MEMORANDUM OF UNDERSTANDING (MOU)

between
EUROPEAN ASSOCIATION FOR THE STUDY OF DIABETES,
hereinafter called **EASD**
and
Members of EASD, any EASD Study Group, Society or Societies requesting (joint) guidelines/statements
hereinafter called **Writing Group**

1. Purpose and Agreement(s)
The purpose of this MOU is to identify clearly the roles and responsibilities of each party as they relate to the …… guideline.

2. Constitution of a guideline or position statement
Guidelines and position statements appear similar. It is not possible to define any robust differences between them, but it may be helpful to consider broadly what is accepted by the terms:
In general, guidelines are algorithmic in approach, directive in advice and address the usual, evidence-based or accepted approach to a clinical condition. There are a variety of published 'guidelines on guidelines' which may be adopted. Guidelines are often used by prescribing committees and national committees to establish or limit practice.

In general, position statements may move away from a direct algorithmic approach to express a clinical view that would be partially evidence-based and partially pragmatic. They are less likely to be algorithmic and less likely to be implementable by prescribing committees and national committees. They may deal with complex contentious issues where the evidence-base is limited, not yet available or never likely to be available. They may express an opinion more easily than a guideline.

3. Definition of a guideline or position statement
a) The document must address a matter relating to clinical diabetes, and should relate to medical practice. This should contribute to decision-making on the relevant issues.
b) Before work commences by the writing group the EASD Executive Committee should be contacted for their agreement concerning:
   - the remit and the constitution of the writing group
   - the proposed final disposition of the paper.
c) The proposed document should be planned to be the length of a paper likely to be published in Diabetologia or other major journals; in general this means under 6000 words. Long, in-depth reviews, papers with chapters (books), and discursive documents will not normally be considered.
d) Guidelines and position statements should be evidence-based as far as possible.
e) Guidelines and statements should have a wide collateral review by others outside the Writing Group.

4. EASD responsibilities under this MOU
EASD shall undertake the following activities:

a) On receipt of a proposal, the EASD Committee on Clinical Affairs (CCA) will nominate official representatives to be part of the writing group. These representatives are obliged to send a written report to the executive office to be forwarded to the Executive Committee, when the first draft has been successfully completed and stating that they are in agreement with the guidelines. It is the duty of the EASD representatives to alert the Executive Committee in a timely manner if, during the writing phase, there are major dissonances which cannot be overcome to their satisfaction, making an eventual positive recommendation to accept the guidelines impossible for them.
b) The executive office of EASD will forward the draft guidelines to CCA for their review, comments and recommendations.
c) The Chairman of CCA will forward their comments and recommendation(s) through the executive office to the Executive Committee.
d) If the Executive Committee agrees to the recommendation(s), the writing group/authors will be informed accordingly and, in the case of recommendations/amendments, asked to implement them.
e) When all recommendations have been implemented to the satisfaction the Executive Committee, the guidelines will be endorsed by the Executive Committee. A final decision on dissemination/publication can only be made after the guidelines have been approved. Then CCA would make a recommendation about the dissemination, including the possibility of publication in Diabetologia, of the finished article.

5. The Writing Group

The proposed constitution of the writing group should be outlined. The provenance, committee selection procedures and authority of the group are of crucial importance, so the procedures need to be explicit and transparent, and guidance should be sought from the EASD Executive Committee.

The Writing Group shall:

a) delineate the remit
b) summarise the topic, the main purpose of the guideline or statement, and to whom it is being addressed
c) declare conflicts of interest
d) propose a timeline
e) follow relevant guidance on formulating statements and guidelines (Appendix)
f) submit draft and final versions of the paper to the EASD executive office. If it is intended that the EASD logo or name be used on pocket versions or extracts, then such material also needs to be submitted.
   Revised versions should be sent to the EASD executive office to be forwarded to CCA for further review.
g) include the costing envisaged together with any pharma or other support available

6. It is mutually understood and agreed by and between the parties that:

In case the EASD Executive Committee, based on CCA's recommendation(s), requests modifications to the draft guidelines, the Writing Group can either

i) decline to implement the recommendations, or

ii) implement the recommendations.

In the case of i), EASD will not endorse the guidelines and they will not be considered as such.

In case of ii), once the guidelines have been approved by CCA and by the EASD Executive Committee, an official letter conveying this decision signed by the President and the Chair of CCA will be passed on to the Writing Group via the executive office. A final certified version of

the guidelines will be sent to the executive office by the Chair of CCA for dissemination and publication as appropriate.

7. Costs

EASD will cover the costs (travel and accommodation) incurred by its nominated representative(s) on the Writing Group. Any further costs must be discussed.

8. Effective Date and Signature

This MOU shall be effective upon the signature of EASD and the Writing Group's authorised official. It shall be in force from (date) …… to (date) …….

EASD and the Writing Group indicate agreement with this MOU by their signatures.

Date + Place	Date + Place
_____	_____
_____	_____
EASD	Writing Group

Appendix:

From bmj.com (2)

Authors of papers presenting clinical management guidelines should ensure that:

- *patient population to which guidelines apply is clearly described*
- *condition(s) to be detected, treated, or prevented is/are clearly defined*
- *circumstances (clinical/non-clinical) in which exceptions might be made in using the guidelines are clearly described*
- *methods for taking into account patient preferences in using the guidelines are clearly described*
- *guidelines have been reviewed by independent experts or peers*
- *guidelines have been piloted or pre-tested, with adequate discussion of how such results have been used*
- *main topics covered by the guidelines are presented clearly, with an accurate summary*
- *methods used to identify and select evidence are described clearly*
- *sources of information used in developing guidelines are referenced adequately*
- *methods used to assess strength of evidence are adequate and are described clearly*
- *method used to synthesise evidence (eg for meta-analysis or decision analysis) are clearly described*
- *methods used to reach expert or group consensus, and strength of consensus are clearly described*
- *those who developed the guideline eg individuals, interest groups are described clearly and are appropriate eg sufficiently multidisciplinary*
- *methods for taking into account potential biases/competing interests among guideline developers are clearly described and adequate*
- *methods used to seek views of interested parties not on the panel are described*
- *each major recommendation can be found easily*
- *recommendations are consistent with each other*
- *recommendations collectively cover all clinically relevant circumstances, or guideline explains why they do not*
- *qualitative and quantitative information is given about the health benefits and potential harms/risks of recommendations eg additional life expectancy, quality adjusted life years*
- *adequate qualitative and quantitative information is given about the costs of recommendations*
- *other guidelines dealing with the same topic are mentioned, and differences discussed*

levels or categories of evidence are expressed thus:

Ia evidence from meta-analysis of randomised controlled trials

Ib evidence from at least one randomised controlled trial

IIa evidence from at least one controlled study without randomisation

IIb evidence from at least one other type of quasi-experimental study

III evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case control studies

IV evidence from expert committee reports or opinions or clinical experience of respected authorities, or both

strength of recommendations is expressed thus:

A directly based on category I evidence

B directly based on category II evidence or extrapolated recommendation from category I evidence

C directly based on category III evidence or extrapolated recommendation from category I or II evidence

D directly based on category IV evidence or extrapolated recommendation from category I, II, or III evidence

date for scheduled review or expiry of the guidelines is given