Safer Medicines in Pregnancy and Breastfeeding Information Consortium

Information strategy
January 2021

ROYAL PHARMACEUTICAL SOCIETY

the Breastfeeding network

RCGP Royal College of General Practitioners

MHRA Regulating Medicines and Medical Devices

nct 1ST 1,000 DAYS NEW PARENT SUPPORT

Royal College of Physicians

UKDILAS UK Drugs in Lactation Advisory Service

BNF

NHS Digital

NHS England

NICE National Institute for Health and Care Excellence

Public Health England

THE ROYAL COLLEGE OF MIDWIVES

Royal College of Obstetricians & Gynaecologists

uktis uk teratology information service

bpas British Pregnancy Advisory Service

1
Background

This strategy has been developed by the Safer Medicines in Pregnancy and Breastfeeding Information Consortium in response to the Commission for Human Medicines report on Hormone Pregnancy Tests, published in 2017.

The strategy focuses on delivering recommendation 11 of the report which is: "Medicines and Healthcare products Regulatory Agency (MHRA) should work with the key information providers to ensure healthcare professionals and patients receive the best available information, and are empowered to make informed decisions and ask questions about any medicines they may be prescribed in pregnancy."

The Consortium is a voluntary group of information providers from different sectors including NHS, regulators and third sector / charitable organisations. All have a common goal of meeting the information needs of pregnant and breastfeeding women, their healthcare providers and anyone else involved in supporting breastfeeding and pregnant women.

The Consortium comprises the following members:

- Breastfeeding Network
- British National Formulary
- British Pregnancy Advisory Service
- Medicines and Healthcare products Regulatory Agency (MHRA)
- National Childbirth Trust
- NHS Digital
- NHS England and NHS Improvement
- National Institute for Care and Health Excellence (NICE)
- Public Health England
- Royal College of General Practitioners
- Royal College of Midwives
- Royal College of Obstetricians and Gynaecologists
- Royal College of Physicians
- Royal Pharmaceutical Society
- UK Drugs in Lactation Advisory Service
- UK Teratology Information Service

2 Problem statement

The information available to women and healthcare professionals about taking medicines when pregnant or breastfeeding can be both inconsistent and inadequate for their needs. Some medicines should be avoided during pregnancy or breastfeeding as they are known to be harmful to the fetus or neonate. However, many women need to take medicines in pregnancy to control underlying chronic or acute disease and their health (and consequently that of their fetus / baby) may be damaged / harmed if important medications are inappropriately discontinued. So inappropriate use or non-use of medicines may contribute to poor health outcomes for women and their babies.

The lack of clear information is largely due to a paucity of evidence and data on the impact of many medications on pregnancy and breastfeeding. This can make the development of information and guidance a challenge. Furthermore, providing support can be complex, involving time and expertise to ensure women are guided responsibly. Women currently find it both overwhelming and confusing to find reliable guidance, answers and appropriate support. Women may not take medication if they are unsure whether it will harm their baby, and/or they may stop or cut short breastfeeding, potentially compromising their own health and that of their baby. In addition, it may not be clear whether the information is from a trusted source.

There is, therefore, a need for reliable and consistent information about medicines used before or during pregnancy and breastfeeding for women and the healthcare professionals who advise them.

It is recognised that different audiences may have different needs in terms of level of detail, language and the methods of delivering information. Likewise, it is recognised that medicines taken in pregnancy and when breastfeeding are two distinct but related considerations and that the therapeutic need may be pre-existing or may arise during pregnancy or breastfeeding. Our approach to providing information needs to take account of these differences and also to support opportunities prior to pregnancy to encourage the safe use of medicines during pregnancy and postnatally to support the choice to breastfeed where medications are being taken.

The aim of providing consistent information is best served by relevant information providers working together, even if the target audience, language and method of delivering the information differs between providers. This strategy outlines our approach for collaboration.

3
Vision

All women will have access to accurate and accessible information to make informed decisions with their healthcare professional about taking medicines before or during pregnancy or breastfeeding.

4
Aims and goals

A consortium of the relevant information providers has been established to work together to ensure healthcare professionals and women have access to the best available information, are empowered to make informed decisions, and ask questions about any medicines they may consider taking in pregnancy and when breastfeeding. The Consortium aims to enhance existing information services to women, not replace them.

The goals of the Consortium are to:

- Ensure information provided by members is up to date with the latest robust evidence
- Agree key messages for communications by member organisations
- Ensure communications aimed directly at women and healthcare professionals are clear, concise, and broadly consistent, with appropriate signposting to more detailed information
- Support enhanced education of healthcare professionals concerning use of medicines before and during pregnancy and breastfeeding.

The Consortium will:

- Identify information gaps and be open and transparent where the evidence does not exist
- Avoid duplication and make effective use of joint resources.

The Consortium has agreed a terms of reference setting out its governance.

5 Consortium commitment

Consortium members commit to working together to become the trusted 'go to' sources for the best available information for both women and healthcare professionals.

Member organisations commit to:

- Participate in Consortium meetings
- Bring important new information to the attention of Consortium members
- Share details with other Consortium members of their conflict of interest policies including, if appropriate, commercial funding sources
- Work within the Consortium to agreed processes for reviewing and sharing information in confidence
- Ensure that information agreed within the Consortium is reviewed using their organisations' internal processes to allow their communications to be updated in a timely manner.

