Toolkit to stimulate reporting and participation in studies/registries for pregnant and breastfeeding women

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WP5 – Dissemination and education for HCPs and pregnant and breastfeeding women and the general public

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Document History

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V0.3	18-Oct-2022	Draft for final review
V1.0	**15-Nov-2022**	**Final version 1.0**

About this Toolkit

WHY use this Toolkit

This Toolkit has been created by experts from Teratology Information Services (TIS) centers, pharmaceutical industry, and communication professionals, to help you:

- to build awareness of the active role healthcare professionals and women[1] can play in increasing knowledge about the safety of medicine use during pregnancy and lactation
- to support your communication campaigns to stimulate the reporting medicine use during pregnancy and lactation, or to stimulate the participation in studies/registries for pregnant or breastfeeding women
- to encourage health care professionals and patients to report on medicine use during pregnancy and lactation; to inform them *where* and *how* they should report on this, and to encourage them to participate in studies/registries.

HOW to use this Toolkit

This Toolkit can be used to guide TIS centers, health authorities (HAs), and other stakeholders on how to plan and initiate a communication campaign for the general population, pregnant women/women of reproductive age and health care professionals (HCPs) at little cost. This includes:

- how to develop key messages directed to relevant target groups; identifying communication channels and strategies available to target and engage the audiences
- how to tailor examples messages and communication materials for social media, other digital channels, and point-of-care materials (e.g., posters or leaflets for distribution in prenatal care providing clinics/waiting rooms, depending on the purpose of the campaign/outreach activity).

WHAT will you find in this tool?

This Toolkit includes:

- General recommendations to develop push-pull strategies and value propositions to support targeted communications
- Step-by-step guide to tailor example messages into digital and print communications and social media campaigns in your country
- Adaptable and affordable materials for digital and print communications and social media campaigns, that can be tailored to your local context and language

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[1] Please note: In this Toolkit, we use the term "pregnant women" as a general term to refer to anyone who is pregnant. We acknowledge that not all people who are pregnant and give birth identify as women. We are committed to equality in society, and no person should feel excluded.

WHO should use this tool?

Health Authorities, TIS centers and other stakeholders who want to raise awareness about the safety of medicine use during pregnancy and lactation and/or want to stimulate reporting of medicine use during pregnancy and lactation or want to simulate participation in studies/registries in their country, to generate better data on adverse effects of medicine use during pregnancy or lactation.

Contents

Acknowledgements

This Toolkit was co-developed in a multi-stakeholder working group representing patient organizations, healthcare providers and researchers, pharmaceutical and diagnostics companies, and external experts. Special thanks to all of you for drafting, editing, reviewing, and maintaining momentum to deliver this Toolkit! resource.

Knowledge transfer

The diversity of EU/EEA Member States means that to facilitate transfer of knowledge, it is especially important to record and monitor the context in which campaigns and evaluations are undertaken.

Given the diversity of contexts across the EU/EEA countries, it may be that specific campaigns and evaluation designs cannot be transferred outright. Nevertheless, lessons learned, both positive and negative, can be shared and will help inform and advance the application of evaluation approaches across countries."[2]

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[2] Campaign-evaluation.pdf (europa.eu)

Background on the Toolkit

This Toolkit is directed to local stakeholders that provide and/or collect information on medication use during pregnancy, such as Teratology Information Service (TIS) centers, Health Authorities (HAs) and Pharmacovigilance (PV) centers. The Toolkit has been developed as a part of the Innovative Medicines Initiative (IMI) ConcePTION Project[3], and is based on extensive discussions on how to effectively reach women throughout Europe exposed to medication during pregnancy. The messages in the Toolkit will need to be adapted to fit the national health care systems, local reporting systems and pregnancy registers, and the communication pathways.

Methodology

Findings from Pilot Campaigns

The Toolkit is based on findings and the results from two communication pilot campaigns, one in the Netherlands undertaken by TIS-Centre Lareb and one in the UK conducted by the UK Teratology Information Services (UKTIS). Both pilot campaigns aimed to stimulate participation into two local drug registers[4]. The pilot campaigns showed that communication campaigns could increase the participation rate by promoting existing systems and validated knowledge databases on the safety of medication use during pregnancy. In addition, the pilot campaigns provided effective communication options for low-cost campaigns using social media.

Background on Pilot Campaigns

The two pilot campaigns proposed communications tailored to the needs of women/midwives/physicians to increase the awareness of and to promote the participation in the local pregnancy drug registrers. Details can be found in the full report3.

The report of the Pilot Campaigns includes:

- A landscape analysis of pharmacovigilance cases of exposure during pregnancy.
- The results of a survey among Teratology Information Services (TIS) on how they handle pregnancy reports or participation in a register, and whether they would appreciate the support to increase the reporting rate or participation in registers.

