the prognosis and it may have treatment consequences.

### 2.2 The mental status examination

It might be tempting to try to determine the incapacitation risk caused by mental disorders by studying actual incapacitations. However, this is practically and methodologically difficult. First of all, observational data cannot be used to establish causal relationships. Also, the population of pilots and ATCO's applying for a medical certificate is fundamentally different from the population actually suffering an incapacitation, and often, no reliable diagnostics have been performed before or after an incapacitation.

In an analysis of commercial aviation incidents and accidents related to a pilot mental health problem, there seemed to be three broad categories of mental disturbances: panic and anxiety attacks, acute psychotic symptoms and inadequate coping in case of negative life-events. As in panic attacks the other pilot could take over control, these were only related to minor incidents. Psychotic symptoms had been related to bad outcomes, such as in a Japan Airlines crash in 1983. Most accidents were caused by situations where likely there was a coping problem, but no reliable formal diagnosis of a mental disorder could be established (Mulder & De Rooy, 2018). Studies on the relationships between specific disorders and accidents suffer the problem of low numbers, unreliable diagnostics and have to a large extent been performed in the general aviation population (Laukkala 2017, Vuorio 2017).

As said, although studying data of actual incapacitations is informative and useful for policy making, these data cannot be used to predict the incapacitation risk of individual mental disorders reliably. In order to avoid any kind of selection bias, in this section the incapacitation risk will be discussed by examining mental disorders by the mental functions that have actually been impaired. For some disorders, this will lead almost automatically to the conclusion that the risk of incapacitation is high (such as in schizophrenia or bipolar type 1 disorders); for other disorders it will much more depend on the nature of the symptoms, such as in an obsessive-compulsive disorder or a social anxiety disorder.

If, for example, a person is suffering from a depressive disorder, it is paramount to know whether only the mood is affected, or if there are suicidal thoughts as well. At the same time, the presence of imperative acoustic hallucinations (e.g., a voice that gives orders) results in a high incapacitation risk, no matter if these hallucinations are due to schizophrenia, a manic episode in a bipolar disorder, a depressive disorder with psychotic features or a borderline personality disorder. Similarly, whereas the presence of delusional thinking or delusions is important to establish, whether the delusions are grandiose, erotomaniac, jealous or persecutory is of less importance for the AME, and this is better left to the psychiatrist providing an expert opinion or treating the patient.

Also, if the incapacitation risk would only be determined by the underlying disorder instead of symptoms, it may cause clinicians to feel a pressure of diagnosing a disorder that is more acceptable due to a lower incapacitation risk, e.g., a generalized anxiety disorder instead of a panic disorder. Furthermore, a focus on symptoms instead of disorders can help to explain to people why their symptoms may lead to an incapacitation risk, and to explain that the incapacitation risk derives from symptoms of a disorder, and not, for example from personal weakness or maliciousness.

Therefore, in this section, 2.2, the scheme of the mental status examination, with an emphasis on those functions that are related to the highest incapacitation risk, will be used to discuss the disorders with a higher risk of incapacitation.

For a more extensive overview of all the signs and symptoms of mental disorders, readers are advised to consult a textbook on psychiatry or a dedicated textbook on the mental status examination. Importantly, although the main elements of the mental status examination are similar in most countries, there are differences in the way the mental status is examined and reported, and it is recommended that practitioners adhere to the practices that are common in the country they are practising in (Hengeveld 2020). This is especially important in case of referrals to mental health professionals. Using methods and medical terms practitioners are unfamiliar with may result in less reliable findings, unclear referrals and in the end even compromise safety.

The mental status examination ideally starts when the applicant is still in the waiting room. If possible, listening how the applicant enters and reports him or herself at the front desk can be informative. For example, if an applicant is rude and hostile towards the desk-agent, but extremely friendly towards the examiner, this may indicate an emotional problem. Offering the applicant coffee or tea is not only a matter of friendliness, but also a good way to establish some casual conversation, for example about the weather, or if the traffic had been busy. If such a conversation will be established, it will not only bring the applicant at ease, but also tells the examiner that there is at least some healthy psychological functioning present.

In the following sub-sections, the following elements of the mental status examination that are feasible for class I and III medical examinations will be discussed:

- general aspect and self-care
- consciousness
- thought
- intelligence and memory
- behaviour
- speech
- mood and affect
- perception
- judgement and motivation
- psychomotricity
- attention
- personality
- self-awareness, introspection and insight

The emphasis will be focused on those features that are easily and reliably detectable by physicians that do not have a background in mental healthcare.

### 2.2.1 General aspect and self-care

The general aspect of the person and the way the contact with the examiner is established, are of great clinical relevance. Examining this already starts when walking from the waiting room to the consultation room.

Self-care can be impaired in a lot of disorders, but this usually indicates more severe symptoms, e.g., due to a psychotic or a depressive disorder. Although a bad self-care may be an important sign of mental disease, some people with severe mental disorders may have an excellent appearance.

It is advisable to describe the appearance as objectively and neutral as possible and to refrain from wording that may be experienced as discriminatory. Features that may be remarkable from a cultural point of view, and that may be unacceptable for many airlines, do not necessarily indicate the presence of a mental disorder. For example, the presence of facial tattoos and piercings may not be accepted by airlines, and may tell something about the applicant's personal and cultural background (which is highly worthwhile to discuss somewhere during the examination), but is not necessarily a sign of a mental disorder. It is also important to assess the posture (for example depressed or anxious people may slightly bend forward and make a timid appearance), gait abnormalities (which may be indicative of neuropsychiatric disorders or neurologic disorders), tics and other movement abnormalities.

The way in which an applicant establishes a contact with the examiner is highly informative. Making contact in a friendly way is the most common, although it is not unusual if the applicant, especially if it is the first mental examination, is somewhat tense and defensive, and it is perceived that the examination may have important career consequences. Also, the eye contact is important to assess. In anxious or tense people, especially in the early phases of the examination the eye contact may be sparse. If this gets better over time, it does not have to be a sign of mental disease. However, if the eye contact remains poor during the whole consultation, or if the applicant stares at the examiner in an uncomfortable way, this may be indicative of discomfort.

It is useful to note whether the individual is being cooperative or not, or that he or she may be hostile, reserved, impolite, arrogant etc.

### 2.2.2 Consciousness

An impaired consciousness or orientation automatically means some amount of incapacitation. Therefore, dementias and delirium indicate that the person should be considered to be incapacitated.

The orientation can be considered good if the applicant arrives on time by him or herself for the appointment. However, in case of doubt, for example when a neurocognitive disorder is suspected, it may be asked

whether the applicant had been brought by someone. One may also ask some questions on daily functioning, for example if driving to a place someone does not know, or traveling by public transport in a busy city, would go well (of course, the latter may also be impaired in case of anxiety or mood disorders, but for different reasons).

Depersonalisation and derealisation indicate that the person experiences extreme feelings of detachment from him or herself or from the environment, and may occur in various disorders (Sadock 2019). If present, the applicant should be referred for further examination.

Although the consciousness may be disturbed in some mental disorders (such as a delirium or an acute intoxication), disturbances in consciousness are extremely unlikely to occur in those applying for a class 1 or 3 medical certificate. The same is true for orientation difficulties. However, it can never be assumed automatically that these are not present, as, with increasing number of candidates, there is a higher chance that applicants exhibiting such symptoms may try to apply.

### 2.2.3 Thought

Disturbances in thought can be both in the form and in the content of thinking.

Regarding the form, there may be slow or a paucity of thinking (e.g. in a depression), or a flight of thinking or extremely fast thinking (e.g. during a manic episode). Sometimes, the continuity of thought may be disturbed, for example if the answers are not logical to the questions that are asked, or associations are very loose (e.g. when asked about one's flying experience, the manic applicant might typically answer: "I am very experienced, experiencing new things is so important, I need to experience what life means...". The form of the thought is best analysed by observing the answers the person gives, but in cases of doubt, it may be asked "Do you think your thoughts are slower than other people, or do you experience your thinking is faster than that of other people and it causes trouble to you?"). Importantly, the sole remark of an individual that he or she thinks faster than many other people is not indicative of a disturbance in thought, this is a feeling people with and without mental disorders often experience.

Disturbances in the content of thinking are hallmark to psychoses. There may be delusions (e.g. a belief that someone has supernatural powers, or that a secret conspiracy is going on), preoccupations, obsessions (e.g. in obsessive-compulsive disorders). In most cases, disturbances in the content of thinking may manifest themselves, especially if the applicant feels at ease. In case of doubt, it is good to ask the applicant whether he or she feels having supernatural powers or believes in supernatural things, thinks that conspiracies are going on, feels being persecuted etc. Some people may be aware that their ideas are strange, and they may not reveal them during the examination, especially if it is a single consultation. In case of doubt, it is useful also to talk to relatives, and to plan one or more follow-up visits to create more trust. It is important to discern delusional thinking from normal religious thinking, behaviour that is normal within the person's culture, and concerns and anxieties that may be a bit odd, but not a sign of disease. For example, during the recent COVID pandemic, a lot of theories that were by many regarded as conspiracy theories were present. If someone believes that such a theory is true, this is not necessarily a sign of mental disease, especially not if the theories are shared by many other people, if the person can acknowledge that other theories and views may also be possible and that other people may have a different viewpoint, and if there are no other signs of delusional thinking.

A normal form and content of thinking are essential to safe flying and controlling air traffic. Disorders of thinking can be extremely dangerous to flight safety. Disorders that influence the form of thinking, such as bipolar disorders, severe depressive disorders, and most notably, psychotic disorders, are associated with a high risk of incapacitation. Also disorders which influence the content of thinking should be considered to relate to a high risk of incapacitation. The presence of delusions may seriously jeopardize flight safety. A good example is the JetBlue incident in 2012, when a captain developed delusions during a flight from New York to Las Vegas (Mulder & De Rooy 2018). Nevertheless, if the form of thinking is normal, there are no psychotic features but only obsessive thoughts are present, e.g., in case of an obsessive-compulsive disorder, the incapacitation risk may be acceptable if the symptoms are not related to flying/air traffic control duties. Also in eating disorders, an obsession with food may be present. The actual impairment risk then mainly depends



on possible distraction during flying, on physical problems due to a low weight (extremely low weight also impairs cognitive functioning) and on any comorbidities. Rigid thinking due to an autism spectrum disorder may be a problem in the more severe cases.

#### 2.2.4 Intelligence and memory

It is always good to get a notion of the applicant's intelligence and memory. Formal IQ-testing is usually not necessary, but the educational background and the phrasing an applicant uses (as long as the examination is performed in the applicant's native language) will provide useful information. Especially in initial applicants who have not yet had a select-in psychological examination, and in which the previous education or career experience is not clear, an intellectual disability cannot be ruled out automatically. Upon indication, the applicant may be referred for formal testing.

Similarly, it is always good to get a notion of the memory of the applicant. If there are clear discrepancies between answers, or if the applicant fails to remember things most people would know, further testing is useful (although an apparent lack of memory may also be a way of psychological defence, or indicate psychological denial. The latter is especially the case if the memory loss and discrepancies are limited to specific areas that may be embarrassing for the applicant).

In active pilots and ATCO's a formal intellectual disability will rarely be found, but a mismatch between intellectual abilities and for example educational demands during flight school or when a change in work environment occurs, may lead to other mental disorders. It is therefore always good to get some idea whether the intellectual abilities match the educational or job demand.

#### 2.2.5 Behaviour

Disorders which lead to behavioural problems almost always indicate an increased risk of incapacitation. Especially in modern aviation, being able to perform as a professional team is paramount, and in case of behavioural problems, this is at risk. Whether the behavioural problems result from a personality disorder or from addiction is of less importance.

Also disorders in which suicidal intentions are present should be considered to have a high incapacitation risk, although from a conceptual point of view, this poses some difficulties. The far majority of suicidal people does not have any intention to harm others (actually, the risk of harming others is for many of these people the reason not to commit a suicide attempt). Therefore, the presence of suicidal thoughts does not necessarily have to lead to a danger to others, and might not even impair the ability to fly or control air traffic. However, given the specific environment of commercial air travel, and the fact that suicidal thoughts are often the result of a serious mental disorder, they should be considered to be incapacitating. Whether the suicidal thoughts result from a psychotic disorder or from a depressive disorder is of less importance then. It is important to explain clearly to the pilot or ATCO though, that he or she is not a danger due to having suicidal thoughts, but that the presence of suicidal thoughts may indicate the presence of a disease that requires treatment. Bluntly regarding people with suicidal thoughts as a danger to flight safety would be stigmatizing and conceptually wrong. Suicide and homicide-suicide are also quite different things (Kenedi 2016). Whereas suicide always arises from a primary suicidal motive, homicide-suicide may either arise from a primary suicidal motive or from a primary homicidal motive. In homicide-suicide events, anger often is an important motive, whereas in non-homicide suicide events, feelings of guilt, hopelessness and depression are often important. For clinicians, it is therefore especially important to address any feelings of anger, and how the applicant deals with these feelings. However, homicide-suicide, especially by means of an aircraft is an extremely rare event, which makes it highly difficult to predict.

Please also see the paragraph in suicide risk assessment on p. 74 of D.1.1 Report on the review of diagnostic measures.

For the purpose of class I and III medical examinations, a full suicide risk assessment or assessment of other risky behaviours is not feasible for an AME. Also in other areas of healthcare, it is common practice that for example general practitioners or emergency physicians can make a general assessment of the suicide risk,

but that the patient is referred to a specialist for a formal risk assessment if necessary. It is recommended that AME's assess possible suicidal feelings, violence and or/ other dangerous behaviour in a similar way. Upon indication, the applicant may be referred to a psychiatrist or clinical psychologist for a formal risk assessment. Assessing the risk of suicide and other risky behaviours is generally assumed to be based on two major principles: the clinical impression and quality of the contact with the patient, and epidemiological risk factors.

A good question to ask about suicidal thoughts is: "Do you sometimes feel so bad that you think you would be better off dead?". Then, it is important to explore what the individual actually thinks. It is good to explain that thinking about suicide in itself is quite common, and that having suicidal thoughts does not have to mean that someone will commit suicide, and that in many cases, people feel much ambivalence towards their suicidal thoughts (Van Hemert et al, 2012). Does the person just think that he would want to be away from everything, or is he thinking about methods to end his life? If so, has he done research on the internet? Or did he already make preparations, or a last will? (De Rooy 2019). A specialist consultation should be asked if there are suicidal thoughts that go beyond purely conceptual thinking about death, and especially if there is a wish to be death, if someone is thinking about death with a wish to commit suicide, if any preparation for a suicide attempt has been made, if the suicidal feelings are being accompanied by other features of mental disease and, most important, in the slightest case of doubt of the AME.

Aggressive behaviour may be predicted by asking questions like "Do you easily get angry?", and 'What do you usually do when you get angry?', "Do you sometimes consider attacking someone?' There are questionnaires to predict aggressive behaviour, but these have been developed in forensic populations (Hengeveld 2019).

Some risk factors for aggressive behaviour are (Hengeveld 2019):

- Previous aggressive behaviour
- Conduct problems before the age of 12
- Being a victim of violence during youth
- Antisocial or impulsive behaviour
- Substance abuse
- Lack of intimate relationships
- Lack of social abilities
- Lack of coping mechanisms
- Non-compliance with therapy or treatments

Also, these risk factors should always be combined with the clinical impression of the examiner, which is a matter of experience. It has to be highlighted that not all forms of aggression, violent and other unlawful behaviour (and other misconduct) are necessarily the result of a mental disorder, and that a lack of professionalism not necessarily means a mental disorder. Also, there will be many people who lack the emotional stability or behavioural control (or the intellectual abilities) to be a commercial pilot or ATCO, but who at the same time do not suffer from a mental disorder. In case of the slightest doubt, the applicant should be referred to the Mental Health Specialist.

## 2.2.6 Speech

A slow and soft and monotonous speech may be indicative of a depressive disorder, whereas a fast and loud speech may indicate agitation. Speech can be affected by several disorders. When a disorder influences speech, it is usually more severe. Whether the speech is soft and low due to a depressive disorder, or loud and fast due to a manic episode or a psychotic disorder, the incapacitation risk can be considered high.

## 2.2.7 Mood and affect

Mood may be depressed (eg in case of a depressive disorder), elated (eg in case of a manic episode), anxious, or angered. Whereas mood can be described as a pervasive and sustained emotion that colours the persons' perception of the world)- so how the person feels, affect can be described as the outward expression of the

person's inner experiences, for example blunted, flattened, labile etc. It tells whether the emotional expression is appropriate to the thought content, culture and setting of the examination (Sadock 2019).

Whereas providing clear descriptions of mood and affect can be challenging, reflecting on the emotions that are observed during the examination, and whether they feel natural or not, is something AME's can do easily. If emotions feel not natural or are difficult to understand or interpret, this may be a good reason for a referral.

A depressed mood due to a depressive disorder may in itself not be related to a higher incapacitation risk, but it is often related to concentration difficulties, loss of attention and sometimes even suicidal thoughts. Therefore, a depressive disorder should in most cases be assumed to have a high incapacitation risk. Also in an adjustment disorder, severe mood symptoms as well as concentration difficulties, may be present. Although usually short-lived, the presence of an adjustment disorder may also be considered to result in an incapacitation risk.

If the mood is anxious, e.g., due to an anxiety disorder, it is important to determine the actual anxiety complaints, before an incapacitation risk can reliably be estimated. For example, fear of flying resulting in sudden panic attacks should be considered to have a high incapacitation risk. On the other hand, social anxiety limited to casual social situations, or a specific phobia for dogs, may not need to impair flying duties.

### 2.2.8 Perception

Not all perceptual abnormalities are a sign of a mental disorder, some may be quite harmless. For example some hallucinatory experiences when falling asleep or when awakening may be normal. Most hallucinations are visual or acoustic, although they also can be olfactory or tactile. In schizophrenia and other psychotic disorders, most people experience predominantly acoustic hallucinations. It may be necessary to ask to the applicant directly if he or she hears voices or sees things that other people cannot see or hear, and if so, what its content may be. It is paramount to determine if the applicant is aware that he or she is experiencing things that may not actually be present. It is important to keep in mind that perceptual abnormalities may also be caused by eye or ear problems. However, in the latter cases, individuals are most often aware or can at least reflect on these. With the exception with benign acoustic hallucinations, for most people suffering hallucinations from mental disorders it is difficult to reflect on them and on the fact that most other people experience things differently. As all perceptual abnormalities, either caused by physical or by mental disturbances, can have a safety impact, applicants should be referred to the appropriate medical specialists for further evaluation. Perceptual abnormalities can also occur as a result of neurocognitive disorders. If the presence of hallucinations is suspected, especially when they are not sleep-related, the applicant should be referred for an extensive mental examination.

If there are perceptual disturbances, the incapacitation risk is high, no matter whether this is due to a psychotic disorder, due to a neurocognitive disorder or even due to an eye problem.

### 2.2.9 Judgement and motivation

A full assessment of the judgement and motivational functions will be beyond the scope of a class 1 or class 3 examination, but it is good to get a sense whether the applicant is highly impulsive or avoidant, and to assess whether he or she is aware of the consequences and reactions of other people to his or her behaviour. Although direct questions may be asked, it may be better to ask an applicant how he or she dealt with a specific situation, preferably a challenging one. Also, the biographical and social history may be informative, especially if the impairments are present for a longer period of time. Education, career and, most importantly, past and recent relations with other people are highly informative. A history of short-lived and troublesome relations, convictions, repeatedly having arguments at school or with managers may be indicative of a problem here.

The same may be true for past and present addictions and substance abuse, although often applicants will not admit addiction or substance abuse when asked direct questions on this, especially if there is the first interaction with an unknown AME.'

### 2.2.10 Psychomotor function

Slowed psychomotor activity may be indicative of depressive disorders. Elevated psychomotor activity (much gesturing, not being able to remain seated during the examinations) may be indicative of several disorders (ADHD, manic episode, a state of agitation, restless legs syndrome etc).

### 2.2.11 Attention

Attention is paramount to performing flying and air traffic control duties. Attention can be impaired in a vast range of disorders, such as depressive disorders, psychotic disorders, post-traumatic stress and anxiety disorders. A diminished attention is one of the hallmarks of ADHD/ADD (Attention Deficit Hyperactivity Syndrome). By influencing attention, all these disorders are associated with an increased incapacitation risk.

However, in the setting of a delimited formal mental examination with little distraction, and possible high consequences for the individual, except for very severe cases attention will likely be good even in the presence of ADHD or a depressive disorder. Therefore, it may be good to ask how activities that require a high attention are being performed, such as simulator sessions, driving on a busy road etc. Especially in initial examinations, when no simulator data or other job records are available, specific questions may be asked, such as if the applicant holds a driver's licence, and if he or she finds it difficult to drive in busy traffic, if when reading a book or watching a movie people have problems focusing on the reading and if they get easily distracted. Also discussing someone's educational background, and if there had been problems at school, is highly informative. ADHD debuts already in childhood, so if this disorder is present, the applicant likely has had problems at school (for example being easily distracted, or being too busy). In case of doubt, the applicant may be referred for further neuropsychological testing.

### 2.2.12 Personality

Personality problems almost always indicate a disturbance in the way people interact with other people, and in the way people deal with emotions. Problems related to this are automatically associated with a higher risk of incapacitation. Therefore, personality disorders, and in some cases also personality features that may be exaggerated by the presence of another disorder, should be considered to have a substantial incapacitation risk. This is especially the case for the so-called cluster B personality disorders, in which difficulties in dealing with emotions are most often acted out by means of aggressive or risk seeking behaviour. Best known for this are people suffering from a borderline personality disorder, but for example also people suffering from a narcissistic personality disorder may develop aggressive and/or suicidal behaviour if they feel assaulted.

Especially for the screening of pilots and ATCO's, describing personality traits by terms of personality disorders is not advisable (this would be far beyond the scope of a normal medical evaluation and is at odds with the fact that personality traits are fundamentally different from personality disorders). For professionals with sufficient experience, it could be considered to use the Big Five personality dimensions of the alternative DSM-5 model for personality disorders (negative affectivity, detachment, antagonism, disinhibition, psychoticism (Krueger et al 2012)), however for many AME's this will not be feasible. Also, for pilots and ATCO's, it might be deterring if their AME makes a judgement of their personality. It might be better to leave a judgement on someone's personality to a psychiatrist or clinical psychologist who performs a thorough mental examination if there is a clinical reason to do so.

Instead, in the routine screening and follow-up of aviation professionals, it might be better to analyse someone's coping, and, if clearly present, to mention notable psychological defence mechanisms. Coping can be best analysed by asking how someone dealt with an emotionally challenging situation. It may be asked how someone dealt with the illness or loss of a spouse, with quarantine measures during the COVID-19 pandemic, with changing rosters etc. For example, heavy drinking, physical aggression, seeking relief in dangerous but thrill-seeking activities indicate unhealthy coping. Taking extreme care for other people (as a means not to be confronted with one's own feelings), avoiding all dangers and excessive sporting may be

better, but still not optimal ways of coping. Humour to put things into a different perspective, talking to relatives and friends, sports and hobbies may be healthy coping mechanisms.

If someone shows resistance to discuss certain emotions or fails to show an emotion that would be appropriate in a certain situation (for example showing grief if someone has lost a relative), this may be a psychological defence mechanism.

### 2.2.13 Self-awareness, introspection and insight

For the purpose of the medical evaluation of commercial pilots and ATCO's, where the majority of people will not have a mental disorder, it will be sufficient to examine whether someone is able to reflect on his or her actions and personality. It is best not to ask direct questions, but to examine this by discussing a challenging situation, and how someone dealt with this, not only on a practical level but also at the level of emotional expression and regulation. Alternatively, it can be asked to describe oneself and one's personality, but this may lead to socially acceptable answers that are of little use, or it may be perceived as intrusive.

When awareness of the disease and insight are lacking, successful treatment is much more difficult, and being able to resume flying/ air traffic control duties will be almost impossible.

In case of mental complaints or of an established mental disorder, it can be asked what this disorder means for the applicant, and how it influences his or her life. Self-awareness and insight are important for accepting a treatment, and especially for psychotherapeutic treatments, (at least some amount of) insight is also required. This is also important when resuming work, as the patient had to be able to detect possible signs of relapse. If this is lacking, for example in an autism spectrum disorder, in a psychotic disorder or in the manic phase of a bipolar disorder, the incapacitation risk should be considered high. For safety, it is paramount that the person is aware of his or her vulnerability, and aware of the symptoms and what to do in case of a sudden decrease in medical fitness.

## 2.3 Mental disorders that have a higher risk of incapacitation

In conclusion, in order to determine the incapacitation risk, it is advisable not to look just at the disorder that has been diagnosed. It is better to look at the actual symptoms and, most importantly, to the mental functions that have been impaired.

As shown, neurocognitive disorders, psychotic disorders, bipolar disorders and depressive disorders (at least moderate and severe) and ADHD are, especially if they are untreated or not in remission, related to a high risk of incapacitation. In case of addiction, the risk mainly comes from the substance that is used, although comorbid behavioural problems or comorbid mental disorders may pose a risk by themselves. For anxiety disorders, the incapacitation risk much more depends on the actual symptoms and features. The same is true for obsessive-compulsive, post-traumatic stress, somatic-symptom and eating disorders. For personality disorders, especially the cluster B personality disorders are related to a high incapacitation risk, but also in case of cluster A and C disorders, it is important to perform a thorough evaluation. Although an adjustment disorder is often considered benign from a clinician's point of view, its symptoms may still be incapacitating (e.g., when distracted due to sleep problems). Although the behavioural and communication problems resulting from an autism spectrum disorder will often yield some risk of incapacitation, it is important to make an individual assessment to determine the actual incapacitation risk. Many pilots with a very mild autism spectrum disorder can make a successful and rewarding flying career.

Under all circumstances, it is important to explain that the incapacitation risk is caused by symptoms of a mental disorder, not by moral weakness, maliciousness, etc. A high incapacitation risk due to mental problems does not make someone a 'bad' person. Symptoms cause a safety risk, not the person suffering from them. In conclusion, is advisable to determine the incapacitation risk individually on a case-by-case basis with an emphasis on the mental functions that have actually been impaired and not on diagnoses.

From a conceptual viewpoint, psychotic, neurocognitive, mood and cluster B personality disorders are related to the highest incapacitation risk.

## 2.4 Risk of recurrence/relapse of mental disorders

As extensively stated in section 3.8 of the MESAFE deliverable D1.1 Report on the review of diagnostic measures, many mental disorders are self-limiting and short term (for example adjustment disorders or specific phobia's responding well to treatment) and are unlikely to come back. Others tend to be relapsing or chronic. Unfortunately, in many mental disorders, even after a full recovery or remission has been achieved, some vulnerability tends to remain. This is especially the case for the more serious mental disorders that require treatment by a psychiatrist or clinical psychologist. This vulnerability is due to the fact that most mental disorders are (at least considered to be) the result of an interplay between genetic factors, experiences during one's lifetime, physical health and sometimes also some amount of bad luck. Treatment can help to alleviate symptoms, but it cannot change genetic factors or erase the past.

Although epidemiological data for the relapse or recurrence risk for several mental disorders exist, these data should be interpreted with caution, and definitely not be directly applied to commercial pilots and ATCO's.

These data are often obtained in large samples, that may be different by means of psychosocial factors, personality factors and physical health from aviation professionals. Also in practice, especially in the more severe cases, often comorbidity is present, making the determination of an individual relapse risk even more difficult. Of course, it is good to keep some epidemiological data in mind when making a risk assessment. For example, the relapse risk after a first depressive episode is about 50%, and after a first psychotic episode it is about 80% (Zorgstanddaard depressieve stoornissen 2018, van Alphen et al 2012). Consequently, the relapse risk for psychotic symptoms will almost always be considered to be too high for class 1 or 3 certification. Nevertheless, the actual risk in the individual patient is difficult to predict, and is also dependent on treatment (continued drug treatment can protect against a relapse), and on psychosocial factors. For good reasons many psychiatrists will be hesitant to describe relapse- and recurrence risks in individual patients in terms of percentages, as this is inherently unreliable.

Actually, when referring to the risk of recurrence or of relapse of mental disorders, we often mean the risk of recurrence or relapse of *symptoms* of mental disorders. Some disorders are considered to be present from early childhood on (autism spectrum disorders, ADHD) for the entire lifespan, other disorders tend to debut in young adulthood and remain for the rest of the life (e.g., personality disorders), others are considered to have a chronic nature after their onset (bipolar disorders, schizophrenia, recurrent depressive disorders). Here, it is not the risk of recurrence or relapse of the disorder that is relevant, but the risk of recurrence or relapse of symptoms. This is different in for example a single episode depressive disorder, an adjustment disorder or in post-traumatic stress disorder, where symptoms may well disappear after recovery and never come back.

Nevertheless, in many cases, the presence of a more serious mental disorder may be indicative of a life-long vulnerability to similar or new mental complaints. This vulnerability should not be considered an incapacitation risk as such, but a factor to be addressed when making a total risk estimation. Importantly, the risk resulting from this vulnerability can be mitigated by good self-care, healthy coping mechanisms and the availability of a good support system. Conversely, even minor and usually self-limiting mental disorders can become chronic and lead to an incapacitation risk when no healthy coping is present and when there is no support from others.

For many disorders (mood disorders, psychotic disorder), the higher number of previous disease episodes, the higher the chance of developing a future episode becomes. For some disorders, especially mood and psychotic disorders, after several disease episodes, a chronic state of a depressed mood or of chronic psychotic symptoms may occur.

When determining the relapse or recurrence risk in the individual patient, it is advised to make a total risk estimation based on applicable epidemiological risk factors, previous disease episodes, personal factors (both protective and risk factors) and comorbidity. It should be accepted that in many cases, the relapse or recurrence risk cannot be described mathematically. It may be better to describe the situation of the individual patient as reliably as possible, and to elaborate on the risk and protective factors that are present.

