

IMI2 821520 - ConcePTION

**ConcePTION**

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

**D5.6 Report on the methods and results of the communication campaign to stimulate reporting and participation in studies/registries and publication of analysis of communication methods**

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## Table of contents

|   |    |
|---|----|
| Abstract.....   | 4  |
| Introduction.....                                       | 6  |
| Methods.....  | 6  |
| Pilot project in the NL.....                            | 6  |
| Pilot project in the UK.....                            | 9  |
| Landscape analysis.....                                 | 11 |
| Results.....  | 12 |
| Pilot project in the NL.....                            | 12 |
| Landscape analysis.....                                 | 15 |
| Discussion.....   | 19 |
| Conclusion.....   | 21 |
| Appendices.....   | 21 |
| Pilot project in the NL – full report.....              | 21 |
| Pilot project in the UK – full report.....              | 21 |
| Questionnaire and answer options of the TIS survey..... | 21 |

## Abstract

The aim of the 5.3 sub-task is to stimulate pregnancy reporting and to increase the awareness that pregnant women and healthcare professionals (HCPs) can play an active role in increasing the knowledge of the fetal effects of drug exposure during pregnancy. This report covers the results from two pilot communication campaigns, one in the Netherlands and one in the UK, aiming to stimulate reporting to two pregnancy drug registers. Additionally, the report includes a landscape analysis of pharmacovigilance cases of exposure during pregnancy and the results of a survey among Teratology Information Services (TIS) to explore how they currently promote their services and encourage prospective pregnancy reporting, and whether they would appreciate support to improve this or create materials to assist in this process. Altogether, the results will be used to create a communication tool kit, that can be used across Europe.

### *The NL pilot study*

The pilot study in the Netherlands (NL) was undertaken by Pharmacovigilance Centre Lareb, to which the Dutch TIS-centre belongs. It included reports to the Dutch Pregnancy Drug Register ('Moeders van Morgen (Mothers of Tomorrow)'), collecting prospective data from pregnant women throughout the Netherlands. Both pregnant women treated with medicines and not treated are included. During one-year, different campaign methods were explored to promote this register (a new website, informative flyer and brochure on drug use for common discomforts during pregnancy and breastfeeding, automatic e-mails sent to pregnant women with an invitation to participate in the drug register via the IT-systems used by the midwives, automatic emails to participate in the register sent via (semi-)commercial partners providing information to pregnant and breastfeeding women, etc). Later (2022) a social media campaigns was carried out. Also, pregnant women vaccinated against COVID-19 were asked to participate in a study about pregnancy and vaccination with a link to the 'Mothers of tomorrow' website. The total number website pages of the Dutch TIS visited increased in 2021 to 1.5 million compared to 1 million the year before (2020). The number of inclusions in the Register during campaign year was 8000, compared to 772 the year before. Most commonly, the women signed up for the register in connection with vaccination against COVID-19. However, about 4000 patients entered the register via other routes, the HCPs being most frequent, but also via commercial partners.

### *The UK pilot study*

The pilot study was undertaken by the UK Teratology Information Services (UKTIS). UKTIS collects pregnancy outcomes via different routes, including via an online facility for pregnant women – *BUMPs* (Best Use of Medicines in Pregnancy). The UK campaign took place during one year, targeting predominantly HCPs caring for pregnant women. The aim was that the HCPs would pass on the information about *BUMPs* to their patients and encourage women to record their pregnancies on the system. The UK campaign was designed to be as low cost as possible, so it could be easily replicated by other TIS-centres. Different campaign methods were used: a) social media, mainly the *BUMPs*/UKTIS Twitter account b) blog posts on the *BUMPs* website, for example highlighting the importance of drug exposure during pregnancy data collection c) a YouTube channel with short videos explaining e.g. how to use the *BUMPs* registry to record a pregnancy d) participation in COVID-related work, e.g., production of infographics directed towards pregnant women regarding risks and benefits of COVID-19 vaccination. The *BUMPs* pregnancy registry had a median increase of 47 created accounts per month during the campaign period, which is the biggest increase since the registry was created in 2015 (vs. a median increase of 26 accounts per month, the year before the campaign). There was a strong positive correlation between the number of tweet impressions and registry account creations measurable of the day of the tweet. During the campaign period, there was a 34% increase in website traffic to the UKTIS website and 5.8% increase in traffic to the *BUMPs* website compared to the previous year.