This Toolkit incorporates the learnings from both inclusions. Each section will have a summary box to point to the most important messages in each section.

Background on PV Reporting in Europe

The need to encourage PV reporting

While there is a clear need to encourage PV reporting, there are several challenges to promote reporting of drug exposure during pregnancy or to promote participation in registers, including the complexity of the national PV reporting systems.

To generate evidence on the use of medicines in pregnancy and lactation, we aim to stimulate HCP and pregnant women to report on medication use during pregnancy or lactation, regardless of the outcome. For knowledge building, all reports on medicine use during pregnancy or lactation are of importance, including both reports of 'normal' outcomes as well as reports on adverse events/effects.

Based on the pilot campaigns in the UK and the Netherlands, a communication campaign could (and should) be undertaken via local stakeholders and adapted to the respective countries' situation. The optimal way to increase the rate of reporting of drug exposure during pregnancy is to use the existing systems of Marketing Authorization Holders' PV department, and Health Authorities.

The landscape analysis of reporting pathways to HAs and MAHs showed that both HCPs and patients report cases, with a large proportion of prospective reports to exising pregnancy registers, but with variability across countries.

This is in line with an exploration undertaken by the IMI ConcePTION, Work Package 5.3 group of the situation in different countries/regions in Europe (UK, The Netherlands, Nordic countries, and Spain) that indicated significant differences/challenges. While in some countries, there are multiple options for women, midwives, and/or physicians to report or a well-established channel broadly used (e.g., Nordic Countries), in other countries it's almost impossible for women to report directly.

In those countries, neither TIS, nor HAs, nor MAHs have reporting options for women or these, if existing, are not easy to find. It is also unclear how easy it is in these countries for the physician and/or midwife to report.

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Before you start...

Before you start setting up a campaign, ensure that your organization is supportive of a campaign and has the capacity to process additional reporting or to process increased inclusion in registers.

TIS Centres in different countries should consider whether it is possible to coordinate a campaign via the ENTIS network to launch campaigns simultaneously or learn from past campaigns.

Consider informing other stakeholders in your respective country about an ongoing campaign and to harmonize messages and information to women and health care professionals about reporting on medicines' use in pregnancy and during lactation or participate in study registesr to collect information.

Use Template below to brainstorm on the campaign planning.

Template for Campaign planning

Campaign Element	Questions to Ask	Reference	Considerations	Actions
Campaign Objective	What are you trying to accomplish?	Step 1	What is the result you are trying to achieve?	Start here
Target Audience	Who are you trying to reach?	Step 2	Be specific. Include demographics, attitudes, concerns.	If you can't define it – what's your plan to figure it out?
Time frame and approach	How long the campaign will run?		Consider phases of the campaign (e.g., 3 weeks of preliminary research, 6-month campaign, 3 months post-campaign evaluation)	
Communication channels to deliver messages	How are you going to reach your audience?	Step 3	E.g., social media, posters, etc.	

Campaign Element	Questions to Ask	Reference	Considerations	Actions
Messages and research	What are you trying to say? Are the messages based on what you know about the opinions of your target audience? What are your two main messages and how will you communicate them? Are you planning on testing your messages?	Step 5	What resonates for you often doesn't work for your target audience. It generally takes research to know the difference	Use qualitative methods to understand the target audience. Pre-testing such as focus groups can further refine and tailor the campaign message to the health and information needs of the target audience.
Give and take	Do you have information regarding medicine safety that are valuable for the target audience? This could e.g., be articles on how to treat general health issues during pregnancies, do you give and take? Women are more likely to report exposures if they receive valuable information in return.	Step 6	Consider link to health portal with information on medication use. Link to a general webpage for reporting or participation in registers.	
Messengers or spokespeople	Are there opportunities in current events or health debates that you can leverage to reach a wider audience with a small number of resources?	Step 4 Step 7		Strategic partnerships, whether with an influencer or the press, will take your message to the next level.

Campaign Element	Questions to Ask	Reference	Considerations	Actions
Budget	How much money do you have to make it happen?	Step 8		If you have the money a way to boost campaign would be to consider popular media where you could publish editorial or opinion text.
Campaign evaluation	How will you know what worked and what didn't? How will you evaluate the impact and success of your campaign?	Step 9	What about a pre and post campaign poll?	Consider engagement metrics with database link for website analytics.

Let's get started!

Step 1: Campaign Purpose/Objective

Every campaign needs an objective, ideally one that can be assessed through different key performance indicators. Think about what it is you want to achieve, and how (and if) that can be measured, to ensure you have clear aims and objectives that connects your communication activity to actual impact on your target audiences.