Some protective- and risk factors regarding the relapse risk are depicted in the table below.

Risk factors	Protective factors
Disorder tends to be relapsing or chronic	Disorder tends to be self-limiting and not to relapse
Bad compliance with treatment	Good adherence to treatment
No support from others	Helpful support system present
Employment difficulties	Stable employment
Physical comorbidity	Good physical health
Mental comorbidity	No mental comorbidities
Relapse risk has not been addressed during treatment	A plan to prevent relapse has been made
More previous episodes	First episode of mental complaints

Table 4 - Protective and risk factors regarding the relapse risk

## 2.5 Mental incapacitation risk related to substance use

Misuse of alcohol and/or drugs is precluding participation in aviation duties. When clear symptoms and/or smell (alcohol, cannabis) are recognised by colleagues, this will (and should) lead to removal of the affected colleague from the workplace and disallowance to perform any professional activities. However, in single pilot operations or single person operations in ATM (position or Ops room staffed by a single person), colleagues might not be present to correct an affected colleague. In such cases use of alcohol or drugs within a critical time period (12 hours) before commencing duties might have catastrophic consequences for flight safety.

Cases where a low dose of alcohol or drugs was used within 12 hours before duty time, or where residual effects or withdrawal symptoms from earlier use are at play, are likely to lead to subtle incapacitation. Subtle incapacitation is a, sometimes difficult discernible, reduced state of alertness characterised by a lack of appreciation of significant factors, cognitive impairment, increased reaction time, and impaired judgement. Because this form of incapacitation is sometimes not, or too late, recognized by colleague crew members, it represents an insidious threat to flight safety. It is assumed that this form of incapacitation occurs much more frequently than sudden incapacitation in which loss of functions is clearly discernible by other crew members.

While subtle incapacitation can be caused by misuse of psychoactive substances per se, it should be taken into account that the misuse may be part of a combination of mental conditions such as depression, anxiety, or preoccupation with personal problems.

According to the EASA guidelines, the term psychoactive substances means alcohol, opioids, cannabinoids, sedatives and hypnotics, cocaine, other psychostimulants, hallucinogens, and volatile solvents, whereas caffeine and tobacco are excluded (<https://www.easa.europa.eu/downloads/21688/en>).

In the present section the mental incapacitation risk will be discussed in relation to the various psychoactive substances mentioned in the EASA guidelines.

### 2.5.1 Alcohol

Alcohol is a central nervous system depressant that causes brain activity to slow down. The following acute effects may threaten flight safety by incapacitating task performance of pilots and ATCOs (Dry et al., 2012; Jacob and Wang, 2020):

- Impaired alertness
- Narrowing of attention: focus on one task

- Neglecting alarm signals
- Underestimation of danger
- Opting for risky solutions, risk taking behaviour
- Ignoring normal procedures
- Unawareness of impaired performance
- Impairment of vision
- Impairment of motor coordination
- Euphoria / Aggression / Anger
- Boosting the effects of fatigue and sedative medication
- Nausea, Headache, Flushing
- Disturbed Sleep and Obstructive Sleep Apnea: Next day fatigue and impaired performance
- Impaired spatial orientation

Effects are potentiated by hypoxia (pilots) and fatigue (both pilots and ATCOs)

It is important to consider that even blood alcohol concentrations (BAC) as low as 0.01 to 0.02% can cause cognitive incapacitation of pilots as well as ATCOs and that BAC levels of 0.03% and beyond may cause significantly incapacitating effects on performance of all aviation tasks (Modell & Mountz, 1990; Billings et al., 1991; Ross et al., 1992; Cook, 1997).

Acute ingestion of alcohol is clearly incompatible with the safe performance of flying operations.

#### **Alcohol-Residual or Hangover effect and impaired sleep**

The commonly used terms hangover and morning-after effects often refer to the physical symptoms after drinking alcohol the night before, such as general malaise, headache, dizziness, dry mouth, stuffy nose, fatigue, and upset stomach. When describing hangover effects on performance, the term “residual effects” is preferred, because after drinking alcohol next-day performance can be impaired, even when subjects notice no subjective physical symptoms (Morrow et al., 1991). Alcohol consumed 8 to 10 hours before starting a duty might have residual negative effects during the duty period, which may go unnoticed by colleagues (Morrow et al., 1990; Taylor et al., 1994; Simons & Valk, 2003). Therefore, residual effects are considered to be a significant threat to flight safety which occurs much more frequently than cases in which a crew member is acutely intoxicated (“visibly drunk”). After drinking the night before, the next morning BAC measured by breathalyser will be 0.00% while there is still alcohol left in cells of the central nervous system causing subtle degradation of cognitive functions and spatial orientation as long as 9 hours after the last alcoholic drink and a night sleep (Simons & Valk, 2003). Residual effects of alcohol on cognitive functioning are often potentiated by the effects of poor sleep, because alcohol use before bedtime disturbs the normal sleep architecture and alcohol is also associated with sleep apnoea. Taking these findings into account, it is recommendable to obey an alcohol free period of 12 hours before commencing safety sensitive aviation duties. This is in contrast to many airlines and/or authorities require pilots and ATCOs to obey an alcohol-free period of 8 to 10 hours before starting their duty.

It is important to consider that alcohol consumption before bedtime may increase the risk of sleep apnoea by 25% (Simou et al., 2018). Alcohol may trigger obstructive sleep apnoea (OSA) and/or worsen the severity of OSA, while OSA may worsen the residual effects of alcohol. Affected individuals may not recognise the extent of sleep disturbance that occurs under these circumstances, increasing the danger that sleepiness and the effects of alcohol consumption will co-occur.

#### **Alcohol withdrawal syndrome**

Alcohol withdrawal syndrome is a set of symptoms that can occur following a reduction in alcohol use after a period of excessive use. Symptoms include anxiety, shakiness, sweating, vomiting, fast heart rate, and a mild fever. More severe symptoms may include seizures, and delirium tremens which can be fatal in untreated patients. Symptoms typically begin around 6 hours following the last drink, are worst at 24 to 72 hours, and improve by 7 days (ASAM, 2020).



### 2.5.1.1 Conclusion

It is concluded that acute as well as residual effects of alcohol and withdrawal after excessive alcohol use can result in incapacitation to perform aviation duties. It is therefore recommended that in order to safeguard flight safety, pilots and ATCOs should refrain of drinking alcohol within a critical time period of 12 hours before the start of their duty and should maintain a healthy lifestyle and should be sensible and moderate on alcohol during off-duty days. AMEs should educate pilots and ATCOs about the flight safety consequences of alcohol misuse and try to identify regular misuse of alcohol or alcohol addiction among their applicants for medical certification.

## 2.5.2 Drugs

All drugs mentioned in the present report affect the cognitive functions and have acute, prolonged, or residual effects, and/or withdrawal symptoms that are incompatible with flying or ATC duties. In the present section the adverse effects on flight safety aspects of the various drugs that are mentioned in the EASA guidelines, and the duration of the effects and withdrawal symptoms will be briefly discussed. For more extensive descriptions of the characteristics of various drugs, the reader is referred to EASA-MESAFE (2023) D3.1 Report on the analysis of the suitability of screening and confirmation tests for misuse of alcohol and drugs (<https://www.easa.europa.eu/en/downloads/137836/en> ).

Only average data are provided because there is considerable variation in individual elimination times of the drugs and large variation in the individual effects and withdrawal duration and symptoms. Moreover, it should be taken into account that in the dance and festival scene use of combinations of various types of drugs is common.

What follows provides a wrap-up of key information about drugs and their adverse effects on safety.

### 2.5.2.1 Opioids

<b>Drugs in this group</b>	buprenorphine, codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydromorphone, levorphanol, methadone, morphine, heroin, oxycodone, oxymorphone, tapentadol, tilidine, and tramadol. Some are also prescribed as painkillers, with oxycodone and tramadol being the most popular oral opioid painkillers in Europe.
<b>Acute adverse effects on safety</b>	sedation, sleepiness, dizziness, respiratory depression, nausea, vomiting, constipation, and -most notorious physical dependence and addiction.
<b>Duration of effects after single dose</b>	depending the type of opioid: can last more than 12 hours (for some sustained-release opioids). Naloxone is the anti-dote; it works for 1 to 1.5 hours and adverse opioid symptoms can re-occur after that time period.
<b>Withdrawal symptoms</b>	depending on duration of use and abruptness of stopping: sweating, hot and cold flushes, muscle/bone/joint pains, runny nose, nausea, diarrhoea or abdominal cramps, headache, muscle cramps, 'goosebumps', dilated pupils, agitation, tachycardia, anxiety, insomnia, opioid cravings.
<b>Duration of withdrawal symptoms</b>	significant decrease in the acute symptoms within 1 week; several weeks for behavioural and emotional symptoms and withdrawal insomnia.

Table 5 - Safety hazards related with opioids use/misuse

### 2.5.2.2 Cannabis

<b>Drugs in this group</b>	cannabis, marijuana (contain naturally derived delta9-tetrahydrocannabinol (delta9-THC, in brief "THC"), dronabinol (pharmaceutical source of THC), and a variety of synthetic cannabinoid receptor agonists (SCRAs; much more potent than cannabis).
<b>Acute adverse effects on safety</b>	euphoria, enhancement of sensory perception, tachycardia, difficulties in concentration, cognitive impairment, episodic and

	working memory impairment. Impairment of cognitive functions on a number of levels—from basic motor coordination to more complex executive function tasks, such as the ability to plan, organize, solve problems, make decisions, remember, and control emotions and behaviour (Crean et al., 2011).
<b>Duration of effects after single dose</b>	in regular users, the effects of marijuana range from 2 -3 hours and for beginners, the 'high' that most people experience, can last up to 15 hours, depending on the amount of THC the cannabis contains. Adverse effects following cannabis intoxication persist at least days or weeks following cannabis abstinence (Bourque and Potvin, 2021).
<b>Withdrawal symptoms</b>	sleep disturbances, including insomnia and experiencing strange dreams, may persist for 30-45 days after stopping (heavy) marijuana use. Stopping after long-term heavy use may lead to the cannabis withdrawal syndrome (DSM-5, <a href="https://www.dsm-5.nl/">https://www.dsm-5.nl/</a> ): anger, irritability, aggression, nervousness, anxiety, restlessness, depression, insomnia, headaches, nausea, vomiting, sweating, abdominal pain, tremors.
<b>Duration of withdrawal symptoms</b>	most acute symptoms resolve within 3 weeks, but insomnia and experiencing strange dreams may persist for 30-45 days after stopping marijuana use (Connor et al., 2022).

Table 6 - Safety hazards related with cannabis use/misuse

### 2.5.2.3 Psilocybin (“magic mushrooms”) and Lysergic acid diethylamide (LSD)

<b>Drugs in this group</b>	Lysergic acid diethylamide (declining popularity), Psilocybin increasing popularity (in various “magic” mushrooms).
<b>Acute adverse effects on safety</b>	anxiety, audio and visual hallucinations, decreased motivation, delusions, drowsiness, flashbacks, impaired memory, lack of coordination, nausea, panic attacks, rapid mood changes, vomiting, weakness.
<b>Duration of effects after single dose</b>	the first effects can occur 15 to 45 minutes after use. Depending on dose and strain of mushrooms the effects can last for 4-6 hours but some effects may linger on for 24 hours.
<b>Withdrawal symptoms</b>	after longer term mushrooms use: anxiety, psychotic symptoms, depression, flashbacks, extreme mood swings, low impulse control, panic episodes, rage, speech difficulties. After long term LSD use: general discomfort, restlessness, anxiety, depression, insomnia, hypersomnia, and -rarely in chronic users- hallucinogen-persisting perception disorder (HPPD; also called hallucinogen-induced echo psychoses) characterised by episodes of visual disturbances in the form of various geometric shapes, objects in the peripheral visual fields, flashes of different colours, enhanced colour intensity, trailing and stroboscopic perception of moving objects, after images, halos and macro- and micropsia (Vis et al., 2021).
<b>Duration of withdrawal symptoms</b>	depending on the length of time and the amount of psilocybin mushrooms has been used. No scientific evidential data available. Episodes of HPPD may persist for years.

Table 7 - Safety hazards related with psilocybin and LSD use/misuse

### 2.5.2.4 Ketamine

<b>Drugs in this group</b>	ketamine, esketamine (used for treatment-resistant depression)
<b>Acute adverse effects on safety</b>	hallucinations, dreamlike states, feelings of invulnerability, anxiety, agitation and aggressive behaviour, amnesia, confusion, reduced awareness of environment, disorientation, out of body experiences, and dissociation (Rosenbaum et al., 2021).
<b>Duration of effects after single dose</b>	effects will last 30-45 minutes after injection, 45-60 minutes after snorting, and 1-2 hours after oral ingestion, but judgement, senses and coordination may be affected for up to 24 hours or longer.

<b>Withdrawal symptoms</b>	anxiety, depression, insomnia, and flashbacks (Lin et al., 2016). Degeneration and damage of nerve cells: Excitotoxicity - induced by glutamate receptor activation resulting in degeneration of dendrites and cell death- can result from ketamine withdrawal, which occurs as a result of long-term ketamine abuse but manifests itself during withdrawals.
<b>Duration of withdrawal symptoms</b>	most withdrawal symptoms will be cleared after 2 weeks, but the nerve cell damage is most often permanent (Choudhury et al., 2021).

Table 8 - Safety hazards related with ketamine use/misuse

### 2.5.2.5 Amphetamines

<b>Drugs in this group</b>	methamphetamine, dexamphetamine, amphetamine, herbal ephedra products containing ephedrine.
<b>Acute adverse effects on safety</b>	increased wakefulness, increased physical activity, lowered self-criticism, risky behaviour, euphoria, feelings of power, strength, self-assertion, and enhanced motivation. Other effects include irritability, insomnia, confusion, tremors, convulsions, anxiety, paranoia, and aggressiveness. Physical effects of methamphetamine include increased respiration, respiratory problems, hyperthermia, cardiac arrhythmia, and extreme anorexia. Its use can result in cardiovascular collapse and death (McKetin et al., 2019).
<b>Duration of effects after single dose</b>	amphetamine is less potent than methamphetamine, but in uncontrolled situations the effects are almost indistinguishable. Following oral use, the effects usually start within 30 minutes. When taking a moderate dose, effects will last about 4 to 12 hours, often followed by listlessness, drowsiness, and depressed mood.
<b>Withdrawal symptoms</b>	irritability, depressed mood, depression, sleep problems, vivid or frightening dreams, severe fatigue, twitching or shaking, changes to appetite, slow thoughts and slurred speech. These symptoms may lead to continuing the use of amphetamine and addiction (McKetin et al., 2019; Zorick et al., 2010).
<b>Duration of withdrawal symptoms</b>	the immediate and main withdrawal symptoms last a few days to two weeks. However, post-acute symptoms can show up weeks, months or even years later.

Table 9 - Safety hazards related with amphetamine use/misuse

### 2.5.2.6 Cocaine

<b>Drugs in this group</b>	Cocaine
<b>Acute adverse effects on safety</b>	euphoric 'high' with hyperstimulation, reduced fatigue, mental clarity, peripheral vasoconstriction, pupillary dilatation, tachycardia, increased blood pressure, and hyperthermia. Some users may show restlessness, irritability, anxiety, paranoia (high doses). Cocaine-related deaths due to cardiac arrest or seizures followed by respiratory arrest have been reported.
<b>Duration of effects after single dose</b>	The high from snorting lasts 15 to 30 minutes, while that from smoking may last 5 to 10 minutes. Increased use can reduce the period of stimulation.
<b>Withdrawal symptoms</b>	After cessation of use a "crash" may follow with symptoms of anxiousness, dysphoria, restlessness, and hypersomnolence. Other withdrawal symptoms may be fatigue, lack of pleasure, anxiety, irritability, sleepiness, and sometimes agitation or extreme suspicion, symptoms associated with suicidal thoughts, or paranoia (NIDA, 2021).
<b>Duration of withdrawal symptoms</b>	in general, acute cocaine withdrawal symptoms may last around 3-4 days. However, some symptoms of cocaine withdrawal can persist for 3-4 weeks in some cases. Craving and depression can last for months after stopping long-term heavy use.

Table 10 - Safety hazards related with cocaine use/misuse

### 2.5.2.7 MDMA (3,4-methylmethamphetamine, ecstasy, XTC)

<b>Drugs in this group</b>	3,4-methylmethamphetamine and many synthetic chemical derivatives
<b>Acute adverse effects on safety</b>	euphoria, elevated self-confidence, moderate derealisation and depersonalization, cognitive disturbances, elevated anxiety and decreased appetite (Vollenweider et al., 1998). Commonly reported acute adverse physiological effects include tachycardia, bruxism, trismus, pupillary dilation, gait instability and nausea (Downing 1986; Peroutka et al., 1998; Cohen 1995; Davison & Parrott 1997). In addition, in high doses MDMA can cause a sharp increase in body temperature resulting in malignant hyperthermia (Hall & Henry, 2006).
<b>Duration of effects after single dose</b>	physiological and mental effects of MDMA can last up to 6 hrs after intake (de la Torre et al., 2004). However ecstasy users generally report a 24- to 48-h period characterized by the persistence of some acute effects. There is evidence that chronic, heavy, recreational use of ecstasy is associated with sleep disorders, depressed mood, persistent elevation of anxiety, impulsiveness, impairment of episodic memory, working memory and attention (Morgan, 2000).
<b>Withdrawal symptoms</b>	symptoms that resemble the “crash” phenomenon reported after psychostimulant administration. The most common symptoms include muscle aches, fatigue, sleep problems, depression, irritability, difficulty in concentrating, and headache (Peroutka et al. 1998; Davison & Perott 1997).
<b>Duration of withdrawal symptoms</b>	users may feel “discontented”, “sad”, and “bored” over 4 days after using the drug. Depression scores of some users may be the range for clinical depression (Curran & Travill 1997). Ecstasy users are at significant risk of sleep disorders, persistent cognitive impairments and disturbances of affect and personality. Some of these problems may remit after abstinence, but residual neurotoxicity and decline of serotonergic function may result in recurrent psychopathology and cognitive decline. After extensive use, abstinent MDMA users show evidence for impairment in verbal and visual memory.

Table 11 - Safety hazards related with MDMA use/misuse

### 2.5.2.8 Gamma hydroxybutyrate (GHB)

<b>Drugs in this group</b>	gamma hydroxybutyrate (GHB) and analogues that are often substituted for GHB: gamma butyrolactone (GBL) and 1,4-butanediol (1,4 BD), which are both available legally as industrial solvents.
<b>Acute adverse effects on safety</b>	sweating, sedation, loss of consciousness or coma, nausea, auditory and visual hallucinations, headaches, vomiting, exhaustion, lethargy, amnesia, and confusion (e.g. Stomberg et al., 2014). Doses in excess of 2ml are likely to be increasingly toxic with sedation and cardiorespiratory depression (Bell & Collins, 2011).
<b>Duration of effects after single dose</b>	GHB effects vary greatly depending on the amount used. Generally, effects are felt within 15 minutes and last for around 3 hours.
<b>Withdrawal symptoms</b>	insomnia, anxiety, tremors, sweating, increased heart rate and blood pressure, psychotic thoughts, hypertensive crisis, severe agitation, delirium, and epileptic seizures (e.g. McDonough et al., 2004). Due to the severity of these symptoms, that may be lethal, users should always be advised to seek specialist medical help for detoxification.
<b>Duration of withdrawal symptoms</b>	users may experience withdrawal symptoms within 6-24 hours of their last dose, and the symptoms may persist for 6 to 12 days or longer. Frequent GHB use may induce prolonged withdrawal symptoms lasting months.

Table 12 - Safety hazards related with GHB use/misuse

### 2.5.2.9 Benzodiazepines and non-benzodiazepines (BZDs and Z-drugs)

<b>Drugs in this group</b>	there are many BZD formulations on the market such as hypnotics like temazepam, ant-anxiety drugs like oxazepam, alprazolam, and anti-seizure medication such as diazepam (valium). The non-benzodiazepines zolpidem, zopiclone, eszopiclone, and zaleplon ("Z-drugs") are mainly prescribed as hypnotic medication.
<b>Acute adverse effects on safety</b>	all BZDs and Z-drugs cause sedation, suppression of REM-sleep, memory impairment, impairment of information processing speed, impaired alertness and attention, impairment of visual processes and motor coordination.
<b>Duration of effects after single dose</b>	<p>the pursued effects of the modern hypnotic BZDs and Z-drugs last 8 to 10 hours after ingestion, but it should be considered that both types hypnotics may have residual (hangover) effects, such as somnolence and decreased alertness on the job which is known to cause occupational injuries (Garbarino et al., 2021). Known adverse reactions of Z-drugs are paradoxical reactions with anterograde amnesia. Zolpidem, zopiclone, and eszopiclone are associated paradoxical reactions such as sleep-walking, sleep-driving, and engaging in other activities while not fully awake (FDA, 2019).</p> <p>The peak effects of the anti-anxiety BZD oxazepam are reached in 2-3 hours and the effects usually wear off within 6-8 hours which means that oxazepam needs to be taken 3 times a day when used for anxiety. For alprazolam the effects last 8-12 hours. Most benzodiazepines are designed for short-term (e.g. 5 days) use and in the smallest dose possible. With longer use they carry a significant risk of dependence. In the context of resuming professional duties, it should be considered that it takes about five half-lives for 98% of a drug dose to clear the body, so alprazolam would take up to 4 days to be fully eliminated from the body. The elimination half-life of oxazepam ranges from 4 to 15 hours. Based on these numbers it could take from 20 to 75 hours for all of a dose of oxazepam to be eliminated.</p>
<b>Withdrawal symptoms</b>	discontinuation of BZDs and Z-drugs can cause a withdrawal syndrome. (Heydari & Isfeedvajani, 2013; Schifano et al., 2019). Withdrawal symptoms after longer or heavy use are (rebound) insomnia, anxiety and panic attacks, depression, tremors, delirium or detachment from reality, muscle spasms, convulsions or seizures (after severe misuse), abnormal body sensations, nausea, and strong cravings for the drug (Pétursson, 1994).
<b>Duration of withdrawal symptoms</b>	most common is a short-lived "rebound" anxiety and insomnia, coming on within 1-4 days of discontinuation, depending on the half-life of the particular drug. The second pattern is the full-blown withdrawal syndrome, usually lasting 10-14 days; finally, a third pattern may represent the return of anxiety symptoms which then persist until treatment is instituted (Pétursson, 1994).

Table 13 - Safety hazards related with BZD and Z-drugs use/misuse

### 2.5.2.10 Nitrous oxide (N2O, Laughing gas)

<b>Drugs in this group</b>	Nitrous oxide
<b>Acute adverse effects on safety</b>	transient dizziness, dissociation, disorientation, loss of balance, fainting, impaired memory and cognition - inhaling from a balloon can cause hypoxia.
<b>Duration of effects after single dose</b>	Following one inhalation a euphoric, pleasant, joyful, empathogenic and sometimes hallucinogenic effect is induced within 10 seconds and disappears within some minutes.
<b>Withdrawal symptoms</b>	There is no evidence of withdrawal symptoms after incidental use of low doses of nitrous oxide. However, development of dependence is insidious and this leads to more frequent daily use in higher daily doses and chronic toxicity which is characterised by damage to the nervous system through interference with vitamin B12 metabolism,

	leading to megaloblastic anaemia and subacute degeneration of the spinal cord and peripheral neuropathy which can be invalidating and can be irreversible (Keddie et al., 2018). Use of nitrous oxide is often related to raves and dance parties where many balloons will be inhaled often in combination with other drugs such as MDMA (ecstasy) and alcohol. When there is suspicion that a pilot or ATCO sometimes uses nitrous oxide, further assessment of the use of other drugs is indicated. Pilots and ATCOs should be warned of nitrous oxide's dependence risk and chronic toxicity causing subacute degeneration of the spinal cord and peripheral neuropathy.
<b>Duration of withdrawal symptoms</b>	No withdrawal symptoms observed after incidental use. No data of withdrawal symptoms after frequent and prolonged use.

Table 14 - Safety hazards related with N2O use/misuse

#### 2.5.2.11 Dimethyltryptamine (DMT) and Ayahuasca

<b>Drugs in this group</b>	Dimethyltryptamine (DMT) and Ayahuasca (contains DMT and monoamine oxidase inhibitors that prevent DMT from being broken down in the gut and liver).
<b>Acute adverse effects on safety</b>	Oral dosing of DMT via ayahuasca produces euphoria, floating sensations, vivid hallucinations, altered sense of time, decreases in motor activity, impairment of cognitive function, depersonalization, elevated blood pressure and heart rate, dry mouth, profuse sweating, bizarre behaviours, psychosis, agitation, anxiety, dizziness, rapid eye movements, chest pain, and overwhelming fear which may last for days. Ayahuasca may impair sleep quality and sleep disturbances are common on the night following administration. There is evidence that DMT may play a role in psychotic symptoms (Carbonaro & Gatch, 2016).
<b>Duration of effects after single dose</b>	Synthetic DMT produces effects within 2 to 5 minutes and effects last approximately 15-20 minutes. Plant-based brews, such as ayahuasca, tend to produce effects within 20 to 60 minutes and last up to 6 hours on average (dos Santos & Hallack, 2019). Most tourists participating in a single ayahuasca ceremony perceive this to be harmless. It should, however, be considered that in some cases psychosis can be triggered (dos Santos et al., 2017). Moreover, sleep disturbances after use of ayahuasca are common and therefore it is recommended to observe at least 24 hours "drug-to-aviation duty time" for pilots and ATCOs who are free of psychotic symptoms after trying a single "tourist ceremony".
<b>Withdrawal symptoms</b>	there are no physical withdrawal symptoms after discontinuation of DMT. The only withdrawal symptoms may be psychological, such as cravings to use DMT again (Drug Science UK, 2022). Prolonged DMT use may lead to the development of flashbacks, persistent psychosis, or hallucinogen persisting perception disorder (HPPD), in which one re-experiences hallucinations and the other psychoactive effects of DMT.
<b>Duration of withdrawal symptoms</b>	No evidence-based data available about the duration of psychological symptoms.

Table 15 - Safety hazards related with DMT and ayahuasca use/misuse

#### 2.5.2.12 Volatile Solvents

<b>Drugs in this group</b>	Volatile solvents include a wide variety of inhalable substances that produce mind-altering effects. Examples include toluene, plastic cement, paint, gasoline, paint thinners, hair sprays, and various anaesthetic gases. A subgroup of volatile substances — alkyl nitrites ("poppers")— are used in the dance club scene.
<b>Acute adverse effects on safety</b>	some minutes after inhalation, dizziness, disorientation, and a short period of excitation with euphoria are observed, followed by a feeling of light-headedness and a longer period of depression of consciousness (EMCDDA, 2022). Potentially dangerous delusions can occur, thoughts are likely to be slowed, time appears to pass



	more quickly, and tactile hallucinations are common. Behavioural effects are accompanied by visual disturbances, nystagmus, incoordination and unsteady gait, slurred speech, abdominal pain and flushing of the skin. Drunken behaviour, unexplained listlessness, anorexia and moodiness may result from volatile substance abuse. Higher doses may produce life-threatening effects such as convulsions and coma. Chronic abuse of toluene-containing products and of chlorinated solvents such as 1,1,1-trichloroethane (also known as methyl chloroform), can produce severe organ damage of the liver, kidneys, and brain. Chronic exposure to solvents such as toluene damages the protective sheath around nerve fibres in the brain and peripheral nervous system.
<b>Duration of effects after single dose</b>	ranges from minutes to an hour and is very much dependent of the type and dose of substance that is inhaled ( <a href="https://vsu.mhc.wa.gov.au/about-vsu/effects/">https://vsu.mhc.wa.gov.au/about-vsu/effects/</a> ).
<b>Withdrawal symptoms</b>	When a person addicted to Inhalants suddenly stops using them, withdrawal symptoms may occur, such as hand tremors, irritability and agitation, excessive sweating, tachycardia, runny eyes or nose, nausea, vomiting, headaches, dizziness, insomnia, cravings, hallucinations, anxiety, depression, psychosis, restlessness, mood changes, impaired memory, difficulty concentrating, and anger outbursts.
<b>Duration of withdrawal symptoms</b>	Withdrawal symptoms generally occur within the first 24 to 48 hours after the last use. The duration and severity of symptoms vary from user to user, but most people go through the worst of withdrawal in about a week. Psychological withdrawal symptoms, such as cravings and depression, can last significantly longer than any physical symptoms. Some Inhalant users have reported suffering from psychological withdrawal for months after quitting.

Table 16 - Safety hazards related with DMT and ayahuasca use/misuse

### 2.5.2.13 Conclusion

All drugs mentioned in the present report have acute, prolonged, or residual effects, and/or withdrawal symptoms that may lead to unacceptably high incapacitation risks and are therefore incompatible with flying or ATC duties (table 17).

<b>Psychoactive Substance</b>	<b>PROBABILITY LEVELS OF PILOTS / ATCOS AFFECTED</b>			<b>INCAPACITATION RISK</b>	
	<b>misuse within critical time before or during duty</b>	<b>residual effects during duty</b>	<b>withdrawal symptoms during duty</b>	<b>misuse within critical time before or during duty</b>	<b>duty during withdrawal period</b>
Alcohol	low	Medium	Low	very high	high
Opioids	low	Medium	Low	very high	high
Cannabis	low	Medium	Medium	very high	high
Psilocybin / LSD	very low	Low	Low	very high	high
Ketamine	very low	Low	Low	very high	high
Amphetamines	low	Low	Low	very high	high
Cocaine	low	Low	Low	very high	high
MDMA (ecstasy)	low	Medium	Medium	very high	high
GHB	low	Low	Low	very high	high
BZDs /anxiolytics/ Z-drugs	medium	Medium	Medium	very high	high
Nitrous oxide	low	very low	very low	very high	high

DMT / Ayahuasca	low	Low	Low	very high	high
Volatile solvents	low	very low	Low	very high	high
Addiction to the above-mentioned psychoactive substances has an extremely high incapacitation risk due to frequent use, residual effects, and cravings.					

