



**Conflicts in
Predictive Dementia
Diagnostics
2017-2019**

**JOINT POSITION STATEMENT OF THE GERMAN STAKEHOLDER
CONFERENCE ON
CONFLICTS IN PREDICTIVE DEMENTIA DIAGNOSTICS**

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Finalized Version

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PREAMBLE BY THE PROJECT MANAGEMENT

A stakeholder conference with 24 experts from Germany took place in Göttingen June 22-23, 2018. During the conference, the opportunities and risks of the new biomarker technology for predicting a risk of dementia were discussed. In the run-up to the conference, 30 of approximately 75 invited stakeholders from relevant organizations and institutions from all over Germany took part with a written statement.

This joint position statement on how to deal with this new technology is the result of the one-and-a-half-day stakeholder conference.

The stakeholder conference was hosted as part of the discourse project “Dilemmas of Predictive Dementia Diagnostics: German Stakeholder Conference for Improving Ethics Competence in Healthcare and Life Sciences”, funded by the German Federal Ministry of Education and Research (BMBF) (project website: www.praediadem.de).

The project team includes Prof. Dr. Silke Schicktanz and Julia Perry, M.A. from the Department of Medical Ethics and History of Medicine of the University Medical Center Göttingen and apl. Prof. Dr. Scott Stock Gissendanner and Benjamin Herten, M.A. from IEGUS – Institut für europäische Gesundheits- und Sozialwirtschaft, Berlin/Bochum.

All 75 originally invited stakeholders have the opportunity to comment on this finalized statement online.

We thank all participating stakeholders and especially the editorial team consisting of Dr. Klaus Gehring, Prof. Dr. Frank Jessen, Prof. Dr. Gabriele Meyer, Dr. Katrin Radenbach and Detlef Rüsing.



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research for better
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I. Fundamental starting position (key result/conclusion)

Methods utilizing so-called biomarkers are available for detecting pathological brain changes caused by Alzheimer's disease. They are used for the diagnosis of dementia.

However, the use of biomarkers² is still lacking both methods and requirements for proper prediction³ of dementia in symptom-free individuals. On one hand, the diagnostic methods that are currently available do not provide precise predictions. On the other hand, there are still no widely acknowledged therapies for preventing or delaying the onset of dementia symptoms. Therefore, a biomarker-based prediction in symptom-free individuals outside of research projects is not recommended in the light of insufficient knowledge about the medical and social implications of possible test results. Even if there were sufficiently validated test procedures in the future, these tests could probably only provide an indication of the risk of developing dementia.

At the same time, however, public and scientific interest in the early diagnosis of dementia in individuals with mild symptoms or healthy ones is increasing. It can be assumed that predictive tests, including blood tests, will be offered and become available in the future, albeit not initially in Germany, but globally via various providers.

With regard to people with mild symptoms, early diagnosis of Alzheimer's disease is possible in the stage of mild (or very mild) dementia. With mild cognitive impairment (MCI), the option exists of predicting the risk of future dementia with biomarkers. If the biomarker findings are clear, then there is a high probability of Alzheimer's disease which will also be manifested as dementia clinically within a few years. Therefore, this is considered an early diagnosis of Alzheimer's disease.

In the case of biomarkers not being completely pathologically altered or borderline, risk estimation is not as certain. If biomarkers are completely unnoticeable, the risk of receiving a dementia diagnosis in the next few years is very low, but cannot be completely excluded. Thus, the problems of prediction mainly arise from ambiguous biomarker findings.

Once tests with better predictive accuracy become available in the future, the following considerations, which concern both the ethical-legal foundations as well as counseling and the embedding in the public discourse, should be taken into account.

II. Necessity of a new societal debate

The following aspects regarding the possible damage and the possible benefits of the prediction of dementia should be considered and further developed in the societal debate.

At the moment, predictive diagnostics do not result in any measures to modify the course of

² By biomarkers we mean measurable substances and conditions in the human body that indicate diseases and disease states.

³ Prediction is a statement about the probability that a disease will occur in the future.

the disease.⁴ The consequences of a prediction of dementia diseases may be severe regarding social and individual matters. Among other things, potential damage occurs in the form of psychological destabilization and stigmatization. A potential benefit could be expected from a changed, health-promoting lifestyle and a constructive confrontation with a possible future cognitive deterioration.

