UK Efforts: Safer Medicines for Pregnant Women and Lactating Women

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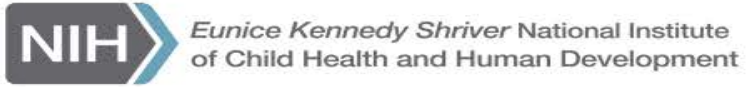

The Medicines and Healthcare products Regulatory Agency (MHRA)

Drs. John Clements and Jane Wooley

- an executive agency of the UK Department of Health and Social Care
- the UK's regulator of medicines, medical devices and blood components for transfusion, responsible for:
  - ensuring their safety, quality and effectiveness
  - helping to inform the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use

Safe and effective medicines in pregnancy

- 700 K pregnancies per year but inadequate guidance for HCPs
- None but essential medicines during pregnancy
  - chronic conditions (eg depression, epilepsy, diabetes, asthma, hypertension etc)
  - pregnancy-related new or exacerbated conditions (e.g. gestational diabetes)
  - acute problems and medical emergencies (eg infections etc)
- Unhealthy mother = unhealthy pregnancy

Expert Review recommendations

12 recommendations with three overarching goals…

i. to support development of safer, more effective medicines in pregnancy

ii. to facilitate more rapid identification of harm from medicines in pregnancy using the best available evidence

iii. to enable informed decision-making through providing consistent, up-to-date information to women and healthcare providers

Developing safer, more effective medicines in pregnancy

- A strategy to co-ordinate and promote teratogenicity research
- Scientific workshop on obtaining better non-clinical data
- Studies to understand better how pregnancy affects the pharmaco-kinetics/ pharmaco-dynamics of medicines
- Opportunities should be provided for obstetricians to receive training in pharmacology
- Better capture and monitoring of data on the safety of medicines during pregnancy

More rapid identification of harm

- Electronic Yellow Card reporting should be made available at point of care
- Regular, independent review by experts of all suspected adverse drug reactions in pregnancy
- Systematically monitor outcomes after taking important regulatory action
- Develop specific guidance for regulators and pharmaceutical industry

Enabling informed decision-making

- Make it easier for women, and health professionals to report any adverse reaction
- Work with the key information providers to ensure best available information
- Build a communication partnership with other bodies within the healthcare system

Thank you