### *Landscape analysis of pregnancy case reports*

Pregnancy cases reported to two databases were queried: 1) The Sanofi Pharmacovigilance (PV) database 2) FDA Adverse Events Reporting System database (FAERS). In both databases, cases reported from EU countries between 2011 to 2021 were extracted if there was at least one event coded with a Medical Dictionary for Regulatory Activities (MedDRA) term of the Standardized MedDRA Query (SMQ) « pregnancy and neonatal topics ». Cases were reported both from HCPs and consumers, but the proportion of consumers reporting to the Sanofi PV database was larger than in the FAERS database (health authority). In most countries, more reports came from HCPs. About half of the reports were identified as being prospectively reported. There was a variability across the countries regarding the number of reports of exposure during pregnancy and the proportion of reports from consumers or HCPs. Among the pregnancy reports, "exposure during pregnancy", was the most frequently reported adverse event, often reported as a single event.

### *Survey among the TIS centres*

A short electronic questionnaire comprising seven questions was sent by email to all TIS centres. Most of the respondents stated that they have the capacity to collect more pregnancy outcome data, and the majority answered that they would be interested in being provided with information and resources about how to promote their services to the general public and HCPs, and specifically via social media.

### **Conclusion**

Both promotional pilot campaigns in the UK and in the NL were successful in increasing the reporting of drug exposure during pregnancy. Also, a low-cost campaign focusing on social media, was efficient, which could be an option for many countries. Support of HCPs of pregnant women, if possible is important. The TIS centres survey suggested that they were generally positive towards collecting more pregnancy reports than presently, and many are interested in receiving support on how to reach out with their services. Since as shown in the landscape analysis, there are major differences between the countries, a general campaign is not feasible and local customization is needed. A communication tool kit will be developed, that can be used and adapted by local stakeholders. The toolkit will also be based on the experiences from the pilot campaigns in the NL and UK.

## Introduction

The main aim of WP5 is to improve the value, quality and harmonization of the dissemination of information on the available evidence related to medicines use in pregnancy and during breastfeeding.

The 5.3 sub-task aim is to engage health care professionals (HCPs), pregnant and breastfeeding women and general public to stimulate pregnancy reporting through pharmacovigilance (PV) systems, by increasing their awareness that they can play an active role in increasing general knowledge about the safety of drug use during pregnancy and breastfeeding.

In addition, originally, there was a second objective on having also communications related to the value of donating milk to the milk banks, but this had to be stopped due to the current absence of options for woman to donate milk across Europe.

To confirm if a general communication campaign targeting all European countries would be feasible, the wp 5.3 team suggested to evaluate two local communication campaigns (pilots) and to undertake a landscape analysis of reporting pathways. The results were then used to decide what is the best approach to improve knowledge on drug safety when taken during pregnancy, by promoting reporting through PV systems in place. This was approved by the ConcePTION management team. Thereby, this deliverable comprises this initial work.

Two pilot campaigns, one in the UK and one in the Netherlands proposed communications tailored to the needs of women/midwives/physicians to increase the awareness, and to promote participation to two pregnancy drug registries. These registries are managed by Teratology Information Services (TIS) in the respective countries.

In addition, a review of pregnancy cases reported to Marketing Authorization Holders (MAHs) and to national Health Authorities (HAs) was completed aiming to analyze the different national reporting pathway of pregnancy cases across Europe, and to identify what would be the best communication pathway to reach our target audience(s) for a communication campaign. This review was expected to provide insights on the following questions

- Who is reporting? Health care professionals (HCPs) or women?
- Which events are reported: only exposure or also adverse outcomes?
- Are all reports retrospective?

