

Annex 1

Proposal for a Training Programme for Users

PROPOSAL FOR A TRAINING PROGRAMME FOR USERS

The first part of the training is theoretical with a presentation of the concepts and methods of HTA. We will very rapidly move to a practical training using cases and examples.

HTA topics will be selected for exercises. Trainees will work on a list of topics including drugs, devices, procedures and will be requested to select those that appear eligible for HTA reports. Trainees will be asked to explain and argue the choice criteria.

It is aimed that exercise will also concern actual HTA reports. Trainees will be asked to search database for reports on a topic they have selected as suitable for HTA in Poland.

A third type of exercise will consist of actual appraisal of HTA reports. Trainees will be given HTA reports on drugs, devices and procedures (e.g. interferon for HCV, ICD triple chamber, mammography screening, laparoscopic surgery) and will appraise them using the methods presented during the theoretical module.

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| Day 1 |
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Introduction to EBM/HTA

History, definition, use for decision, translation into practice
What is innovation in health matters ?
Content of an HTA report : How to read and use an HTA report

EBM and drugs, medical devices, procedures; diagnostic, screening

Objective

- Why a clinical trial ?
- Efficacy vs. effectiveness, safety data management
- Clinical trials vs. epidemiological studies

Background information

- Literature search
- Different scientific values of medical journals – impact and credibility (per review, impact factor)
- Establish the present state of knowledge regarding a specific field (severity of an illness, treatments already available ...)
- Knowledge about the work of other European Agencies (EMA, HAS, NICE, IQWiG ...) or networks (ICH, INAHTA ...) [also applicable to HTA]

Quality

- Good Clinical Practice (GCP)
- Conflict of interests

Methodology (part 1)

- Observational and experimental trials; their advantages and drawbacks
- Understanding uncertainty (sample size, p, CI, statistical significance, ...)
- Randomisation, blind
- Hierarchy of evidence and grading classifications
- Relevance of evaluation criteria-outcomes, composite criteria

Day 2

EBM and drugs, medical devices, procedures; diagnostic, screening

Methodology (part 2)

- Choice of comparator, the use of placebo or active comparators
- ITT, PP
- Non inferiority/superiority studies
- Indirect comparisons
- Epidemiological data (prevalence, incidence)
- Meta-analyses
- Bias

Practical use

- Clinical relevance : Difference between statistical and clinical significance

Health Technology Assessment (HTA)

Introduction to health economics, budget impact and priority setting

Concept of Health Technology Assessment and Economic evaluation in HTA

Types of economic evaluations (cost-minimization, cost-effectiveness, cost-utility, cost-benefit)

Terms of reference for HTA reports in the Polish context

Validity criteria of economic analysis, critical appraisal of economic evaluation

Levels of evidence for HTA and guidelines

How to read a model in the decision making process and economic analysis

Use of HTA in selected countries - relationship with reimbursement and BBP ; comparison of HTA reports / assessment and appraisal

Preliminary conclusions

Role of a scientific expertise in a decision making process

HTA in creation of Basic Benefit Package and standardization of medical practice. Drug reimbursement lists, formularies

Day 3

Morning

Searching literature data on Internet : Medline, Cochrane Library, National Guidelines Clearinghouse Website and other relevant internet sources

Training on examples.

Computers linked to Internet will be necessary (one PC connected to Internet for two trainees). A glossary on EBM/HTA terminology will be distributed.

Afternoon

Innovation vs. progress : Prioritisation exercise on the basis of examples (e.g. me-too medicinal products, herbal medicines, acupuncture, see also the INAHTA list)

Day 4

Morning

Methodology of clinical trials

Exercices on examples (e.g. interferons, drug eluting stents, mammography in breast cancer screening), three groups, each working on either medicinal products, medical devices and medical procedures (work on publications)

Afternoon

Methodology of clinical trials

Exercices on examples, three groups, each working on either medicinal products, medical devices and medical procedures (work on publications)

Day 5

Morning

Methodology of clinical trials

Exercices on examples, three groups, each working on either medicinal products, medical devices and medical procedures (work on publications)

Afternoon

HTA evaluation

Analysis of an HTA report

End of the training

Conclusions

Evaluation forms :

- Multiple choice questions to assess the added-value of the training to be completed by the trainees
- Questionnaire for trainees' feed-back on the one-week training programme