Describe here
What is your campaign purpose? What is the objective of the Campaign*?*

- *Increasing the number of reports in our systems or increase the participation in registers*
- *Increasing the number of hits on our websites*
- *Increasing the number of followers on our social media*

Step 2: Identify Target Audiences: HCPs in early pregnancy care in your country and/or pregnant women directly

Points to consider when identifying target audience for the campaign

- Where do women get their information in your country? (e.g. HCPs, social media,internet, midwives, specialists)
- What groups of women are you considering for your campaign? (e.g., women planning pregnancies, pregnant women, pregnant women taking medications, mothers, etc.)
- Which healthcare professionals do women in these target groups see for pregnancy care?
- What type of maternal care is most used in the country? Midwives? Obstetrician-gynaecologists? GPs? Specialists?
  - After the first visit to HCP – GPs, gynecologist, midwives?
- Are there other HCPs you would like to target e.g. pharmacists after prescribing medications?

▪ Consider HCPs of diverse backgrounds when lower-income pregnant women receive care.

> **Summarize here**
>
> *Which HCPs are most seen in early pregnancy care in your country?*
>
> *Write the HCPs and groups of women you would like to target for your campaign.*

Step 3: Choose key communication channels to target your audience

The key question here is which channels and strategies have the greatest potential for reaching your audience through as many channels and activities as possible.

Use the **Table** below to determine what communication channels you would like to use to target your audience.

Channel	Purpose	Recommendations
Website / Promotional Webpage	Providing information about you campaign objectives Link to relevant information Link to route of reporting or to sign-up to participate in register Centralize campaign	▪ Do not ask the public to report exposures during pregnancy unless you can provide the information on how to report it. ▪ Ensure that it is clear how the target audiences can report exposure during pregnancies and their outcomes ▪ Try to coordinate with other pregnancy and breastfeeding information or services in country to encourage common information sources.
Poster and Pamphlet distribution at Points-of Care	Engaging women at points-of-care (e.g., doctor visits, midwife consultations etc.)	Consider the type of material – distributed waiting room pamphlets, waiting room video, signs, business cards with the URL of your campaign website, or posters.
Social Media (Twitter, Instagram, Facebook)	Raising awareness, informing, and calling to action	**Use visual content** ▪ Tweets that include media (e.g., graphics or video) have significantly wider reach and engagement (share or link clicks), than text only.

		▪ See Annex 1 and ConcePTION-SoMo-Toolbox and Twitter-graphics-templates [separate attachments] if you are interested in implementing social media campaigns.
YouTube	Raising awareness, informing, and calling to action YouTube serves as a repository for videos, that you can embed in other Channels	▪ Short, succinct text-based videos can deliver key messages in plain language with the aim to support engagement in social media, raise awareness, and call to action. ▪ YouTube is probably mainly a repository for video that you can embed in other channels, using a horizontal format will make them fit most websites. ▪ To drive engagement, you should ensure video formats have the right length and format when shared directly in-stream on different platforms. ▪ Landscape video works well on Twitter (max. length 2:20min), However, if you are considering a campaign on Instagram or Facebook, you should consider the formats used there (square), and lengths. Check the platform before you put resources into video!
Key messages for Organization's Newsletter	Raising awareness, informing, and calling to action	Use your newsletters to deliver key messages and calls to action.
Publications	Disseminating results and provision of evidence to target audience.	See ConcePTION publications for evidence.
Media (TV, radio, press) and Web	Raising awareness and communicating results to all audiences, including patients and women of reproductive age.	Consider issuing a press release and contact journalists you know are interested in the topic. Many daily papers and professional journal's welcome opinion texts and debate articles. You could also ask to be invited to a podcast or ask to write a guest blog post (refer to Annex 1, ConcePTION-SoMo-Toolbox and Twitter-graphics-templates *[separate attachments]* for implementation of social media campaigns).
Editorials, informative articles and opinion	Raising awareness and communicating results to all audiences through journals, newspapers, and blogs	As a complement to digital communication materials and social media campaign**.** This is a strategy that allows to deliver the information to **where the women are** (e.g., social media, online discussion forums). If you already have an audience in your own

| | | channels, a blog post or news item could be an effective form of communication. You could also ask to write for an existing blog (see above) |
| | | Think about where your audience finds information: Patient organizations have websites and social media presence, have a look at blogs for professionals and outlets from their organizations, and have a look at the platforms that pregnancy bloggers and influencers can provide access to! You could also take a look at the platforms used by companies that sell products to women - perhaps a collaboration can benefit your campaign? |

Points to consider

- Find out where the target audience gathers online and offline, for example whether there are social media platforms or apps extensively used by pregnant women. Where do we find the pregnant women directly? Webpages, discussion forum, social media, apps?