The potential for harm and benefit is also relevant for the family system and the social network. Possible harm and benefit are also conceivable on a societal level. This concerns, among other things, the danger of inadequate data protection, especially in connection with a potentially negative influence on further working life, or stigmatization, but also positive effects on social participation and the expansion of prevention programs.

Possible harm and benefit can change over time. Although initial studies on the harm and benefits of a biomarker-based risk assessment for dementia are available, comprehensive and conclusive scientific findings on the harm and benefits of the prediction of dementia are still missing.

Dementia is widely regarded as a human catastrophe because people have the idea that they are no longer themselves. This leads to the fear of losing control and being left alone. A political-social discourse on the question “How do we want to live with dementia?” could also take people’s fears into account. We call for people with dementia to be perceived as human beings in their dignity and to be recognized as part of our society. This includes being able to accept and endure diagnoses and to enable social participation. At the same time, good solutions for a life with dementia must be promoted. If prospects of life with dementia improve significantly and corresponding living spaces are created, the individual could consider predictive tests more calmly in the future.

Socio-cultural patterns of interpretation of ageing and dementia are of great importance in the discussion of dementia prediction. The development of methods for predicting dementia takes place in a social context that is often characterized by negative, emotionally charged patterns of interpretation and evaluations of dementia, as well as by stigmatization of those affected. Such a climate can fuel fears and increase the anxiety about the risk of dementia, possibly changing the self-image of people with a conspicuous test result (“healthy patients”) and impairing their outlook on life. Furthermore, prediction of dementia can contribute to a further medicalization and pathologization of age-associated risks and, in the context of social models of healthy, successful ageing, can also promote ideas of dementia as an individual fate or even personally caused failure.

⁴ This statement relates to Alzheimer’s disease. For reasons of readability, the term “dementia” is used in this opinion. However, the term “dementias” would be more precise because of the difference in the severity and course of the symptoms.

Against this background, we call for the strengthening of a culturally sensitive⁵, well-informed, intergenerational and balanced social understanding on the issue of dementia, within the framework of which negative views on dementia are worked on and reduced by promoting an inclusive society (Ratification of the Convention on the Rights of Persons with Disabilities 2012).

The establishment of such an understanding should be promoted on various levels. Scientific societies can work towards an appropriate public representation of dementia. The portrayal of dementia in the media is an important area of reference on which life with dementia should neither be demonized nor played down. Authentic portrayals include self-reports by primary patients and their relatives.

A social climate in which the prediction of dementia would become the norm should be counteracted. People should not be put under legitimation pressure when they choose to refrain from prediction.

This also concerns educational institutions. The discussion on dementia could be initiated in school curricula as a multidisciplinary topic in subjects such as German, social studies, biology, religion, or ethics and in this way also reach the families of pupils and students. In addition, institutions of vocational, continuing and higher education in the social and health care system must also promote critical reflection of the way the relevant professions present age and dementia.

Scientific evidence on the damage and benefits of predicting dementia is extremely limited. This is why we see a considerable need for research. Although there is a high social interest in basic research into the treatment of dementia's causes, efforts should also be made in the field of health services research to enable citizens to lead a better life with dementia.

III. Fundamental ethical-legal considerations on the discussion of biomarkers both for prediction for asymptomatic patients and on the basis of the syndrome of a mild cognitive impairment (MCI)

An increased probability of getting dementia in the future has no potential for external health damage from which third parties should be protected in due time. **The voluntary nature of a prediction of dementia must be secured in the long run and must not be undermined by corresponding expectations or incentive structures (e.g. bonus systems for life and health insurances). Although the consequences of dementia also affect the friends and family of those affected, in some cases to a considerable extent, this does not justify exerting pressure on people to have themselves tested. In addition, all counterproductive incentive or sanction practices must be excluded under penalty of law.**

⁵ This includes religious sensitivity.

The psychosocial consequences of a positive finding can be severe. Affected persons must have the opportunity to assert their right not to know at any time. The right to not knowing is rooted in the (basic) right of informal self-determination. It is by no means automatically an expression of pathological repression, but rather usually documents a person's decision to shape his or her own life without the pressure of burdensome prognoses and to protect him- or herself against secondary illnesses that can result from knowledge of the risk of getting ill.

At the same time, the right to know is valid – also as a consequence of the right to informational self-determination. People must be given the opportunity to inform themselves about individual disease risks at an early stage.