A survey was also conducted among TIS to get insight into:

- Whether they presently receive reports on pregnancy exposures
- If they have the capacity to receive more reports
- If they would appreciate a communication tool kit to support them in their work to increase the reporting rate and how such a tool kit should be tailored

## Methods

### Pilot project in the NL

The full methodology of the NL study is available in Appendix 1.

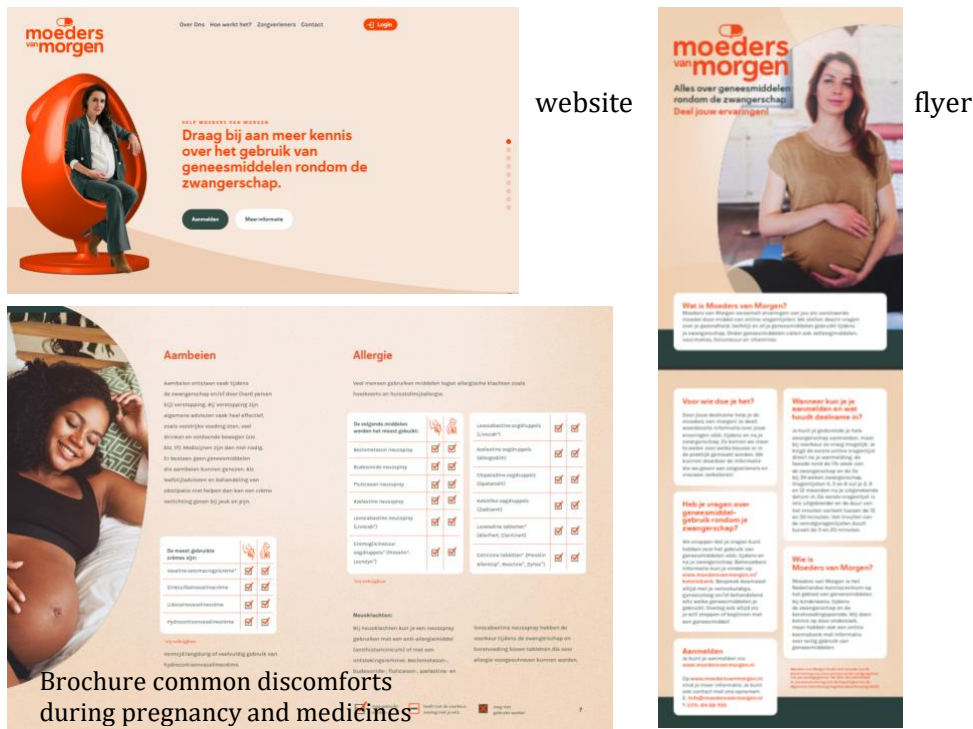
The Dutch Pregnancy Drug Register (in Dutch brand name 'Moeders van Morgen', literally translated 'Mothers of Tomorrow') belongs, together with the Teratology Information Service (TIS) of the Netherlands to Pharmacovigilance Centre Lareb. It was initially set up to obtain insight into medication use among pregnant and breastfeeding women and potential effects on maternal and fetal/infant health. The register has a prospective cohort design and collects data from pregnant women throughout the Netherlands. Data collection started in 2014 through web-based questionnaires completed by the participating women. Both women treated with medicines and not are included.

During one-year, different campaign methods were explored and evaluated with three main goals:

1. Increasing brand awareness
2. Dissemination of information
3. Increase participation in the register, and therefore, collect more data on medication use among pregnant and breastfeeding women and potential effects on maternal and fetal/infant health.

**Dissemination of information**

A new website, informative flyer and brochure on drug use for common discomforts during pregnancy and breastfeeding were developed (see Figure below).