- What professional organizations are the HCPs in? The best way to reach HCPs may be through professional associations. In some countries, labour unions could be considered.

- Find out IT systems for HCP professionals most used by health caregivers in an early stage of pregnancy, and whether it would be possible to incorporate a request to report pregnancies or to invite for participation in registries via these existing systems.

- Consider publishing articles on frequently visited websites for pregnant women or though collaborating with frequently used pregnancy Apps.

Summarize here

What are the main communication channels you would like to use to target your audience? For women? For HCPs?

How will you use them?

Step 4: Identify strategies to target your audience

A campaign strategy is a set of tools and tactics to reach and influence different audiences through different channels. How do you reach women? How do you reach health care professionals? With whom are your working together? What do you tell them? What are you asking them to do? What is the format? Timing? Channel?

- Include information on where/how to report or to participate in a register and link to more information (e.g., campaign webpage) in all communications:
  - o What is the main route of reporting or participation in a register in your country for HCPs?
  - o What is the main route of reporting or participation in a register in your country for pregnant or breastfeeding women?
- Promote in local language and translate to minority languages to include pregnant/lactating women from ethnic minorities and large immigrant communities, where feasible.

Points to consider

- Use the opportunity to support pharmacovigilance (PV) reporting on medicine use in pregnancy is a very important topic. Experience has shown that campaigns related to COVID-19 vaccination have increased the number of reports to pregnancy registers and increased awareness. Examples for COVID include:
  - o an infographic directed at pregnant women regarding the risks and benefits of COVID-19 vaccination in pregnancy.
  - o an infographic directed to HCPs to help them navigate the treatment options available for pregnant women with COVID-19 infection'.
- Use national events – relevant conferences or local TV programmes or radio, for example, and their associated hashtags to get your message out to new groups.
- Piggyback the campaign on vaccination campaigns in the healthcare setting (e.g., new-born vaccination shots, "hot topics" of health policy (e.g., COVID-19).
- Try to forge links with organized and active citizens and organisations locally that share your interests and concerns.
- Engage with champions/influencers - people already raising the maternal health/pregnancy and medicine agenda in wider groups, influencers/public figures who are currently pregnant.
- Contact pregnancy App provider if available in country.

Other strategies to raise awareness and encourage women to report or to participate in a register include:

- Identify conferences where patient organisations for diseases affecting women of reproductive age participate and ask to put this topic on the agenda.
- Produce materials & toolkits for patient organisations to support them in communicating with their members and advocating for the topic.

Example messages

- The Knowledge Bank[5] can help patient organisations to build a stronger connection with their pregnant and breastfeeding members by being able to offer safety information about their medicines.
- Medicine safety in pregnancy and during lactation is important, and we should all be vigilant on reporting the use of medicines during pregnancy and lactation.

Describe here

What are the communication tools and tactics (strategy) you will use in your campaign?

Using social media

- Low-budget approaches using social media, graphics and existing software can be effective.
- Automated tweets (e.g., posted using a free software account such as 'Tweetdeck' for Twitter and Hootsuite for other social media) and ad-hoc Tweets regarding relevant issues can be utilised to keep followers engaged with a relatively small time-investment.
- Create catchy and attractive graphics and visuals with short, punchy, and easily understood messages and calls to action.
- Consider timing: when is your audience awake and using social media? Early in the week is often better than on a Friday afternoon.
- Engage with champions/influencers who are already raising the maternal health/pregnancy and medicine topics in wider groups.
- Link to existing evidence-based, expert-endorsed health education for pregnant women.
- Target a wide range of patient' groups and cover a broad range of medicinal products.

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[5] The ConcePTION Knowledge Bank is currently under development and will be an EU centralised digital knowledge bank containing up-to-date information of medicine use before and during pregnancy and lactation and the risks of untreated disease (in English) for a selection of diseases and drugs that are common in pregnancy by combining information from different sources and providing common knowledge.

- Consider different types of users, including those with higher or lower education levels and literacy, as well as addressing cultural, social, and educational barriers to ensure effective use of such resources.
- Think about what you convey in your visual messaging: make sure that any images to illustrate pregnancy or breastfeeding are not exploiting women's bodies. the people portrayed should also be representative of the population they are meant to reach. Inclusive visual communication is always better!

Write two strategies that you would like to use in your social media campaign (e.g., visual message, text message, timing and what you will ask your audience to do)

1.

2.

Budgeted work with commercial partners, if applicable, to reach audience

- A Pilot study was conducted by the TIS centre Lareb, in cooperation with commercial partners:
  - One of the conclusions was that working with commercial partners does work, but there are high costs related to the collaboration with these parties.
  - An important lesson from the study in the Netherlands is that collaboration with parties exclusively targeting pregnant women, as compared to parties proceeding in childhood, is most successful.
  - An estimation of the budget for the pilot campaign, with a summary of the activities and duration can be found in the final report of this pilot.
  - Simple leaflets can be handed out to pregnant woman by their health care professional to explain the campaign, or the need for reporting or participation in registers.
  - Freely available post-cards with URL to webpage and hashtag for low key distribution (e.g., in waiting rooms).