The existence of validated test procedures for the prediction of dementia is a prerequisite for being able to think about being able to comply with the **right to know** at all. Those affected must be comprehensively informed about the probability of false-positive and false-negative findings, the prognosis and the psychosocial consequences for their future way of life.

In such cases, it is strongly recommended that the mandatory provision of counseling be considered. Counseling⁶ – medical and psychological – is in principle voluntary, but not whether it should be offered or not. When tests become available, quality-assured, standardized counseling services (as described below) must also be provided.

Counseling should take place within the framework requested by the person seeking advice. Ideally, this should be done with the involvement of relatives, with the consent of the person seeking advice. However, there can be considerable conflicts of interest. If, for example, the risk of disease is genetically predisposed, the right of the potentially affected relatives not to know is to be respected directly.

The recognition of the right to know or not to know and a possible mandatory provision of counseling should be defined in guidelines on the prediction of dementia.

IV. Specific recommendations for counseling

Comprehensive counseling services on the prediction of dementia with biomarkers are currently still standardized, but available in sufficient quantities. **To this end, quality standards and strategies for competence development must be developed for counseling (guideline development or framework agreement). Counseling must be clearly specified and differentiated as follows.**

⁶ During the stakeholder conference, the question of the extent to which counseling should be mandatory and how this should be legally secured was discussed in detail but not finally agreed upon. In particular, the recommendation of obligatory counseling was compared to the voluntariness of counseling. Furthermore, the weighting of a recommendation was discussed, i.e. a simple recommendation or a recommendation with emphasis. The selected formulation of “mandatory provision of counseling” is proposed by the editorial team as a consensus recommendation.

Basic structure:

1. To provide medical, social, clinical-psychological and clinical-neuropsychological counseling. This should take place during the entire diagnostic-interventional process (before, during and after the diagnosis) in a needs-oriented and formalized manner.
2. All those involved in the diagnostic process should be involved in counseling (physicians, social workers, psychologists, nurses). Counseling should be directed at the person seeking advice or at the patient, his/her relatives and their network.
3. Qualified, independent and individual-centered counseling for the individual is necessary, which takes prediction into consideration as well as, where desired, his/her relatives and includes three central aspects:
 - A. **Medical aspects**, i.e. communication of facts and their explanation with reference to “diagnostic aspects” (e.g. basics of the disease, possibilities, relevance, reliability and predictive accuracy of the test procedure, alternatives to the test procedure, discrepancy between findings and therapeutic as well as preventive options).
 - B. **Psychosocial aspects** (e.g. consequences for individual life planning, individual added value of prediction, advance decrees, lifeworld aspects). This second aspect of counseling should be multidisciplinary. This should take into account the diversity of the service providers as well as the representatives of those affected and their relatives (in the sense of “peer-to-peer counseling”, self-help). In addition, crisis intervention (dealing with the emotions and ideas associated with the findings regarding the future) and, finally, psychotherapeutic support in the search for a future way of life with the knowledge of a possible future dementia should also be offered.
 - C. **Counseling on social law and life management**. This also includes planning elements for coping with everyday life (clarification about supply options) and for advance care planning.
4. Individual and comprehensive counseling is a prerequisite for a self-determined and balanced decision on the question of the meaningfulness of carrying out prediction of dementia. **The aim of the counseling session** prior to a test must be to enable a provider-neutral prerequisite for a well-considered decision based on factual information. This also includes exploring the desire for knowledge/ non-knowledge. In concrete terms, this involves reducing anxiety, preventing depression and suicide, clarifying clinical neuropsychological compensation for cognitive deficits, improving the quality of life, avoiding “useless costs” of further diagnostics and “doctor hopping”, maintaining self-determination and promoting social participation as well as reducing discrimination and stigmatization. Furthermore, the development of dysfunctional disease-related behaviors, including depression and adjustment disorders and/or behaviors associated with these disorders must be prevented. The decision on the details of the diagnostic process and possible measures in the field of psychotherapy or neuropsychological therapy must be made in the counseling session with the person

concerned and – if desired by the person concerned – the members of their social network.

