THE 13TH CONGRESS OF THE
EUROPEAN ASSOCIATION FOR CLINICAL PHARMACOLOGY AND THERAPEUTICS (EACPT)
PRAGUE, CZECH REPUBLIC
JUNE 24-27, 2017

PHARMACOVIGILANCE TRAINING FOR SPECIALIST ONCOLOGY NURSES – A TWO WAY EVALUATION

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Introduction

Nurses can play an important role in adverse drug reaction (ADR) monitoring and reporting in a hospital setting. However it is doubtful whether they are adequately prepared for their role in pharmacovigilance. In the development of the new prescribing qualification module for specialist oncology nurses we wanted to dedicate attention to the topic of pharmacovigilance and ADR reporting.

Aim

Determine the value of an ADR reporting assignment for pharmacovigilance centres and specialist nurses during their prescribing training module.

Methods

The "prescribing qualification" for specialist oncology nurses allows them to prescribe a limited set of frequently prescribed drugs. We incorporated an introduction lecture on pharmacovigilance, an adverse drug reporting assignment and a group discussion on the reported ADRs in this module (see figure 1).
The quality of reported ADRs was measured with the 'Clinical Documentation tool to assess Individual Case Safety Reports' (ClinDoc) tool. Furthermore, the relevance of the reports was evaluated regarding seriousness, additional monitoring of the drug by the European Medicines Agency (EMA) and lack of labelling information of the ADR. Furthermore we evaluated the value for the specialist nurses together with the preparedness of these specialist nurses for their role in pharmacovigilance in an e-survey.