*Table 17 - Estimated probabilities of cases of affected pilots or ATCOs reporting for duty and estimation of the severity of the resulting incapacitation risk. All estimations are solely based on expert opinion also taking anecdotally and publicly reported cases*

As is shown in table 17, the incapacitation risks associated with use of the psychoactive substances are high to very high. Therefore, identification and treatment of misuse of these substances is an important measure to prevent incapacitation of pilots and ATCOs performing safety-sensitive aviation tasks. In this context, AMEs should develop a pro-active approach which includes informing pilots and ATCOs about the severe consequences of psychoactive substance misuse on the incapacitation risk, exploring misuse risks via history taking, and -when in doubt- further testing and consulting a mental health specialist who is experienced in alcohol and drugs addiction problems. This is even recommended in case an applicant spontaneously mentions that s/he has used “some cannabis” “only once” during a dance party some days prior to commencing duty.

Guidelines and techniques regarding identification of misuse of psychoactive substances and related problems are provided in the MESAFE deliverable D-3.1 Report on the analysis of the suitability of screening and confirmation tests related to misuse of psychoactive substances. Using the guidelines mentioned in this report most cases of misuse problems might be identified or prevented.

Individuals who are found to be addicted to alcohol and/or drugs should be adequately treated and supported to resume their professional duties after they have proven to maintain sobriety for a sufficiently long period (2 years, but based on the individual case this period might be reduced by the National Authority).

## 2.6 Mental incapacitation risk related to biological treatment

As described in section 3.1 of D1.2, the compatibility of biological treatment options for mental disorders with aviation duties depends on the duties, the disorder, the effects of the treatment, and the side-effects of the treatment. As a general rule, such evaluation is best made on an individual basis by a psychiatrist, in cooperation with the AME. The following equation can be used as a basis for evaluating the compatibility with aviation duties: Total compatibility with flight/ATC duties = compatibility of the underlying disorder x compatibility of the biological treatment (risks and side-effects) x benefits of the biological treatment.

This section should be read in conjunction with section 3.1, 3.2 and 3.3 of Deliverable 1.2. Here, we will provide some general guidelines for determining whether a biological treatment is compatible with a class 1 or class 3 certification. These are general guidelines from which deviations may be possible or necessary after careful assessment of the applicant.

### 2.6.1.1 Antidepressants

#### **Selective Serotonin Reuptake Inhibitor (SSRI) and Selective Norepinephrine Reuptake Inhibitor (SNRI) treatment.**

The recommendations made in chapter 3 of D1.2 are also relevant here, so the reader is advised to read this section in conjunction with this chapter 3 of D1.2, especially section 3.1.1.

After starting treatment, for both class 1 and class 3 certificate holders, it is recommended not to perform actual operations as long as the symptoms:

- are not yet completely or almost completely in remission for at least three months (to be discussed at individual-case basis)
- there are side-effects (such as dizziness, nausea, gastro-intestinal problems, sleeping difficulties and tiredness) that may affect operations
- within 4 weeks after a dosage increase.



The three months period was chosen because it needs to be certain that the remission is lasting (and not only reflecting a short period of improvement or even the onset of a manic episode because of underlying bipolarity). If the symptoms are in remission and the prognosis is good, it is recommended that the pilot or ATCO already starts with the necessary training before the actual decision to return to duties is made, so within the three months period. Making steps towards working again can be highly motivating and help to speed up the recovery. Also, the results obtained during training can be informative for the subsequent assessment. For example, if a pilot already started studying emergency procedures after a long period of sick leave, whether or not he could concentrate well on this, is useful information.

For initial applicants of a class 1 or class 3 certificate, it is recommended to take a longer waiting time after remission, at least six months or longer, and only to provide medical certification if the symptoms of the disorder are fully in remission. The reason for this is that the amount of stress during flight school and in the early phases of the career is generally higher than during later career stages, peer-support etc are not yet available to the extent these are available for pilots later during their career, and a prolonged period of sickness during flight school may have adverse career consequences, making it more difficult for people to report sick. Also, for student-pilots there is no occupational physician involved who can monitor well-being in relation to flight duties for a longer period of time. If in an initial applicant a serious mental vulnerability exists, besides formally verifying whether the applicant qualifies for a class 1 or 3 certificate, it may also be the moral responsibility of the AME to inform him or her about the career difficulties he or she may encounter, or refer the applicant to reliable sources of information about both the rewarding but also the challenging elements of a flying career. For initial applicants with mental complaints, it is furthermore important to verify the motivation to start flying. A flying career can be highly rewarding, but it is not the solution for depressed feelings or a feeling of disappointment about one's life so far. Such issues may be better dealt with first during a therapy.

### **Tapering antidepressants**

- The decision to taper or stop treatment should be made by the patient and the treating psychiatrist together. Patients should be informed about the risks of stopping antidepressants suddenly, both in terms of physical symptoms and in terms of relapse risk.

If the antidepressant is being prescribed by a general practitioner, unless the GP is highly experienced with regards to mental health, for class 1 and 3 certificate holders it is recommended to refer the patient to a specialist first. The following recommendations with regards to tapering are made:

- A tapering scheme is made or supervised by a psychiatrist.
- Tapering is performed in slow steps during a longer period of time (three to six months, longer upon indication).
- During and at least two years (this timeframe can be discussed on an individual-case basis) after discontinuation of treatment, regular clinical follow-up is performed, in order to detect a possible relapse early.
- It is recommended not to perform flying duties at least for two weeks after the reduction of a dosage, or when side-effects of the reduction are present.
- It is good to check out on these side-effects actively, by a follow-up appointment, and not just to instruct the patient to call if problems arise.
- Upon indication, the use of tapering strips (which are available for some antidepressants) may be considered, but this is generally not necessary. If using tapering strips is necessary, it is advised not to perform flying or ATC duties during the tapering.

As mentioned in deliverable 1.2, discontinuation of antidepressants can only be considered safe if measures have been taken to mitigate a possible relapse-risk.

Some of the most prominent side-effects during the discontinuation phase may be described by the so-called FINISH acronym (Vinkers et al 2021): Flu-like symptoms, Insomnia, Nausea, Imbalance, Sensory, Hyperarousal. Nevertheless, in most patients, ending SSRI treatment goes without major problems.

### **Tricyclic antidepressants**

The same advises as applicable to SSRI's and SNRI's apply here. Additionally, it is recommended to monitor blood levels periodically. Special consideration should be given to possible anticholinergic side-effects and the sedative effect TCA's may have. Mostly, TCA's are chosen as second line of treatment, and therefore, TCA-treatment may indicate that the underlying disorder is more severe, and that the relapse-risk is higher. Tapering TCA's has been studied less well compared to tapering SSRI's, and good monitoring during a tapering phase is extremely important (Vinkers et al, 2021). It can be considered to consider applicants during the discontinuation phase of a TCA and during the first months afterwards, as unfit.

### **Bupropion**

The same remarks as with regards to SSRI treatment apply here. It should be noted that there is less experience with using bupropion in aviation professionals, and that the data on tapering bupropion in comparison with SSRI treatment are scarce. It could be considered to regard applicants during the discontinuation phase of bupropion and during the first months afterwards, as unfit.

### **Mirtazapine**

Due to its sedative properties, mirtazapine is not a first choice treatment for aviation professionals, and in most cases it will be disqualifying due to its sedative properties, especially if the applicant has to work irregular duties. If there are no side-effects present, the same remarks as with regards to SSRI treatment apply.

### **MAO-inhibitors**

Due to the fact that MAO-inhibitors are usually reserved for the most severe disorders, their considerable side-effects, and their frequent interactions with other drugs, their use will generally not be compatible with class 1 or 3 certification. In case of a prolonged complete remission with no side-effects, certification can be considered, after extensive examination by a psychiatrist.

#### **2.6.1.2 Electro-convulsive therapy**

Both because the severity of the disorders ECT is applied for, and the cognitive side-effects, ECT-treatment should be considered not to be compatible with class 1 or 3 certification.

#### **2.6.1.3 Light therapy**

It is recommended to consider the same recommendations as in case of SSRI use, as far as they are applicable. Practically, it can be considered acceptable when the light therapy is part of a treatment program supervised by a psychiatrist and if all symptoms are in full remission. It is especially important to monitor effects on sleep. In most cases, resuming flying duties will be possible after the treatment had been ended, but in rare cases, e.g. if the treatment is prophylactic and the patient receives it annually, flying during the treatment period can be considered acceptable.

#### **2.6.1.4 Repetitive Transcranial Magnetic Stimulation rTMS**

As this kind of treatment is relatively new, it is advised only to allow certification if

- The rTMS treatment has been finished.
- Symptoms have been in remission for at least three months.
- Good clinical follow up and measures to prevent relapse have been taken.

#### **2.6.1.5 Anti-psychotic treatment**

Due to the severity of the underlying disorders and the fact that most antipsychotics have sedative side-effects, their use should be considered as disqualifying for medical certification. Sometimes atypical antipsychotics are being described off-label for sleeping difficulties. As long as someone suffers a condition requiring antipsychotics to aid sleep, class 1 or 3 certification is generally not possible

#### **2.6.1.6 Stimulants**

Due to the short half-life, the rebound effect often experienced and the fact that these drugs are prescribed for concentration difficulties, they should not be considered compatible with class 1 or 3 certification,

especially not if the applicant is working irregularly. The fact that they may be misused to fight fatigue, is an additional problem.

#### 2.6.1.7 Anxiolytics

All benzodiazepines have sedative side-effects, and therefore, their use is incompatible with flying duties. Continuous benzodiazepine use should be considered disqualifying. From a pharmacological point of view, their use may not be problematic if they are only used long before or after flight duties. Many patients are prescribed a benzodiazepine only to be used in case of anxiety attacks or when feeling very tense. However, the presence of a disorder requiring benzodiazepines for anxiety attacks or feeling highly emotional should be considered disqualifying. Only occasional use of a benzodiazepine after flight duties or long before to aid sleeping, may be considered acceptable for certification in some cases. In these cases, the risk is comparable or lower than moderate alcohol use.

#### 2.6.1.8 Brain surgery

A status after brain surgery for a mental disorder should be considered disqualifying, as there is little experience with this kind of treatment and it is usually reserved for treatment-resistant cases.

#### 2.6.1.9 Mood-stabilisers

Given the disorders they are being prescribed for, and their considerable side-effects, the use of mood-stabilisers will generally be regarded to be disqualifying. Only in very rare circumstances, exceptions can be considered, e.g. if the original symptoms were relatively mild, if the symptoms have been in remission for a long time (years), and if there are no side-effects.

## 2.7 Mental issues after an incident/accident

As extensively stated in section 3.8 of the MESAFE deliverable D1.1 Report on the review of diagnostic measures", not all mental disorders are featured by abnormal, unpredictable and deviant behaviours. Some of them are featured by maladaptive psychophysiological reactions to life changing events and stressors.

After accidents and incidents pilots and ATCOs can become greatly affected, or sometimes the opposite is the case when they are apparently not affected at all. Those at the sharp-end are in fact very often the last defence and if this defence fails the label human error often comes into play. There is a kind of assumption within pilots and ATCOs training: that if they follow rules and procedures, then they will not have an accident. So if something happens they will take the blame.

Having an accident impacts the body with the release of stress hormones. Most people react differently to the same situation and it's hard to predict how one will react. In general, the state of the witness depends on how serious the accident or incident was. Some may be traumatized, some may feel guilty, some might be frightened or in shock and some not very much affected at all. Incidents and accidents may represent a risk factor when a mental disorder or comorbid mental disorders pre-exist.

When it comes to the assessment of the mental incapacitation risk, data should be collected about recent incidents and accidents as well as their post-traumatic effects and how they might impact on mental health, including potential impact on pre-existing mental disorders, if present.

People, in fact, have a different susceptibility and vulnerability to the condition of stress, also in relation to the greater or lesser direct involvement in the traumatic experience. However, it has been established in several studies that even mediated exposure can generate post-traumatic stress disorder (PTSD) conditions. See the MESAFE deliverable D-1.1 Report on the review of diagnostic measures for the description of the PTSD symptoms. Being a condition of complex mental distress and deriving from multiple factors, both personal and environmental, the diagnosis of PTSD is not univocal or simple and is generically referred to as "the condition of acute stress that occurs following exposure to a traumatic event". Among the factors that certainly contribute to the development of different levels of PTSD, there are the specific characteristics of the event that causes it and the degree or mode of exposure of the victim, the characteristics of individuals, in terms of their medical, mental and family history, the modalities of intervention in the post-trauma period.

Some victims manifest states of anxiety and bad memories that are resolved with proper treatment and with time. At the other extreme, however, there are individuals in whom the traumatic event causes long-term negative effects.

According to the US National Institute of Mental Health (NIMH), the diagnosis is not always made systemically, and in many cases PTSD patients are treated only for the most purely physical symptoms, without adequate consideration of the overall picture of symptoms. For the purposes of aeromedical assessment of mental fitness for Class I and Class III, it is important to check, among other things, whether the following symptoms of PTSD are present:

- Intrusion episodes: People with PTSD have sudden memories that manifest themselves very vividly and are accompanied by painful emotions. Sometimes, the experience is so strong that it makes it seem to the individual involved that the traumatic event is repeating itself.
- Avoidance: The individual with PTSD tries to avoid contact with anyone and anything that leads them back to trauma. Initially, the person experiences an emotional state of disinterest and detachment, reducing his capacity for emotional interaction and managing to conduct only simple and routine activities. The lack of emotional processing causes an accumulation of anxiety and tension that can become chronic, leading to real depressive states.
- Hypersensitivity and hypervigilance: People with PTSD sometimes act as if they are constantly threatened by trauma. They react violently and suddenly, cannot concentrate, have memory problems and constantly feel unsafe. Sometimes, to alleviate their state of pain, people turn to alcohol or drug consumption. A person with PTSD may also lose control over their lives and therefore be at risk for suicidal behaviour.
- Attitude towards work: People with PTSD sometimes complain of insecurity in carrying out their work. It is also important to consider whether the person with PTSD feels confident in continuing their work or whether they do not prefer to change roles.

## 2.8 Risk of lack of self-declaration

As discussed in section 3.6 of the MESAFE deliverable D1.1 Report on the review of diagnostic measures, for many mental disorders denial is a relatively frequent symptom leading to a reduced rate of self-declaration. So, the safety assumption according to which an applicant suffering from a mental health disorder will seek help and self-declare her/his condition might fail.

Risk factors for lack of self-declaration are:

- Feelings of shame and guilt in the individual
- Concerns for unsuccessful treatment/recovery
- Concerns for loss of licence
- Impaired self-awareness
- Underestimation of the negative effects of mental discomfort on mental functions
- Stigmatising culture in social and family environment
- Blame-culture towards mental disorders in the organizational environment

Indeed, self-declaration of mental discomfort helps prevent that mental issues escalate into negative effects for safety and for the health of people suffering from them. The risk of lack of self-declaration of mental discomfort may be mitigated by:

1. Detection of signs and symptoms of mental issues by the AMEs
2. History taking by the AMEs
3. Collecting relevant documentation by the AMEs
4. A supportive and just-culture oriented environment towards mental health and psychological discomfort
5. Peer support

The first 3 are implemented into psychodiagnostic guidelines in section 4.6 of this document. The fourth and the fifth will be addressed in the next tasks of the MESAFE project.

## 2.9 Wrap-up and take-home messages

Psychotic, neurocognitive, mood and cluster B personality disorders are related to the highest incapacitation risk. However, in order to determine the incapacitation risk, it is advisable to not just look at the disorder that has been diagnosed. It is better to look at the actual symptoms and, most importantly, to the mental functions that have been impaired.

Disturbances in the following mental functions can be considered as incapacitating: general aspect and self-care, consciousness, thought, intelligence and memory, behaviour, speech, mood and affect, perception, judgement and motivation, psychomotricity, attention, self-awareness, introspection and insight. Describing personality traits by terms of personality disorders is not advisable. Instead, in the routine screening and follow-up of aviation professionals, it might be better to analyse someone's coping.

There are some features of mental status disturbances that are easily and reliably detectable by physicians that do not have a background in mental healthcare by means of observation and targeted questions. However, some features of mental status disturbances might be hardly detectable by physicians that do not have a background in mental healthcare by means of observation and targeted questions. In these situations, referral to the MHS might be necessary.

When determining the relapse or recurrence risk in the individual patient, it is advised to make a total risk estimation based on applicable epidemiological risk factors, previous disease episodes, personal factors (both protective and risk factors) and comorbidity.

Acute as well as residual effects of alcohol and withdrawal after excessive alcohol use can result in incapacitation to perform aviation duties.

All drugs mentioned in the present report have acute, prolonged, or residual effects, and/or withdrawal symptoms that may lead to unacceptably high incapacitation risks and are therefore incompatible with flying or ATC duties. Therefore, identification and treatment of misuse of these substances is an important measure to prevent incapacitation of pilots and ATCOs performing safety-sensitive aviation tasks.

Guidelines and techniques regarding identification of misuse of psychoactive substances and related problems are provided in the MESAFE deliverable D-3.1 Report on the analysis of the suitability of screening and confirmation tests related to misuse of psychoactive substances. Using the guidelines mentioned in this report most cases of misuse problems might be identified or prevented.

The compatibility of biological treatment options for mental disorders with aviation duties depends on the duties, the disorder, the effects of the treatment, and the side-effects of the treatment. Tapering or stopping treatment is a complex process with severe implications as detailed in 2.6.1.1 and consequently should be made by the patient and the treating psychiatrist together giving proper consideration to the principles detailed in section 2.6.1.1. As a general rule, all evaluations are best made on an individual basis by a psychiatrist, in cooperation with the AME.

Incidents and accidents may represent a risk factor when a mental disorder or comorbid mental disorders pre-exist. When it comes to the assessment of the mental incapacitation risk, data should be collected about recent incidents and accidents as well as their post-traumatic effects and how they might impact on mental health, including potential impact on pre-existing mental disorders, if present.

For many mental disorders denial is a relatively frequent symptom leading to a reduced rate of self-declaration. Possible barriers to manage the risk of lack of self-declaration of mental discomfort are necessary.

For the scope of MESAFE, the following take-home messages can be taken into consideration:

Take home ID	Take home message
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2.1	<p>To address the safety impact of mental disorders it is recommended to:</p> <ul style="list-style-type: none"> <li>• examine the mental status and detect potential alterations of general aspect and self-care, consciousness, thought, intelligence and memory, behaviour, speech, mood and affect, perception, judgement and motivation, psychomotricity, attention, self-awareness, introspection and insight.</li> <li>• address the risk of recurrence/relapse of mental disorders' symptoms, risk related to substance abuse, risk related to biological treatment, mental issues after an incident/accident, risk of lack of self-declaration</li> </ul> <p>The referral to the mental health specialist might be necessary.</p>
2.2	<p>When determining the relapse or recurrence risk in the individual patient, it is advised to make a total risk estimation based on applicable epidemiological risk factors, previous disease episodes, personal factors (both protective and risk factors) and comorbidities.</p>
2.3	<p>AMEs should develop a pro-active approach which includes informing pilots and ATCOs about the severe consequences of psychoactive substance misuse on the incapacitation risk, exploring misuse risks via history taking, and -when in doubt- further testing and consulting a mental health specialist who is experienced in alcohol and drugs addiction problems.</p>
2.4	<p>After starting biological treatment for mental disorders, for both class 1 and class 3 certificate holders, it is recommended not to perform actual operations:</p> <ul style="list-style-type: none"> <li>• as long as the symptoms are not yet completely or almost completely in remission for at least three months (to be discussed at individual-case basis)</li> <li>• as long as there are side-effects (such as dizziness, nausea, gastro-intestinal problems, sleeping difficulties and tiredness) that may affect operations</li> <li>• within 4 weeks after a dosage increase.</li> </ul> <p>For initial applicants of a class 1 or class 3 certificate, it is recommended to take a longer waiting time after remission, at least six months or longer, and only to provide medical certification if the symptoms of the disorder are fully in remission.</p> <p>As a general rule, such evaluation is best made on an individual basis by a psychiatrist, in cooperation with the Aeromedical Examiner.</p>
2.5	<p>The decision to taper or stop treatment should be made by the patient and the treating psychiatrist together. The following recommendations with regards to tapering are made:</p> <ul style="list-style-type: none"> <li>• A tapering scheme is made or supervised by a psychiatrist.</li> <li>• Tapering is performed in slow steps during a longer period of time (three to six months, longer upon indication).</li> <li>• It is recommended not to perform flying duties at least for two weeks after the reduction of a dosage, or when side-effects of the reduction are present.</li> </ul> <p>It is good to check out on these side-effects actively, by a follow-up appointment, and not just to instruct the patient to call if problems arise.</p>
2.6	<p>Incidents and accidents may represent a risk factor when a mental disorder or comorbid mental disorders pre-exist. Adequate check of the presence of post-traumatic symptoms should be implemented: among physical symptoms, it is important to check, among other things, whether intrusion, avoidance and hypersensitivity symptoms are present. It is also important to evaluate whether the person with PTSD feels confident in continuing their work or whether they do not prefer to change roles.</p>
2.7	<p>Possible barriers to manage the risk of lack of self-declaration of mental discomfort include:</p> <ul style="list-style-type: none"> <li>• Detection of signs and symptoms of mental issues by the AMEs</li> <li>• History taking by the AMEs</li> <li>• Collecting relevant documentation by the AMEs</li> <li>• Peer support</li> <li>• A supportive and just-culture oriented environment towards mental health and psychological discomfort</li> </ul>

Table 18 - Take-home messages on mental health and aviation safety

### 3. The Mental incapacitation risk assessment

This section provides a review of the incapacitation risk levels related to mental disorders, including the definition of low/medium/high incapacitation levels. In this section, the MESAFE mental incapacitation risk assessment methodology will be presented. The proposed methodology implements the knowledge about mental disorders, presented in chapter 1, into a risk assessment approach.

This methodology is a way to address the questions: (i) “how can the safety impact of mental disorders be assessed in quantitative terms?” and (ii) “how to identify the applicants with mental pathologies who have a higher risk of incapacitation and to quantify that risk?”, which are included in the EASA technical specifications of the project.

#### 3.1 Current aeromedical incapacitation risk assessment methods

Prevailing methods to estimate the incapacitation risk of aircrew caused by medical events are generally based on expert opinion and/or on the principles of the 1% rule, as developed by ICAO (ICAO, 2012). While evidence and arguments used for expert opinion are diverse and difficult to collect, the principles of the “1% rule”, discussed below, are clearly described.

##### 3.1.1 The 1% rule

In accordance with the acceptable risk of incapacitation of flight crew caused by medical events resulting in a fatal accident by several member states, ICAO has set their target all cause maximum fatal accident rate at 1 in  $10^7$  flying hours, with human “failure” constituting 1/10 of the risk and human failure caused by medical incapacitation comprising 1/10 of the human failure risk, which makes  $1/10 \times 1/10 = 1/100$  of the total risk. This means that medical incapacitation should not result in a fatal accident more often than 1/10<sup>9</sup> hours. Based on these assumptions, a pilot flying a two-pilot aircraft can have an incapacitation risk of no more than 1/10<sup>6</sup> hours, and the target medical cause fatal accident rate of no more than one in 10<sup>9</sup> hours will be achieved, because the presence of a second pilot reduces the risk by a factor of 1000. This is because of the following assumptions:

- In a multi-pilot aircraft only 10% of flight time is critical (risk reduced by a factor of 10) as incapacitations are assumed to occur randomly. Therefore only 1 in 10 in-flight incapacitations will occur during a critical stage of flight (take-off and landing) and thus pose a flight safety risk.
- Only one in 100 incapacitations occurring at a critical stage of flight is likely to result in a fatal accident (risk further reduced by a factor of 100).
- Therefore, the total risk reduction with the addition of a second pilot is  $1/10 \times 1/100 = 1/1\,000$ , i.e., the risk is 1/1000 of the risk of single pilot operations.
- For a pilot with an incapacitation risk of one in 10<sup>6</sup> hours, a second pilot therefore reduces the risk of a fatal accident from medical pilot incapacitation from 1 in 10<sup>6</sup> hours to 1 in 10<sup>9</sup> hours.

An incapacitation rate of 1:10<sup>6</sup> hrs approximates to a rate of 1% (or 1:100) per annum, assuming that there are 8 760 - close to 10 000 (or 10<sup>4</sup>) - hours in one year. This formed the basis of the ‘1% rule’, which was (and is) widely used in assessing medical risk in aviation.

Considering the acceptable risk of incapacitation of flight crew caused by medical events, ICAO Doc 8994 states that “a pilot flying a two-pilot aircraft can have an incapacitation risk of no more than one in 10<sup>6</sup> hours, and the operation will achieve the target medical cause fatal accident rate of no more than one in 10<sup>9</sup> hours, since the presence of a second pilot reduces the risk by a factor of 1000” (ICAO, 2012). Since it was assumed that there are 8760 hours in a year ( $\sim 10^4$ ), the acceptable annual medical event rate to meet this target is 1% per year ( $10^4 \times 10^2 = 10^6$ ). This formed the basis of the ‘1% rule’, which was (and is) widely used in assessing medical risk in aviation. However, it should be considered that the 1% rule has significant limitations. It is based on a series of assumptions only relevant to short (1 hour) flights with critical flight times limited to take-off and landing (6 min). Moreover, medical events are assumed to result in complete incapacitation of



one pilot and it is assumed that a co-pilot could safely deal with incapacitation of the other pilot, occurring during a critical period of landing and take-off, in 99 times out of 100. It assumes that an incapacitation occurring outside the 6 minutes of safety critical phases of flight poses no safety risk with the other pilot expected to take over and land the aircraft safely in all cases. The “1% rule” cannot apply to a solo pilot flying in public transport operations, because it is derived from two pilot operations and the availability of a second pilot to take over in the event of one pilot becoming incapacitated.

Despite these constraints, the “1% rule” has become a commonly used tool for aeromedical risk assessment in flying operations. It should be considered that the rule is based on contentious assumptions that only allow a prediction of the risk of complete incapacitation during the take-off and landing phase of flight. Therefore, the “1% rule” might be applicable to the risk of acute events, such as sudden death, loss of consciousness, or complete loss of functioning by cardiovascular, cerebrovascular, neurological, or thrombo-embolic disorders.

For risk prediction of other causes and other levels of incapacitation, ranging from subtle to complete, the “1% rule” is less suitable. This is particularly true for mental disorders. Mental health events may lead to the full range of incapacitation levels and may threaten flight safety throughout the entire flight. E.g. suicide by aircraft has occurred during cruise flight; or a pilot with aggressive behaviour or having a panic attack can interfere with normal flight operations during the entire flight. For these reasons it is recommended to explore alternatives based on modern risk management principles for estimating incapacitation risks related to mental health.

### 3.1.2 Modern Risk Management: Risk matrices

Risk management in many safety-critical fields, such as aerospace engineering, is based on the principle that the assessment of risk involves the probability of an occurrence and the potential consequences of any event. This led to the development of risk matrices, which plot the potential operational impact of an event (risk severity) against the probability of occurrence of the event.

In their Safety Management Manual Doc 9859, ICAO (2018) advocates and explains these principles. An example is a 5x5 risk matrix as described in Doc 9859 shown in Figure 1.

Risk Probability		Risk Severity				
		Catastrophic A	Hazardous B	Major C	Minor D	Negligible E
Frequent	5	5A	5B	5C	5D	5E
Occasional	4	4A	4B	4C	4D	4E
Remote	3	3A	3B	3C	3D	3E
Improbable	2	2A	2B	2C	2D	2E
Extremely Improbable	1	1A	1B	1C	1D	1E

Figure 1 - 5x5 Risk Matrix showing the risk probability and the risk severity (ICAO, 2018).

The five severity levels in fig. 1 are defined as:

- Catastrophic: multiple fatalities – equipment destroyed;
- Hazardous: crew cannot perform their tasks, serious injury, major damage;
- Major: significant reduction in safety margins, serious incident, injury to persons;
- Minor: Nuisance, operating limitations, use of emergency procedures, minor incident;
- Negligible: no significant consequences.

Colours indicate the levels of tolerability (acceptability) of the risk: red = intolerable; yellow = tolerable with safety risk mitigation; green = acceptable. According to the ICAO Safety Management Manual (ICAO, 2018) recommended consequences (actions) related to each level of tolerability are:

- Intolerable: Take immediate action to mitigate the risk to tolerable or stop the activity.



- Tolerable: Can be tolerated based on safety risk mitigation. Management decision to accept the risk.
- Acceptable: Acceptable as is. No further safety risk mitigation is required.

Based on the principle that the assessment of risk involves the probability of an occurrence and the potential consequences of any event, risk matrices allow a more detailed risk assessment than the one-dimensional “1% rule.” These matrices can provide a semiquantitative assessment of the flight safety and operational impact of a broad spectrum of medical conditions with variable probabilities of occurrence.

A single risk matrix cannot reflect the operational impact of a medical event for all aircrew and ATCOs roles. To reflect the operational impact of a medical event incorporating different operational roles, a series of risk matrices that reflect the varying operational risk pertinent to specific aircrew/ATCO role should be developed.

The implementation by organisations of formal risk management programmes which include risk identification, quantification and mitigation was adopted by medical management teams, including the International Space Station Multilateral Space Medicine Board, which incorporated a risk matrix approach to assessing risk for certification of Space Station crewmembers (Gray G. *et al.*, 2019).