Draft ideas on what you would do if you had an additional budget to amplify messages?
For example, if printed materials would support your campaign, or if budget to extend your social media reach would be helpful.

For more strategies to amplify message in social media campaigns see **Annex 1: Communication Tips, ConcePTION-SoMo**-Toolbox and Twitter-graphics-templates [separate attachments].

Step 5: Develop and refine key messages

Key messages should contain three parts (See Annex 1: Communication Tips)

- Facts and evidence to support claims
- Take-home messages
- Call-to-action

Points to consider

- Are there pregnancy registries available locally that can be publicised?
- If you have budget, you can test your messages among focus groups or target audience – a low-cost test option would be to define three to five supporters in the form of "persona" (e.g., occupation, interests, etc.). Understand how to approach each persona regarding your initiative and draft the strategy accordingly.
- Research what kind of language they use, what appeals to them and what does not.

Key points to consider for HCPs

- You need to make it easy for health caregivers to invite/inform their patients in reproductive age. This can be achieved by embedding semi-automatic invitations within existing healthcare IT systems.
- Encourage HCPs to discuss medication use during pregnancy:
  - Pre-pregnancy: upon prescribing any medication for chronic condition to women of reproductive age.
  - At the first visit at maternal care clinic after a woman becomes pregnant.
  - Prescribing medications to pregnant women. The exposure should be registered as soon as possible.
- It is important to also report the outcome of the pregnancy, not only exposure.

Brainstorm your key messages here
See Annex 1 for the key messages and adapt them to your local country, communication channel and audience. Examples of this are offered in ConcePTION-SoMo-Toolbox and Twitter-graphics-templates [separate attachments].

Checklist for key messages

Consider these questions after you have drafted your key messages

- Do you use an active voice? Are your messages positive?
- Do you use plain language and when possible, also the national language? If a teenager, or a non-native speaker, will be able to understand it the first time they read, then you are at the right level!
- Are you inclusive in your written and visual messages? If you do consider diversity, remember not to use people as tokens, and that sometimes, including one group can alienate another.
- Do you portray women as active subjects (e.g., in visual communications by avoiding 'male gaze'[6] images)?
- Do you address the audience in the first person (e.g., 'you', 'your medicines', 'your health')?
- Test your messages on members of your target audience. How do they react?

Step 6: Incorporate value propositions for women and HCPs

Points to consider

- Ensure good value proposition for HCPs and women in key messages: Give and take is important.
- Women need information on medication use for pre-existing/chronic medical conditions (showed increased need for information in focus groups).

  - Example: Develop specific articles on topics like seasonal allergies and treatment options
- Consider what you can offer to women or HCPs in return for their support, for example:
  - Public access to a knowledge bank of data concerning outcomes of use of medicinal products in pregnancy (e.g., local or ConcePTION[7]).
  - Knowledge bank would save them time – in addition –patients could be likely to use the knowledge bank as it is Internet based.

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6 Male gaze: the perspective of a notionally typical heterosexual man considered as embodied in the audience or intended audience for films and other visual media, characterized by a tendency to objectify or sexualize women.

7 The ConcePTION Knowledge Bank is currently under development and will be an EU centralised digital knowledge bank containing up-to-date information of medicine use before and during pregnancy and lactation and the risks of untreated disease (in English) for a selection of diseases and drugs that are common in pregnancy by combining information from different sources and providing common knowledge.

Examples from the Pilot Campaigns

- In the Netherlands, 'Moedersvan morgen' ('Tomorrow's mothers") developed a new website, informative flyer and brochure on drug use for common discomforts during pregnancy and breastfeeding.

- Furthermore, health caregivers were given free access to information material for the pregnant women (both recruiting material (flyer) as well as informative material (brochure with common illnesses and allowed/ unsafe drugs). Mainly the brochure answers questions from patients, meaning that these questions were not asked to healthcare providers.

- Lastly, health care professionals had access to the Dutch Knowledge Bank. All in all, also for health caregivers the process of giving and taking is important to keep in mind.

Summarize here

What will you offer to women or HCPs to get their support?

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Step 7: Develop webpage for campaign with how and where to report medicine exposure in pregnancy or how and where to participate in a register

- You should have a campaign website for landing page on your website, with a simple URL, where you provide information about the aim of the campaign.
- Ensure that there is information on where to report exposures in pregnancy and pregnancy outcomes or where to sign-up to participate in a register is featured prominently on webpage.
- Encourage HCPs and women to rely on European knowledge bank or regional knowledge bank that might exist in country of the campaign to ensure consistent high-quality recommendations.

