A FRAMEWORK FOR A REGISTER OF BIOLOGICAL AGENTS IN RHEUMATOLOGY

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INTRODUCTION

In January 2012, 215 patients were undergoing treatment with biological agents in the Rheumatology Unit (RU) at Mater Dei Hospital. A register for biological agents used in rheumatology enhances the pharmacovigilance that is of benefit in patients being treated with biological agents.

AIM

To develop a framework for a tailor-made biologics register for the RU, to be known as the Maltese Rheumatology Biologics Register (MRBR). The data generated by this register will:

- Provide information on the pharmacoepidemiological trends associated with biological agents in the local setting
- Provide evidence regarding outcomes of therapy for individual patients
- Contribute towards the formulation of more definite answers to the questions of cost, safety and efficacy within the local scenario.

METHOD

Two meetings were held with a 7-member expert panel (2 rheumatologists, 2 pharmacy academics and 3 members of the healthcare team of the RU). The framework was produced through discussions with the panel, drawing from their clinical experience and key articles published by the British Society of Rheumatology Biologics Register (BSRBR)\(^1\) and the European League Against Rheumatism (EULAR)\(^2,3\). It was agreed by the panel that the first section of the register would gather baseline information while the second section would gather follow-up data.

A preliminary plan for the register was formulated during the first meeting by discussing ‘EULAR points to consider when establishing a drug register’ by Dixon et al., 2010\(^4\). It was pointed out during this meeting that the BSRBR and other European registers\(^4\) lack direct input from the pharmacists involved in the treatment. A second meeting comprised of a validation of the first section of the register and planning of the second section. A final validation was carried out through a specially formulated expert panel questionnaire (EPQ).

RESULTS AND DISCUSSION

The framework of the register is illustrated in Figure 1. Data for the MRBR will be gathered using four questionnaires based on those used by the BSRBR\(^2\). These are to be filled in by the patients, consultants or health professionals involved. The insertion of a field entitled ‘Pharmaceutical Care Issues’ in the second section will allow direct input from the pharmacists involved. This unique characteristic enhances Adverse Drug Reaction (ADR) reporting and encourages collaborative drug therapy management\(^7\), improves overall patient care.

![Figure 1: An Outline of the Framework for the Maltese Rheumatology Biologics Register](http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Reportingsuspectedadversedrugreactions/Druganalysisprints/in dex.html)

The reporting of adverse events is organised into system organ classes and reaction types, according to the relevant Drug Analysis Prints found on the UK Medicines and Healthcare products Regulations Agency website in November 2011\(^8\). This section is linked to the current version of Malta Medicines Authority Adverse Drug Reactions report form, facilitating reporting of ADRs as required under the Malta Pharmacovigilance Regulations\(^9\).

The expert panel questionnaire produced results that strongly favour the establishment of this register in the RU. The healthcare team of the RU suggested that extra staff should be brought in to run the register and alleviate the time burden that they would otherwise incur to fill in the questionnaires in a busy clinical setting.

CONCLUSION

The proposed framework of the register has been validated among a team of specialists and is ready for implementation. A characteristic feature of this register is the field where pharmacists can directly input relevant information encouraging a multidisciplinary approach to patient management.

REFERENCES