The following sections describe an approach to aeromedical risk management which incorporates risk matrices and how they can be used in aeromedical decision-making with respect to mental incapacitation risk. The proposed approach aims at integrating the aeromedical mental health assessment into the overall framework of the aeromedical risk assessment process of health problems.

## 3.2 The MESAFE mental incapacitation risk assessment methodology

This section implements the aforementioned approach into a methodology for mental incapacitation risk assessment. This methodology is composed of the following activities:

- Activity 1: identify the “**mental incapacitation events**”
- Activity 2: decide what **professional roles** to consider
- Activity 3: define **severity** levels
- Activity 4: define the **probability** levels
- Activity 5: develop the **risk matrix** for each mental incapacitation event per each professional role
- Activity 6: identify the **acceptable** risk level

### 3.2.1 The mental incapacitation events

The mental incapacitation events are psychopathological symptoms potentially impacting the safety of flight and air traffic control operations. The proposed list of mental incapacitation events is based on some alterations of mental functions, as presented in the section 2, and includes:

- Suicide
- Murder-suicide
- Aggressive behaviour
- Agitation
- Intrusive thoughts - compulsions
- Depersonalization - derealisation
- Reduced alertness and executive functioning
- Panic attack
- Somatic symptoms (not caused by an unrelated physical disease)
- Hallucinations
- Delusions

As anticipated, they are NOT mental disorders’ diagnoses-based. Rather, they are based on psychological functions’ alterations and consequent hazardous behaviours.

### 3.2.2 Professional roles

In the MESAPE project we are addressing classes 1 and 3 of aeromedical certification. The following roles will be taken into account:

- CLASS 1
  - Single pilot
  - Captain /First officer
- CLASS 3
  - ACC/TMA ATCO
  - Tower ATCO / Rtower ATCO

From a mental incapacitation risk perspective, single pilots have a higher attributable risk than Captains/First Officers working in a multicrew operational environment. Controllers are considered to have an attributable risk equivalent to professional pilots.

### 3.2.3 The severity levels

The mental incapacitation events have an impact on safety. However, this impact is not the same for all the events. To measure the safety impact of mental incapacitation events, severity and probability levels have to be defined.

The example of ICAO (2018) shown in figure 1 is a generic matrix derived from risk management of mechanical failures which can be used and adapted for management of medical incapacitation risks. The generic example version uses five severity levels. When determining the consequences of a medical event on flight safety, a classification in 4 severity levels may also be considered and is recommended by some military organisations (RCAF, 2020; USAF, 2020). The classification of the Royal Canadian Air Force (RCAF, 2020) and Gray et al. (2010) leads to four classes of severity levels. For each class of medical event, the probable outcome is based on evaluation of three variables: (a) the impact on the flight operation and flight safety, (b) the effect on the operational performance of the individual crew member, and (c) the requirement for medical attention (RCAF, 2020; Gray et al., 2010). The following severity classes are defined:

- Class 1 events:
  - a) minimal or no operational impact; no risk to flight or mission safety.
  - b) low or minimal negative effects on performance.
  - c) routine medical follow-up required.
- Class 2 events:
  - a) may compromise the flight operation; no risk to flight or mission safety.
  - b) moderate negative effects on performance.
  - c) requires post-flight medical follow-up.
- Class 3 events:
  - a) may result in flight safety hazard and high probability of compromising the flight operation, or mission.
  - b) major negative effects on performance.
  - c) requires immediate medical attention.
- Class 4 events:
  - a) Likely to result in flight safety critical event and termination of the flight, or mission.
  - b) total incapacitation of the crew member.
  - c) Requires immediate advanced medical care.

It should be considered that the above-mentioned classification is made for risk assessments related to military missions, in which aircrew might be wounded or otherwise incapacitated. In that case, the urgent need for medical care might be a reason to abort the mission (while flight safety may not be compromised). These military risk matrices are also aimed to estimate the risks of mission failures, whereas risk assessment in civil aviation is to estimate the safety risk of flight operations. It is therefore, considered not relevant to

include the requirement for medical care of the incapacitated crew member in the severity levels to be used in civil aviation (medical care can be provided after landing).

For reasons of uniformity and practical civil aeromedical use the generic ICAO 5x5 matrix is recommended giving a wider range of relevant severity levels (and giving a wider range of relevant probabilities, see section 3.2.5). The recommended severity levels are:

- Catastrophic: multiple fatalities – equipment destroyed;
- Hazardous: crew cannot perform their tasks, serious injury, major damage;
- Major: significant reduction in safety margins, serious incident, injury to persons;
- Minor: Nuisance, operating limitations, use of emergency procedures, minor incident;
- Negligible: no significant consequences.

It should be considered that the potential consequences of a medical event may differ for single pilot, multi-crew, or ATC operations. E.g. in most ATC operations there are opportunities to quickly replace an ATCO suffering from a medical event. It is recommended to define different severity levels which are tailored to single pilot, multi-crew, and ATC operations.

### 3.2.4 The probability levels

The probability (also called likelihood) of a technical failure to occur in an aircraft is generally expressed as the risk per flight hour (e.g. “occurrence of major failure conditions must be between  $10^{-5}$  and  $10^{-7}$  per flight hour” - CS 25.1309), but the risk and consequences of technical failures is not 1:1 comparable to that of incapacitation of human beings, such as pilots and ATCOs (e.g. unlike technical failures, human failures may or may not happen during activity and the range of incapacitation levels is likely to be broader than that of technical failure levels).

An important consideration is that expression of risk per flight hour is less practical and less insightful for the medical risk assessor. For many medical disorders epidemiological data are available about prognosis and risks of complications or deterioration of the condition. These epidemiological data are generally expressed as the percentage of risk per year, per 5 years, or per 10 years. These data are perfectly suited to be used for an assessment of the probability of a medical event occurring related to the medical condition under review. The probability of a medical event is in that case derived from a careful evidence-based review of available medical literature, along with best estimates from clinical experts.

This approach is also used by the aeromedical risk assessments in the military aviation environment (RCAF, 2020; USAF, 2020; Gray et al., 2019) and space missions (Gray et al., 2010). In the military and space settings the probability for each potential event is for example categorized as: (i) Likely – risk for an event greater than 2% per year; (ii) Possible – risk for an event 1-2% per year; (iii) Unlikely – risk for an event 0.5-1% per year; (iv) Highly unlikely – risk for an event less than 0.5% per year.

If there are multiple potential medical events related to the condition, a best estimate for the probability of each separate event can be included in the matrix, but in that case it might be practical as well as prudent to take the risk of the condition with the highest probability of a medical event as leading to estimate the overall incapacitation risk.

The above categorization of probability levels is originally based on a standard classification of cardiovascular risk stratification based on risk factors, such as the Framingham risk estimation (D'Agostino et al. 2008) which classifies risk as low (<10%/10 years or <1%/year), intermediate (10%–20%/10 years or 1%–2%/year) and high (>20%/10 year or >2%/year). It should be considered that 1) modern cardiovascular risk stratification models use different, and mostly lower, risk percentages (e.g. SCORE2 classifies 2.5%/10 years as low, 2.5-7.5%/10 years as intermediate, >7.5% as high risk; SCORE2, 2021); and 2) for low-impact medical events, some aeromedical organisations may find event rates >2%/year acceptable while in critical military missions, a predicted incapacitation rate of <1%/year may be unacceptably high. This is illustrated by the risk matrix developed by the US Air Force Aeromedical Consultation Service Medical Risk Assessment and Airworthiness Matrix (AMRAAM) (Keirns et al 2022) which uses 5 levels of probability in a 5x4 matrix: frequent (>99%/year); probable (60-90%/year); occasional (10-60%/year); remote (1-10%/year); and improbable (<1%/year). It

should be considered that these probability levels were defined for military missions in which not only flight safety is a factor but also mission effectiveness. In analogy with the AMRAAM risk matrix (Keirns et al., 2022) we propose 5 levels of probabilities:

- Frequent
- Occasional
- Remote
- Improbable
- Extremely Improbable

Based on these principles, the probability levels of mental incapacitation events should measure their potential occurrence number per year, not having to convert to a future expected flight hour level. The estimation should be based on clinical judgement combined with epidemiological data directly, when available.

The probability that a mental incapacitation event would happen depends on:

- presence of one mental disorder or more (comorbidities) and their degree of dangerousness, violation of society standards, statistical deviance, social discomfort, subjective distress, maladaptiveness, irrationality and unpredictability (the 7 mental illness indicators)
- risk of recurrence/relapse
- psychoactive substance abuse
- risks related to biological treatment
- life stressors
- physical health (somatic comorbidity)
- recent incidents/accidents
- risk of lack of self-declaration
- successful treatment and protective factors

These were also highlighted in the MESAFE deliverable D1.1 1 Report on the review of diagnostic measures among the factors to evaluate when making decisions about the certification of mental fitness.

Both probability and severity levels can be lowered by mitigation measures. These will be addressed in task 4 of the MESAFE project.

The above probability (likelihood) categorisation provides together with the classes of severity classification a risk matrix.

### 3.2.5 The MESAFE risk matrix

In 3.1.2, the use of risk matrices has been explained and proposed. To summarize, risk matrices have 3 main advantages over the 1% rule and similar “one-dimensional” acceptable risk assessments:

- The risk matrix visualises several levels of probability, opening up the possibility of assessing events that do not cause full incapacitation, where higher probabilities can be accepted depending on severity.
- The risk matrix visualizes several levels of severity, opening the possibility of assessing different flight safety outcomes of a given event and probability, and is therefore usable for different crew roles and air traffic control operations.
- The risk matrix offers better communication with pilots and ATCOs regarding risk than the 1% rule or other medical risk communication, as the risk matrix is the standardized tool for assessing risk in flight operations both in EASA states and internationally.

A series of risk matrices were developed by the NATO cardiological working group (Gray et al 2019); these risk matrices were particularly suited to establish different acceptable risk levels across different aviation crew roles. This principle can also be used assessing a mental incapacitation event. The USAFSAM Risk assessment matrix (Keirns et al 2022) gathers the risk assessment into one matrix, using the severity axis to

include differences in crew roles. This risk matrix quantifies probability into a larger range from less than 1% to more than 99%. For mental incapacitation events, this might be relevant, as some mental incapacitation events may happen often, thus severity making the most important impact on the final risk assessment.

As anticipated in section 3.2.2, the following professional categories in the mental health risk assessment may form a basis for mitigation strategies where needed:

- Class 1: (i) Multicrew Pilot (First officer & Captain); (ii) Single Pilot;
- Class 3: (i) ACC and TMA; (ii) Tower and Rtower ATCOs.

The difference in redundancy of Multicrew or single pilot, and ACC/TAMA ATCO or Tower/Rtower ATCO may be portrayed in different risk matrices or scored in one single matrix where severity is taken into account. MESAFE proposes a single risk matrix for mental incapacitation events because of the often complex interaction between mental incapacitation events and the situation at hand, unlike, for instance, a cardiological event. The single matrix would use the crew roles as risk reducing or risk mitigation factor where this would be appropriate.

A 5X5 risk matrix is proposed, giving a wider range of relevant probabilities than proposed in Gray et. al. (2019), but also keeping the low-probability categories which are important for very high severity levels such as suicide or murder-suicide. The ICAO and EASA standard risk matrix axis are kept; Risk severity horizontal, and risk probability vertical. The risk probability categories from ICAO are kept, but specified in percentages in order to be able to use epidemiological data directly.

Using the risk matrix requires knowledge of operational effects of mental incapacitation events. Such a risk matrix should only be used by an AME assisted by a qualified Aviation mental health professional and in consultation with operational competence.

Not all conditions may be scored within the annual probability categories on the Y-axis. These are conditions where affecting the flight operation itself is motivated by the mental health. Examples are Murder-suicide or obsessive-compulsive actions related to flight. Such conditions must be scored using a lifetime probability (rather than annual probability) using the same acceptability categories.

The MESAFE matrix for mental incapacitation event risk assessments is presented in Figure 2.

The use of the matrix follows these steps (in the correct order):

- Define possible mental incapacitation events that may affect the ability to perform duties effectively and safely.
- Classify each event into Catastrophic, Hazardous, Major, Minor or Negligeable. Use operational competence to make this assessment, and include the pilot or ATCO him/herself.
- For the mental incapacitation event, find the probability per year using epidemiology if available, and/or clinical judgement based on the history and evaluation of the pilot or ATCO.
- Find the correct colour/score for each mental incapacitation event.

MESAFE MATRIX			Catastrophic - A	Hazardous - B	Major - C	Minor - D	Negligible - E
Risk assessment of mental health			May cause catastrophic event	may cause flight safety critical event	May compromise flight safety	Reduced effectiveness and capacity to adapt to operational requirements	Minimal impact on flight safety
	Frequency per year	Flight hours between each event (approx) *	Total incapacitation	Severe incapacitation	Major decrement on performance	Minor to moderate performance compromise, may continue duties	Minimal impact on performance
Frequent 5	> 1/month	100	5A	5B	5C	5D	5E
Occasional 4	1-10 times	1.000	4A	4B	4C	4D	4E
Remote 3	10-99%	10.000	3A	3B	3C	3D	3E
Improbable 2	1-10%	100.000	2A	2B	2C	2D	2E
Extremely improbable 1	<1%	>1.000.000	1A	1B	1C	1D	1E
*given random onset of event unconnected to flight. If event is connected to flying activity (e.g. Murder suicide or flight anxiety),use career frequency rather than yearly							
	Risk unacceptable					**Operational risk reduction could be co-pilot, backup crew, time window to land helicopter etc. Personal risk factors could be close follow-up by psychologist, peer-support etc. Formalised risk reduction is documented and required in the certificate.	
	Risk unacceptable, but may in some cases be acceptable after thorough review and specific mitigation. A medical board should in such cases be employed**						
	Risk may be acceptable - may require operational and/or personal risk reduction**						
	Risk acceptable						

Figure 2 - The MESAFE Matrix mental event risk assessment

The range of possible problems, or mental health incapacitation events, can be very wide. This applies both in severity and frequency. In order to address this issue, a matrix which allows for a broader range and nuances for evaluations may be employed by adding a colour orange where special and more advanced evaluations are necessary. By also adding frequencies of mental health incapacitations happening several times per year, this matrix may also be used for evaluating milder mental health events which nevertheless may need evaluations as to flight safety. As such evaluations may be difficult, a medical board should in such cases be employed. Figure 2 depicts a matrix where these considerations have been allowed to be met.

### 3.2.6 The acceptable risk levels

Acceptable risk levels are within the green sector.

If the risk score for any mental incapacitation event is not within the green sector, risk mitigation measures should be applied by including occupational role such as dual pilot, redundancy in ATCO workplace and an open exchange of medical information between the clinical, AME, mental health expert and applicant, or other factors. A new score given mitigations can then be applied.

If the final risk score for any of the mental incapacitation events depends on mitigations to be acceptable, the appropriate limitation must be applied on the medical certificate. Mitigation measures may be biological or psychological treatment, special follow up by a mental health professional or AME, or other treatment or observation measures. In addition, changes or safety measures in the Pilot or ATCO's work environment may be put in place.

## 3.3 Wrap-up and take-home messages

The safety impact of mental disorders can be assessed, both in qualitative as well as quantitative terms, by means of a sound risk assessment methodology.

This report proposes a mental incapacitation risk assessment methodology, which is based on recent ICAO provisions. The methodology includes the following principles:

- It is recommended to identify mental incapacitation events, which are not based on mental disorders' diagnoses, but rather based on psychological functions' alterations and consequent hazardous behaviours.
- It is recommended to use a risk matrix approach, in which probability and severity are plotted, for the risk assessment of incapacitation caused by mental incapacitation events. A matrix of 5 severity levels and 5 probability levels (5x5 matrix) is considered to be suited for this purpose.
- it is recommended to express probability levels as percentage of risk/year based on evidence-based epidemiological data and -where necessary- clinical expert opinion.

The probability that a mental incapacitation event would happen depends on several factors as detailed in section 3.2.4 above.

The determination of the acceptability of the risk, and with that the colour associated with each cell of the matrix, requires careful consideration taking into account the type of operation for which the risk is assessed (civil multi-crew ops, civil single pilot ops, ATC ops). From a mental incapacitation risk perspective, single pilots have a higher attributable risk than Captains/First Officers working in a multicrew operational environment. ATCOs are considered to have an attributable risk equivalent to professional pilots.

The risk matrix can act as an important communication tool to be discussed with the applicant, because it is focused on incapacitation events rather than on diagnoses of mental disorders. As already said, under all circumstances, it is important to explain that the incapacitation risk is caused by symptoms of a mental disorder, not by moral weakness, maliciousness, etcetera. A high incapacitation risk due to mental problems does not make someone a 'bad' person. Symptoms cause a safety risk, not the person suffering from them.

For the scope of MESAFE, the following take-home messages can be taken into consideration:

Take home ID	Take home message
3.1	The safety impact of mental disorders can be assessed, both in qualitative as well as quantitative terms, by means of a sound risk assessment methodology.
3.2	<p>Mental incapacitation events are hazardous behaviours due to mental issues. Events to be taken into account include:</p> <ul style="list-style-type: none"> <li>• Suicide</li> <li>• Murder-suicide</li> <li>• Aggressive behaviour</li> <li>• Agitation</li> <li>• Intrusive thoughts - compulsions</li> <li>• Depersonalization - derealisation</li> <li>• Reduced alertness</li> <li>• Panic attack</li> <li>• Somatic symptoms (not caused by an unrelated physical disease)</li> <li>• Hallucinations</li> <li>• Delusions</li> </ul>
3.3	Mental incapacitation events' probability and severity are plotted by means of a 5x5 matrix
3.4	<p>The probability that a mental incapacitation event would happen depends on:</p> <ul style="list-style-type: none"> <li>• presence of one mental disorder or more (comorbidities) and their degree of dangerousness, violation of society standards, statistical deviance, social discomfort, subjective distress, maladaptiveness, irrationality and unpredictability (the 7 mental illness indicators)</li> <li>• risk of recurrence/relapse</li> <li>• psychoactive substance abuse</li> <li>• risks related to biological treatment</li> <li>• life stressors</li> <li>• physical health (somatic comorbidity)</li> <li>• recent incidents/accidents</li> </ul>

	<ul style="list-style-type: none"> <li>• risk of lack of self-declaration</li> <li>• successful treatment and protective factors</li> </ul>
3.5	The determination of the acceptability of the risk, and with that the colour associated with each cell of the matrix, requires careful consideration taking into account the type of operation for which the risk is assessed (civil multi-crew ops, civil single pilot ops, ATC ops).
3.6	From a mental incapacitation risk perspective, single pilots have a higher attributable risk than Captains/First Officers working in a multicrew operational environment. Controllers are considered to have an attributable risk equivalent to professional pilots.
3.7	The risk matrix can act as an important communication tool to be discussed with the applicant, because it is focused on incapacitation events rather than on diagnoses of mental disorders.

*Table 19 - Take-home messages on mental incapacitation risk assessment*



## 4. Psychodiagnostic options for mental incapacitation risk detection

In the previous section, it has been highlighted that clinical judgement should be applied to determine the probability and severity levels of mental incapacitation events. It has also been said that the probability that a mental incapacitation event would happen depends on:

- presence of one mental disorder or more (comorbidities) and their degree of dangerousness, violation of society standards, statistical deviance, social discomfort, subjective distress, maladaptiveness, irrationality and unpredictability (the 7 mental illness indicators)
- risk of recurrence/relapse
- psychoactive substance abuse
- risks related to biological treatment
- life stressors
- physical health (somatic comorbidities)
- recent incidents/accidents
- risk of lack of self-declaration
- successful treatment and protective factors

Mental health specialists have several tools to assess these factors.

What follows provides an extensive review of psychodiagnostic tools currently available to assess mental health, which are clustered by tests, questionnaires and interviews. Psychodiagnostic guidelines for Aeromedical Examiners complement this information. This section provides:

- a description of psychodiagnostic tests including frequency of assessment, cost-effectiveness, comparison with other diagnostic methods used for the respective mental pathology(ies) and availability of state-of-the-art tests at EU Member State level
- an analysis of the ability of psychodiagnostic tests and options to:
  - assess the short-, medium- and long-term evolution of mental pathologies, i.e. risk of recurrence or relapse;
  - prove suitable to operational needs for each class of aeromedical certification and their respective acceptable risk of flight crew incapacitation.

This is the answer to the question: “which diagnostic methods can be used for screening purposes, which for confirmatory purposes, and which for monitoring purposes, according to the class of aeromedical certification?” included in the EASA technical specifications.

Moreover, this section addresses the following challenges reported by AMEs with respect to the current procedures for the aeromedical mental fitness assessment, both for initial applicants and revalidation/renewal (see the MESAFE deliverable D1.1 Report on the review of diagnostic measures for an extensive presentation of the data collected by means of the online survey targeted to AMEs):

- Applicants’ opposing attitudes to disclose information
- Difficulties in identifying symptoms
- Insufficient training on mental health
- Absence of clear, robust, and validated questionnaires and interviews
- Impossibility to access the applicant psychosocial and medical history; no access to earlier AME’s record
- Insufficient cooperation among AMEs and mental health specialists

## 4.1 Types of tests

As explained in section 4.4.1 of the MESAFE deliverable D1.1 Report on the review of diagnostic measures, a macro classification distinguishes between tests of maximum performance and tests of typical performance (Pedrabissi and Santinello, 1997).

Maximum performance tests are those in which right and wrong answers are presented and in which, usually, there is a time limit. The person is asked to give the best of him/herself, and the goal is to check how much he is able to solve a certain task. A classic example of a maximum performance test are the intelligence and aptitude tests that are centred on reasoning skills, but also attention tests (for example, barrage tests) and memory tests (re-enactment, repetition, narrated memory). These tests are used to evaluate the person's cognitive functioning and are here presented as "Cognitive tests" (section 4.1). The timing of administration is extremely variable, ranging from tests that can be very fast, such as the MMSE-2 - Mini-Mental State Examination, 2nd Edition -, which requires from 5 to 20 minutes depending on whether you use the short, standard or extended form, and tests which take a long time, as in the case of the WAIS-IV - Wechsler Adult Intelligence Scale, Fourth Edition (2013) -, which requires about 90 minutes. The timing of administration is fundamental and to be considered according to the context and light conditions.

The performance tests are those aimed at knowing the typical behavioural of the person, so they do not examine what s/he is able to do but what s/he does in everyday life. Since the theoretical basis underlying these tests is broader and more heterogeneous (this includes tests of personality, temperament, preferences, values, etc.) there is less agreement on what are the characteristics detected by a performance test. Unlike maximum performance tests where it is not possible to distort (unless the person wants to simulate a disorder of the cognitive sphere), in the tests of typical performance it is possible (and probable) that people distort trying to make believe that a certain trait is more or less present in them than it actually is. For this reason, in the performance tests (self-report) scales of validity are reported, to understand if the person has distorted in an improved or worsening sense or if he has responded at random. Clearly in a maximum performance test you cannot make believe that you have a greater ability than you have. Performance tests are generally self-report (e.g., MMPI-2), but can also be interviews (e.g., SCID interviews). In both cases, the person speaks directly to the assessor and chooses how much to open, what to share and what not. The answers are given on the basis of awareness: in other words, the person reads the question, understands it and consciously chooses what to answer (lies might be a possible option). So, when choosing to work with a self-report, it is essential that a relational context has been created such that the person feels he can trust and in which he feels safe, precisely to avoid those attitudes just described. In addition, following the guidelines indicated in the manuals regarding the rules of administration is essential to better manage the response behaviour of the person. Very often it happens that, for a long time, some tests in which it is explicitly indicated to supervise the administration phase, are left to the person, giving the opportunity to do them alone. It is not the best way to manage the administration: people, in fact, can do them in different moments or distract themselves with phone calls and the internet, or not have something clear, needing explanations.

Among the typical performance tests there are personality tests and psychodiagnostic tests, which will be respectively presented in sections 4.2 and 4.3.

Personality tests are not meant to diagnose and assess mental disorders. Indeed they can be used in the framework of the selection process of pilots and ATCOs to evaluate their fitness with the required organizational profiles they are applying for.

Psychodiagnostics Tests (i.e., Minnesota Multiphasic Personality Inventory (MMPI-A), Rorschach Test, Beck Depression Inventory (BDI), Anxiety Inventory) are meant to assess the presence of a mental disorder, or the severity of its symptoms. Among these tests there is the MMPI and MMPI-2, which have accumulated seven decades of validation with pilots and other aerospace personnel. Valid pilot and ATCOs norms are available for the MMPI-2 which is recommended by the FAA for pilot and ATCOs assessments (FAA, Guide for Aviation Medical Examiners, MMPI-2 Versus MMPI-3). Indeed, it is important to use tests that are validated in the reference aviation population when assessing mental health of pilots and ATCOs for the sake of mental fitness certification.

#### 4.1.1 Cognitive tests

Scientific evidence supports the generally accepted opinion that the risk of mild cognitive impairment increases with age, although there is evidence suggesting that declines in cognitive abilities between the age of 40 to 65 are small. However, there is considerable inter-individual variation in cognitive functioning of individuals in this age group. Because mild cognitive decline might lead to subtle incapacitation during performance of safety-sensitive tasks in aviation, it is important to screen for any cognitive decline related to the performance of safety-sensitive tasks in aviation.

As explained in section 4.6 of the MESAFE deliverable D1.1 Report on the review of diagnostic measures, although cognitive test batteries are useful to determine whether a candidate has the cognitive abilities to become a good pilot or ATCO (select-in “the right stuff”), it is not possible to decide about an applicant’s cognitive fitness for the job solely on the basis of the score achieved in a neuropsychological, or neurocognitive test battery (Mackenzie Ross, 2017; EASA-MESAFE, 2022; p. 85-87). Neuropsychological assessment has never been developed as a ‘pass’ / ‘fail’ instrument to screen individuals for highly skilled jobs.

To detect possible neurocognitive shortcomings the recommended aeromedical examination should be based on the two most important pillars: 1) the AME interview (history taking), and 2) Operational information: occupational history and functioning of the pilot or ATCO in the event of incidents and accidents and during simulator sessions, proficiency checks and training courses.

On the other hand, the results of cognitive tests or battery of cognitive tests can provide useful background information in the process of deciding on the medical certification of an individual who has been referred by the AME/AeMC for a specialist evaluation.

There are currently no cognitive tests available that are suited to predict flight or ATC performance or to identify subtle impairments in cognitive functioning of pilots or ATCOs who show no discernible symptoms of (mild) cognitive decline. Meaningful interpretation of results of individuals who have no discernible symptoms is difficult due to lack of validated cut-off points that predict safe performance. It is emphasized that neurocognitive or neuropsychological tests performed as a routine measure without indication (e.g. suspicion of the AME) or clinical question will not provide useful results in the context of determining pilot’s or ATCO’s cognitive abilities to safely execute aviation tasks. An AME/AeMC who, based on observations or operational reports, suspects cognitive impairment of an applicant has to refer this pilot or ATCO for neuropsychological assessment by a neuropsychologist, neurologist, or psychiatrist. As part of a specialist examination the applicant’s performance on a cognitive test battery can provide useful information in the process of deciding on the medical certification of the pilot or ATCO. Therefore, cognitive, or neuropsychological tests are useful tools for specialist examination, but not for general screening (EASA-MESAFE, 2022; p.85-87). It is therefore not recommended to use neurocognitive tests to identify mild cognitive impairment (MCI) for the aeromedical screening of pilots and ATCOs who show no discernible symptoms.

It is considered that simulator checks, line checks, occupational history, and peer review provide the best opportunities to detect below standard performance that may be caused by mental problems or neurocognitive impairment. This consideration, initially stated by Evans (2011), is supported by a study group including representatives of ICAO, NASA-Ames, and FAA (Potocko, 2019).

To detect possible neurocognitive shortcomings the recommended aeromedical examination should be based on the two most important pillars (EASA-MESAFE, 2022; p. 85-87):

- The AME interview (history taking; see section 4.6.2), and
- Operational information: occupational history and functioning of the pilot or ATCO in the event of incidents and accidents and during simulator sessions, proficiency checks and training courses (EASA-MESAFE D1.1, 2022; p. 85-87). It is therefore important that the AME is informed about the results of the simulator, line, and ATC checks. However, national and international data protection constraints represent a challenge in implementing exchange of this information.

To achieve a possibility for data exchange between simulator instructors and trainers and the AME, relevant stakeholders, including pilots and ATCOs, should be involved. Considering that privacy laws prevailing in many countries might disallow the exchange of such information, methods to obtain this necessary information are currently still to be developed. In that context, pilots or ATCOs might be mandated to self-report the results of their checks to the AME or -preferably- submit the simulator examiner's report to the AME or Competent Authority of the pilot. Or examiners and trainers might –with explicit informed consent of the applicant– inform the AME or the medical assessor of the Competent Authority of the pilot about any suspicion of MCI that may emerge from the results of proficiency and line checks.

Preferably, instructors and operational examiners should be trained to identify signs of impaired cognitive performance and to discuss their concerns with the pilot in question. They might stimulate the pilot to self-report the problems to the AME/AeMC, or to a Peer Support Programme, or get the pilot's approval by a written informed consent to share the concerns with the AME/AeMC, while guaranteeing strict confidentiality. To detect possible neurocognitive shortcomings, essential cognitive factors of flight performance should be incorporated in the regular mandatory License Proficiency Checks (LPC) or Operator Proficiency Checks (OPC). It is recommended to include tasks demanding a high cognitive effort, such as emergency procedures, and by adding other stressors such as time constraints, the cognitive effort is expected to be very high allowing signs of mild cognitive decline, that in other situations are compensated by experience and automated actions, to become manifest. In the context of designing useful simulator scenarios, a part of the Observable behaviours proposed for the 'pilot instructor and evaluator competency framework' detailed in ICAO Doc9868 (ICAO, 2020) are useful. The use of existing criteria for observable behaviours makes sense because these are already known for many instructors and examiners and more will become familiar with them.