HCPs and (semi-)commercial partners and combinations:

- Automatic e-mail invitation via HCPs: within the Netherlands, pregnancy care for most women (90%), starts in the first-line care, with midwives. An automatic e-mail was sent to patients with information and an invitation to participate to 'Moeders van Morgen' register was incorporated to the IT systems used by midwives can be sent to the client within a few clicks, meaning that the amount work for the HCPs is limited.
- Campaign activities with (semi-)commercial partners: In the Netherlands there are several (semi-) commercial parties (Zwangerenportaal, 24Baby, WIJ, Cavai) to inform pregnant women on all pregnancy and baby related topics: in the same way, once they create an account to a dedicated application, patients are receiving they will receive an invitation by e-mail (see Figure below) to participate in the register. Furthermore, marketing via information were disseminated (i.e. advertorials, informative articles, etc), as well as advertisement on the websites and within e-mails, social media campaigns was done and evaluation of its impact to evaluate brand awareness progression.
- A social media campaign (3x 2weeks)



Figure 1; Example of invitation e-mail via Zwangerenportaal

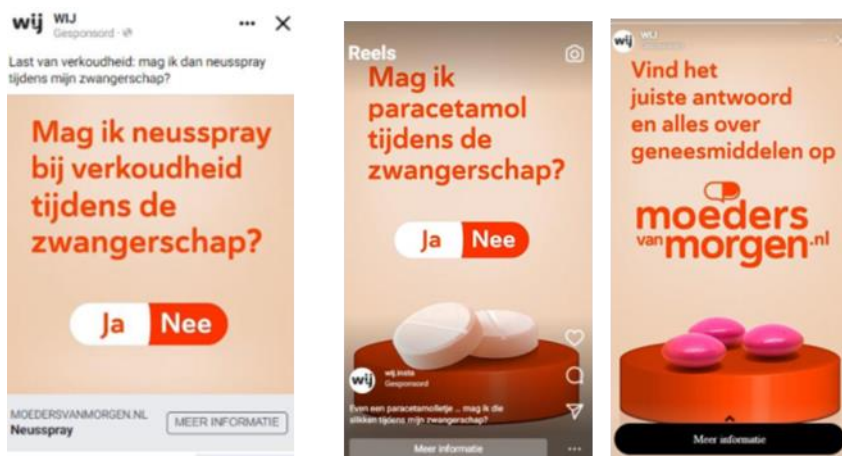


Figure 4; Example of social media posts

In addition, a huge amount of publicity for the registry was gained due to COVID-19. Indeed, every person in the Netherlands who would like to be vaccinated should fill in a form, and one question was if someone is pregnant. If yes, it was explained that women can participate in a study about pregnancy and vaccination, with a link to the website.

### Measurement of activities

Different methods were used to measure the effect of the campaign activities. First, with all collaboration partners we had

- numbers of view Dutch TIS website pages
- number views of 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 it is unknown via which route women entered the website before signing up. However, in their first questionnaire the register is asking women via which



channel they did hear from the register.

## Pilot project in the UK

The full methodology of the UK study is available in Appendix 2.

The UK Teratology Information Service (UKTIS) is commissioned by the UK Health Security Agency, to provide expert clinical teratology advice to HCPs and patients. UKTIS collects pregnancy outcomes via different routes:

- Enquiries from HCPs regarding gestational exposures to medication and chemicals in ongoing pregnancies (prospectively followed-up)
- Enquiries from HCPs concerning adverse pregnancy outcomes following gestational exposure events (retrospectively followed up)
- An online reporting facility for pregnant women – *BUMPs* (*Best use of Medicines in Pregnancy*), allowing women to report their pregnancies prospectively or retrospectively. The *BUMPs* registry was launched in 2014

The UK campaign focused on the *BUMPs* record, as it was a relatively new feature and had limited promotion previously. The aims were:

1. To raise awareness of UKTIS and *BUMPs* among HCPs
2. To increase patient reporting of exposures to UKTIS through a My *BUMP*'s Record and HCP reporting via enquiry line
3. To increase use of UKTIS and *BUMPs* medicines in pregnancy online resources

The campaign took place between the 1st of January 2021 to the 8th of February 2022 and predominantly targeted HCPs who care for pregnant women. The aim was that the HCPs would pass on the information about *BUMPs* to their patients and encourage women to record their pregnancies on the system.

