References

Chapter 23

- 1 Franks ME, Macpherson GR, Figg WD. Thalidomide. *Lancet.* 2004;**363**(9423):1802–11.
- 2 Food and Drug Administration. Reviewer Guidance. Evaluating the Risks of Drug Exposure in Human Pregnancies. Food and Drug Administration, 2005. Available from: http://www.fda.gov/downloads/Drugs/.../Guidances/ucm071645.pdf (last accessed 18 November 2015).
- **3** Koren G. Medication Safety in Pregnancy and Breastfeeding: The Evidence-Based A-to-Z Clinician's Pocket Guide. New York, McGraw-Hill Medical, 2007.
- **4** Kallen B, Olausson PO. No increased risk of infant hypospadias after maternal use of loratadine in early pregnancy. *Interntaional Journal of Medical Science*. 2006;**3**(3):106–7.
- **5** Schwarz EB, Moretti ME, Nayak S, Koren G. Risk of hypospadias in offspring of women using loratadine during pregnancy: a systematic review and meta-analysis. *Drug Safety.* 2008;**31**(9):775–88.
- **6** Lupattelli A, Spigset O, Twigg MJ, Zagorodnikova K, Mårdby AC, Moretti ME, et al. Medication use in pregnancy: a cross-sectional, multinational web-based study. *British Medical Journal Open.* 2014;**4**(2):e004365.
- 7 Marchetti F, Romero M, Bonati M, Tognoni G. Use of psychotropic drugs during pregnancy. A report of the international co-operative drug use in pregnancy (DUP) study. Collaborative Group on Drug Use in Pregnancy (CGDUP). European Journal of Clinical Pharmacology. 1993;45(6):495–501.
- **8** Daw JR, Hanley GE, Greyson DL, Morgan SG. Prescription drug use during pregnancy in developed countries: a systematic review. *Pharmacoepidemiology ₱ Drug Safety*. 2011;**20**(9):895–902.
- **9** Mitchell AA, Gilboa SM, Werler MM, Kelley KE, Louik C, Hernandez-Diaz S. Medication use during pregnancy, with particular focus on prescription

- drugs: 1976–2008. *American Journal of Obstetrics and Gynecology*. 2011;**205**(1):51 e1–8.
- 10 Lacroix I, Hurault C, Sarramon MF, Guitard C, Berrebi A, Grau M, et al. Prescription of drugs during pregnancy: a study using EFEMERIS, the new French database. *European Journal of Clinical Pharmacology*. 2009;65(8):839–46.
- **11** Kulaga S, Zargarzadeh AH, Berard A. Prescriptions filled during pregnancy for drugs with the potential of fetal harm. *BJOG*. 2009;**116**(13):1788–95.
- **12** Cleary BJ, Butt H, Strawbridge JD, Gallagher PJ, Fahey T, Murphy DJ. Medication use in early pregnancy-prevalence and determinants of use in a prospective cohort of women. *Pharmacoepidemiology* & Drug Safety. 2010;**19**(4):408–17.
- 13 Engeland A, Bramness JG, Daltveit AK, Ronning M, Skurtveit S, Furu K. Prescription drug use among fathers and mothers before and during pregnancy. A population-based cohort study of 106 000 pregnancies in Norway 2004–2006. *British Journal of Clinical Pharmacology.* 2008;65(5):653–60.
- **14** Hardy JR, Leaderer BP, Holford TR, Hall GC, Bracken MB. Safety of medications prescribed before and during early pregnancy in a cohort of 81,975 mothers from the UK General Practice Research Database. *Pharmacoepidemiology & Drug Safety.* 2006;**15**(8):555–64.
- **15** Piper JM, Mitchel EF Jr. Prenatal exposure to prescribed drugs in Tennessee Medicaid, 1983–1988. *Paediatric & Perinatal Epidemiology*. 1991;**5**(4):402–9.
- **16** Buitendijk S, Bracken MB. Medication in early pregnancy: prevalence of use and relationship to maternal characteristics. *American Journal of Obstetrics and Gynecology.* 1991;**165**(1):33–40.
- **17** Donati S, Baglio G, Spinelli A, Grandolfo ME. Drug use in pregnancy among Italian women. *European Journal of Clinical Pharmacology*. 2000;**56**(4):323–8.

