European Network of Centres
for Pharmacoepidemiology and Pharmacovigilance

ENCePP-HTA Working Group 2014 survey of members' experience in conducting research to support HTA

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1. Background

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) [1] aims to further strengthen the post-authorisation monitoring of medicines. The network mostly includes public and not-for-profit organisations, but participation is open to for-profit organisations such as contract research organisations (CROs), provided they are focussed on pharmacoepidemiology and pharmacovigilance research and perform studies commissioned by third parties .

With the growing interest in incorporating Health Technology Assessment (HTA) related outcomes into post-authorisation studies (PAS), an ENCePP HTA working group (WG) has been established. Its mandate includes capacity building for the conduct of PAS that meet the needs of regulators and HTA bodies in a resource-conscious and efficient manner [2].

2. Objective and methods

A survey of the 139 centres in ENCePP was launched on 17 June 2014 to identify indicators of experience in conducting research with HTA outcomes. The compiled results from individual centres on competence would be used as an index of capacity of the network to potentially accommodate the inclusion of HTA outcomes in PAS. Questions were also included as a training needs analysis.

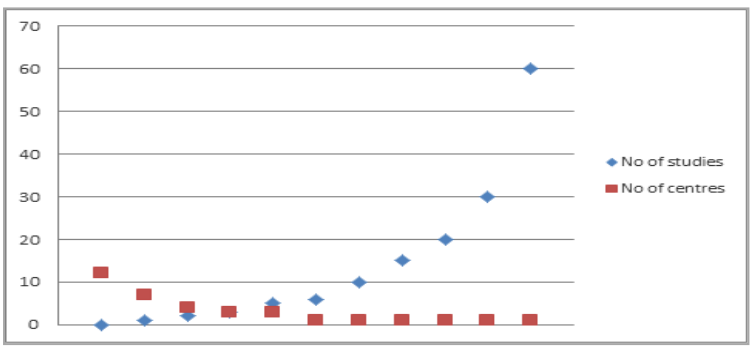
3. Results

Responses were received from 35 of the 139 centres that then formed the network.

12/35 (34%) of the respondents categorised themselves as university based, an equal number 12 (34%) as for-profit organisations. 7 (20%) were charity or non-profit organisations, 6 (17%) were hospital- and the remaining 5 (11%) government-based.

32 centres reported that in the previous 24 months they had actively participated in studies where specific HTA outcomes had been collected. However, a large proportion of these studies were conducted by a small number of centres (one centre conducted 60) and so these data are highly skewed, as shown in the following figure:

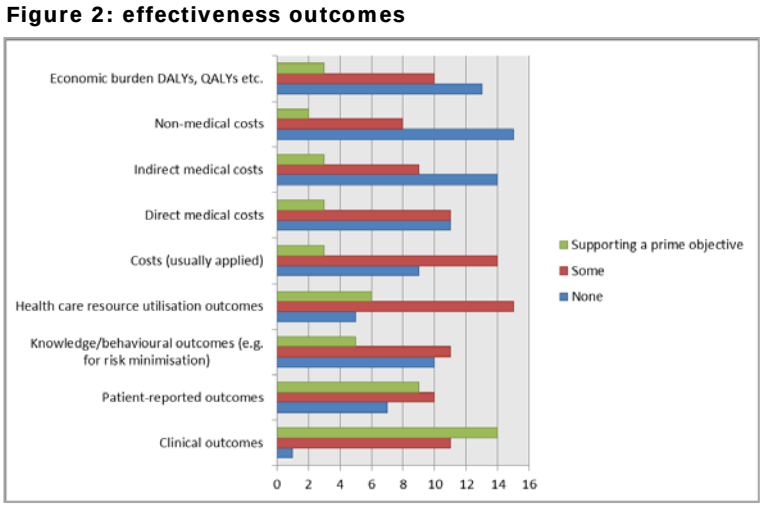
Figure 1: conduct of studies with HTA outcomes



Twenty centres reported that in the past 24 months they had been involved in studies that collected disease specific quality of life measures directly from the patient, their carer, parent or guardian.

A series of questions drilled further down into the outcomes collected and these are presented by study objective in Figure 2 for the 26 centres that reported having collected 'effectiveness' outcomes:

Figure 2: effectiveness outcomes



10 centres reported direct collaboration with an organisation whose primary area of work is HTA. 9 reported carrying out modelling activities to determine cost-effectiveness or budget impact that may be used to inform policy decisions.

From the training needs analysis, the three most frequently identified skills development interests were comparative effectiveness research (60% of respondents), healthcare resource utilisation (43%) and patient reported outcomes methods (43%).

4. Discussion

The apparently low response rate needs to be seen in the context of the network being focussed on pharmacovigilance and pharmacoepidemiology. The centres who responded are likely to be those with interest and experience and while this picture may not be representative of all ENCePP centres (primarily focusing on safety), the results have confirmed that a proportion of centres within ENCePP are conducting research with HTA outcomes. The results are therefore an index of current European capacity and will be helpful in defining approaches to building this, including training.

The detail of the responses will serve to assess how the ENCePP Research Resources Database [3] might be used to reflect the competencies in HTA outcomes of individual centres.

The results also indicate that there is a level of experience that can form the basis for the development by the WG of a considerations paper on practice in conducting studies that include HTA and drug safety outcomes with a view to either developing a stand-alone good practice guidance or integrating into existing guidance.

5. Conclusions

An important proportion of ENCePP centres have experience in conducting studies with endpoints relevant to HTA. Given the increasing interest in individual studies responding to both regulatory and HTA questions, ENCePP may be a useful platform to develop European capacity to deliver such studies.

References

1. http://www.encepp.eu/
2. http://www.encepp.eu/structure/documents/ENCePPWGHTAMandate.pdf
3. http://www.encepp.eu/encepp/resourcesDatabase.jsp

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