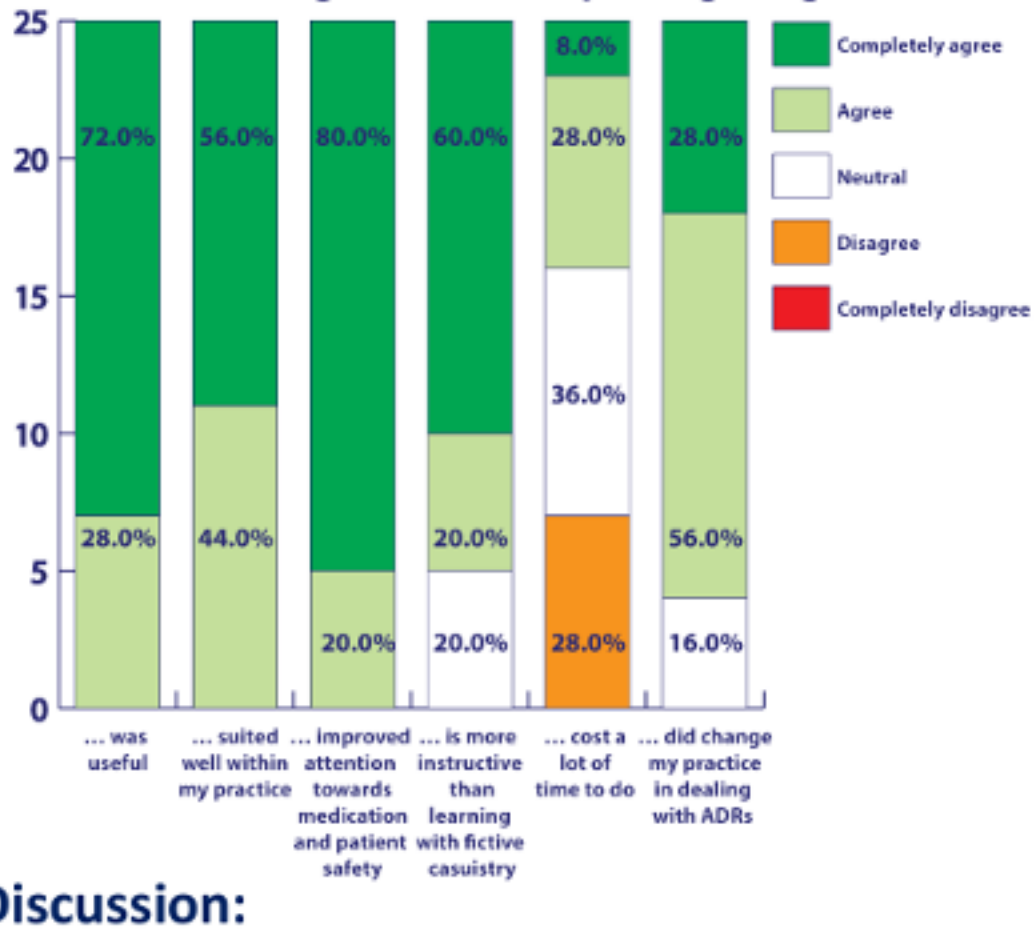
Conclusion

The ADR reporting assignment is usefull for specialist oncology nurses and drug safety

Results

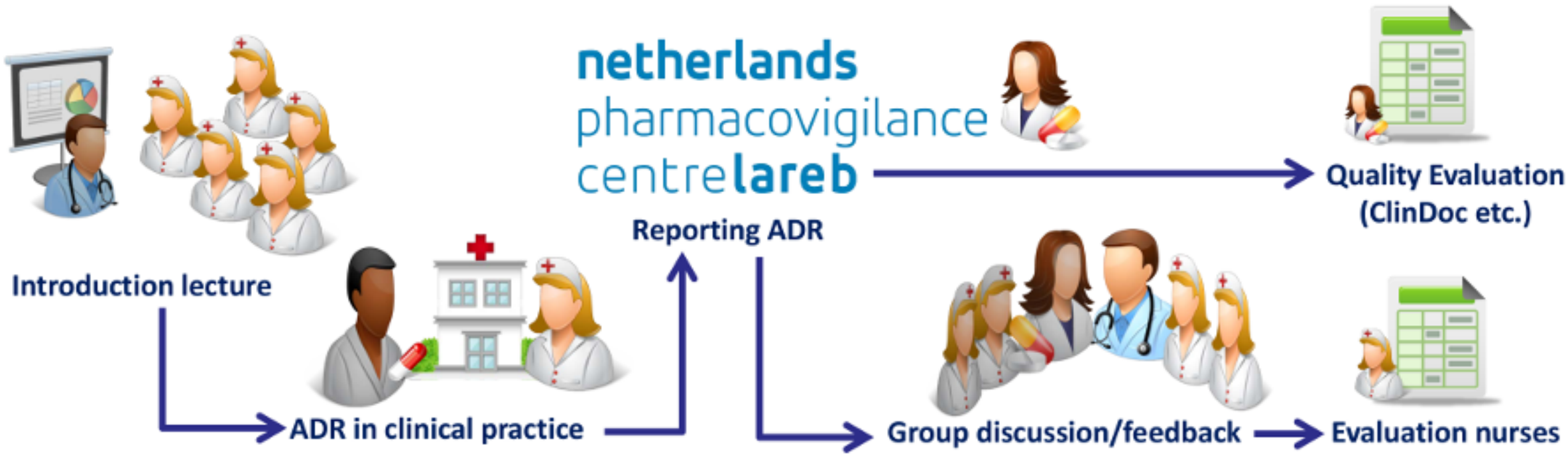
A total of 33 ADRs were reported during the assignment of whom 76% (n=25) concerned chemotherapeutic agents. Based on the ClinDoc tool 97% (n=32) of the reports were well documented, 1 was moderately documented. A large proportion 39% (n=13) of the reports were considered serious according to the CIOMS criteria. The suspect drugs were listed for additional monitoring by EMA in 15% (n=5) of cases and in 21% (n=7) the reported ADR was not labelled in the Summary of Product Characteristics.

The Pharmacovigilance ADR reporting assignment ...



Discussion:

Future research is needed to determine the long term effects of an ADR reporting assignment in the workplace, and if such assignments are valuable for other students who are less experienced or in other health care professions.



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