To achieve the above-mentioned recommended practise, it is important to involve simulator instructors/examiners, trainers, pilots, ATCOs, AMEs, and aviation psychologists in designing the procedures and preconditions. The discussions about privacy legislation that will follow will be difficult and challenging, but should be solvable when all parties aim at reduction of flight safety risks.

#### **4.1.2 Personality tests**

As explained in section 4.7 of the MESAFE deliverable D1.1 Report on the review of diagnostic measures, personality tests cannot be used for diagnosing mental disorders. Indeed these assessment tools are measures for personality traits rather than disorders.

##### **4.1.2.1 Introduction to personality**

Personality refers to individual differences in characteristic patterns of thinking, feeling and behaving. The idea of categorizing people by traits can be traced back as far as Hippocrates; however more modern theories have come from Gordon Allport, Raymond Cattell, Hans Eysenck, as follows:

- Biological theories (Hans Eysenck) link genetics with personality traits. e.g. introverts have high cortical arousal, leading them to avoid stimulation.
- Behavioural theories (B.F. Skinner, John B. Watson) consider personality as a result of interaction between the individual and the environment.
- Psychodynamic theories (Sigmund Freud, Erik Erikson) focus on the influence of the unconscious mind and childhood experiences on personality.
- Humanistic theories (Karl Rogers, Abraham Maslow) highlights the relevance of free will and individual experience as well as the need for selfactualization.
- Trait theories (H. Eysenck, Gordon Allport, Raymond Cattell) state that personality is made up of a number of broad traits.

Indeed personality traits are prominent aspects of personality that are exhibited in a wide range of important social and personal contexts. In other words, individuals have certain characteristics that partly determine their behaviour; these traits are trends in behaviour or attitude that tend to be present regardless of the situation.

The Personality profiling has been in common use for over sixty years. Sometimes referred to as psychometric testing or psychological profiling, it is a means of measuring an individual's personality in a particular situation. It is not a measure of intelligence or ability; rather, it measures the likelihood of behaviour. This is grounded on three facts:

- Personality is organized and consistent.
- Personality is generally stable, it can be influenced by the environment.
- Personality causes behaviours to happen.

Many longitudinal studies demonstrated that personality is rather stable, in particular starting from early adulthood, when upper brain regions have matured— e.g., when the prefrontal cortex is able to hold a tight grip on emotions arising from phylogenetically old brain areas (Montag & Panksepp, 2017).

The consistency paradox is the observation that a human being's personality tends to remain the same over time, while their behaviour can change in different situations. Many personality characteristics are relatively constant throughout a person's life, but people can act in all sorts of ways (even ones that seem to be opposite of their personality) in different situations, e.g. even the most even-tempered and easy-going person can be driven to violence when put under enough stress or pressure. But what happens when your job requires you to act against your natural personality for an extended period of time? The costs of acting against your personality are stress and health problems (Balsari-Palsule, 2015).

Each of us has a personality that exhibits persistent patterns over time (patterns that influence our lives). People adapt to their situations and that makes it challenging to predict a given individual's behaviour at a certain moment in time. In other words, personality matters—as do the situations we face.

In the Grant study, for over 75 years, researchers have been following a group of men from the Harvard classes of 1939-1944 (2 were from the U.S. Senate, one served in a presidential Cabinet, and one was President J.F.K.). The men continue to be studied to this day. Three personality traits (Neuroticism, Extraversion, and Openness) exhibited significant correlations across the 45-year interval (Soldz and Vaillant, 1999). The warmth of childhood relationship with mothers matters long into adulthood: men who had "warm" childhood relationships with their mothers earned an average of \$87,000 more a year than men whose mothers were uncaring. Men who had poor childhood relationships with their mothers were much more likely to develop dementia when old (Soldz and Vaillant, 1999). The warmth of childhood relationship with fathers correlated with: lower rates of adult anxiety; greater enjoyment of vacations; increased "life satisfaction" at age 75 (Soldz and Vaillant, 1999).

Under what circumstance can personality change? A Major trauma in life i.e. post-traumatic Stress Disorder PTSD (Arsova et al, 2016).

#### **4.1.2.2 List of selected personality tests**

What follows provides basic information on the following self-report measures for personality traits:

- The California Psychological Inventory (CPI)
- The Dominance, Influence, Steadiness and Conscientiousness Test (DISC)
- Profiles XT
- The Myers-Briggs
- NEO-PI-R
- 16 PF+

The California Psychological Inventory (CPI) measures personality traits including sociability and dominance. It is noted as having more subjective interpretation and needing a psychologist to interpret the results.

The Dominance, Influence, Steadiness and Conscientiousness Test (DISC) measures style of personality and self-image, and is known to be useful for teambuilding, and assessing and addressing cultural fit and chemistry. Below the DISC matrix.

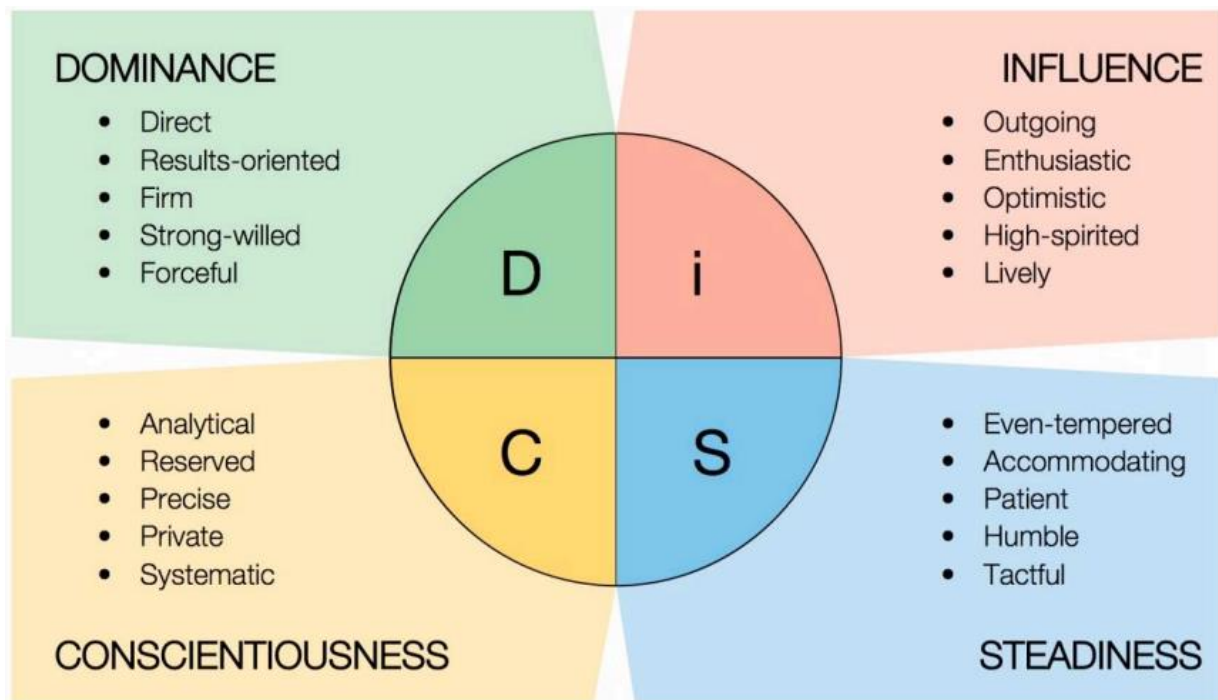


Figure 3 - The Dominance, Influence, Steadiness and Conscientiousness Test (DISC) (Owen et al., 2017)

The Profiles XT measures cognitive skills and job success potential and has been found useful for hiring, comparing jobs and succession planning.

The Myers-Briggs test measures personality type and how an individual processes information, and is best used to understand how one communicates. It is not recommended for selection or for clinical diagnostics. Below the Myers-Briggs Type Indicator.



Manifesting universal values  
and valuing people

Pulling people with ideas  
to an optimistic future

Personal

Logical

SF

ST

<b>ENFJ</b> <b>Teacher</b> Smooth talking charmers. Very inspiring & motivational. Often clergy. People leaders & persuaders. Great salespeople. Very relationship-oriented. Like to motivate groups.	<b>INFJ</b> <b>Counselor</b> Work is to inspire others to achieve great things. Great visionaries of human possibilities. Serious academicians. Often professors or offer themselves to a religious order.	<b>INTJ</b> <b>Mastermind</b> If they say they are going to do something, they do it. Likely to be corporate leaders, scientists. Believe everything has room for improvement. Superior planners and visionaries of systems.	<b>ENTJ</b> <b>Field Marshall</b> Very leadership-oriented. Likely to be top executives, business persons. Big on reducing inefficiency, ineffectiveness. Take charge people. Can be overwhelming to less outgoing types.
<b>ENFP</b> <b>Champion</b> Second only to ESFPs for fun. Warm lives filled with excitement and romance. Very enthusiastic and creative. Often teachers, artists, writers. Great need for diversity and change.	<b>INFP</b> <b>Healer</b> Noble servants aiding society. Different from ISFPs, they try to tackle long term problems. Often psychologists or counselors. Want to save the whales and rainforests.	<b>INTP</b> <b>Architect</b> Deepest analysts of problems to be solved. Often physicists, scientists. Most aloof of types. Critical thinkers.	<b>ENTP</b> <b>Inventor</b> Want one exciting challenge after another. Love to problem solve. Good at analysis, consider themselves full of ingenuity and ideas. Often involved in computer, systems analysis, design.
<b>ESFP</b> <b>Performer</b> Number one in fun and enthusiasm. Always invite ESFPs to your party. The most generous of all types. Warm, friendly, vibrant people. Excellent at customer service.	<b>ISFP</b> <b>Composer</b> Quietly harmonious with world. Very observing, benevolent. Inclined toward work with people in need. Work to solve problems of the immediate such as homeless, stopping hunger.	<b>ISTP</b> <b>Operator</b> Ready to try anything once. Flashed with the rush of life. Seek excitement. A love of tools and the utility they offer. Inclined toward mechanical devices, can take apart & reassemble anything.	<b>ESTP</b> <b>Promoter</b> Excitement seekers. Never feel more alive than when taking risks. Great negotiators on the front end. Excellent promotional & entrepreneurial capabilities if someone else follows through.
<b>ESFJ</b> <b>Provider</b> Hosts & hostesses. Graciousness of this type makes them excellent at entertaining, coordinating. May be teachers, nurses. Very conscious of appearances, should should's.	<b>ISFJ</b> <b>Protector</b> A high sense of duty. Upholders of family tradition. Often found in traditional helping professions including nursing, elementary education, etc.	<b>ISTJ</b> <b>Inspector</b> Does of what should be done. Masters at completing practical details and adding finishing touches. Get-it-done people. Superb administrators. Duty bound & obligated, often military.	<b>ESTJ</b> <b>Supervisor</b> Administrators, workers, pillars of strength in community. Loyal mates, parents, employees. Often promoted to management positions. Dependable, consistent, straightforward.

Figure 4 - Myers-Briggs test (Myers, 1962)

Below the rationale of PF16 is provided.

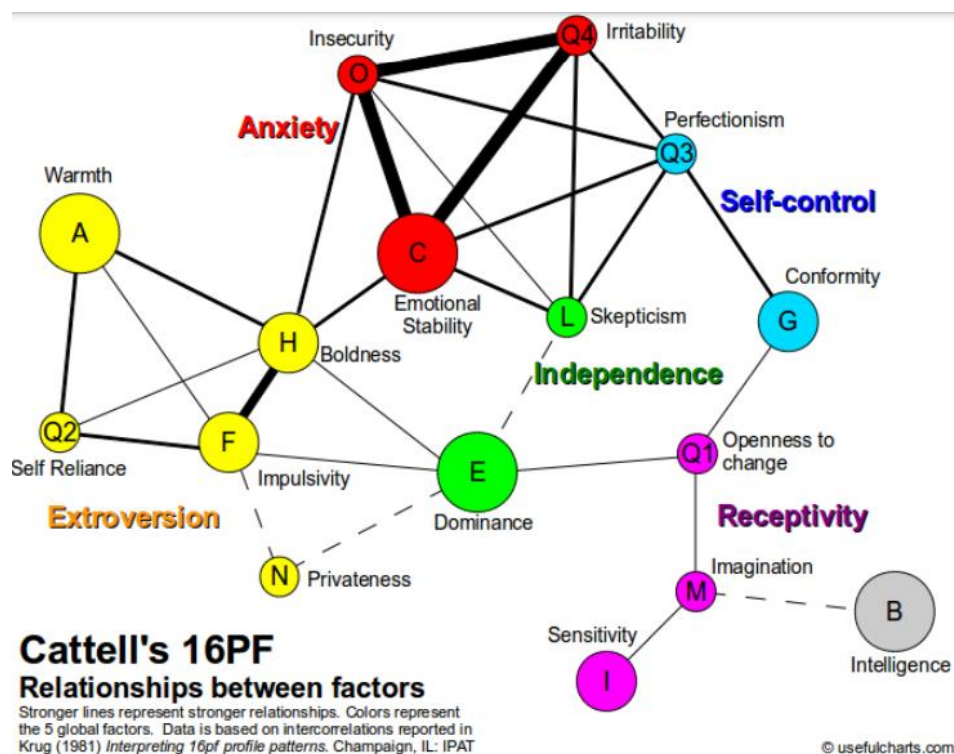


Figure 5 - 16 PF (Cattell & Cattell, 1995)

The NEO-PI-R test was originally developed for use with adult men and women without overt psychopathy, but was later shown to also be useful for people at all ages.

NEO PI-R logic is based on the Five Factors Personality Model (FFPM), describing five personality traits: N - Neuroticism E - Extraversion O - Openness to Experience A - Agreeableness C - Conscientiousness.

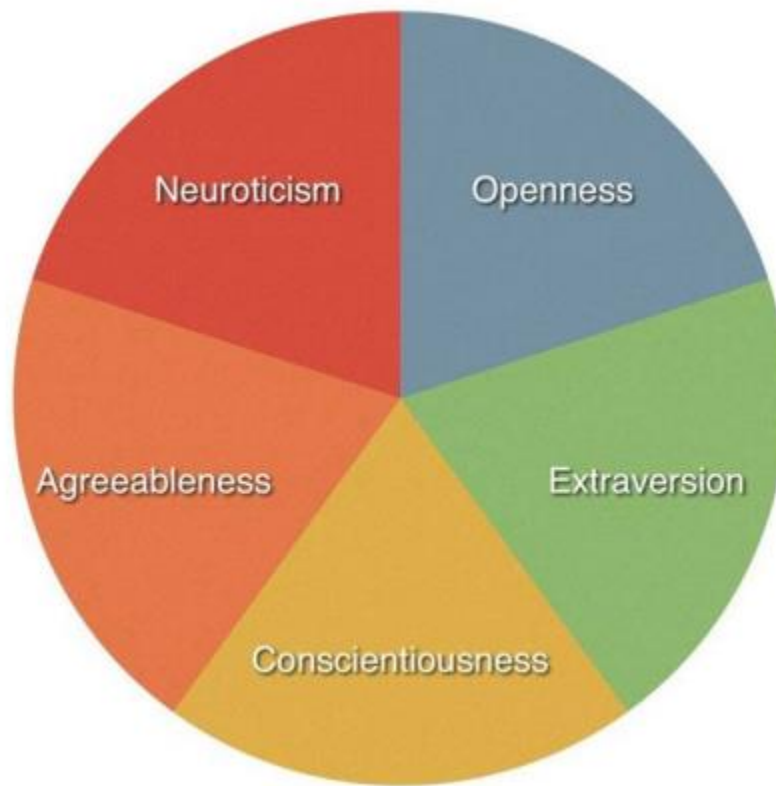


Figure 6 - The Five Factors Personality Model (FFPM) of NEO-PI-R (McCrae et al., 2005)

NEO Personality Inventory - Revised (NEO PI-R) comprises 240 statements, to which the individual responds by stating: 'strongly disagree', 'disagree', 'neutral', 'agree', or 'strongly agree' with a given proposition about themselves. The strengths of the NEO PI-R are: simple logic; scientifically based; more factual than feeling; used in military aviation; reference to past research.

Neuroticism	Extraversion	Openness	Agreeableness	Conscientiousness
N1 - Anxiety	E1 - Warmth	O1 - Fantasy	A1 - Trust	C1 - Competence
N2 - Angry hostility	E2 - Gregariousness	O2 - Aesthetics	A2 - Straightforwardness	C2 - Order
N3 - Depression	E3 - Assertiveness	O3 - Feelings	A3 - Altruism	C3 - Dutifulness
N4 - Self-consciousness	E4 - Activity	O4 - Actions	A4 - Compliance	C4 - Achievement striving
N5 - Impulsivity	E5 - Excitement-seeking	O5 - Ideas	A5 - Modesty	C5 - Self-discipline
N6 - Vulnerability	E6 - Positive emotions	O6 - Values	A6 - Tender-mindedness	C6 - Deliberation

Figure 7 - NEO-PI-R factors (McCrae et al., 2005)

The NEO PI-R can be used to get a quick personality profile of the respondent for recruitment purposes. NEO inventories are used around the world for basic research on personality structure and development, they are also intended for clinical use even if the test is not designed as a psychodiagnostic tool (Costa & McCrae, 2008). Counsellors, clinical psychologists, and psychiatrists can leverage on NEO PI-R to understand the strengths and weaknesses; assist in diagnosis; establish rapport; provide feedback and insight; anticipate the course of therapy; select optimal forms of treatment.

However, as with any test, the results are only reliable if the candidate has been honest and did not cheat. With personality tests, it is tempting to select the option you think the assessor wants to see. But doing this will yield the wrong results.



### 4.1.3 Psychodiagnostic tests

#### 4.1.3.1 Projective tests

Projective tests are psychological tests of typical performance consisting of intentionally ambiguous visual stimuli, notably inkblots (as for example the Rorschach Test) and enigmatic pictures (as for example the Thematic Apperception Test), to evoke responses that may reveal facets of the subject's personality by projection of internal attitudes, traits, and behaviour patterns upon the external stimuli. Indeed this type of test is based on the Freudian theory of attributive projection: if the stimulus is ambiguous and lacks a specific meaning, what the subject grasps is an attribution of contents that belong to the unconscious of the subject himself and, consequently, a projection of hidden aspects of her/his personality. The subject's task is usually to provide a description or tell a story inspired by the represented stimuli.

Other projective methods involve requiring subjects to build wooden block structures, complete sentences, paint with the fingers, or provide handwriting samples; additional methods include association tests in which spoken words work as the stimuli.

This section will briefly describe the Rorschach test and the Thematic Apperception Test, which are the most represented psychological projective tests.

The Rorschach test is a psychological test providing a global personality description. It provides information about how the person sees and perceives the world around her/him, how s/he processes information and her/his cognitive functioning style. The Rorschach Test also offers information on how the person relates to the social world and what image s/he has of her/himself, as well as how s/he lives, experiences and processes emotions. In addition, it offers information on any discomfort that may be present and on how the person manages stress. The test was introduced in 1921 by the Swiss psychiatrist Hermann Rorschach. It attained peak popularity in the 1960s, when it was widely used to assess cognition and personality and to diagnose certain psychological conditions.

During the administration of the Rorschach test the person is asked to describe what s/he sees in 10 inkblots, some of which are black or grey and some others have patches of colour. To administer the Rorschach, the examiner needs the 10 tables, a pen and some sheets, a time-keeping tool to take note, per each table, of the total time of response by the subject and the latency time to provide the reply. Moreover, the examiner must schedule the right moment to administer the Rorschach in the context of the other tests and interviews: in general, it is not recommended to administer the Rorschach test in the context of the first visit. Moreover, it is important to ask to the applicant if s/he has already replied to the Rorschach test: If the answer is affirmative, and at least 5 years have not passed since the last administration, it is better not to repeat the Rorschach but necessary to adopt, instead, different tests.

Responses to the Rorschach test are typically scored on the basis of the location in the blot of the thing seen, the kind of stimulus characteristic emphasized (e.g., form or colour), and the content of the percept (e.g., animal). From response scores, the psychologist attempts to describe the subject's personality, often by comparing scores with established norms.

The Rorschach test can be interpreted with different methods, derived from the methodological ramifications originating from the initial working groups on the test, from the early twentieth century onwards. Among these, Exner, in the seventies, achieved a Comprehensive System that would integrate the empirical results of the various methods and then submitted the test to large-scale statistical analysis. Exner took up Rorschach's emphasis on the perceptual and structural aspects of ink spots. His studies added psychometric validity to the Rorschach test and reliability as a psychodiagnostic tool.

Interpretation of a subject's responses is not highly standardized, however, despite the introduction in 1974 of the Exner scoring system, which was developed to address weaknesses in the Rorschach test. Thus, though it is still used, the Rorschach test is generally considered to be an unreliable method for psychological assessment and diagnosis.

The Thematic Apperception Test (TAT) presents the subject with pictures of persons engaged in a variety of activities (e.g., someone with a violin). While the pictures leave much to one's imagination, they are more

highly specific, organized visual stimuli than are inkblots. The test consists of 30 black and white pictures and one blank card (to test imagination under very limited stimulation). The cards are presented to the subject one at a time, and s/he is asked to make up a story that describes each picture and that indicates the events that led to the scene and the events that will grow out of it. S/he is also asked to describe the thoughts and feelings of the persons in the story.

Although some content-analysis scoring systems have been developed for the TAT, attempts to score it in a standardized quantitative fashion tend to be limited to research and have been fewer than has been the case for the Rorschach. This is especially the state of affairs in applied settings in which the test is often used as a basis for conducting a kind of clinical interview; the pictures are used to elicit a sample of verbal behaviour on the basis of which inferences are drawn by the clinician.

The usefulness and reliability of projective tests depend on a number of factors, including the extent to which identical personality interpretations can be reached by different evaluators using the same test data and the extent to which those interpretations are supported by assessments of personality from other sources (e.g., personality inventories and clinical observation). In consideration of such factors, psychologists are sharply divided over the value of projective tests, despite their prominence in both personality research and therapeutic practice.

#### **4.1.3.2 Self-report tests for the diagnosis of mental disorders**

##### **4.1.3.2.1 *The Minnesota Multiphasic Personality Inventory (MMPI)***

The MMPI arises from the need of the two authors to have a practical and effective test to elaborate psychiatric diagnoses and to determine the severity of the disorder. The test measures abnormal or deviant behaviour and is grounded on empirical data, derived from the observation of mental disorders' signs and symptoms in clinical settings. The MMPI is known as being best used in court settings as a clinical instrument. The MMPI-2 (Minnesota Multiphasic Personality Inventory -2) (1989) is a self-administered broad-spectrum test consisting of 567 dichotomous items, which refer to the following rating scales:

- 10 basic clinical scales (e.g. Hs - hypochondria, D - depression, Pa – paranoia, etc) with 3 associated control scales (L - lie, F - frequency; K – correction);
- 15 content scales (e.g. anxiety, phobia, health concern, relationship/work-related issues, bizarre ideation, antisocial behaviour, social discomfort, non-compliance with treatment);
- 15 additional clinical scales (alcohol and substance abuse, hypercontrolled hostility, Post Traumatic stress disorder, family issues);
- 5 additional validity scales (F-back – Unusual answers, Trin – random answers, Vrin – Inconsistent responses, Fp – psychopathological frequency, S – Superlative self-presentation).

The MMPI-2 is the psychological test most frequently used in clinical, forensic and orientation contexts, as it provides a lot of information about the person examined, such as somatic symptoms, psychiatric ones, emotional, ideative, behavioural, relational characteristics, etc. The test was in fact developed to evaluate personological and psychopathological functioning.

MMPI-2 can be easily administered to both individuals and groups of people. For the understanding of the items is required a degree of education achievable with the completion of the basic school.

The correct interpretation of the results requires, by the examiner, skills in the psychometric, psychopathological, personological fields.

The MMPI-2 has the highest number of control scales of any test in the world and among all the psychological tests has the largest number of scientific publications in English.

The MMPI-2-RF test (Minnesota Multiphasic Personality Inventory -2 – Restructured Form) is a self-assessment questionnaire that represents the latest evolution of the MMPI-2 test. Although the MMPI-2-RF uses part of the MMPI-2 items, it should be considered as an alternative and not as a simple short form. The main differences between the two versions of the test are described in the table below:

<b>MMPI-2</b>	<b>MMPI-2-RF</b>
---------------	------------------

567 item	338 item
Gender-based norms	General norms (no Gender-based norms available)
Aim: result in a psychopathological diagnosis on the basis of the mental disorders categories	<p>Aim: result in a psychopathological diagnosis on the basis of the recent DSM V criteria, as follows:</p> <ul style="list-style-type: none"> <li>• the 40 categories of personality and psychopathology</li> <li>• the spectrum of mental disorders (internalizing, externalising, psychotic)</li> </ul>

*Table 20 - Main differences between the MMPI-2 and the MMPI-2-RF*

In the development path of the MMPI-2-RF the first step was to define and isolate the construct of demoralization, a non-specific factor common to many mental disorders, which contributes to making clinical scales heterogeneous. The construct of demoralization concerns experiences of unhappiness, helplessness, dissatisfaction, malaise, and is conceptualized as a continuum between high negative activation and low positive activation. In this way it becomes possible to understand if a high score is an expression of the central problem of each scale (for example depression, social introversion, etc.) or if it is due to a strong anguish experienced by the subject.

The MMPI-2-RF can be administered, like the MMPI-2, in any situation when the personality areas and problematic dimensions, including social dangerousness and responsiveness to treatment, have to be investigated. It can be administered in paper format (with booklet and response sheet), via computer (using special software) or in audio-recorded mode (not available in all countries).

#### **4.1.3.2.2 The Millon Clinical Multiaxial Inventory IV (MCMI-IV)**

The Millon Clinical Multiaxial Inventory (MCMI-IV) is a self-report measure for personality disorders, composed of 195 true/false questions. The test is available in English and Spanish language. About 30 minutes are required to administer the test. The MCMI-IV aims at describing personality traits and detecting mental disorders.

The items of this test were formulated starting from T. Millon's theoretical construction on personality, unlike the MMPI items that were identified on an empirical basis following a descriptive approach.

The MCMI-III has 29 scales grouped into 5 clusters:

- Personality scales
- Severe personality disorders
- Clinical syndromes
- Severe clinical syndromes
- Validity scales

The 29 scales reflect, therefore, a specific theory of personality and psychopathology, linking directly to the nosographic classification and conceptual terminology of the DSM, in a line with it both from a diagnostic and a theoretical point of view. Millon, in fact, was a member of the working group for the drafting of the DSM-III.

The test is usually administered and scored by a clinical psychologist.

#### **4.1.3.3 Specific scales for mental disorders signs and symptoms**

These are tools clinicians or researchers use to measure psychiatric symptoms such as anxiety, depression, and so on.

The most used for depression:

- The Beck Depression Inventory II (BDI-II)
- The Hamilton Depression Rating Scale (HDR-S)

The BDI-II is the most widely used instrument for measuring the presence and severity of depression in the world both in the normal population and in psychiatric patients. Although the BDI-II showed adequate psychometric characteristics in terms of test-retest reliability, internal consistency and construct validity, its content validity appeared increasingly doubtful along with the various editions of the DSM.

The HDR-S is a scale that investigates 21 different areas that are relevant for the evaluation of the depressive state of the subject. As an evaluated period, the last days are taken into account, up to one week before the interview. The areas are: depressed mood, guilt, suicidal ideas, initial insomnia, intermediate insomnia, prolonged insomnia, work and interests, slowing of thought and words, agitation, anxiety of psychic origin, anxiety of somatic origin, gastrointestinal somatic symptoms, general somatic symptoms, genital symptoms, hypochondria, introspection, weight loss, diurnal variation of symptoms, depersonalization, paranoid symptomatology, obsessive symptomatology. Each of the 21 areas represents a single item of the scale, to each of which the examiner during the interview must assign a score ranging from 1 (absent) to 5 (severe) or from 1 (absent) to 3 (clearly present) depending on the items and the severity of the symptoms. The examiner will assign an overall value to each investigated area using the following scores: 0 (absent) 1 (mild) 2 (moderate) 3 (severe) 4 (very severe). The total score will be calculated by adding the points from 0 to 4 of each of the 21 areas investigated. The score thus obtained will be an indication of the possible presence of depression and, possibly, of its severity.

Anxiety is a common condition but at the same time a very complex concept. Among personality traits, none is as popular and intuitive as anxiety. From a clinical point of view anxiety is a technical term and refers to the apprehensive anticipation of a danger or a future negative event accompanied by feelings of dysphoria or physical symptoms of tension. The elements exposed to risk can belong to both the internal and external world.

However, anxiety is not necessarily pathological. In fact, a certain amount of anxiety is adaptive because it increases performance and alertness. Anxiety becomes maladaptive when it worsens performance and decreases concentration: in this sense we speak of pathological anxiety. In addition, anxiety can be acute or chronic: it is acute when it is reactive to events, has a short duration and happens in a balanced personality; It is chronic when it is reactive to mild events, is persistent and recurrent and happens in a predisposed personality.

The term anxiety is often associated with the following symptoms or associations of symptoms: fear-terror, agonizing expectation of imminent danger, nervousness-motor restlessness, diffuse muscle tension, afinalistic motor activity, moderately distressing ideation, unrealistic recurrent and repetitive worries, dysphoric mood with rapid unmotivated changes, irritability-hyperactivity, physical disorders without organic basis, iterative hypochondriac concerns, agitation.

