P25

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Pregnancy Prevention Programs in Europe: A Multidisciplinary Approach to Isotretinoin Use by Women

Background: Pregnancy prevention programs (PPPs) are in place for some medicines known to be teratogens. PPPs aim to allow women of childbearing potential to take these medicines whilst ensuring they are not exposed during pregnancy. PPPs measures include limiting prescribers and indications for prescription, requiring pregnancy tests and contraception use and providing women with information on teratogenicity. Isotretinoin is one such medication used for the treatment of acne. Aim: To investigate the availability of data from different sources including European electronic healthcare databases and clinical records to evaluate PPPs. Methods: An inventory was completed as part of the EUROmediCAT project on six databases capturing pregnancy and prescribing data: Norway, the Netherlands, Tuscany/Emilia Romagna regions of Italy, Wales and the rest of the UK. In addition, clinical records from one specialist dermatological clinic were examined retrospectively for women to whom isotretinoin had been prescribed. Results: Prescribing of isotretinoin was mainly by specialists. In non-UK regions, prescribing data on products with a PPP was available irrespective of whether issued in primary or secondary care. In the UK/Wales, data was limited to primary care. In Italy, prescribing data was limited to products reimbursed with data for contraception not available; in other regions some contraceptive prescribing was captured. Clinical records provided a complimentary source of data in Emilia Romagna. No databases routinely captured pregnancy tests. In all regions, data enabled prescription durations and exposure to be estimated. Data on brand versus generic was present in most databases whilst indication for prescribing was not available in Italian or Dutch databases being partially captured in the other regions. Conclusion: Additional data sources are required to monitor the prescribing of products with a PPP and compliance with PPPs. A pilot study is proposed to register in a specialist dermatological clinic patient details including pregnancy tests carried out and indication for which isotretinoin was prescribed with active follow-up in place for patients not returning to the clinic. Creation of a limited number of specialist prescribers in a multidisciplinary team including gynecologists and congenital anomaly registries and health care database analysts could allow PPPs to be better evaluated.