CIECA Report Medical Fitness to Drive Comorbidity

Report covering the answers to the questionnaire about medical fitness to drive and comorbidity final / October 2019

CIECA Topical Group on Fitness to Drive

Sub group 2: Setting Standards for the Evaluation of Medical Fitness to Drive

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1. INTRODUCTION

In the European Union, when applying or renewing a driving license, drivers must meet the minimum standards of physical and mental fitness as defined in Annex III of the European directive (EU DIRECTIVE 2006/126/EC).

The Annex III 'Minimum Standards of Physical and Mental Fitness for driving a power-driven vehicle' lays down the medical conditions which can compromise driving safety. By defining minimum standards the EU Commission tries to create a common 'medical baseline' which needs to be met by all EU driving licence holders. The annex sets the minimum (common) requirements both (and sometimes differently) for group 1 and group 2 licences. Not all National minimum standards are identical however, as the standards set by Member States may be stricter than those set out in the Annex.

The Annex III¹ includes 13 chapters, namely eyesight, hearing, locomotor disability, cardiovascular diseases, diabetes mellitus, neurological disease and obstructive sleep apnoea syndrome, epilepsy, mental disorders, alcohol, drugs and medicinal products, and renal disorders. The final chapter concerns 'miscellaneous conditions'. It includes organ transplants and artificial implants, as well as the category 'not mentioned above'.

In the 'miscellaneous provision' it is stated that as a general rule, where applicants or drivers suffer from any disorder which is not mentioned in the preceding paragraph but is liable to be, or to result in, a 'functional incapacity' affecting safety at the wheel, driving licenses shall not be issued or renewed unless the application is supported by authorized medical opinion and, if necessary, subject to regular medical check-ups.

The mentioned concern in the Annex about 'functional incapacity' is a common concern in medical practice. The functional state of a patient is not only determined by the medical diagnose alone. Total patient functioning is the result of coping mechanisms or the lack of those, interactions between several diagnoses, personality characteristics, behavioral components, etc. In rare cases functionality might even clearly be reduced without an apparent clear-cut diagnose. It explains why a driver can be considered as unfit to drive, although there is no single medical condition implying unfitness.

Although the Annex III mentions individual and 'narrow' medical conditions, if a medical practitioner is involved in determining Fitness to Drive (FTD), he will inevitably apply the 'art of medicine' by taking into account the aforementioned complexity. This complexity of determining total patient functioning and its relevance for FTD evaluations is also reflected in the definition of 'Fitness to Drive' and associated 'Driver Assessment' adopted by the CIECA members of the Fit to Drive Topical group²:

Fitness to drive is the state of having adequate physical, visual, and cognitive function, and no medical³ nor behavioural contra-indication to driving⁴. It is considered as a driver characteristic or a description of a driver and is further defined by the absence



¹ 10 October 2019

² Minutes of Fit to Drive Topical Group / Subgroup 1 meeting, Brussels, 18 October 2018

³ medical includes psychological and neuro psychological

⁴ CIECA Fit to Drive meeting in London, July 2018

of any functional (sensory-perceptual, cognitive, or psychomotor) deficit, or medical condition, or personality characteristic that significantly impairs an individual's ability to fully control the vehicle while conforming to the rules of the road and obeying traffic laws, or that significantly increases crash risk⁵. and

Driver Assessment is a multi-disciplinary clinical process to create an opinion on fitness to drive (FTD) referring to the EU Driving Licence Directive. A clinical process determines functional consequences of medical challenges in terms of physical, (neuro)psychological, behavioural and attitudinal aspects.

To refer to the 'functional incapacity' mentioned in the Annex III and to the complexity of 'total patient functioning' we propose to use the term 'comorbidity'. There is no consensus on the meaning of the term comorbidity. Related constructs are multimorbidity, morbidity burden, and patient complexity.

In this paper 'comorbidity' is defined as the presence of one or more additional mental, neurodevelopmental, medical, or physical conditions, diseases or disorders co-occurring with (that is, concomitant or concurrent with) a primary condition, disease or disorder relevant to fitness to drive. It is here interpreted as the notion of burden of illness or disease, defined by the total burden of dysfunction and is therefore linked to the concept of total impact on patient-reported outcomes, including functioning. Hence, the comorbidity concept, as referred to here, reflects not only the multiplicity of conditions, but also the interactions between them, influencing the total burden of dysfunction. This total burden is determined not only by health-related characteristics, but also by socioeconomic, cultural, environmental, and patient behaviour characteristics. Comorbidity, in the clinical setting, is associated with worse health outcomes, more complex clinical management, and increased health care costs.

2. METHOD

The questionnaire was sent out by email in December 2018 to 31 countries, all CIECA members. They were sent reminders on two occasions after the initial submission. An introductory letter explained its context, purpose, and requirements of the respondents.

The questionnaire first explained the concept by providing the definition as above, and consecutively consisted of 7 questions. All questions had either two or three response options and also allowed free text clarification. Fifteen (15) countries responded to the questionnaire: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Great Britain, Lithuania, Luxembourg, Ireland, Norway, Portugal, Spain, Sweden.

With the questionnaire we tried to understand if and how this concept of comorbidity is covered in the implementation of the FTD procedure by the different EU member states.



⁵ Transportation Research Board, 2016

3. RESULTS⁶

All (N=15, 100%) countries replied that the notion of comorbidity is somehow being taken into consideration in the FTD decision process. However, in only 4 countries (27%) was this concept mentioned in the legal regulation or guidelines. Three countries (20%) stated that it is referred to in a general way, as in the Annex III; one country (7%) is more specific and uses the term 'multi-morbidity' complemented with clinical examples in its guidelines.