What follows is a selected list of measurement scales for anxiety:

- The Beck Anxiety Inventory
- The Hamilton Anxiety Scale
- The State-Trait Anxiety Inventory
- The Penn State Worry Questionnaire
- The Yale Brown Obsessive-Compulsive Scale

The Beck Anxiety Inventory measures the annoyance level of the physical and mental manifestations of anxiety, from a cognitive point of view. The goal is to assess the severity of anxiety in adults and distinguish anxiety from depression. The evaluated period coincides with the last week and time of the interview. The inventory consists of 21 items, each of which describes a common symptom of anxiety. The inventory is self-administered and takes 5-10 minutes to complete.

The Hamilton rating scale for anxiety is the best-known and most widely used anxiety rating scale, especially in clinical psychopharmacology research. The scale has no diagnostic purpose but only serves to quantify anxiety in patients already diagnosed as suffering from anxiety disorders. It can be considered the prototype of scales consisting of categories of symptoms: it explores 14 categories of symptoms including anxiety, tension, neurovegetative symptoms, somatic symptoms and behaviour during the interview. The evaluation

requires a free interview and refers, for the symptomatology reported by the patient, to the previous week. The assessment is complemented by the observation of behaviour, although the greatest emphasis is placed on what the patient reports. HAM-A is the most widely used scale in the study of anxiety and its modifications under treatment and, although it is not able to distinguish the different specific anxiety disorders, it has probably proved to be the most capable of effectively discriminating the effects of treatment in anxious patients.

The State-Trait Anxiety Inventory measures state and trait anxiety. It goes back to Cattell to have distinguished within the construct of anxiety 2 fundamentally different meanings: one referring to an emotional state of an individual at a given time and in a given situation; the other referring to a personality variable that can cluster different individuals. However, it is thanks to Charles Spielberger that this definition has become currently used and the technical names still in use of state anxiety and trait anxiety have spread internationally. State anxiety is a transient emotional condition of the individual which can vary in intensity and fluctuate from time to time depending on the circumstances. Trait anxiety refers to relatively stable individual differences regarding predisposition to anxiety. These characteristics predispose the subject to the tendency to respond to situations that are perceived as threatening with the increase of anxiety as a state. The STAI has a psychodiagnostic purpose for the detection of state and trait anxiety and for the verification of the effectiveness of psychopharmacological and psychotherapeutic treatments. The test is structured in 2 self-administered questionnaires, state-A and trait-A, of 20 items each. The answer is evaluated in terms of intensity according to a 4-point Likert scale.

The Penn State Worry Questionnaire (PSWQ) is a questionnaire that measures the tendency of the subject to ruminate. In brooding, rather than worrying the subject mentally repeats to her/himself that things are going wrong or that something bad could happen at any moment, but s/he does it with a singular lack of modulation and detail. To complete the test, subjects must answer 16 items on a 5-point Likert scale. Higher scores indicate a greater tendency to ruminate. PSWQ is a scale that has good stability and reliability, effectively discriminates normotypic subjects from subjects suffering from generalized anxiety disorder but does not correlate with other tools that measure anxiety.

The Yale-Brown Obsessive Compulsive Scale (Y-BOCS) is the most widely used structured interview in the world in the scientific field for the qualitative and quantitative evaluation of obsessive-compulsive symptoms. They consist mostly of obsessions and compulsions. Obsessions are unwelcome and distressing ideas that repeatedly appear in the mind against one's will. Compulsions are behaviours or acts that the person feels compelled to do, even if they can be recognized as senseless or excessive; sometimes resisting these acts can prove difficult: the person may get to experience anxiety that does not diminish until the behaviour has been implemented. The measurement of the characteristics of each point starts from the week before until (and including) the time of the interview. This rating scale is designed to be used as a semi-structured interview: the interviewer should rate the elements in the order indicated and use the expected questions; however, he is free to ask supplementary questions for the sake of clarity.

#### **4.1.3.4 Tests for trauma- and post-traumatic stress disorder assessment**

Many interviews and self-administered tools are available for the diagnosis of Post-Traumatic Stress Disorder (PTSD). The instruments administered by the clinician may require a greater expenditure of resources while those self-administered can be completed by the patients themselves in the waiting room. Most measuring instruments include at least the 17 symptoms of PTSD reported by DSM IV.

Probably the most precise interview for this purpose is the Clinician Administered PTSD Scale (CAPS) which consists of a short checklist to evaluate the history of the traumatic event (life events Checklist) and is the only standardized diagnostic interview that assesses both the frequency and severity of each symptom of PTSD reported by the DSM IV. The CAPS also has the advantage of performing a precise rating which is possible thanks to the fact that the answers are anchored to behavioural descriptions ensuring high reliability. Its administration time varies between 40 and 60 minutes. CAPS is a means to assess the frequency and intensity of the size of each symptom, the interference of symptoms on the patient's social and occupational functioning, the severity of the PTSD symptom complex, the overall improvement of the patient compared to the initial assessment, the validity of the evaluations carried out.

## 4.2 Other psychodiagnostics options

In this section, the use of questionnaires and clinical interviews as additional psychodiagnostic tools regarding mental health issues for class 1 and class 3 assessments will be discussed. These are meant to complement the evaluation that can be achieved by means of tests.

As explained in section 4.7 of the MESAFE deliverable D1.1 Report on the review of diagnostic measures, psychodiagnostic tests taken as standalone assessment measures do not enable a psychological diagnosis. In addition to this, very few dedicated and validated tests and questionnaires for pilots, ATCO's and other aviation professionals exist. Valid pilot and ATCOs norms are only available for the MMPI. Moreover, tests and questionnaires hardly predict the mental health status in between two medical examinations.

On the other hand, tests and questionnaires might still be useful to speed up some data collection and support the part of the interview addressing mental complaints.

### 4.2.1 Structured interview of DSM-5

Although the structured interview for the DSM-5 (SCID-5) can be a useful and reliable diagnostic tool, its use in aeromedical evaluations is bothersome. Actually, there are several variants of the SCID-5 available, for example for clinical or for research settings, or for the detection of personality disorders. For aeromedical examinations, the SCID-5-CV (Clinician Version) or the QuickSCID-5 (First & Williams 2021) are most useful to be discussed. Although AME's might use the SCID-5 voluntarily to improve or aid their interviewing skills, mandatory use of the SCID-5 in aeromedical assessments is not recommended for several reasons.

- Translations of the SCID-5-CV or the QuickSCID are not available in the languages of all EASA member States. For example, no French translation is available.
- The SCID-5-CV may be too lengthy (it may take 30-120 minutes).
- Not all AME's will have sufficient experience with mental health to apply the SCID-5 without additional training.
- The QuickSCID is shorter to apply, but consists almost entirely of closed-end questions, making the risk of underreporting too high.
- Also for the SCID-5-CV, the risk of underreporting is a problem.
- The SCID-5 has only been validated to a limited extent, and not been developed for or validated in the pilot or ATCO population.
- Specific aviation-related issues are not covered (e.g. how does the applicant deal with irregular working hours or frequently changing rosters), whilst these issues are paramount when assessing mental health in aviation professionals.

Nevertheless, as long as they feel sufficiently experienced, are aware of the possible risk of underreporting, and if they give sufficient attention to specific aviation related issues that may influence mental well-being, AME's with enough time may use the SCID-5 to support the mental health assessment.

### 4.2.2 Clinical interview

For the detection of mental disorders, the clinical interview combined with the mental status examination can be considered the backbone of the assessment.

It is recommended that AME's develop interviewing skills regarding mental health that yields relevant information on the one side, but that also create a comfortable and trusted atmosphere on the other side. In such an atmosphere, the clinical interview is likely to be the most informative. A professional medical attitude does not have to hamper the creation of a personal setting. Spending some effort to create a comfortable interview room, and taking some minutes for an informal talk may be highly rewarding. How to conduct a good clinical interview cannot be learned from books, and definitely not be described in clinical guidelines, it is a matter of practice and experience. The way to conduct an interview and to establish a good working relationship with the applicant is also dependent on local cultural and social factors. A good way to improve interviewing skills is by training and intervision with colleagues, and for example to conduct an

interview together with a colleague from time to time, and to discuss and learn from each other's interviewing techniques.

For clinical interviews, it is recommended to create the most trusted atmosphere, and then to address the following points, not necessarily in this order. The more experience one has, the easier it becomes to elaborate more on specific features, if necessary, to change the order of the questions etc.

- Any mental complaints.
- Any mental complaints in the past, and any treatment by mental health professionals in the past.
- Any family history of mental disease.
- Mood during the last weeks to months.
- Things that the applicant can enjoy, that give him or her energy, that he or she looks forward to (in many mental disorders, especially in depressive disorders, this is problematic).
- Sleep and feeling fit during the day (and if not, what kind of sleeping difficulties there are).
- Appetite.
- Concentration (this is best asked by practical questions, such as a ability to concentrate during a landing, or during a simulator session, but also when reading a book or watching a television movie or series).
- Feelings of guilt, of experiencing life as worthless, feelings of sometimes thinking to be better off dead. If these are present, what kind of feelings, any suicide plans. The presence of these feelings in the past, including past suicide attempts.
- Any anxiety complaints.
- Any obsessive-compulsive complaints.
- Any feelings of losing contact with the world or with reality.
- Traumatic experiences in the past that still cause problems.
- Eating problems.
- Deliberate self-harm.
- Any addictions.
- Upon indication it is good to address memory, hallucinations, experiencing extremely fast or slow thinking, experiencing supernatural powers, being part of secret conspiracy's etc.
- Coping: how does the applicant deal with painful, difficult or challenging situations?
- It can be considered to ask the applicant to describe him- or herself. This may be indicative of some personality features, but in the context of an aeromedical examination it may result in a socially acceptable description of the ideal pilot with little clinical value. It may be better therefore to address this in a more subtle way during the biographical history.
- A biographical history wherein the family the applicant was raised in, childhood, education and career and personal relationships are addressed. It may be considered to develop a questionnaire with some factual questions such as on how the family was composed, education, etc to make this more efficient, and to give more attention to the emotional side of life-events. It is paramount to address the social contacts and functioning from early on, and to check how important life-changes were dealt with (e.g. going to high school, leaving home to study in a different city, getting a permanent relationship, getting children, losing relatives etc). At these life-changing moments, mental disorders are most likely to become prominent. It is also good to explicitly address any career setbacks and how the applicant dealt with them emotionally, and any problems in interpersonal relationships.

Especially these biographical questions can be perceived as intrusive, and it is important to explain why these questions are asked: the mental health of someone can be better understood against the background of his or her personal history.

Once again, a good clinical interview cannot be described by guidelines, but is a matter of practice and experience.

### 4.2.3 Questionnaires

As described in deliverable D1.1, questionnaires cannot be used to replace a clinical interview. They may be used to support it though, although the examiner should be aware of the possible shortcomings:

- No questionnaires have been validated for use in a pilot or ATCO population applying for a medical certificate.
- All questionnaires carry a risk of underreporting, especially if applied in aeromedical examinations.

There is not a single questionnaire that can be advised to support the assessment. The examiners should choose a questionnaire that is available and validated in the language of the applicant, short and easy to administer. Examples are the PHQ-4 (Kroenke 2009), PHQ-9 (Kroenke 2001) and the SQ-48 (Carlier 2012). Preferably, one that is commonly used in primary and/or mental healthcare settings in the country they are working in, is chosen.

An AME can consider developing a questionnaire for addressing some more factual questions, such as any previous mental health treatments, the education obtained and current family situation, so that during the actual interview, more time is available for discussing situations with an emotional impact, instead of taking notes about factual events. Still, even purely factual information from a questionnaire should always be doublechecked during the interview, because sometimes people tend to forget, either deliberately or accidentally, to report all relevant information.

### 4.2.4 Digital phenotyping and AI applications

Recently, researchers have proposed to use information from digital sources such as smartphones and wearable technology to objectify mental health characteristics. Big data analysis methods can be used to detect patterns reflecting mental disease, for example by using smartphone or social media use data. In the future, perhaps data from simulator sessions or even from the aircraft themselves may be used for detecting mental health issues, but at this moment, such techniques are not available yet. If specific diagnostic tools for aviation professionals would become available, it will be important to test and validate them in the same way as regular new diagnostic procedures, and also to give sufficient attention to ethical questions that may arise. As of 2023, although there are several promising developments, scientific data are insufficient to support the use of digital phenotyping and AI techniques in aeromedical examinations. Furthermore, important challenges regarding privacy and safeguarding that personal data are only used on a voluntary basis, exist. When used as a screening technique there is a risk of 'playing', meaning that someone is giving certain input to influence the algorithm deliberately. It is not unthinkable that in discussion groups of (aspiring) pilots, information on how to deal with these algorithms is shared. In a similar way, such information on how to perform during selection procedures and psychological tests for flight training is also shared, or even offered for a fee by commercial companies. Digital phenotyping and AI techniques seem mainly promising for monitoring the mental health of people with a known mental disorder, and not for random screening. Especially in the aviation world, a tool providing a quick and clear answer whether someone has a mental disorder and whether there is a risk to aviation safety would be very welcome. Unfortunately, no such tool not yet exists, but this may not hinder commercial parties to try to make money by selling these kind of techniques. It should be advised only to take their claims seriously if the reliability of their technique has been shown in peer-reviewed scientific journals of sufficient quality. A tool that is able to detect all common mental disorders reliably and with a minimal time effort will easily be published in a high-impact journal.

Nevertheless, although not yet useful in aeromedical examinations, developments regarding digital phenotyping and artificial intelligence are worth of being followed-up. The table below is based on a recent publication by Müller and De Rooy, reflecting the challenges and ways to overcome them with respect to using digital phenotyping in aviation professionals (Müller & De Rooy, 2021).

Challenges regarding digital phenotyping	Possible solutions
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Reliability: how well do digital biomarkers associate with mental health?	<p>More RCT's comparing digital phenotyping with clinician's prediction</p> <p>Comparison of different parameters</p> <p>More research into developing algorithms</p> <p>Investigating the use of machine learning</p> <p>Research in healthy individuals</p>
Clinical utility: does it help to improve symptoms and clinical evaluation?	<p>Testing benefits of quick detection of onset/relapse</p> <p>Research into role of monitoring in treatment or during follow-up</p> <p>Defining clinical outcomes based on symptoms in future studies</p>
Privacy: how much personal information will be gathered?	<p>Data are regarded as medical data to which medical confidentiality laws are applicable</p> <p>Protection of data by dedicated regulation</p> <p>Restricted amount of and 'content-free' data modalities</p> <p>Retractable informed consent</p>
Regulation: who is accountable for proper use and protection of data?	<p>Only approved apps: guidance for clinicians</p> <p>Only use by healthcare professionals</p> <p>Healthcare professional is responsible for choosing reliable commercial apps</p>
Application: what should it be used for?	Monitoring, but not screening, not mandatory

*Table 21 – Challenges and solutions regarding digital phenotyping (Müller & De Rooy, 2021)*

#### 4.2.5 Questionnaires for substance abuse

There are many questionnaires developed to identify misuse of alcohol and/or drugs. Their suitability for screening purposes varies with the target group for whom the questionnaire was developed, the aim of the questionnaire (e.g., to identify alcohol dependence, hazardous drinking, or follow-up during treatment), and the cut-off points used. There is a multitude of questionnaires that use essentially the same basic questions. Many questionnaires contain additional detailed questions of which the specificity depends on the purpose and target population (e.g. patients of addiction treatment clinics, individuals referred to mental health expert).

As the task of AMEs is to screen a potentially denying population in which the prevalence of misuse is likely to be low (see the MESAFE deliverable D3.1 Report on the analysis of the suitability of screening and confirmation tests for misuse of alcohol and drugs), it is recommendable that the AMEs use essential basic questions to identify a suspicion or “red flag” concerning use of psychoactive substances. In case suspicion is raised, more detailed questions should be asked and/or the applicant should be referred to a consulting mental health specialist, who will diagnose the case and decisions concerning grounding and treatment can be made. For clinical psychological or psychiatric use several very detailed questionnaires are available such as the Alcohol Use Disorders Identification Test (AUDIT-10 - Babor et al., 2001), Drug Abuse Screening Test (DAST-10, DAST-20, DAST-28 - Skinner, 1982), and the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST- WHO, 2010). For a description of these dedicated tests the reader is referred to the

section 5.2 of the MESAFE deliverable D3.1 Report on the analysis of the suitability of screening and confirmation tests for misuse of alcohol and drugs.

Questionnaires that are potentially suitable to be used for routine aeromedical screening of pilots and ATCOs by AMEs, should be less detailed and highly sensitive questionnaires that address the essential questions that could lead to identifying “Red Flags”. Therefore, only brief sensitive questionnaires that are considered suitable and practical for the purpose of AMEs will be discussed in the present report.

The available brief screening questionnaires provide sufficiently useful questions to be used by AMEs when exploring suspicion-raising points (red flags) for psychoactive substance misuse in the applicant’s history. AMEs are advised to try and build a trustful relationship with the applicant and to use the questions provided by the available questionnaires and “wave them in” into the conversation with the pilot during the aeromedical examination as part of a general health promotion discussion that addresses a variety of health issues, such as mood, quality of sleep, current sources of stress, stress coping abilities, and alcohol and/or substance use.

The following examples of questions from available questionnaires are recommended to be included in the screening interview:

- How often do you have a drink containing alcohol? (as a starting question)
- How many units of alcohol do you drink on a typical day when you are drinking?
- Do you like to relax after work, having a drink?
- Do you sometimes use medications or substances to feel better? How many times last year?
- Are you aware that use of alcohol and mood changing substances can affect your work capacity?
- Have you ever felt you needed to cut down on your drinking?
- Have people annoyed you by criticizing your drinking?
- Have you ever found guilty about drinking?
- In the past year, how often have you used (NIDA Quick Screen):
  - 5 or more drinks a day (for men) / 4 or more drinks a day (women)?
  - Prescription drugs for non-medical reasons?
  - Illegal drugs?

If the answers to the questions and/or symptoms, or medical problems which may be related to alcohol or drugs misuse, have raised the AME’s suspicion s/he might consider complementing the interview by questions focusing on the quantities, frequency, and consequences (e.g. relational or occupational problems) of alcohol and/or drug misuse. In case the applicant’s answers confirm the AME’s suspicion of misuse, the applicant should be referred to a consulting mental health specialist for further evaluation and establishing the case for decision making about grounding or treatment.

#### **4.2.5.1 Questionnaires for alcohol misuse**

##### **Single Question Alcohol Screen**

The single screening question is: “Have you recently consumed more than 5 drinks (more than 4 drinks for females) in one day?”

This question has been found to be effective in identifying at-risk drinking among primary care patients. In a sample of 394 adult patients recruited from primary care waiting rooms, the single-question screen was 81.8% sensitive and 79.3% specific for the detection of unhealthy alcohol use. Test results were similar to that of a commonly used three-item AUDIT screen (see below), and were affected very little by subject demographic characteristics (Smith et al., 2009).

The Single Question Alcohol Screen is suited to be asked orally as part of the aeromedical history taking. Aviation personnel who report having exceeded the defined number of drinks one or more times within the past year are considered positive and further evaluation using more detailed questions about quantities, frequency, and consequences of drinking is needed.

##### **AUDIT-3**

Since the publication of the AUDIT guidelines for use in primary care, many adapted and/or shortened versions of the 10-point AUDIT have been developed and validated for clinical use. One of frequently used shortened versions is the AUDIT-3 (also called AUDIT-C), which uses the first 3 questions of the AUDIT-10 questionnaire as shown in below table. These first 3 questions of the AUDIT-10 cover the domain of hazardous alcohol drinking, questions 4-6 cover dependence symptoms, and questions 7-10 cover the domain of harmful alcohol use (Babor et al., 2001). The stage of hazardous drinking, covered by questions 1-3, is the early and risky stage of alcohol misuse. Because the alcohol screening of pilots and ATCOs should be focused at identifying risky cases as early as possible, the hazardous stage is essentially what the AME/AeMC should try to identify. Therefore, the AUDIT-3 questionnaire is suited for use in the aeromedical screening practice as part of the medical history interview. The three questions should therefore preferably be woven in into the medical history interview. The questionnaire can also be administered on paper or electronically, but in that case pilots and ATCOs will likely treat it as a “ticking-box” exercise and most of them will answer NO to the three questions.

The AUDIT-3 has the advantage that it identifies both excessive regular drinking and excessive occasional (binge) drinking in only three questions.

Questions	Scoring System					
	0	1	2	3	4	score
How often do you have a drink containing alcohol?	Never	Monthly or less	2 to 4 times per month	2 to 3 times per week	4 times or more per week	
How many units of alcohol do you drink on a typical day when you are drinking?	0 to 2	3 to 4	5 to 6	7 to 9	10 or more	
How often have you had 6 or more units if female, or 8 or more if male, on a single occasion in the last year?	Never	Less than Monthly	Monthly	Weekly	Daily or almost daily	

Table 22 - The 3-item Alcohol Use Disorders Identification Test: AUDIT-3 (Babor et al., 2001)

AUDIT-3 performed similarly to the full AUDIT-10 in detecting risky drinking and had equivalent AUROC (area under receiver operating characteristics) curves when used to identify risky drinking in patients visiting primary health care centres (0.935 compared to 0.920 for AUDIT-10). The term “drink” in questions 2 and 3 encompasses amounts of alcohol ranging from 8 grams to 13 grams. Where a standard drink is defined as an amount outside this range (e.g. 20 grams), it is recommended that the response categories are modified accordingly. For screening of a population of pilots and ATCOs it is recommendable to use a prudent approach in which sensitivity is high. This would enable to “catch” every case, while accepting a risk of false positives. With a cut-off score of 5 for men the AUDIT-3 had a sensitivity of 92.4% and specificity of 74.3% (Gual et al., 2002). When using higher cut-off scores the sensitivity will decrease and the specificity will increase. For screening purposes cut-off scores of 5 for men and 4 for women are advisable.

The questions of the AUDIT-3 are suited to be used in aeromedical history taking. It is recommended that if a score of  $\geq 5$  among men and  $\geq 4$  among women is observed, a more in-depth assessment of drinking pattern and alcohol-related problems should be carried out. For this purpose, question 4 -10 of the AUDIT-10 can be used and -if necessary- a combination with biochemical tests.

### CAGE questionnaire

This questionnaire consists of four questions (abbreviation CAGE explained by the bald words):

1. Have you ever felt you needed to <b>Cut</b> down on your drinking?	NO = 0	YES = +1
2. Have people <b>Annoyed</b> you by criticizing your drinking?	NO = 0	YES = +1
3. Have you ever found <b>Guilty</b> about drinking?	NO = 0	YES = +1
4. Have you ever felt you needed a drink first thing in the morning ( <b>Eye opener</b> ) to steady your nerves or to get rid of a hangover?	NO = 0	YES = +1

Table 23 -The CAGE questionnaire. The name is an acronym composed of the bold printed words in its four questions (Ewing, 1984)

The CAGE's brevity may make it a useful screening and case-finding tool for primary care physicians as well as for AMEs. Aertgeerts et al. (2001) found that the CAGE questionnaire performed poorer than several variations of the AUDIT questionnaire. The CAGE questionnaire is commonly considered a valid tool for detecting alcohol abuse and dependence in medical and surgical inpatients, ambulatory medical patients, and psychiatric inpatients (average sensitivity 0.71, specificity 0.90), however, its performance in primary care patients is varied (Dhalla & Kopec, 2007).

For aeromedical screening purposes the separate questions of the CAGE questionnaire can best be "woven-in" into the medical history taking. Standard administration of a paper/pencil or electronic version is not recommended, because in that case pilots and ATCOs will likely treat it as a "ticking-box" exercise and most of them will answer NO to the four questions.

#### 4.2.5.2 Questionnaires for drugs misuse

There are many detailed questionnaires designed to screen for drugs and most of these are designed to screen in a clinical, criminal, detoxification, and social health care populations. Commonly used examples are the above-mentioned Drug Abuse Screening Test (DAST), the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST), and the Drug Use Disorders Identification Test (DUDIT). The NIDA Quick Screen and together with the Single-Question Screening Test for Drug Use, both DAST and ASSIST will be briefly discussed in the present report. The DUDIT will not be discussed because this questionnaire has only been validated in criminal justice and detoxification settings and is therefore not considered for use in the aeromedical screening practice.

#### NIDA Quick Screen for alcohol and drug misuse

The National Institute on Drug Abuse (NIDA) Quick Screen (NIDA, 2020) combines a single alcohol screen and single drug screen.

On a scale of Never / Once or Twice / Monthly / Weekly / Daily or almost daily, applicants have to answer the question: In the past year, how often have you used:

- 5 or more drinks a day (for men) / 4 or more drinks a day (women)?
- Prescription drugs for non-medical reasons?
- Illegal drugs?

If the applicant answers "Never" to all questions the screening is complete and the AME can reinforce abstinence. Answers that raise suspicion (e.g. weekly 5 or more drinks per day, or weekly use of prescription drugs for non-medical reasons or illegal drugs) a more detailed assessment of alcohol- or drug-related problems should be carried out and -if necessary- biochemical testing may be considered. For the alcohol part the sensitivity can be estimated to be similar to that of the Single Question Alcohol Screen (around 81%; Smith et al., 2009); for the drug part the sensitivity is also high (range 82% - 100%; Smith et al., 2010). The high sensitivity is advantageous for the screening of pilots and ATCOs, but it should be considered that this high sensitivity is at the cost of a lower specificity (67%-79%) and, thus, an appreciable false positive risk.

In analogy with the considerations and reasoning related to the above CAGE questionnaire, for aeromedical screening purposes the separate questions of the NIDA questionnaire can best be “woven-in” into the medical history taking.

### **Single-Question Screening Test for Drug Use**

Like the single alcohol screening question mentioned above, this instrument allows easy screening for illicit drugs and the misuse of prescription medications by asking:

“How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons (for example, because of the experience or feeling it caused)?”

The test has a high sensitivity (range 82% - 100%; Smith et al., 2010) at the cost of a lower specificity (67%-79%). Test results were similar to that of the 10-question DAST, and were affected very little by subject demographic characteristics. As a screening test (as opposed to an assessment of severity or a diagnostic tool) the single-question screen performed almost as well as the longer DAST-10 in the primary care population that was studied (Smith et al., 2010).

It is concluded that the Single Question Screening Test for Drug Use is suited to be asked orally as part of the aeromedical history taking.

Aviation personnel with a response of  $\geq 1$  is considered at risk and further evaluation using more detailed questions and biochemical methods is needed.

### **Questions on alcohol and drugs use included in questionnaires currently used by European AMEs/AeMCs**

Several mental health screening questionnaires used by AMEs/AeMCs include the following questions about use of alcohol and drugs:

- Sometimes I feel guilty after drinking alcohol – Yes/No? (also in CAGE questionnaire)
- I rather like to relax after work, having a drink – Yes/No?
- Sometimes I use medications or substances to keep me better – Yes/No?
- I think that use of alcohol and mood-altering substances do not affect my work capacity – Yes/No

Like the other questionnaires discussed in the present report, these questions presently used by European AMEs/AeMCs are not validated for use in the framework of a mandatory aeromedical examination. However, the questions regarding alcohol and drugs use (see e.g.: Rios Tejada, 2018) seem useful for AMEs to be used as mnemonic and to be “woven-in” into the face-to-face medical history taking. In particular, the last three questions mentioned above may be useful to include in the interview because answers to these questions reflect the applicant’s feelings and views related to use of alcohol and/or drugs, which might open the way to more in-depth interviewing.

It is considered that answers to these questions have very limited value when asked as part of a paper/pencil or electronic mental health questionnaire because pilots and ATCOs will know what they should answer to be declared fit (“tick-box exercise”).

### 4.3 Review of psychodiagnostics tests and options

This section presents a qualitative analysis of the aforementioned psychodiagnostics tests and options that may be used to assess the risk of incapacitation.

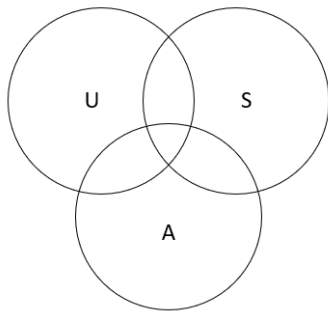


Figure 8 - Harwood (1993),  
Relationship between usability,  
suitability, and acceptability.

The analysis has been performed on three main levels (figure 8): usability (U), intended as the operational aspects of the tests and options as well as their characteristics; suitability (S), intended as tests and options eligibility for the specific domain; and acceptability (A), intended as the relation between the usability and suitability of tests and options capacity to analyse relevant aspects of the domain. Usability is characterized as a bottom-up, tests and options driven process, while suitability is characterized as top-down and problem-driven (Rasmussen & Goodstein, 1988). User acceptability is influenced by the usability and suitability of the tests and options.

The analysis involves the tests that have been presented so far, as follows:

- The California Psychological Inventory (CPI)
- The Dominance, Influence, Steadiness and Conscientiousness Test (DISC)
- Profiles XT
- The Myers-Briggs
- NEO-PI-R
- 16 PF+
- Rorschach and other projective test
- MMPI-2
- The MCMI-IV
- The Beck Depression Inventory II (BDI-II)
- The Hamilton Depression Rating Scale (HDR-S)
- The Beck Anxiety Inventory
- The Hamilton Anxiety Scale
- The State-Trait Anxiety Inventory
- The Penn State Worry Questionnaire
- The Yale Brown Obsessive-Compulsive Scale
- CAPS
- Cognitive tests
- SCID-5
- Interviews
- Questionnaires
- Questionnaires for substance abuse

The results of the analysis are reported below in the form of a table (see below) and discussed more specifically in the following sections.