In aiming to provide the best available information, Consortium members will consider (within the remit of their scope and publications):

- Latest scientific evidence
- Categories of medicines and therapeutic areas (such as prescription-only and over-the-counter medicines, chronic vs acute conditions)
- Language (terminology for the target audience)
- Mechanism of dissemination (Apps, websites, helplines, paper)
- Layering of information in different levels of detail, with each level available to women and healthcare professionals, to allow personalisation of advice.

It is recognised that Consortium members will have internal processes and governance procedures that have to be followed when updating information in their publications. It is therefore understood that Consortium members will highlight any difficulties that their own organisations may have in supporting the conclusions of the Consortium on a particular issue, before publishing them. In order to facilitate a mutual understanding and acceptance of the Consortium position, the following will be encouraged:

- Sharing of assessment reports or other scientific analysis, prior to decision-making
- Participation of Consortium members in expert advisory meetings, or other consultation meetings held by partner organisations.

It is also understood that the role of different Consortium organisations may place some constraints on the exact messages that they promote (for example the MHRA may not actively promote unlicensed or off-label use of medicines). However, every effort should be made by Consortium organisations to avoid publication of messages which may be regarded as contradictory or incoherent.

6
Scope of consortium work

There are three areas of information for authorised medicines (including herbal medicines), available on prescription and over the counter, on which the Consortium will focus to align its safety guidance in relation to pregnancy and breastfeeding:

1. Current safety information for existing medicines on the market.
2. New safety information for existing medicines.
3. Safety information for new medicines coming onto the market.

7 Working procedures

Consortium members will avoid duplication of effort and rely on agreed processes in order to deliver consistent information in a timely way. To enhance how the Consortium works together, separate procedures will be developed to undertake the three areas of work and tested using pilots.

The Consortium will define and agree processes for the following three circumstances:

1. When inconsistences in existing guidance about medicines are identified.
2. Agreeing and embedding new information or guidance into our resources.
3. Ensuring consistent information is provided about new products on the market with relevance to pregnancy or breastfeeding.

Where inconsistencies and differences of opinion between organisations arise, we will discuss and work to resolve these in the group's meetings or by written procedures.

Because this is a complex landscape, where necessary, subgroups may be created to focus on specific areas, such as preconception, pregnancy and breastfeeding, led by the relevant Consortium member organisation. We will ensure that overall consistency is applied to communications from any subgroups.

The Consortium will utilise the principles of shared decision-making and consider risks and benefits of alternative treatment or no treatment in developing its advice.

In line with the Consortium's commitment to providing guidance based on evidence from robust sources of data when new safety concerns are confirmed, members should aim to:

- Search regularly for new published data
- Seek expert input
- Promptly update guidance
- Gain agreement of messaging.

Where robust data do not exist, this should be made clear.

8
Quality standard

To make it easier for women and healthcare professionals to have confidence in information, Consortium members will work towards identifying and adopting effective ways of indicating that the information is based on trusted sources that adhere to the Consortium's quality criteria. These criteria will be agreed once systems and processes are embedded and all Consortium members have secured agreement internally.

9
Accessibility of information

The Consortium will make it as easy as possible for all women, including those with access needs, to find and use our information through our websites, using current industry recognised guidelines or standards. However, we recognise that not every woman will have easy access to digital information so we will look to overcome these barriers where we can with the resource we have available.

Consortium members will actively work together, and with other relevant organisations, on campaigns and the harmonising of key messages.

Different levels of detail may be required depending on the woman's need at a particular stage in her 'journey' and therefore layering of information should be supported (e.g. summary advice; more detailed information; and underlying evidence available to women and their healthcare professionals if they wish to seek it). Specialist healthcare professionals will require access to more detailed information when treating patients with complex health issues. The Consortium will support the use of signposting for women and healthcare professionals who require this.

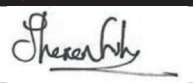
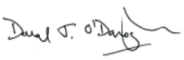
The Consortium will work with relevant professional bodies to review and improve the information and training provided to healthcare professionals when providing advice to women taking medicines in pregnancy and breastfeeding.

10
Action plan and resourcing

Once the Consortium has agreed the strategy to achieve its vision, an action plan will be developed in order to establish the new procedures in practice. This will also include monitoring the impact of the measures which will be reviewed by the Consortium and any Ministerial sponsor put in place.

January 2021

Signed on behalf of Consortium organisations

Organisation	Name	Role	Signed
Breastfeeding Network	Ms Shereen Fisher	CEO	
British National Formulary	Ms Kate Towers	Head of Content, BNF Publications	
British Pregnancy Advisory Service	Ms Clare Murphy	Director of External Affairs	
MHRA	Dr June Raine	Interim CEO	
National Childbirth Trust	Ms Elizabeth Duff	Senior Policy Adviser	
NHS Digital	Mr Robert Cleary	Associate Director, Content for the NHS UK programme	
NHS England and NHS Improvement	Prof Jacqueline Dunkley-Bent	Chief Midwifery Officer	
NICE	Dr Paul Chrisp	Director, Centre for Guidelines	
Public Health England	Prof Catherine Swann	Deputy director - maternity and community	
Royal College of General Practitioners	Dr Victoria Tzortziou Brown	Joint Honorary Secretary of Council	
Royal College of Midwives	Ms Mervi Jokinen	Practice and Standards Professional Advisor	
Royal College of Obstetricians and Gynaecologists	Dr Edward Morris	President	
Royal College of Physicians	Prof Donal O'Donoghue	Registrar	
Royal Pharmaceutical Society	Ms Sandra Gidley	President	
UK Drugs in Lactation Advisory Service	Ms Laura Kearney	Regional Principal Medicines Information Pharmacist	
UK Teratology Information Service	Dr Kenneth Hodson	Head of UKTIS