All countries (N=15; 100%) replied that the concept of comorbidity constitutes an integral element in the holistic evaluation of the medical assessment. Hence, even in the absence of formal criteria, the physician concerned in the FTD process always has the opportunity to apply the concept of comorbidity in the interpretation of the clinical data.

About half of the countries replied that the concept can equally be applied in the formal psychological assessment. Taking into account that not all responding countries actually include this type of assessment and that some countries were inconclusive in their answers, we can infer that in 8 countries (57%) comorbidity can influence the formal psychological outcome, and that only 4 (28%) countries confirmed that it can not.

A similar conclusion can be made concerning the comorbidity aspect in the driving assessment. After correction similar to above, we can infer that 7 countries (50%) confirm that comorbidity can and that in 4 countries (28%) cannot influence the driving outcome.

Despite the apparent agreement of the importance and relevance of the concept, and the widespread application, only two countries (13%) report reference to a quantifiable measure of comorbidity. One country (7%) refers to a verifiable and published measure, the Charlson Comorbidity Index (CCI)⁷. The Charlson Comorbidity Index is a method of categorizing comorbidities of patients. Each comorbidity category has an associated weight (from 1 to 6), and the sum of all the weights results in a single comorbidity score. The higher the score, the more likely the predicted outcome will result in mortality or higher resource use of the patient. However, its applicability to road safety or FTD is unclear as there are almost no peer-reviewed studies of FTD using the Charlson index.

The fact that the concept is not officially defined or legally acknowledged in most countries, and additionally is not really quantifiable, apparently does not prevent clinicians from using the concept of comorbidity, nor does it lead to apparent ethico-legal challenges or issues. Most countries (N=11, 73%) do not report issues of medical or professional secrecy in case of apparent or undocumented comorbidity. Three countries (20%) report that the concept could pose problems related to professional or medical secrecy. Two of them (13%) posited a potential contradiction between legal and ethical exigence. These can arise for example when comorbidity legally cannot be taken into account, for example due to a strict formalised procedure, but on medico-ethical grounds the clinician feels the concept is determinative.

⁶ We realise that percentages based on small numbers need to be interpreted very cautiously and might seem uninformative. We provide them only to give a general indication. The reported percentages are not corrected for missing or inconclusive data, and are therefore not always based on the full number of respondents.

⁷ https://www.mdcalc.com/charlson-comorbidity-index-cci

4. DISCUSSION

It is confirmed that although in most countries the concept of comorbidity is not legally nor objectively defined, it is generally considered to be a relevant factor in FTD adjudication. This is due to the fact that in all countries a physician is at the core of the FTD procedure and that for a clinician it is obvious that total patient functioning is not only determined by one diagnosis or the sum of the different diagnoses, but is mediated by its interactions, confounded by other elements like coping mechanisms, personality characteristics, behavioral components etc. This multi-factorial determination is reflected in the definitions of FTD and the associated driver assessment provided.

At least partly related to the problem of quantifying the concept, and in particular with respect to FTD outcome, it follows that comorbidity seems to be applied mostly clinically rather than legally or formally. Thus, it seems to primarily influence the formation of a clinical opinion and thereby clinical FTD decision taking, rather than being a formal administrative element in the final FTD decision. This is further confirmed by the observation that very few of the countries that responded to the questionnaire, formally included the concept in their respective FTD criteria. It is evident that if or when member states transpose the EU criteria into clinically usable guidelines, the concept might more easily be defined, explained, and put into commonly applied FTD opinion making practice.

Since comorbidity is apparently considered to be a clinical concept, it is confirmed that it can influence not only the medical aspects, but possibly also the psychological and practical driving aspects of FTD. The association with the psychological and practical aspects of FTD was however reported to be to less prominent than with the medical aspect. That the relationship is not at all obvious in this respect was confirmed by at least one research study that failed to find an association between comorbidity and reduced driving performance.8 The perturbed relationship with the FTD psychological outcome might be explained by the fact that at least some FTD psychological assessments are less 'clinical' and more 'psycho-technical'. For any assessment, the more formalized, automatized, and itemized the assessment is, the less likely the rather 'interpretative' comorbidity concept can be taken into account. Additionally, the same holds for the driving assessment. The more the outcome of this assessment is based on administrative, itemized and quantified scoring, the less obvious it is that comorbidity can be taken into account. Even, if the person providing the driving outcome has no clinical background, or is not clinically informed about the drivers' global functional status, the concept can never be fully exploited. Hence the merit of comorbidity in psychological and driving assessments in the FTD procedure depends on the clinical implementation and application of those assessments.

5. CONCLUSION

The inclusion of comorbidity in the FTD procedure is generally considered to be of importance. It is considered to be medically valid in forming as a holistic appreciation of human

⁸ Carr DB, Barco PP, Babulal GM, Stout SH, Johnson AM, Xiong C, Morris JC, Roe CM. Association of Functional Impairments and Co-Morbid Conditions with Driving Performance among Cognitively Normal Older Adults. PLoS One. 2016 Dec 22;11(12):e0167751.

functioning, relevant in determining safe driving. However, few countries include this concept explicitly in their FTD criteria. For this reason, some countries experience medico-legal issues in including the impact of comorbidity in FTD decision making. Efforts need to be made to operationally define the concept of comorbidity as this will assist clinicians in applying the concept systematically and thus support consistency and uniformity in FTD clinical decision making. Since comorbidity is as yet difficult to operationalize, and hence is an interpretative concept, the more administrative, itemized, and quantified any assessment or decision is, the less influential the concept can be. Its association with fitness to drive remains as yet unknown.