	Usability						Suitability					Acceptability	
	Requirements for administration	Availability at EU member states level	Professionals profiles to be involved	Frequency of assessment	Cost	Time and tools required for data collection and analysis	Compliance with operational needs and associated acceptable incapacitation risk	Validated statistical standards on pilots and ATCOs	Sensitivity to the incapacitation risk	Ability to detect the risks of incapacitation recurrence or relapse	Validity time-frame (short-, medium- and long-term)	Ability to assess the short-, medium- and long-term evolution of mental pathologies	Comparison with other diagnostic methods used for the respective mental pathology(ies)
<b>The California Psychological Inventory (CPI)</b>	Respondent aged 13 up	English	Psychologist, psychiatrist and Subject-matter expert	1-2 years	Essential guide: \$156.00; Interpretation guide: \$145.00; + other manuals	45-60 minutes, tools: official self-report inventory	No	No	No	No	No	No	Different theoretical framework, but similar to DISC, XT, Myers-Biggs, NEO-PI-R, and 16PF+
<b>The Dominance, Influence, Steadiness and Conscientiousness Test (DISC)</b>	n/a	11 languages	Psychologist, psychiatrist and Subject-matter expert	1-2 years	\$80-200	15-20 minutes; Self-assessment official material (paper or web)	No	No	No	No	No	No	Different theoretical framework, but similar to CPI, XT, Myers-Biggs, NEO-PI-R, and 16PF+
<b>Profiles XT</b>	n/a	32 languages	Psychologist, psychiatrist and Subject-matter expert	Variable	\$100/One-time	60 minutes; Paper or computer format	No	No	No	No	No	No	Different theoretical framework, but similar to CPI, DISC, Myers-Biggs, NEO-PI-R, and 16PF+
<b>The Myers-Briggs</b>	n/a	21 languages	Psychologist, psychiatrist and Subject-matter expert	3 months, 1 year	\$50 for basic results	45 minutes	No	No	No	No	No	No	Different theoretical framework, but similar to CPI, DISC, Myers-Biggs, NEO-PI-R, and 16PF+
<b>NEO-PI-R</b>	Respondent aged 12-20 or 21 up	40 languages	Counsellors, clinical psychologists, and psychiatrists	Variable	\$40-50 or more	40-60 minutes	No	Yes, military aviation	No	No	Yes	Yes	Different theoretical framework, but similar to CPI, DISC, XT, Myers-Biggs, and 16PF+

<b>16 PF+</b>	n/a	30 languages	Psychologist, psychiatrist and Subject-matter expert	Variable	\$200 or more	35-50 minutes	No	No	No	No	No	No	Different theoretical framework, but similar to CPI, DISC, XT, NEO-PI-R, and Myers-Biggs
<b>Rorschach and other projective test</b>	Administration not recommended at first visits	n/a	Certified examiner	At least every 5 years if already administered	Complete kit \$500		No	No	No	No	No	No	Similar to TAT
<b>MMPI-2</b>	Respondent's Basic school education and at least 18 years old	English, Spanish, French	Clinical Psychologist, Psychiatrist	Once; variable	Complete kit \$650	40-60 minutes; Paper or computer or audio-recorded format	No	No	Yes	No	No	No	Self-report, similar to MCMI-IV, but measures a broad range of psychopathology
<b>The MCMI-IV</b>	Respondent aged 18 up	English, Spanish	Clinical psychologist, psychiatrist	Once, variable	Starter kit \$200	30 minutes, paper or digital form	No	No	No	No	No	No	Self-report, similar to MMPI-2, but with stringer focus on personality disorders
<b>The Beck Depression Inventory II (BDI-II)</b>	n/a	20 languages	Clinical psychologist	3-6 months	Complete kit \$165	10 minutes, Questionnaire	No	No	No	No	No	No	Similar to HDR-S
<b>The Hamilton Depression Rating Scale (HDR-S)</b>	Administration considers the last week	10 languages	Clinical psychologist	2 weeks-1 month	Free	15-20 minutes, Interview	No	No	No	No	No	No	Similar to BDI-II
<b>The Beck Anxiety Inventory (BAI)</b>	Respondent aged 17 up	English, German, French, Chinese, Spanish and others	Medical or Mental health professionals	Test-retest 1 week	Starter kit \$165 (print); \$107 (digital)	Self-administered	No	No	No	No	No	No	Similar to HAM-A and STAI
<b>The Hamilton Anxiety Scale (HAM-A)</b>	Administration considers the last week	English, French, Spanish, Chinese	Medical or Mental health professionals	2 months	Free	10-15 minutes; Interview, and behavioural observation	No	No	No	No	No	Yes	Similar to Beck Anxiety Inventory and STAI
<b>The State-Trait</b>	n/a	48 languages	Medical or Mental health professionals	2 months	\$50-100	10-20 minutes;	No	No	No	No	No	Yes	Similar to HAM-A and Beck



<b>Anxiety Inventory (STAI)</b>						2 self-administered questionnaires							Anxiety Inventory
<b>The Penn State Worry Questionnaire (PSQW)</b>	n/a	English, Spanish	Medical or Mental health professionals	Test-retest 8-10 weeks	Free	Self-administered questionnaire	No	No	No	No	No	No	Similar to Y-BOCS
<b>The Yale Brown Obsessive-Compulsive Scale (Y-BOCS)</b>	n/a	16 languages	Medical or Mental health professionals	Test-retest 1 week	Free	5-15 minutes; Structured interview	No	No	No	No	No	No	Similar to PSQW
<b>CAPS</b>	n/a	10 languages	Medical or Mental health professionals	Test-retest 1 week	Free for health professionals	40-60 minutes Short checklist	No	No	Yes	No	No	No	PTSD scales
<b>Cognitive tests</b>	n/a	Variable	Neuropsychologist, Neurologist, or Psychiatrist	Variable	Variable	Variable	No	No	No	No	No	No	Simulator checks, line checks, peer review, and occupational history > cognitive tests
<b>SCID-5</b>	Training on MH needed by respondents	10 languages	Mental health professionals; Usable by trained AMEs	Variable	\$115	30-120 minutes	No	No	No	No	No	No	Similar to clinical interviews but up to 10 modules
<b>Clinical Interview</b>	Personal setting, trusted atmosphere, training for AMEs	Variable	Psychologist, Psychiatrist, Trained AMEs	Variable	Variable	Variable	No	No	Yes, theoretically	Yes, theoretically	No	No	Similar to SCID-5, but less structured and based on experience and practice
<b>Questionnaires</b>	They complement interviews	Variable	Psychologist, Psychiatrist, Trained AMEs	Variable	Variable	Variable time, tools used in primary and or mental healthcare settings in the specific country	No	No	No	No	No	No	Less specific compared to questionnaires for substance abuse
<b>Questionnaires for substance abuse</b>	AME training, trusted setting	Variable	Psychologist, Psychiatrist, Trained AMEs	Variable	Variable	Variable time, pen-and-paper or electronic questionnaires	No	No	No	No	No	No	More specific questionnaires compared to the aforementioned

Table 24 - Review of psychodiagnostics tests and options

### 4.3.1 Usability

While psychodiagnostic tests can be a valuable tool in the assessment of psychological conditions, it is important to use them appropriately, and with the necessary expertise and resources. Generally, they should only be administered and interpreted by trained professionals with expertise in psychodiagnostic assessment, with some exceptions. For instance, questionnaires and questionnaires for substance abuse may be used by AMEs with the proper degree of training.

#### 4.3.1.1 Requirements for administration

it is important to be aware that some psychodiagnostic tests may have specific requirements, such as language proficiency, specific cultural knowledge or specific ages, which may affect their validity and reliability when administered to individuals from different backgrounds. Generally, these psychodiagnostic tests and options, shall be used with adults.

#### 4.3.1.2 Availability at EU member states level

Access to these psychodiagnostics tests may not be available in all EU states, or may be limited by resources or funding. Validated translations are not common, but they exist. Main developments have been made in the personality tests where they are used for personnel selection and recruitment.

#### 4.3.1.3 Professional profiles to be involved

Psychodiagnostic tests should only be administered and interpreted by mental health specialists who have the necessary training and expertise in psychodiagnostic assessment. This includes licensed psychologists and psychiatrists who have received specialized training in psychological assessment. Mental health professionals who use these tests should also be familiar with the specific test they are using, including the test's theoretical background, administration procedures, and scoring methods. They should also be aware of the potential biases or limitations of the test, and take these into account when interpreting the results.

#### 4.3.1.4 Frequency of assessment

Another important consideration when it comes to psychodiagnostic tests is that different types of tests have different requirements and limitations. For example, personality tests may require an individual to wait a certain amount of time between test administrations to ensure accurate results. This is because personality traits can be relatively stable over time, and administering the test too frequently may yield inconsistent or unreliable results. On the other hand, tests used to assess conditions such as depression or anxiety may require pre- and post-tests to evaluate changes in symptoms over time. This can help mental health professionals track the effectiveness of treatment and adjust treatment plans as needed.

It is important for mental health professionals to be familiar with the specific requirements and limitations of the tests they are using, and to administer them in accordance with best practices and established protocols. This can help ensure that the results obtained are accurate, meaningful, and useful for informing treatment decisions.

#### 4.3.1.5 Cost

Another important consideration when it comes to psychodiagnostic tests is the cost involved. Depending on the test, the administration and interpretation can be quite expensive, which can be a significant barrier for AMEs and AeMCs who need the tests but may not be able to afford them. Additionally, the cost of these tests may be a challenge for MHS that do not have the resources to purchase the necessary testing materials or hire staff with specialized training in psychological assessment.

This cost factor can limit access to psychodiagnostic tests, particularly for those in lower income brackets, and may also impact the availability of testing in certain geographic locations.

#### 4.3.1.6 Time and tools required for data collection and analysis

The administration time for psychodiagnostic tests can vary depending on the type of test being used. Generally, most personality tests require 40-60 minutes for the administration, which can be a significant

amount of time for both the applicant being tested and the mental health professional administering the test. However, some tests may have shorter administration times, such as those that are designed to assess specific symptoms or domains of functioning. These shorter tests can be useful in certain situations where time or resources are limited, or when a quick assessment is needed to inform treatment decisions.

Regardless of the length of time required for administration, most psychodiagnostic tests require the use of official materials, guides, and manuals to ensure accurate administration and interpretation of results. In addition to official materials, mental health professionals may also need specialized training or certification to administer certain types of tests. For example, some tests may require specialized training in specific areas such as neuropsychological assessment, or may require certification through a professional organization in order to be used.

### 4.3.2 Suitability

When it comes to suitability, it is important that psychodiagnostic tests are fitted for specific domains, such as the aviation industry. Some psychodiagnostic tests have been used in the aviation industry to assess the psychological functioning of pilots and other aviation personnel. However, not all psychodiagnostic tests are suitable for this domain, as the demands and stressors of the aviation environment can be unique and require specific assessments. Research has shown that some psychodiagnostic tests, i.e., the Minnesota Multiphasic Personality Inventory (MMPI), have been found to be suitable for use in the aviation domain. These tests have been specifically developed and validated for use in aviation settings, and can provide useful information about an individual's psychological functioning and potential risk factors in this context.

#### 4.3.2.1 Compliance with operational needs and associated acceptable incapacitation risk

Psychodiagnostic tests can provide valuable information about an individual's psychological functioning, but it is important to ensure that the tests used are appropriate for the specific operational needs of the aviation industry, and that they do not pose an unacceptable risk of incapacitation.

However, in the aviation domain, very few psychodiagnostic tests have been found to be fully compliant with operational needs and associated acceptable incapacitation risk.. This highlights the need for continued research and development in this area, as well as close collaboration between mental health professionals and aviation industry stakeholders to ensure that appropriate testing protocols are developed and implemented.

#### 4.3.2.2 Validated statistical standards on pilots and ATCOs

To date, almost none of the available psychodiagnostic tests have been specifically validated for use on pilots and ATCOs. This means that mental health professionals who work with aviation personnel must use caution when interpreting test results and making treatment recommendations. It is important to consider the unique demands and stressors of the aviation industry when selecting and administering psychodiagnostic tests, and to use tests that have been validated for use in comparable safety-critical environments.

#### 4.3.2.3 Sensitivity to the incapacitation risk

In the aviation industry, the risk of incapacitation due to psychological factors such as anxiety, depression, or substance use is a serious concern. However, to date, no psychodiagnostic test has been found to have high sensitivity to the risk of incapacitation.

#### 4.3.2.4 Ability to detect the risks of incapacitation recurrence or relapse

While some psychodiagnostic tests may be useful in identifying initial risk factors for incapacitation, few have been identified as being able to reliably predict the risk of incapacitation recurrence or relapse, especially if it occurs in between two medical examinations. To address this limitation, mental health professionals who work with aviation personnel should use a comprehensive and multi-faceted approach to evaluating and monitoring mental health. This may involve a combination of psychodiagnostic tests, clinical interviews, behavioural observations, and ongoing monitoring of psychological functioning over time.

#### 4.3.2.5 Validity timeframe (short-, medium- and long-term)

Many mental disorders can fluctuate in severity over time, with symptoms increasing or decreasing in severity over weeks, months, or even years. This means that a test that is valid for assessing symptoms at one point in time may not be valid for assessing symptoms at a later point in time. To address this limitation, mental health professionals who use psychodiagnostic tests must be mindful of the time frame of the mental disorder being assessed and select tests that are valid for that time frame. For example, some tests may be designed to assess symptoms over the past week, while others may be designed to assess symptoms over the past month or longer.

It is also important for mental health professionals to use a combination of tests and clinical assessments to gain a comprehensive understanding of an individual's mental health status over time. This may involve regular check-ins and assessments to monitor symptoms and treatment progress.

### 4.3.3 Acceptability (from the point of view of AMEs)

#### 4.3.3.1 Ability to assess the short-, medium- and long-term evolution of mental pathologies, i.e. risk of recurrence or relapse

It is important to note that few, if any, psychodiagnostic tests have been found to be able to assess the short-, medium-, and long-term evolution of mental pathologies on their own. Instead, mental health professionals must use a combination of tools and assessments to gain a comprehensive understanding of an individual's mental health status over time, i.e., complementing with clinical interviews and questionnaires.

#### 4.3.3.2 Comparison with other diagnostic methods used for the respective mental pathology(ies), i.e. interviews

While psychodiagnostic tests can be a valuable tool for mental health professionals, they are not the only method of diagnosis, nor are they always the most appropriate method.

Interviews, for instance, can be a highly effective means of diagnosing mental health conditions, as they allow mental health professionals to gather information directly from the patient and observe their behaviour and emotional state in real time. Ultimately, the choice of diagnostic method depends on a range of factors, including the individual patient's needs and preferences, the nature and severity of their symptoms, and the expertise of the mental health professional conducting the assessment. In some cases, a combination of diagnostic methods may be most effective in ensuring a comprehensive and accurate diagnosis.

## 4.4 Psychodiagnostic guidelines

The aforementioned psychodiagnostic options should be complemented by the following methods for a comprehensive understanding of mental health.

### 4.4.1 Building trust (active listening, effective doctor-patient communication)

Among the factors affecting a frank discussion of mental health issues between an AME and a pilot or ATCO, mistrust between pilots or ATCOs and AMEs is considered as a major barrier to identify mental health problems and mental support of pilots or ATCOs (EASA-MESAFE, 2022; p. 90-94).

Mistrust may be caused by a variety of factors, such as stigma concerning psychiatric or psychological disorders, fear of loss of licence if mentioning or admitting to have mental health problems, lack of awareness regarding the negative effects of mental health problems on safety-sensitive task performance, and lack of information of the decision-making process for unfitness and the appeal procedures (EASA-MESAFE, 2022; p. 90-94).

Problems which AMEs face when trying to identify mental health problems, may stem from AME functioning and characteristics of the applicant pilots and ATCOs, as well as the system in which these examinations take place.

Lack of trust on the side of applicants for aeromedical certification is likely to lead to underreporting of health issues that might be a threat to flight safety (AvWeb Online; Strand et al., 2022). Therefore, it is important to consider and tackle the trust problem in the communication between pilots/ATCOs and AMEs. An ongoing relationship between the pilot or ATCO and the AME provides a firm basis for building up trust, enabling health promotion and facilitating better communication both during, and between, examinations. Such firm relationship with the AME, might stimulate the pilot or ATCO to consult her/his AME about mental health or medical problems that may emerge between medicals and which could affect flight safety, or could be prevented from becoming more severe health and safety problems.

While the sources of mistrust are known, a direct solution may not be easy. Professionalism, honesty and trust are the building blocks of a good working relationship between an AME and a pilot or ATCO. This does not happen overnight. It requires work from both parties. AMEs and pilots/ATCOs together should foster a culture where disclosure by the pilot or ATCO of potentially career threatening medical problems is likely. When such problems are disclosed, the pilot can expect a supportive response to his problems and then both can work together towards a shared goal of a long and safe career in aviation (ECA-ESAM-EAAP, 2015).

The following tools and measures are recommended to mitigate mistrust:

- It should be emphasized that AMEs, pilots, and ATCOs share the same aim: to keep the pilot or ATCO healthy and working safely. Pilots and ATCOs should know what they can expect from their AME and AMEs should learn that flight safety and a healthy and fulfilling career are top priorities for a professional pilot or ATCO. AMEs should clarify that this is also something that the AME works for together with the pilot or ATCO.
- To achieve a trustful relationship, pilots and ATCOs should learn about the aims of the AME job and the methods that AMEs use to achieve optimal safety.
- AMEs should learn and utilize methods to build rapport and trust with the pilot in a nonthreatening environment (AsMA, 2016).
- AMEs should take sufficient time for the aeromedical interview and should not treat the aeromedical examination as a “box ticking” exercise. AMEs should follow, or learn to follow, the principles of an open and effective medical interview as described in section 7.1.2 History taking.
- AMEs should be interested in the professional and social life of their applicant and should know what the applicant expects from them.
- AMEs should know current developments in the aviation industry and the environment in which their applicants work.
- AMEs should make their applicants feel comfortable in a nonthreatening environment and explain the aim and contents of the examination. They should use a personalized approach, listen carefully and give and ask feedback.
- AMEs should have a frank and open approach and be honest about probable safety risks of the disclosed (mental) health problems and discuss next steps concerning referral, treatment, and prognosis in relation to health and professional career.
- The AME should make clear that if the applicant identifies any areas for which s/he would like to have further support, the AME can recommend ways to address these problems outside of the medical, in order to prevent them becoming an issue that could impact the applicant’s fitness for flying or ATC work in the future (this might include Peer Support Programmes, specialised counselling, or support from a professional association).
- Anything that does not directly impact the aviation safety risk should remain confidential between the applicant and the AME (ECA-ESAM-EAAP, 2015).
- AMEs and safety trainers should educate pilots and ATCOs on the following principles:
  - Self-reporting of addiction or mental health problems will improve flight safety
  - One can recover from addiction and/or mental health problems and can resume aviation duties after recovery.
  - Self-reporting can be the start of regaining a healthy and safe pilot career.

*Trust and alliance between applicants and AMEs, and organizational context.*

Even if the applicants may trust their AME, the final decision of unfitness is often made by a medical assessor whom the applicant does not know. In most cases, the exact decision-making process for unfitness is not known to the pilot or ATCO. Because this is likely to enhance mistrust levels, the following recommendations are made to contribute to building trust on an organisational level:

- Transparent decision-making processes should be devised, also on the medical assessor and national authority level in order to improve predictability for the pilot and ATCO and trust in the system itself.
  - Procedures for a complaint should be explained.
  - The decision making process should include the pilot's or ATCO's own viewpoints on the flight safety implications as well as on diagnostic conclusions.
- Different ways of achieving a better and more transparent decision process should be explored in order to improve the contextual distrust in aviation medical systems that exists with many Pilots and ATCOs. In that context, implementation of an Ombudsman-system might be considered.

#### 4.4.2 History taking (including stressors and life-changing events)

History taking of the applicant pilot or ATCO is the most important part of the aeromedical examination and is the most important means of identifying suspicion ("red flags") of mental health problems and psychoactive substance misuse (see the MESAFE deliverable D3.1).

Most clinical interviews by AMEs will most probably be structured interviews. The advantage of structured interviews is that these are standardised which avoids missing aero-medically important questions. The disadvantage is that it may hinder an open and informative communication with the interviewees due to the fixed questions and the rigid structure. A rigid structure may also prevent interviewees to open up about emotional problems. As proposed by Bor et al., (2017), "a reasonable compromise is to divide a mental health assessment interview into a loosely structured first half followed by a more structured and systematic second half". The loosely structured start of the interview is to provide the AME with a "picture" of the pilot's or ATCO's life, family, and occupational environment. In this context, recommended subjects of questions and conversation are:

For initial aeromedical examinations:

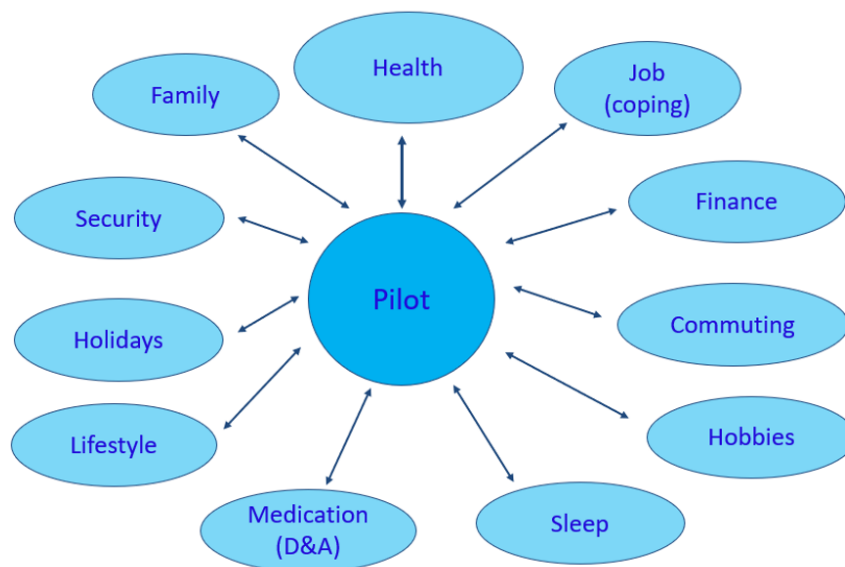
- general attitudes to mental health, including understanding possible indications of reduced mental health in themselves and others;
- coping strategies under periods of psychological stress or pressure in the past, including seeking advice from others;
- childhood behavioural problems;
- interpersonal and relationship issues.

For all aeromedical examinations (Hudson & Herbert, 2017; see figure X):

- The Job: type of flying (pilots) or ATC work; employer details; length of service in current employment; full-time/part-time; total flying hours; hours flown since last medical; roster pattern: long-, medium-, short-haul; number of sectors flown in a duty period; Also for ATCOs: are rosters reasonable?; fatigue; job satisfaction/; attitude towards job; aspirations for future career development; difficulties with operational crew resource management (CRM); any difficulties with employer and/or other colleagues and managers; company peer support?
- Commuting: distance to work; commuting time; ease of commuting; mode of travel; return journey home.
- The applicant's role and attitude in accidents or incidents, problems in training or proficiency checks, behaviour or knowledge relevant to the safe exercise of aviation tasks relevant for their class of licence.
- Coping strategies under periods of psychological stress or pressure in the past, including seeking advice from others.
- Family arrangements: married, co-habiting, or single; ages of children; childcare; family life; health issues family; partner employment.

- Interpersonal and relationship issues, including difficulties with relatives, friends, and work colleagues.
- Security: (for pilots) airport security checks; fear of terrorism, unruly passengers?
- Finance: concerns about money; debts; overtime; second job?
- Hobbies: other interests, hobbies; what do you do in your spare time? Loss of interest in hobbies, sport, or other activities may herald depression or misuse of psychoactive substances.
- Holidays: how many times/year; where do you go?; does the family join?

Asking questions regarding mood, quality of sleep, current sources of stress (such as work, fatigue, financial, home and family, bereavement), and alcohol and/or substance use is recommended. These questions should be woven into the conversation with the pilot during the aeromedical examination as part of a general health promotion discussion that addresses a variety of health issues, both mental and physical.



*Figure 9 - The components of a thorough pilot medical interview (adapted from Hudson & Herbert, 2017)*

Particular attention should be given to life stressors that can be part of the “carry-on luggage” of pilots and ATCOs. Known life stressors that might have a negative impact on safe functioning in aviation are:

- work related problems
- bereavement
- financial worries
- health concerns
- relationship / family difficulties
- separation from family, loneliness
- social demands (incompatible with work demands)

The COVID-19 pandemic may have triggered mental health problems to emerge. There is evidence that above-mentioned life stresses may lead to significant mental health problems in some cases (Hammen, 2005; Young, 2008).

After this more loosely structured interview, a structured medical history taking should follow with questions on:

- Health, illness, symptoms, organ systems (functioning, complaints)
- Sleep: quality and amount (at home and on stopovers); jet lag / shift work; rest arrangements prior to duty; sleep medication? Snoring (OSA)?
- Exercise/diet: activities; diet; food during work.
- Medication: prescribed; over-the- counter; via internet

- Drugs/alcohol/smoking habits: alcohol type/amount/binge drinking; suggested bottle to throttle time; social / party drugs; legal highs; driving license offences?

As required by EASA in AMC1 MED.B.055 Mental health (EASA, 2022), the following aspects should particularly be taken into consideration when conducting the mental health examination: appearance, attitude, behaviour, mood, speech, thoughts process and content, perception, cognition, insight, and judgement. The method of interview and history taking as described in this section offers the opportunities to consider and observe these aspects.

All information that gives clues to potential problems should be followed by a dedicated in-depth interview. When there is an indication for mental problems, including misuse of psychoactive substances, pilots/ATCOs should be referred to a mental health expert.

#### 4.4.3 Access to previous AME's records and the threshold of reporting mental health history

As medical history is the most important part of any diagnostic activity or functional health evaluation, exact information about past health problems is crucial for the AME's work. Mental health is no exception, as there is no EKG or blood test that will show up mental health problems of the past. Any underreporting may therefore easily mislead the judgment of an AME who has a pilot or ATCO for a medical check-up.

Although the magnitude of underreporting is not well known, a recent study found that 8% of a group of 1616 different aviation license holders admitted to underreporting drug or alcohol abuse and other mental health issues. (Strand et al, 2022). It is important to point out, though, that such underreporting need not be intentional. The pilot or ATCOs own recollection of past health, including mental health problems, might be absent or biased. It is understandable that a pilot or ATCO might downplay past symptoms or mental health issues, given his or her perception that such issues may impact their certification. Even if we do not count in such mechanisms, there is evidence that human memory changes over time, not only as anecdotal reports, but also studied in neurobiological research (Söderlund et al, 2012).

One important way to get around possible underreporting, is to have access to previous history - In particular, previous AME records are of importance for any evaluation regarding fitness to fly or operate as an ATCO, since such records would include not only past history known to a previous AME, but also the evaluation of such history in relation to performing duties safely. Commonly used computer programs for pilot/ATCO certification in Europe, such as EMPIC, includes a possibility to access previous examinations performed by previous AMEs directly in the system. This requires a written acceptance from the pilot or ATCO in question, and is therefore optional for the current AME to access. It is presumably a common practice to get acceptance from the pilot/ATCO to gain access of such records, but there are no known data regarding the use of this option in practice, or the non-use of it.

Given the points discussed above, access to previous AME reports seem necessary for a correct evaluation of the pilot or ATCO. In fact, it might be considered malpractice for an AME not to check previous examination reports if at all available.

A pilot/ATCO not allowing an AME to access previous records, is a possibility, even though it would to some extent undermine trust between the AME and the pilot/ATCO. Also, there is nothing to stop a pilot or ATCO to go to another AME if such access is not wanted – this might in fact also keep the AME from asking for such access.

Nevertheless, a consideration should be made whether access to AME records should be made mandatory for any AME examination, and if this is not available online the pilot/ATCO should provide such records when he or she changes his/her AME.

The EAMR (European Aero-medical Repository), which recently came into place, does provide details of certification examination outcomes. However, it does not contain diagnoses or other aeromedical problems of the past. Such details in a centralised database as the EAMR would be useful to provide historical information for the examining AME. As such a database does not exist to date, any access to previous AME



records must therefore be between the current AME, the pilot or ATCO in question, and the medical assessor of the licensing authority of the applicant. Any mandatory check for previous records should therefore have an explicit responsibility for the current AME, making such a request to the pilot or ATCO in question.

#### 4.4.4 Access to medical records

The issue of access to medical records for the AME was an important finding in the report from the Germanwings tragedy (BEA, March 2016). France's BEA air accident investigation board recommended both to ICAO and to the European Commission the following:

*"The European Commission in coordination with EU Member States define clear rules to require health care providers to inform the appropriate authorities when a specific patient's health is very likely to impact public safety, including when the patient refuses to consent, without legal risk to the health care provider, while still protecting patients' private data from unnecessary disclosure"*

In addition, a follow-up sentence was aimed at the European commission: "These rules should take into account the specificities of pilots, for whom the risk of losing their medical certificate, being not only a financial matter but also a matter related to their passion for flying, may deter them from seeking appropriate health care"

These recommendations are important, in that they state the two main reasons for important information regarding pilot and ATCO health not to come to the attention of the AME in the evaluation of aircrew.

That is:

- Medical secrecy laws, designed to protect the pilot.
- Pilot (or ATCO) healthcare avoidance in general (not only to the AME).

The first bullet point refers to a patient right, so to waive this right Physicians (or psychologists) need to have rules under which circumstances this right can or shall be waived. Some nations have such legislation, where a pilot or psychologist not only may, but has a duty to inform the relevant authority should he or she become aware of a patient having health issues that are not in compliance with license medical requirements. Examples of such countries are New Zealand, Canada, and Norway. Other nations have ethical medical standards which have a similar effect which is accepted by society and law, without explicit legislation.