- **18** Larivaara P, Hartikainen AL, Rantakallio P. Use of psychotropic drugs and pregnancy outcome. *Journal of Clinical Epidemiology*. 1996;**49**(11):1309–13.
- 19 Bonassi S, Magnani M, Calvi A, Repetto E, Puglisi P, Pantarotto F, et al. Factors related to drug consumption during pregnancy. *Acta Obstetricia et Gynecologica Scandinavica*. 1994;73(7):535–40.
- **20** Rubin JD, Ferencz C, Loffredo C. Use of prescription and non-prescription drugs in pregnancy. The Baltimore-Washington Infant Study Group. *Journal of Clinical Epidemiology*. 1993;**46**(6):581–9.
- 21 Bonati M, Bortolus R, Marchetti F, Romero M, Tognoni G. Drug use in pregnancy: an overview of epidemiological (drug utilization) studies. *European Journal of Clinical Pharmacology*. 1990;38(4):325–8.
- 22 De Vigan C, De Walle HE, Cordier S, Goujard J, Knill-Jones R, Ayme S, et al. Therapeutic drug use during pregnancy: a comparison in four European countries. OECM Working Group. Occupational Exposures and Congenital Anomalies. *Journal of Clinical Pharmacology*. 1999;52(10):977–82.
- **23** Collaborative Group on Drug Use in Pregnancy (CGDUP). Medication during pregnancy: an intercontinental cooperative study. *International Journal of Gynaecology and Obstetrics*. 1992;**39**(3):185–96.
- **24** EURAP Study Group. Utilization of antiepileptic drugs during pregnancy: comparative patterns in 38 countries based on data from the EURAP registry. *Epilepsia*. 2009;**50**(10):2305–9.
- **25** Ystrom E, Vollrath ME, Nordeng H. Effects of personality on use of medications, alcohol, and cigarettes during pregnancy. *European Journal of Clinical Pharmacology.* 2012;**68**(5):845–51.
- 26 Schaefer C, Peters PWJ, Miller RK. Drugs During Pregnancy and Lactation: Treatment Options and Risk Assessment, 2nd edn. Amsterdam, London, Elsevier, 2007.
- 27 Soriano LC, Bateman BT, García Rodríguez LA, Hernández-Díaz S. Prescription of antihypertensive medications during pregnancy in the UK. *Pharmacoepidemiology & Drug Safety*. 2014;23(10):1051–8.
- 28 Crijns HJ, van Rein N, Gispen-de Wied CC, Straus SM, de Jong-van den Berg LT. Prescriptive contraceptive use among isotretinoin users in the Netherlands in comparison with non-users: a drug utilisation study. *Pharmacoepidemiology & Drug Safety*. 2012;21(10):1060–6.

- **29** Daw JR, Mintzes B, Law MR, Hanley GE, Morgan SG. Prescription drug use in pregnancy: a retrospective, population-based study in British Columbia, Canada (2001–2006). *Clinical Therapy*. 2012;**34**(1):239–49, e2.
- **30** Lacroix I, Damase-Michel C, Lapeyre-Mestre M, Montastruc JL. Prescription of drugs during pregnancy in France. *Lancet*. 2000;**356**(9243):1735–6.
- 31 Olesen C, Thrane N, Henriksen TB, Ehrenstein V, Olsen J. Associations between socio-economic factors and the use of prescription medication during pregnancy: a population-based study among 19 874 Danish women. European Journal of Clinical Pharmacology. 2006;62(7):547–53.
- **32** Wen SW, Yang T, Krewski D, Yang Q, Nimrod C, Garner P, et al. Patterns of pregnancy exposure to prescription FDA C, D and X drugs in a Canadian population. *Journal of Perinatology*. 2008;**28**(5):324–9.
- **33** Feldman Y, Koren G, Mattice K, Shear H, Pellegrini E, MacLeod SM. Determinants of recall and recall bias in studying drug and chemical exposure in pregnancy. *Teratology.* 1989;**40**(1):37–45.
- **34** Addis A, Sharabi S, Bonati M. Risk classification systems for drug use during pregnancy: are they a reliable source of information? *Drug Safety*. 2000;**23**(3):245–53.
- 35 Olesen C, Sorensen HT, de Jong-van den Berg L, Olsen J, Steffensen FH. Prescribing during pregnancy and lactation with reference to the Swedish classification system. A population-based study among Danish women. The Euromap Group. *Acta Obstetricia et Gynecologica Scandinavica*. 1999;78(8):686–92.
- 36 European Medicines Agency. Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: From Data to Labelling. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003307.pdf (last accessed 18 November 2015).
- **37** Huybrechts KF, Palmsten K, Mogun H, Kowal M, Avorn J, Setoguchi-Iwata S, et al. National trends in antidepressant medication treatment among publicly insured pregnant women. *General Hospital Psychiatry*. 2013;**35**(3):265–71.
- **38** Bakker MK, Kolling P, van den Berg PB, de Walle HE, de Jong van den Berg LT. Increase in use of selective serotonin reuptake inhibitors in pregnancy during the last decade, a population-based cohort

