DEVELOPMENT OF A UK NATIONAL PRESCRIBING SKILLS ASSESSMENT

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Summary: Prescribing of medicines is the key clinical activity in the working life of most doctors. In recent years, a broad consensus regarding the necessary competencies has been achieved. Each of these is a complex mix of knowledge, judgment, and skills. Surveys of those on the threshold of their medical careers have revealed widespread lack of confidence in writing prescriptions. A valid and reliable assessment of prescribing competence, separate from an overall assessment of medical knowledge and skill, would have many benefits for clinical governance and patient safety, and would provide a measure of the success of training programs in therapeutics. Delivering such an assessment presents many challenges, not least of which are the difficulty in identifying a surrogate marker for competent prescribing in clinical practice and the challenge of ensuring that competence assessed in a controlled environment predicts performance in clinical practice. This talk will describe the approach being used in the United Kingdom to develop an online “OSCE” assessment of prescribing and sets out the requirements for its development, scope, composition, and delivery. It will describe the current status in the development and implementation of the UK national Prescribing Skills Assessment for final-year medical students.

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NOVEL ANTIDIABETICS: SHOULD THEY BE USED AT ALL—AND IN WHOM?

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Summary: During the past few years, several new classes of antidiabetic drugs have appeared on the market, such as glucagon-like-peptide analogs, dipeptidyl peptidase-4 inhibitors, renal glucose reuptake inhibitors, and insulin analogues with different kinetic properties. Although these drugs have mostly very attractive modes of action, their use in clinical practice can be limited by nonsuperiority with regard to existing treatments, and increased costs, as well as the lack of knowledge on hard end points and long-term safety. This is of particular concern with regard to cardiovascular protection or risks, as has become evident from the past experience, for example, with rosiglitazone. A possible solution to this problem is to individualize antidiabetic therapy by taking into account the age, obesity, renal function, and therapeutic compliance, as well as other factors of the patient, with the aim of choosing drugs that offer individualized additional benefits for selected patients.

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ASSESSMENT OF DRUG-INDUCED LIVER INJURY FROM CLINICAL TRIAL DATA

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Summary: Proper analysis of liver safety data is multivariate by nature and has to take into account time dependency of observations. Current standard tools for liver safety assessment are summary tables, individual data listings, narratives, and static graphs. An efficient complementary approach is use of interactive graphics, ideally in a team-based setting. A systematic workflow including predefined graph templates helps to ensure completeness of evaluations, supports hypothesis generation and testing, and facilitates identification of the most suitable graphics for publishing and regulatory reporting. The use of interactive graphics instead of focusing on static graphs enables a project team to jointly assess biomarker data, helps to thoroughly query the data from different perspectives, and fosters team ownership of both analysis and conclusions. This talk presents a systematic workflow for liver safety assessment using a series of interactive graph templates.

Disclosure of Interest: None declared.

DEVELOPMENT OF ADR REPORTING AND MONITORING IN CHINA

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Summary: Today, drugs play an important role in human disease prevention and treatment, as well as protection of health. In China, along with the development of medicines and the health care system, rational drug use and drug safety are becoming increasingly important concerns. In the early 1980s, the Chinese government started to carry out pilot projects to monitor ADR. In March 1998, we formally joined the WHO International Drug Monitoring Program. After nearly 20 years of practice, China ADR monitoring was strengthened in terms of legal framework, monitoring systems, information technology application, administrative control, capital investment, and other aspects. Although China’s ADR monitoring has developed rapidly, we still face many challenges. The revised edition of “Management Measures of Adverse Drug Reactions Reporting and Monitoring” had been promulgated in July 2011, with the intent to further standardize the requirements and procedures of ADR reporting. We also intend to intensify the verification, investigation, and evaluation of case reports. We also continue to strengthen exchange and communication with WHO and other countries on drug safety information. We hope to learn best practices and encourage innovation in China’s ADR monitoring system to ensure rational and safe use of drugs.

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SJÖGREN OCULAR DISEASE TREATMENT

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Summary: Sjögren’s syndrome is a systemic autoimmune disease that results in tear film instability, hyperosmolarity, chronic irritation, and inflammation of the ocular surface. Treatment can be either conservative or invasive based on the severity of the disease. The basic aim of the treatment is to improve the quality of life and reduce subjective complaints and objective ocular surface irritation. The first line of treatment is tear substitution with artificial tear drops, gels, and ointments. In moderate cases, preservative-free tear supplementation, topical anti-inflammatory therapy, and retinol treatment is recommended. Temporary or permanent punctal plug occlusion, therapeutic contact lenses, or using a moisture chamber can also be an option. In severe cases, the application of topical autologous serum, systemic anti-inflammatory therapy, androgen substitution, secretagogues, and surgical intervention can be effective. As a future perspective, causal therapy of the disease will play a greater role, such as cyclosporine therapy, secretion stimulation, growth factor containing artificial tears, and immunomodulants.

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