However, many nations have medical secrecy laws and/or medical cultures which precludes any disclosure of medical information to authorities except in extreme circumstances. An example of this is Germany (Kenedi et al. 2019). In November 2016, EASA submitted a Working Paper to the European Commission on the issue of balancing patient confidentiality and public safety. This issue is therefore an unresolved political question, but remains important from a flight safety perspective.

The second bullet point, pilot or ATCO avoidance of medical disclosure in general (not only to the AME), cannot be solved by only changes in regulation or a change in reporting culture on the part of physicians. It might, however, be an even more important factor in order to bring safety-critical medical issues to the attention of the aeromedical system. Pilots or ATCOs might not tell their healthcare provider what their occupation is, or might even avoid healthcare for fear of medical disclosure of a non-qualifying condition. This might be more common than we think. In fact, a recent study in the USA found that 56% of 3765 pilots had a history of healthcare avoidance behaviour due to fear of losing their aeromedical certificate. Of these, the 47% (n=1721) sought informal medical care, and 28% misrepresented or withheld information on a written healthcare questionnaire for fear of aeromedical certificate loss (n=994) (Hoffman et al 2022).

Avoidance behaviour not only prevents relevant information for the AME, but also prevents that the pilot or ATCO receives the best treatment for their condition. Therefore, this may have both short-term and long-term consequences for both pilot/ATCO health and flight safety.

It may not be possible to solve the issue of underreporting or healthcare avoidance behaviour in pilots or ATCOs completely, but it might be possible to improve openness on the part of license holders substantially.

There are two distinct issues that may have a bearing on this, namely clear and transparent processes, and risk-based decision making.

Today, the aeromedical decision-making system may make pilots or ATCOs feel disempowered. Aeromedical decision-making is seldom transparent, and the EASA system of aeromedical certification is no exception. Final decisions in difficult aeromedical cases are performed by Medical Assessors (often alone, although they may seek advice). Such decisions are also usually made without involving the pilot or ATCO, also often without involving the AME. Practice may vary from country to country. However, this practice may lead to disempowerment and lack of trust and may be a root cause of underreporting and healthcare avoidance. A more transparent system, where not only decision responsibility is defined, but also the decision process is defined and clear, may decrease disempowerment and improve trust in the system on the part of pilots and ATCOs. This would include a clear and real possibility of appeal or review, and information about the system being well known to pilots and ATCOs. In practice, this is often not a real possibility, particularly in small countries where aeromedical competence is scarce. Here, countries may collaborate to form a better basis of making decisions, for example medical boards for difficult cases.

Important decisions about the pilot or ATCOs future are often performed in a rule-based fashion. Although this may be bureaucratically correct, and may be seen to contribute to "level playing field", such decision-making is one-dimensional and may to some extent misrepresent real risk. Aeromedical regulations in this context are used in a prescriptive way rather than in a safety management or risk-based way. ICAOs "flexibility clause" is traditional way of defining the solution to this problem. There might, however, be a fear that flexibility may lead to less predictable outcomes rather than improve decision quality. A risk management process in difficult cases, using a risk matrix would be more precise and also improve transparency. This is also a framework by which pilots are used discuss and manage risk. Such a risk management framework was proposed by a Aviation Cardiology Supplement to BMJ in 2019, developed by a NATO aviation cardiology working group. (Gray et al, 2019) This framework uses a risk matrix that takes into account medical risk, license class and operational role. A further development and simplification has been developed recently for the US Air Force (Kearns et al 2022).

Use of such risk matrices may improve the precision and accountability of aeromedical decisions and facilitate risk-based decision making. This would probably provide additional trust on the part of pilots and ATCOs, also as risk matrices are tools of modern safety analysis which they are used to and understand.

In addition to the above points which may lower the threshold of reporting medical history and improving the access to medical records, there may be other more general principles which may improve reporting. Positive communication, highlighting the benefits of early diagnosis during the medical examination allowing early treatment and return to duty may be such a principle. Also, enhanced medical education for AMEs and applicant, including understanding health risks and advice on a healthy lifestyle. Focusing on prevention and addressing mental health issues early may in this context be helpful.

#### 4.4.5 Access to psychological/psychiatric records and sharing information with mental health practitioners and experts

Medical confidentiality laws are different in the various EASA member states, and the problem of balancing the interest of public safety with that of medical privacy goes far beyond aerospace medicine. Furthermore, it is questionable to what extent the European Union has jurisdiction to make rules regarding medical confidentiality in individual member states.

For the purpose of this paragraph therefore, it will be assumed that the AME or mental health expert has been given access to medical records voluntarily by the applicant. Besides, no matter how the local medical confidentiality laws are, for a good working relationship it is always better to receive information with the consent of the applicant. Of course, the consequences of not allowing to share information should be borne by the applicant, and the applicant should be informed that not providing relevant information may result in disqualification.

Information from medical records is only useful when used in the right way, and when the examiner is aware of the risk of bias that may be present in this information, as well as some practical impediments that may occur:

- Medical records have been made with the purpose of logging diagnostic and treatment procedures, not with the purpose of informing aeromedical assessments.
- Notes in records often reflect the impression of the clinician, especially in psychotherapeutic treatments and are often not objective or factual.
- Medical reporting is highly different among psychiatrists, psychologists, mental health nurses, and other professionals. Even within professionals of the same profession, differences in reporting can be huge.
- Much of the information in medical records, especially in the reports of treatment sessions, is not relevant for aeromedical decision making. For example, whereas the presence mental symptoms is relevant, details of a shameful experience during childhood are not necessary for the aeromedical decision-making.
- Analysing entire mental health records takes a lot of time.

Instead, it may be better to focus on the diagnostic assessments, letters that have been sent to GP's and occupational physicians, referral-letters etc, that are usually easily identifiable in medical records.

If possible, it is even better to ask the treating clinician clear and well-defined questions about the diagnosis and treatment. In order not to put pressure on the therapeutical relationship and to get the most accurate information, it is best to ask factual questions, such as what diagnosis had been made, what treatment had been initiated, if a risk of suicidal behaviour had been determined etc. It is better not to ask the opinion of the clinician whether or not the applicant will be able to perform aviation duties, or whether or not there is a risk for flight safety. Not only that clinicians do not have the training and knowledge to answer this kind of questions properly, but such questions may also bring them into conflict between loyalty to their patients and the interest of public safety. Therefore, the judgement on whether or not someone is able to perform aviation duties is better left to the AME in cooperation with independent aviation psychiatrists and psychologists.

It may be considered to develop a guidance list of standard questions that aeromedical experts can ask to mental health practitioners. Questions may be:

- What were the initial complaints?
- What were the diagnostic findings, and can you send the latest mental examination?
- What diagnosis had been made?
- What symptoms are still present?
- What treatment has been initiated and what is the current treatment?
- Is the patient experiencing any side-effects?
- Has the applicant ever made a suicide attempt or deliberately harmed him/her-self?
- Has the applicant ever been in a mental health crisis or requiring emergency mental health services? If so, what was the nature of the crisis?
- Has the applicant ever been admitted to a mental hospital or to a psychiatry ward in a general hospital? If so, for how long, and what treatment has been initiated?
- Can you give a prognosis?
- How long do you expect the treatment to continue?

Most mental healthcare providers are not familiar with providing information for aeromedical assessments. It should be made clear to them that the purpose of sharing this information is different from information requests from example from insurance or occupational physicians. They should be informed that the more comprehensive and accurate the information is, the bigger the chance will be that the applicant can obtain a medical certificate. It may be good to develop some kind of letter or leaflet with information about the aeromedical assessment to accompany a request for information for mental healthcare providers.

If it would be necessary to study an entire medical record, this is best left to an independent mental health professional.

Also, when asking questions to independent mental health experts, it is useful to ask clear and well-defined questions to mental health experts, such as:

- Is a mental disorder present?
- If so, what is the classification?
- What treatment is indicated, or is the current treatment sufficient?
- Are there risks directly related to the mental disorder or its treatment with regards to working in a safety-critical function in an aviation environment?
- What is the prognosis?

Exchanging information ideally would be a continuous process as long as the applicant is being treated by a mental healthcare specialist, and the mental healthcare provider should be encouraged to share (with consent of the applicant) relevant information to the occupational physician and AME when necessary, not only when a medical certificate has to be renewed. Additionally, to sharing written information (and although it may be time consuming and difficult to organize), in more complex situations it might be considered to share information during an (online) meeting with the applicant, the AME/occupational physician and the mental healthcare provider together. As said, mental healthcare providers should be informed well about the purpose of the aeromedical assessment, otherwise they might not be motivated to cooperate.

AME's should remember that some aviation professionals -with and without mental disorders- may have a strong personality, and may put pressure on the healthcare providers only to share information that is beneficial for them. In other cases, some patients may not have shared all their mental problems with their healthcare provider. Especially in long lasting psychotherapeutic treatment, there is a risk that the therapist becomes biased in favour of the applicant and fails to detect risks adequately. Therefore, even if all relevant information has been shared by the mental healthcare provider, the decision whether or not the applicant is fit remains at all times the responsibility of the AME, and in case of any doubt it may be wise to ask for an independent evaluation by one or more independent aviation mental health experts.

#### 4.4.6 Access to other relevant documentation (simulator)

The AME may use other information than medical history from the pilot/ATCO or medical records to inform the decision of medical fitness.

The risk of mental health issues affecting flight safety is not easily assessed by other pilots/ATCOs, but any reports of earlier incidents involving the pilot or ATCO may be obtained. Primarily, this is information that should be obtained from the pilot or ATCO herself – and there is a question of this on the current EASA application form.

In special cases, further documentation may be obtained by the head of operations of the pilot or ATCO in question. If so, such information should be sought in understanding and collaboration with the pilot/ATCO herself to avoid a breach of trust.

Access to simulator training documentation might be helpful as supplement for assessment of mental health issues which may affect cognitive function in a more or less continuous fashion. Such issues may include medication use, symptoms appearing often, or more situational mental health problems.

A *specific* simulator assessment could focus on suspected cognitive problems relating to the mental health issues at hand, such as e.g. working memory or simultaneous capacity. This could be set up as a medical flight test, a procedure which EASA regulations already provides for. Such a medical flight test should be planned and executed in collaboration with an aviation psychologist and the flight instructor in order to ensure relevant test content for that particular case. Guidance material for developing such tests should be developed.

#### 4.4.7 Diagnostic measures that can be used for screening purposes, which for confirmatory purposes, and which for monitoring purposes, according to the class of aeromedical certification

For both class 1 and class 3 medical assessments, it is recommended to address mental wellbeing and mental complaints during the interview (see 4.4.2), and to assess the main psychological functions (see 2.2). This can be supported by a questionnaire, but there is no sufficient evidence to recommend one questionnaire specifically. Importantly, the use of a questionnaire cannot replace the clinical interview, and especially not the mental status examination. This is both the case for initial examinations and for renewals. For an initial examination, it is especially important to address any negative life-events in the past, and how the applicant coped with them. For renewals, it is especially important to address any negative events that happened after the last examination, and how the applicant dealt with it. It is advised that the examiner establishes some routine in addressing mental health. Especially examiners with less experience may consider using a standardized clinical interview such as the SCID-5, but there are no scientific data to mandate this.

There are no scientific arguments for applying different diagnostic procedures in case of class 1 and 3 examinations, mental disorders can be equally troublesome for both commercial air pilots, air traffic controllers and RPA-operators, so detecting mental disorders is equally important.

A pilot with a negative history for mental health issues and a problemless career perhaps has a smaller a priori risk than an initial applicant for some disorders, but can still develop mental problems. Although personality disorders, autism spectrum disorders and ADHD will usually already be present during the initial examination, depressive disorders, bipolar disorders, anxiety disorders can occur at any age. More importantly, differentiating between the various disorders is not so relevant for the AME, the applicant is better referred to a mental health expert for this. As the emphasis of the aeromedical examination is on detecting the presence of a mental disorder, there seems to be no good reason for applying an entirely different approach in initial or renewal examinations, especially not if the AME does not yet know the applicant from previous examinations. If an applicant has had an extensive mental health assessment by a mental health professional, the results of this assessment will only be valid for a limited period of time, depending on the type of the assessment that has been done.

Of course, biographical questions, questions about the mental health history and the family history do not need to be asked every examination again. Nevertheless, in renewal examinations, especially with regards to mental complaints, there is a risk that the applicant did not mention certain information -deliberately or not- during a previous examination, this is good to keep in mind, especially if an AME sees the applicant for the first time. And if the applicant has been examined by the same AME for several times, the mental health questions may be addressed more informally and smoothly. Having a somewhat informal conversation about the children of the applicant, hobby's the applicant can enjoy, about a new type-rating or about changes in operational issues and how the applicant dealt with that, whilst at the same time monitoring speech, mimic, gesture etc. may be much more informative than bluntly asking questions regarding mood, sleep, appetite etc. Especially if an AME has received sufficient training and if the AME is sufficiently experienced with mental health issues and knows the applicant from previous examinations, addressing mental health in a somewhat informal and personal way, should be encouraged.

For an initial examination, it is especially important to address any negative life-events in the past, and how the applicant coped with them. For renewals, it is especially important to address any negative events that happened after the last examination, and how the applicant dealt with it. It is advised that the examiner establishes some routine in addressing mental health.

#### 4.4.8 Professional profiles involved

To implement the aforementioned guidelines, a close collaboration with MHSs is recommended. This is important:

- to properly address the mental incapacitation risk (severity and probability of mental incapacitation events)

- because the presence of biological/psychotherapeutic treatment in between two aeromedical examinations and/or in a given current timeframe is included among the measures to mitigate the mental incapacitation risk
- to train AMEs on interviewing skills
- to support the decision-making process on the mental fitness certification especially when data collected are unclear or discrepant
- to support the decision-making process on the mental fitness certification especially when data collected are unclear or discrepant
- to address the compatibility of biological treatment for mental disorders with operational requirements
- when there is a suspicion of psychoactive substances use and misuse

The cooperation processes between AMEs and MHSs will be further detailed in the next tasks of the MESAFE project.

## 4.5 Wrap-up and take-home messages

There are currently no cognitive tests available that are suited to predict flight or ATC performance or to identify subtle impairments in cognitive functioning of pilots or ATCOs who show no discernible symptoms of cognitive decline. Simulator checks, line checks, peer review, and occupational history provide the best opportunities to detect below standard performance that may be caused by mental problems or neuro-cognitive impairment. Simulator instructors/examiners, trainers, pilots, ATCOs, AMEs, and aviation psychologists should be involved in designing the procedures and preconditions for obtaining operational information needed for cognitive screening of pilots and ATCOs. Please refer to section 4.1.1 for further details.

Personality tests cannot be used for diagnosing mental disorders. Indeed these assessment tools are measures for personality traits rather than disorders.

For the detection of mental disorders, the clinical interview combined with the mental status examination can be considered the backbone of the assessment.

No psychodiagnostic test and/or questionnaire can be used to replace the interview. Valid pilot and ATCOs norms are only available for the MMPI. An AME can consider to develop a questionnaire for addressing some more factual questions, such any previous mental health treatments, the education obtained and current family situation, so that during the actual interview s/he can focus on the most relevant points.

- For clinical interviews, it is recommended to create the most trusted atmosphere, and then to address to points described in section 4.2.2

The available brief screening questionnaires provide sufficiently useful questions to be used by AMEs when exploring suspicion-raising points (red flags) for psychoactive substance misuse in the applicant's history. AMEs are advised to try to "wave them in" into the conversation with the pilot during the aeromedical examination as part of a general health promotion discussion that addresses a variety of health issues, such as mood, quality of sleep, current sources of stress, stress coping abilities, and alcohol and/or substance use. Details on possible questions are provided in section 4.2.5.

Especially biographical questions can be perceived as intrusive, and it is important to explain why these questions are asked: the mental health of someone can be better understood against the background of his or her personal history. It is recommended that AME's develop interviewing skills regarding mental health that yields relevant information on the one side, but that also create a nonthreatening and trusted atmosphere on the other side. To achieve this, they can leverage on active listening techniques and:

- can emphasize that AMEs, pilots, and ATCOs share the same aim: to keep the pilot or ATCO healthy and working safely.

- should have a frank and open approach and be honest about probable safety risks of the disclosed (mental) health problems and discuss next steps concerning referral, treatment, and prognosis in relation to health and professional career.
- should educate pilots and ATCOs on the following principles:
  - Self-reporting of addiction or mental health problems will improve flight safety.
  - One can recover from addiction and/or mental health problems and can resume aviation duties after recovery.
  - Self-reporting can be the start of regaining a healthy and safe pilot career.

The decision-making process should always include the pilot's or ATCO's own viewpoints on the flight safety implications as well as on diagnostic conclusions.

There are no scientific arguments for applying different diagnostic procedures in case of class 1 and 3 examinations. Moreover, as the onset of mental disorders can be at any point during one's lifetime it seems not logical to follow a largely different diagnostic approach in the interview for initial or renewal examinations.

One important way to get around possible underreporting is to have access to previous history as well as previous reports by other practitioners and MHSs, if any. Previous AME records are of importance for any evaluation regarding fitness to fly or operate as an ATCO, since such records would include not only past history known to a previous AME, but also the evaluation of such history in relation to performing duties safely. Commonly used computer programs for pilot/ATCO certification in Europe, such as EMPIC, includes a possibility to access previous examinations performed by previous AMEs directly in the system. This requires a written acceptance from the pilot or ATCO in question, and is therefore optional for the current AME to access. It is presumably a common practice to get acceptance from the pilot/ATCO to gain access of such records, but there are no known data regarding the use of this option in practice, or the non-use of it. Access to simulator training documentation might be helpful as supplement for assessment of mental health issues which may affect cognitive function in a more or less continuous fashion. Such issues may include medication use, symptoms appearing often, or more situational mental health problems. In special cases, further documentation may be obtained by the head of operations of the pilot or ATCO in question. If so, such information should be sought in understanding and collaboration with the pilot/ATCO herself to avoid a breach of trust.

Close collaboration with MHSs is recommended throughout the whole process.

For the scope of MESAFE, the following take-home messages can be taken into consideration:

Take home ID	Take home message
4.1	For the aeromedical assessment of mental health, no psychodiagnostic test and/or questionnaire can be used to replace the clinical interview.
4.2	For both class 1 and class 3 initial and revalidation/renewal, it is recommended to address mental wellbeing and mental complaints during the interview, that can be supported by a questionnaire.
4.3	Available brief screening questionnaires provide sufficiently useful questions to be used by AMEs when exploring suspicion-raising points (red flags) for psychoactive substance misuse. AMEs are advised to try and build a trustful relationship with the applicant and to use the questions provided by the available questionnaires and "wave them in" into the conversation with the pilot during the aeromedical examination as part of a general health promotion discussion.
4.4	As currently there are no cognitive tests available that are suited to predict flight or ATC performance or to identify subtle impairments in cognitive functioning of pilots or ATCOs who show no discernible symptoms of cognitive decline, simulator instructors/examiners, trainers, pilots, ATCOs, AMEs, and aviation psychologists should be involved in designing the procedures and preconditions for obtaining operational information needed for cognitive screening of pilots and ATCOs.

4.5	One important way to get around possible underreporting is to have access to previous history as well as previous reports by AMEs, other practitioners and MHSs, if any. Such information should be sought in understanding and collaboration with the pilot/ATCO herself to avoid a breach of trust.
4.6	A more transparent (certification) system, where not only decision responsibility is defined, but also the decision process is defined and clear, may decrease disempowerment and improve trust in the system on the part of pilots and ATCOs. This would include a clear and real possibility of appeal or review, and information about the system being well known to pilots and ATCOs.
4.7	There are no scientific arguments for applying different diagnostic procedures in case of class 1 and 3 examinations. As the onset of mental disorders can be at any point during one's lifetime it seems not logical to follow a largely different diagnostic approach in the interview for initial or renewal examinations.
4.8	A larger focus on prevention, positive communication, more education on mental health and highlighting the importance of early diagnosis may be helpful in supporting a lower threshold of reporting mental health issues.
4.9	Aeromedical decision-making should be risk-based in order to be precise and accountable. A risk matrix approach which also is more understandable for pilots and ATCOs may therefore lower threshold of reporting.
4.10	It is recommended that AME's develop interviewing skills regarding mental health that yields relevant information on the one side, but that also create a nonthreatening and trusted atmosphere on the other side.
4.11	<p>A close collaboration between AMEs and MHSs is recommended:</p> <ul style="list-style-type: none"> <li>• to properly address the mental incapacitation risk (severity and probability of mental incapacitation events)</li> <li>• because the presence of biological/psychotherapeutic treatment in between two aeromedical examinations and/or in a given current timeframe is included among the measures to mitigate the mental incapacitation risk</li> <li>• to train AMEs on interviewing skills</li> <li>• to support the decision-making process on the mental fitness certification especially when data collected are unclear or discrepant</li> <li>• to address the compatibility of biological treatment for mental disorders with operational requirements</li> <li>• when there is a suspicion of psychoactive substances use / misuse</li> </ul>

*Table 25 – Psychodiagnostic options for incapacitation risk detection*



## 5. Conclusions and next steps

The table below summarizes the key findings of this document.

Take home ID	Take home message
2.1	<p>To address the safety impact of mental disorders it is recommended to:</p> <ul style="list-style-type: none"> <li>• examine the mental status and detect potential alterations of general aspect and self-care, consciousness, thought, intelligence and memory, behaviour, speech, mood and affect, perception, judgement and motivation, psychomotricity, attention, self-awareness, introspection and insight.</li> <li>• address the risk of recurrence/relapse of mental disorders' symptoms, risk related to substance abuse, risk related to biological treatment, mental issues after an incident/accident, risk of lack of self-declaration</li> </ul> <p>The referral to the mental health specialist might be necessary.</p>
2.2	<p>When determining the relapse or recurrence risk in the individual patient, it is advised to make a total risk estimation based on applicable epidemiological risk factors, previous disease episodes, personal factors (both protective and risk factors) and comorbidities.</p>
2.3	<p>AMEs should develop a pro-active approach which includes informing pilots and ATCOs about the severe consequences of psychoactive substance misuse on the incapacitation risk, exploring misuse risks via history taking, and -when in doubt- further testing and consulting a mental health specialist who is experienced in alcohol and drugs addiction problems.</p>
2.4	<p>After starting biological treatment for mental disorders, for both class 1 and class 3 certificate holders, it is recommended not to perform actual operations:</p> <ul style="list-style-type: none"> <li>• as long as the symptoms are not yet completely or almost completely in remission for at least three months (to be discussed at individual-case basis)</li> <li>• as long as there are side-effects (such as dizziness, nausea, gastro-intestinal problems, sleeping difficulties and tiredness) that may affect operations</li> <li>• within 4 weeks after a dosage increase.</li> </ul> <p>For initial applicants of a class 1 or class 3 certificate, it is recommended to take a longer waiting time after remission, at least six months or longer, and only to provide medical certification if the symptoms of the disorder are fully in remission.</p> <p>As a general rule, such evaluation is best made on an individual basis by a psychiatrist, in cooperation with the Aeromedical Examiner.</p>
2.5	<p>The decision to taper or stop treatment should be made by the patient and the treating psychiatrist together. The following recommendations with regards to tapering are made:</p> <ul style="list-style-type: none"> <li>• A tapering scheme is made or supervised by a psychiatrist.</li> <li>• Tapering is performed in slow steps during a longer period of time (three to six months, longer upon indication).</li> <li>• It is recommended not to perform flying duties at least for two weeks after the reduction of a dosage, or when side-effects of the reduction are present.</li> </ul> <p>It is good to check out on these side-effects actively, by a follow-up appointment, and not just to instruct the patient to call if problems arise.</p>
2.6	<p>Incidents and accidents may represent a risk factor when a mental disorder or comorbid mental disorders pre-exist. Adequate check of the presence of post-traumatic symptoms should be implemented: among physical symptoms, it is important to check, among other things, whether intrusion, avoidance and hypersensitivity symptoms are present. It is also important to evaluate whether the person with PTSD feels confident in continuing their work or whether they do not prefer to change roles.</p>
2.7	<p>Possible barriers to manage the risk of lack of self-declaration of mental discomfort include:</p> <ul style="list-style-type: none"> <li>• Detection of signs and symptoms of mental issues by the AMEs</li> </ul>

	<ul style="list-style-type: none"> <li>• History taking by the AMEs</li> <li>• Collecting relevant documentation by the AMEs</li> <li>• Peer support</li> <li>• A supportive and just-culture oriented environment towards mental health and psychological discomfort</li> </ul>
3.1	The safety impact of mental disorders can be assessed, both in qualitative as well as quantitative terms, by means of a sound risk assessment methodology.
3.2	<p>Mental incapacitation events are hazardous behaviours due to mental issues. Events to be taken into account include:</p> <ul style="list-style-type: none"> <li>• Suicide</li> <li>• Murder-suicide</li> <li>• Aggressive behaviour</li> <li>• Agitation</li> <li>• Intrusive thoughts - compulsions</li> <li>• Depersonalization - derealisation</li> <li>• Reduced alertness</li> <li>• Panic attack</li> <li>• Somatic symptoms (not caused by an unrelated physical disease)</li> <li>• Hallucinations</li> <li>• Delusions</li> </ul>
3.3	Mental incapacitation events' probability and severity are plotted by means of a 5x5 matrix
3.4	<p>The probability that a mental incapacitation event would happen depends on:</p> <ul style="list-style-type: none"> <li>• presence of one mental disorder or more (comorbidities) and their degree of dangerousness, violation of society standards, statistical deviance, social discomfort, subjective distress, maladaptiveness, irrationality and unpredictability (the 7 mental illness indicators)</li> <li>• risk of recurrence/relapse</li> <li>• psychoactive substance abuse</li> <li>• risks related to biological treatment</li> <li>• life stressors</li> <li>• physical health (somatic comorbidity)</li> <li>• recent incidents/accidents</li> <li>• risk of lack of self-declaration</li> <li>• successful treatment and protective factors</li> </ul>
3.5	The determination of the acceptability of the risk, and with that the colour associated with each cell of the matrix, requires careful consideration taking into account the type of operation for which the risk is assessed (civil multi-crew ops, civil single pilot ops, ATC ops).
3.6	From a mental incapacitation risk perspective, single pilots have a higher attributable risk than Captains/First Officers working in a multicrew operational environment. Controllers are considered to have an attributable risk equivalent to professional pilots.
3.7	The risk matrix can act as an important communication tool to be discussed with the applicant, because it is focused on incapacitation events rather than on diagnoses of mental disorders.
4.1	For the aeromedical assessment of mental health, no psychodiagnostic test and/or questionnaire can be used to replace the clinical interview.
4.2	For both class 1 and class 3 initial and revalidation/renewal, it is recommended to address mental wellbeing and mental complaints during the interview, that can be supported by a questionnaire.
4.3	<p>Available brief screening questionnaires provide sufficiently useful questions to be used by AMEs when exploring suspicion-raising points (red flags) for psychoactive substance misuse. AMEs are advised to try and build a trustful relationship with the applicant and to use the questions provided by the available questionnaires and "wave them in" into the conversation</p>

	with the pilot during the aeromedical examination as part of a general health promotion discussion.
4.4	As currently there are no cognitive tests available that are suited to predict flight or ATC performance or to identify subtle impairments in cognitive functioning of pilots or ATCOs who show no discernible symptoms of cognitive decline, simulator instructors/examiners, trainers, pilots, ATCOs, AMEs, and aviation psychologists should be involved in designing the procedures and preconditions for obtaining operational information needed for cognitive screening of pilots and ATCOs.
4.5	One important way to get around possible underreporting is to have access to previous history as well as previous reports by AMEs, other practitioners and MHSs, if any. Such information should be sought in understanding and collaboration with the pilot/ATCO herself to avoid a breach of trust.
4.6	A more transparent (certification) system, where not only decision responsibility is defined, but also the decision process is defined and clear, may decrease disempowerment and improve trust in the system on the part of pilots and ATCOs. This would include a clear and real possibility of appeal or review, and information about the system being well known to pilots and ATCOs.
4.7	There are no scientific arguments for applying different diagnostic procedures in case of class 1 and 3 examinations. As the onset of mental disorders can be at any point during one's lifetime it seems not logical to follow a largely different diagnostic approach in the interview for initial or renewal examinations.
4.8	A larger focus on prevention, positive communication, more education on mental health and highlighting the importance of early diagnosis may be helpful in supporting a lower threshold of reporting mental health issues.
4.9	Aeromedical decision-making should be risk-based in order to be precise and accountable. A risk matrix approach which also is more understandable for pilots and ATCOs may therefore lower threshold of reporting.
4.10	It is recommended that AME's develop interviewing skills regarding mental health that yields relevant information on the one side, but that also create a nonthreatening and trusted atmosphere on the other side.
4.11	<p>A close collaboration between AMEs and MHSs is recommended:</p> <ul style="list-style-type: none"> <li>• to properly address the mental incapacitation risk (severity and probability of mental incapacitation events)</li> <li>• because the presence of biological/psychotherapeutic treatment in between two aeromedical examinations and/or in a given current timeframe is included among the measures to mitigate the mental incapacitation risk</li> <li>• to train AMEs on interviewing skills</li> <li>• to support the decision-making process on the mental fitness certification especially when data collected are unclear or discrepant</li> <li>• to address the compatibility of biological treatment for mental disorders with operational requirements</li> <li>• when there is a suspicion of psychoactive substances use / misuse</li> </ul>

Table 26 - D2.1 take-home messages

In the next tasks of the project, we will implement these findings into a mental fitness certification process, including:

- description of the process
- mitigation measures, acting as safety barriers to improve both severity and probability of the mental incapacitation events.
- supporting materials (e.g. a simple excel risk tool to aid AMEs/mental health professionals/pilots/ATCOs to evaluate risk)

- suggested recommendations for multidisciplinary collaboration with mental health specialists and peer support groups
- training and educational material both for AMEs and mental health specialists on their collaboration.

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