- study from the Netherlands. *British Journal of Clinical Pharmacology*. 2008;**65**(4):600–6.
- **39** McManus P, Mant A, Mitchell PB, Montgomery WS, Marley J, Auland ME. Recent trends in the use of antidepressant drugs in Australia, 1990–1998. *Medical Journal of Australia*. 2000;**173**(9):458–61.
- **40** Charlton R, Jordan S, Pierini A, Garne E, Neville A, Hansen A, et al. Selective serotonin reuptake inhibitor prescribing before, during and after pregnancy: a population-based study in six European regions. *BJOG*. 2015;**122**(7):1010–20.
- **41** Heikkila AM. Antibiotics in pregnancy a prospective cohort study on the policy of antibiotic prescription. *Annals of Medicine*. 1993;**25**(5):467–71.
- **42** de Jonge L, Bos HJ, van Langen IM, de Jong-van den Berg LT, Bakker MK. Antibiotics prescribed before, during and after pregnancy in the Netherlands: a drug utilization study. *Pharmacoepidemiology & Drug Safety.* 2014;**23**(1):60–8.
- **43** Santos F, Oraichi D, Berard A. Prevalence and predictors of anti-infective use during pregnancy. *Pharmacoepidemiology & Drug Safety.* 2010;**19**(4):418–27.
- **44** Källén BA, Otterblad Olausson P, Danielsson BR. Is erythromycin therapy teratogenic in humans? *Reproductive Toxicology.* 2005;**20**(2):209–14.
- **45** Romoren M, Lindbaek M, Nordeng H. Pregnancy outcome after gestational exposure to erythromycin-a population-based register study from Norway. *British Journal of Clinical Pharmacology*. 2012;**74**(6):1053–62.
- **46** Osterberg L, Blaschke T. Adherence to medication. *New England Journal of Medicine*. 2005;**353**(5): 487–97.
- **47** Vermeire E, Hearnshaw H, Van Royen P, Denekens J. Patient adherence to treatment: three decades of research. A comprehensive review. *Journal of Clinical Pharmacy and Therapeutics*. 2001;**26**(5):331–42.
- **48** Lupattelli A, Spigset O, Nordeng H. Adherence to medication for chronic disorders during pregnancy: results from a multinational study. *International Journal of Clinical Pharmacy*. 2014;**36**(1):145–53.
- **49** Kennedy J. Herb and supplement use in the US adult population. *Clinical Therapy.* 2005;**27**(11):1847–58.
- **50** Hall HG, Griffiths DL, McKenna LG. The use of complementary and alternative medicine by pregnant women: a literature review. *Midwifery*. 2011;**27**(6):817–24.

- **51** Kennedy DA, Lupattelli A, Koren G, Nordeng H. Herbal medicine use in pregnancy: results of a multinational study. *BMC Complementary and Alternative Medicine*. 2013;**13**:355.
- **52** Crijns I, Bos J, Knol M, Straus S, de Jong-van den Berg L. Paternal drug use: before and during pregnancy. *Expert Opinon on Drug Safety*. 2012;**11**(4):513–18.
- 53 Malm H, Martikainen J, Klaukka T, Neuvonen PJ. Prescription drugs during pregnancy and lactation a Finnish register-based study. European Journal of Clinical Pharmacology. 2003;59(2):127–33.
- 54 Andrade SE, Gurwitz JH, Davis RL, Chan KA, Finkelstein JA, Fortman K, et al. Prescription drug use in pregnancy. *American Journal of Obstetrics and Gynecology*. 2004;191(2):398–407.
- 55 Hurault-Delarue C, Lacroix I, Vidal S, Montastruc JL, Damase-Michel C. [Drugs in pregnancy: study in the EFEMERIS database (2004 to 2008)]. *Gynecologie, Obstetrique & Fertilitie*. 2011;39(10):554–8.
- **56** Bateman BT, Hernandez-Diaz S, Huybrechts KF, Palmsten K, Mogun H, Ecker JL, et al. Patterns of outpatient antihypertensive medication use during pregnancy in a Medicaid population. *Hypertension*. 2012;**60**(4):913–20.
- **57** Piper JM, Baum C, Kennedy DL. Prescription drug use before and during pregnancy in a Medicaid population. *American Journal of Obstetrics and Gynecology*. 1987;**157**(1):148–56.
- **58** Sambamoorthi U, Akincigil A, McSpiritt E, Crystal S. Zidovudine use during pregnancy among HIV-infected women on Medicaid. *Journal of Acquired Immune Deficiency Syndrome*. 2002;**30**(4):429–39.
- **59** Charlton RA, Cunnington MC, de Vries CS, Weil JG. Data resources for investigating drug exposure during pregnancy and associated outcomes: the General Practice Research Database (GPRD) as an alternative to pregnancy registries. *Drug Safety*. 2008;**31**(1):39–51.
- 60 Sharma P, Parekh A, Uhl K. An innovative approach to determine fetal risk: the FDA Office of Women's Health pregnancy exposure registry web listing. *Womens Health Issues.* 2008;18(4):226–8.
- 61 Schaefer C, Hannemann D, Meister R. Post-marketing surveillance system for drugs in pregnancy 15 years experience of ENTIS. *Reproductive Toxicology*. 2005;20(3):331–43.

