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CSF biomarker utilisation and ethical considerations of biomarker assisted diagnosis and research in dementia: perspectives from within the European Alzheimer's Disease Consortium (EADC)

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Cerebrospinal fluid (CSF) biomarker analysis for dementia diagnostics (ie, the analysis of amyloid b42, total tau and phosphorylated tau) is increasingly used in clinical practice.¹ However, there is still debate among researchers and clinicians about the sensitivity and specificity of various biomarker analyses, especially when comparing dementia subtypes.² The lack of consensus and heterogeneity for evidence on CSF biomarker use and validity is likely to have resulted in variable practices: belief in the utility of biomarker measurement has likely stimulated the use of CSF analysis in clinical practice in some places whereas elsewhere this practice probably has not been adopted at all. The extent of this variability in clinical practice is currently unknown but hypothesised to be considerable.³

Aim

To investigate the extent to which CSF biomarkers are collected for clinical practice and for research purposes in state of the art memory clinics across Europe, with assessment of related consenting approaches.

Methods

We asked all 54 memory research centres from the European Alzheimer's Disease Consortium (EADC) (<http://eadc.alzheimer-europe.org/introduction.html>) about practical and ethical aspects of CSF biomarker collection in dementia diagnostics as part of an online survey on medical and research practice in these centres. The EADC includes centres from 18 countries. Centres have been selected

as EADC members because of their expertise in clinical and basic research on Alzheimer's disease and related disorders. Most centres are leading centres on dementia care and research in their countries.

Results

The survey had a 63% response rate. CSF was collected for routine clinical use in 56% and for scientific use in 87% of responding centres but while 56% of the centres took CSF routinely, only 44% of all centres used the measurement of CSF biomarkers as part of the diagnostic process. Although all centres reported that they obtained informed consent before collecting CSF biomarkers, the scope of consent taking was variable: 44% of the centres obtained separate consent for each biomarker to be collected whereas 85% obtained informed consent for all possible future research use. Furthermore, in the case of biomarker research, 65% of the centres retained the ability to relate biomarkers to patients. More than half of the centres (59%) reported sending materials abroad for diagnostic and/or scientific reasons, but no centres commercially sold their biomaterials.

Conclusion

From the centres surveyed here it seems that there is wide acceptance and practice of obtaining informed consent for collecting CSF biomarkers across Europe. However, there seem to be variable practices with regard to the acquisition of these biomarkers for research and clinical use. Also, ethical procedures with respect to handling of these materials, such as asking consent for future use, shipment of materials and anonymisation of samples, varied between centres. Despite the growing application of biomarkers in diagnostic criteria,^{3,4} we are only at the beginning of a potentially biomarker dominated era in dementia research and memory clinics. The successful maturation of this era in Europe would be facilitated by the development of practical and ethical guidelines for application of CSF biomarkers in dementia care practice as well as in research.⁵

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