5. **After the test**, the aim of the counseling must be to deal with the test result and possible consequences as well as to offer long-term support. In the event of a diagnosis, concrete needs-oriented support services must be further developed. This should also **include the provision of support or supervision**, i.e. the promotion, maintenance and compensation of everyday skills and/or assistance with social right problems, the maintenance of communication with and in the social environment, the strengthening and support of the social environment, etc.
6. **Overall, the importance of counseling needs to be strengthened. To this end, access routes must be facilitated and, if necessary, a right to counseling must be anchored in law.** Scientific societies and representatives of those affected and their relatives should give concrete content in this regard. The municipalities should create framework conditions for access to counseling within the framework of services of general interest. Interdisciplinary and inter-professional treatment and counseling, not only in the clinical field, must be financed. There, the financing of persons with specialist training in gerontology, psychology, social work and nursing is needed. In the outpatient sector, we recommend joint psychological, nursing and social work counseling and treatment in GP, specialist, geriatric and neuropsychological practices and social counseling centers.

V. Identified research needs

1. The patient-relevant damage and benefit of biomarkers for the prediction of dementia must be investigated in clinical studies with resilient study designs. Long-term studies and, in particular, high-quality, randomized controlled clinical trials with patient-relevant endpoints must be demanded.
2. The operationalization of patient-relevant endpoints should be expanded to include not only mortality, morbidity and health-related quality of life, but also endpoints such as long-term clinical outcome, lifestyle modifications and resource use.
3. The entire diagnostic therapy chain must be represented in a benefit assessment. There must be an accepted procedure (treatment pathway) for future patients. A better (e.g. earlier, more accurate) diagnosis is only of benefit if the prediction has an effect on the prognosis.
4. A possible test must have high reliability and diagnostic accuracy. A sufficiently long study period must be considered to be able to determine the possible manifestation of dementia. The damage resulting from false positive diagnoses must be investigated.⁷

⁷ An over-diagnosis is defined as an actually correct-positive diagnosis, which would not have caused any symptoms during one's life (see Carter SM, Rogers W, Heath I, Degeling C, Doust J, Barratt A. The challenge of over- diagnosis begins with its definition. BMJ 2015; 350: h869).

Controlled studies are necessary to investigate the test procedure in combination with a care pathway.

5. It is essential to promote research in the field of dementia counseling. Target group-oriented, evidence-based counseling approaches, counseling guidelines and decision-making aids in the context of risk communication can only be developed from the knowledge of existing research on counseling and the consequence of specialized research on counseling in the field.

Appendix A: Further development of medical practice guidelines

Specific request for guidelines and research for patients with mild cognitive impairment (MCI).

Further development of medical practice guidelines for mild cognitive impairment (MCI):

In contrast to the preceding recommendations on the use of predictive factors for dementia prediction in symptom-free individuals, minimum requirements and standards must be formulated for the preparation, clarification, implementation and interpretation of **diagnostic procedures for the identification of patients with MCI with underlying Alzheimer's disease**, as mentioned in the starting positioning of this joint position. It is important to record depressiveness, depression and especially suicidal tendencies in the run-up to the informed consent consultation on diagnostics. On one hand because depression is also associated with cognitive deficits (especially of the executive functions), but above all because the results of predictive testing themselves can lead to depressiveness and suicidal tendencies and in this group a careful risk assessment, transmission of findings and aftercare must be carried out. Depression can present the image of a cognitive disorder and should not be confused with the early stage of dementia or MCI.

Standardized written information and standardization of patient consent must be requested in advance to the informed consent consultation of the corresponding diagnostic procedure. A quality-assured, standardized consulting service with medical and psychosocial content must be provided. A staged procedure with the possibility of reflection time must be adhered to. The aim is *informed consent*, i.e. the competent participation of an informed patient. It must be ensured and verified that the language used is comprehensible for the patient group concerned.

Specific competences are to be expected from the informing persons, which are to be acquired as qualifications through defined further and advanced training. These include skills for the selection and interpretation of biomarkers, knowledge of comorbidities and differential diagnoses, as well as techniques of conversation.

Clear recommendations on the use of biomarkers and, if necessary, on combinations of biomarkers as well as on the combination of biomarkers with other diagnostic findings (e.g. neuropsychology, structural MRI, PET, etc.) are required for the diagnostics to be used. The laboratories carrying out the tests must be obliged to provide quality certificates, certifications and to participate in interlaboratory tests. For the imaging to be used, the concrete methodology and interpretation must be identified as well as for neuropsychological diagnostics to determine the specific syndrome. For all methods, solid clinical accompanying research with real world data is preconditioned.