Examples of materials directed to HCPs

- Link to form to report pregnancy exposures for HCPs (Is it easy for HCPs to complete? Is it tied with messages of the societal importance?).
- Direct HCPs to specific campaign materials to share with women (e.g., brochures or pamphlets).
- Provide relevant information for speaking with women about medication use during pregnancy (Include posters in national language for patients, waiting rooms, websites if available).
- Include key messages, such as when to speak to women about medication use during pregnancy, societal importance of PV reporting.
- Reputable websites for information for HCPs (e.g., BUMPs, Lareb, TIS Centers).
- Link to where to find additional training materials.

Brainstorm here

What contents or materials can be put on your webpage for HCPs?

Examples of materials directed to women

- Link to the form to report pregnancy exposures and pregnancy outcomes or the link to sign up to participate in a register.

- Reputable websites for information for women and pregnancy resources (e.g., BUMPs, Lareb, TIS Centers).
- How women can help spread awareness – key messages to share on social media.
- Use infographics to explain pregnancy PV.

> ***Brainstorm here***
>
> *What contents or materials can be put on your webpage for pregnant women?*

Checklist for general landing page

Consider these questions when developing and testing webpage:

- Is it easy to find - domain name that is short, relevant, and easy to remember?
- Has it been adapted to the local (organizational and/or cultural) context, and is your information available in (all) the right language(s)?
    - Is it useful - Consider links to health portals for information on medication use during pregnancy or lactation, or links to other relevant information?
- Is it self-explanatory - It should explain the problem your campaign addresses, the solution you envision?
- Is it motivating? – how does it appeal to encourage women or HCPs to report or to participate in a register?
- Is it captivating? - does it have catchy visuals, graphics, or videos to appeal to target audience?
- Does it have a call to action?

Step 8: Measure activities, effectiveness and outcomes, if possible

Points to consider

- Collecting feedback and results can improve messages and campaigns.
- Use existing platforms for measuring activities (e.g., your website should have a statistics platform, and newsletter software and social media all provide metrics on both the number of people reached and how many individuals engage with your content).
- Funding restrictions may limit the extent to which all possible outcomes can be measured.
- Consider questionnaires or polls about how you heard about us on webpages or communications.

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Table 2: Different ways to measure impact of campaign

Measurement	Purpose	Example Measures
Campaign activities	Measures the performance of campaign activities. (Be aware that these responses may not directly translate in increased reporting or increased participation in registers).	▪ How many people did the campaign reach, and how many engaged with your content? Number of views, clicks frequency of message distribution ▪ How many flyers and posters were disseminated? ▪ Did paying for social media post promotion extend your reach? ▪ How many website hits? You can look at some responses to your call to action (e.g., link clicks, website visits).
Campaign effectiveness	Measures how well people remember the campaign	▪ Can people articulate what the campaign was about? ▪ Did the campaign increase awareness of its key issue? Did the campaign increase awareness about the importance of reporting among HCPs?
Outcomes	Measures whether or not behaviors or attitudes changed as a result of the campaign.	▪ Has there been increase in reporting or in the number of participants in a? ▪ Has the reporting become less fragmented?

Discuss here

How do you plan to measure the effectiveness of your communications (e.g., reach, engagement), and how can you assess the impact of your campaign?

Examples from the pilot campaigns

Twitter analytics and UKTIS and BUMPs website statistics for previous years were used as benchmarks to assess the impact of the campaign on key statistics such as Twitter follower number, Tweet engagement and website hits.

The number of new records in the BUMPs pregnancy registry was compared to previous years and correlated with campaign Tweets. Although the posts generally generated the most hits in the first 7 days of publication, they had a mean hit rate of around 5-6 hits/day throughout the year.

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For the Netherlands, different methods were used to measure the effect of the campaign activities. First, with all collaboration partners had regular meetings and/or received reports on:

- Number views or our communication activities
- Number of click throughs to our website (i.e., website visitors). This was measured both by the partners as well as at our side, by using Google Analytics in combination with Urchin-tracking module (UTM) codes.
- Number of inclusions: this method is indirect, since women were not tracked at Dutch website, but very important. A questionnaire was developed in the register to ask women via which channel they did hear from the register.

Tool 1: Social media toolbox with adaptable graphics

To support and facilitate communication on social media, we have developed hands-on toolkits for Twitter and Facebook/Instagram. These toolkits include examples of what to do, and what not to do, and why.

- Ready-to-use design templates that can be adapted to local country/language.
- It is easy: we use PowerPoint!
- Explains how to export and save images.
- Tells you where good and free photos can be found.
- Explains how to craft a message with a call for action.