- 4
- **62** Nava-Ocampo AA, Koren G. Human teratogens and evidence-based teratogen risk counseling: the Motherisk approach. *Clinical Obstetrics and Gynecology*. 2007;**50**(1):123–31.
- **63** Hardy JB. The Collaborative Perinatal Project: lessons and legacy. *Annals of Epidemiology*. 2003;**13**(5):303–11.
- **64** Heinonen OP, Slone D, Shapiro S. *Birth Defects and Drugs in Pregnancy*. Littleton, MA, Publishing Sciences Group, 1977.
- **65** Mitchell AA, Cottler LB, Shapiro S. Effect of questionnaire design on recall of drug exposure in pregnancy. *American Journal of Epidemiology*. 1986;**123**(4):670–6.
- **66** Rockenbauer M, Olsen J, Czeizel AE, Pedersen L, Sorensen HT. Recall bias in a case-control surveillance system on the use of medicine during pregnancy. *Epidemiology*. 2001;**12**(4):461–6.
- 67 Mackenzie SG, Lippman A. An investigation of report bias in a case-control study of pregnancy outcome. *American Journal of Epidemiology*. 1989;129(1):65–75.
- **68** Wettermark B, Zoega H, Furu K, Korhonen M, Hallas J, Norgaard M, et al. The Nordic prescription databases as a resource for pharmacoepidemiological research a literature review. *Pharmacoepidemiology & Drug Safety*. 2013;**22**(7):691−9.
- **69** Stephansson O, Granath F, Svensson T, Haglund B, Ekbom A, Kieler H. Drug use during pregnancy in Sweden assessed by the Prescribed Drug Register and the Medical Birth Register. *Clinical Epidemiology*. 2011;**3**:43–50.

- 70 EUROmediCAT website: www.euromedicat.eu.
- **71** van Gelder MM, Bretveld RW, Roeleveld N. Web-based questionnaires: the future in epidemiology? *American Journal of Epidemiology*. 2010;**172**(11):1292–8.
- **72** Eysenbach G. Improving the quality of Web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). *Journal of Medical Internet Research*. 2004;**6**(3):e34.
- 73 Altman DG. Practical Statistics for Medical Research. London, Chapman & Hall, 1991.
- **74** Margulis AV, Setoguchi S, Mittleman MA, Glynn RJ, Dormuth CR, Hernandez-Diaz S. Algorithms to estimate the beginning of pregnancy in administrative databases. *Pharmacoepidemiology & Drug Safety*. 2013;**22**(1):16–24.
- **75** Skurtveit S, Selmer R, Tverdal A, Furu K, Nystad W, Handal M. Drug exposure: inclusion of dispensed drugs before pregnancy may lead to underestimation of risk associations. *Journal of Clinical Epidemiology*. 2013;**66**(9):964–72.
- 76 Cohen LS, Altshuler LL, Harlow BL, Nonacs R, Newport DJ, Viguera AC, et al. Relapse of major depression during pregnancy in women who maintain or discontinue antidepressant treatment. *Journal of the American Medical Association*. 2006;295(5):499–507.
- 77 van Gelder MM, van Rooij IA, de Walle HE, Roeleveld N, Bakker MK. Maternal recall of prescription medication use during pregnancy using a paperbased questionnaire: a validation study in the Netherlands. *Drug Safety.* 2013;**36**(1):43–54.