The toolbox is available for download[8].

Tool 2: Adaptable print materials

See more about creating inclusive promotional materials in here:

ConcePTION-D5.2.pdf (imi-conception.eu)

An example of an infographic developed for the UK campaign to explain in plain language what pharmacovigilance is) is available for download. This infographic was used to accompany tweets and to illustrate the Pregnancy Pharmacovigilance blog post. This no-cost graphic was created in PowerPoint and can be adapted and/or translated for use by other organizations.[9]

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[8] Social media toolbox: Holm, Anna, & Fernow, Josepine. (2022). ConcePTION social media toolbox for Twitter, Facebook, Instagram & LinkedIn. Zenodo. https://doi.org/10.5281/zenodo.7657294
Adaptable graphics: Anna Holm, & Josepine Fernow. (2022). ConcePTION social media template, portrait format. Zenodo. https://doi.org/10.5281/zenodo.7464338
Anna Holm, & Josepine Fernow. (2022). ConcePTION social media template, landscape format. Zenodo. https://doi.org/10.5281/zenodo.7464278
[9] Adaptable Pharmacovigilance Infographic: Oliver Alison, & Stephens Sally. (2023). ConcePTION: Adaptable Pharmacovigilance Infographic. Zenodo. https://doi.org/10.5281/zenodo.7708562

Tool 3: Reference for Target Groups and Key Messages

Target group 1: Pregnant women and/or women planning pregnancy, and their partners

Key messages

- Use of medication during pregnancy is widespread.
- There is not enough safety data and a lack of reliable and consistent information.
- Optimal treatment may not always be compatible with pregnancy.
- Women with chronic conditions are particularly affected by gaps in knowledge about medicine use in pregnancy.
- Pregnant women can play an active role in pharmacovigilance and contribute to the available data.

There are organisations available in some countries to help women make informed choices about medicine use in pregnancy and whilst breastfeeding.

Example messaging (with examples of hashtags for use on social media)

- Nine out of 10 #pregnant women take at least one prescription #medicine, yet pregnant women have adequate safety data for less than 5% of medicines. Find information on safe medication use during #pregnancy and #breastfeeding here [URL]. #medsinpregnancy, #maternity
- We offer a freely accessible website with #medsinpregnancy information from experts regarding the safety of different medications during pregnancy at [URL].
- Do you have concerns if your medicine is safe to use in #pregnancy (or #breastfeeding)? We are here to support you to make informed decisions along with your doctor [URL].
- Help us build the evidence for medicine safety in pregnancy. If you are using medicines during your pregnancy, ask your doctor or midwife to register this at [URL], or you can tell us about it yourself at [URL].
- Women with chronic conditions need to know that their medicines are safe for use in pregnancy and are particularly affected by gaps in the knowledge. Help mothers of the future by telling us about your medicine use in pregnancy here [URL]. #chronicillness, #medsinpregnancy
- Want to know how we gather the evidence for the safety of medicines in pregnancy? Find out more and how you can help.

Target Group 2: HCPs (Prescribers, pharmacists, midwives, nursing staff, specialists)

Key messages

- Building drug safety evidence through pregnancy pharmacovigilance is important: it will help you to give pregnant and breastfeeding women the care they need and to feel confident providing treatment and advice.

- HCPs can play a key role in building the evidence by reporting cases or inviting/supporting participation in registers and medicine exposure in pregnancy or lactation.

- There are organisations and information resources available to support your prescribing decisions for pregnant and breastfeeding women.

Example messaging (with examples of hashtag use for social media)

- We offer freely accessible, up-to-date information about the safety of drugs in pregnancy and breastfeeding at [URL]. #medsinpregnancy, #MedTwitter

- There are significant discrepancies between online data sources on medicine use in pregnancy (https://doi.org/10.1080/14740338.2021.1935865). Find high quality information for healthcare professionals here [URL knowledge bank/organisation's own information]. #medsinpregnancy, #MedEd, #MedStudents

- #Doctors and #pharmacists, we need your help to build the evidence for medicine safety in pregnancy. Report medicine exposures in pregnancy here [URL]. #MedTwitter, #medsinpregnancy, #Pharmacy

- #Pharmacovigilance (PV) provides vital evidence for the safety of medicines in #pregnancy. But what is PV and how can healthcare professionals and #pregnant women help? [pharmacovigilance infographic (see our example on Page....), URL].

Tool 4: Adaptable advanced tools for communication campaigns

To support and facilitate more advanced communication campaigns, we have developed a set of adaptable, ready-made materials. These have been piloted in The Netherlands as part of "the Moeders van morgen" campaign, run by Bijwerkingencentrum Lareb. The materials have been translated into English and prepared for anyone to adapt.These materials can be adapted by professional designers utilizing the Adobe design suite. Examples of these materials are available here[10]. The package contains:

- Web banners in various sizes
- A flyer
- An infographic and
- Various social media images

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[10] Willemen, Marjolein. (2023). ConcePTION: Advanced Adaptable Communication Materials. Zenodo. https://doi.org/10.5281/zenodo.7730670. The full set of materials is available upon request (mailto:imiconception@gmail.com).

Annex 1: Communication Tips

Tips! What to do

- **Create a story people can relate to.** It should provide a visual vision of what life will be like when more reporting happens. Be clear. Don't assume the audience knows where the story is going.

- **Try to put yourself in the shoes of the listener.** What concerns might your audience/reader have about reporting adverse events? What about data ownership or data privacy? What could the listener or audience be concerned about?

- **Keep information simple,** as your audience may have a basic understanding of the health system. Remember, if you are pregnant, you are overloaded with information and HCPs are very busy with very little time. Does this information help them? What value proposition does the message speak to?

- **Multiply your message across multiple channels** (e.g., videos, emails, speeches, social media posts, press releases) so it's more easily remembered

- **Work collaboratively with different stakeholders** (e.g., patient advocates, individual patients, HCPs) to ensure that different perspectives are considered when building a campaign

Tips! What not to do

- Avoid using words not widely known or used (e.g., 'teratology'). Wording should avoid causing distress or guilt.

- Adapt language for the audience: women search for 'breastfeeding' or 'nursing' rather than 'lactation'. Try using interchangeable synonyms for search engine optimization (SEO) (e.g., 'medicines' should be interchanged with 'drugs', 'nursing' with 'breastfeeding' etc.).

- Refrain from using the term 'HCPs' in messages. Point to the specific point-of-care used in the country (e.g., 'talk to your midwife about X', versus 'talk to your HCP about X').

Communication Risks

Risk	Mitigation strategy
Objectification of women	Use an active voice in editorial content, ensuring women are portrayed as active subjects, instead of passive objects. Make sure strategic decisions are taken in visual communications to ensure images of women and women's bodies are as representative as possible of European women's ethnicities, abilities, and body shapes. Make sure to monitor the sentiment of reactions and take care to ensure that images of pregnant women portray women, not just bodies.
Non-inclusive language	Consider using the term "partners" instead of fathers but be mindful of the target audience when deciding how to talk about women. Using the term women and mothers allows you to communicate in an active voice but to

	be inclusive, "pregnant people" can be considered. Deciding to use a more inclusive vocabulary can alienate most of the target audience. Consider using a blanket statement, e.g., 'Please note: For simplicity and clarity, on this page, we use the term "pregnant women" as a general term to refer to anyone who is pregnant. We acknowledge that not all people who are pregnant and give birth identify as women, and it is important that evidence-based care for maternity, perinatal and postnatal health is inclusive. We are committed to equality in society, and no person should feel excluded from our services or information.'[1]
Be mindful in the flood of information	Pregnant and breastfeeding women are flooded with information both online and offline, usually tapping into women's fears. Account for this in your strategy and make sure you're not exploiting vulnerabilities and fears. In addition, make sure the information is a consensus opinion that generally aligns with national guidelines.

[1]Effective Communication About Pregnancy, Birth, Lactation, Breastfeeding and Newborn Care: The Importance of Sexed Language - PMC (nih.gov)

How to construct a key message

1. **Frame the message.** Connect your campaign theme with the current limitations of knowledge of safe medication use and discrepancies among data sources.

2. **Support your statements with facts and evidence.** Facts should support the claim that there is in fact a knowledge gap and why there is a need for safety evidence. For example: 'Almost 90% of pregnant women take at least one medicine, but we don't always know how safe the medicines are.'

3. So what? **Explain why the message is important to your target audience and support with a "take-home message".** In other words, do not only state a problem, but provide a solution as well. For example: 'Almost 90% of pregnant women take at least one medicine, but we don't always know how safe the medicines are. Women who are pregnant or breastfeeding, deserve to know if their medicines are safe. Based on strong science.'

4. **Messages should offer mechanisms for engagement**. A call to action (for example encouraging reporting medicine use, responding to a survey, participation in a register, reading a report or a publication in a journal, watching a video, or registering to join a webinar) will engage the audience. For example: 'Women who are pregnant or breastfeeding deserve to know if their medicines are safe. Based on strong science. Join us in the upcoming webinar to find out more.'

5. **Adapt your message to various audiences and channels**. For example, by using plain language when addressing all lay audiences, and a tone that fits the channel (e.g., informal for social media). Examples of this are offered in social media toolkits (less formal, plain language, active voice) as seen in Figure 2.

Figure 2: adapting messaging for social media