### Dissemination of information

Social media was mainly used to promote the registry. The campaign was designed to be low cost, so it could easily be replicated by other TIS centres and low resource organisations.

The *BUMPs*/UKTIS Twitter account @medsinpregnancy was chosen as the primary social media platform since it was the most well-established UKTIS channel. Automated tweets (posted using a free software account 'Social Oomph' <https://www.socialoomph.com/>) and *ad hoc* Tweets regarding topical issues keep followers engaged with the work of UKTIS. 'Traffic' to the @medsinpregnancy Twitter account has been relatively stable in the years preceding the pilot campaign and therefore provided benchmark statistics against which the impact of the campaign could be measured. The UKTIS Twitter account has a mixture of HCPs and patient/general public followers providing a wider audience base than Facebook and Instagram which are predominantly used by patients.

Here are examples of Tweets used during the campaign period:

**Automated tweet**



**Awareness day tweet**



**Blog promotion tweet**



Six blog posts were published on the *BUMPs* website during the promotional period, see <https://www.medicinesinpregnancy.org/Blog/>. The blog posts highlighted the work that UKTIS do, the importance of medicines in pregnancy data collection and provided an interview with a woman discussing the experience of chronic condition in pregnancy.

An infographic was developed to explain in plain language what pharmacovigilance is. 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 organisations:



A YouTube channel was created for UKTIS and a short video was scripted and recorded to explain e.g., the purpose of UKTIS and PV reporting and how to use the *BUMPs* pregnancy registry to record their pregnancy. Both videos were made using free video editing software and used no specialist equipment.

Here is an example of a video: How to make a 'My Bumps' record:

<https://www.youtube.com/watch?v=e3vn2vLu2wQ>

During the promotional campaign UKTIS were involved with the national collection of COVID-19 vaccination exposure in UK pregnant women as part of a UK national surveillance programme, carried out in collaboration with other UK organisations. It was decided not to utilize the *BUMPs* patient reporting portal as this added another layer of complexity to the data collection process. Women and HCPs were asked to use the UKTIS dedicated telephone line to report COVID-19 vaccine exposures instead.

Increased traffic to UKTIS and the *BUMPs* websites was noted due to the COVID-19 related work carried out in 2021. This included publication of systematic evidence reviews for the treatment of COVID-19 infection in pregnancy and COVID-19 vaccinations in pregnancy. A number of infographics directed at pregnant women regarding the risks and benefits of COVID-19 vaccination in pregnancy were produced collaboratively and promoted on various platforms. UKTIS also, created an infographic/flowchart to help HCPs navigate the treatment options available for pregnant women with COVID-19 infection. These products were heavily promoted on Twitter and by other organisations.

UKTIS participated in a European study on the effects of the pandemic on pregnant women and promoted the study via the UKTIS/*BUMPs* twitter account. The Royal College of Obstetricians and Gynaecologists (RCOG) agreed to promote this study on behalf of UKTIS and tagged UKTIS in the promotion. This stimulated almost 200 women to participate in the study and it is likely that this also raised awareness of the UKTIS/*BUMPs* twitter account, and potentially, the service as a whole.

#### Measurement of activities

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.

## Landscape analysis

### Landscape analysis of pregnancy case reports

A review of pregnancy cases reported to Marketing Authorization Holders (MAHs) and to national Health Authorities (HAs) was completed, to better understand who is reporting cases of exposure during pregnancy or lactation (HCPs or patients), to which organization are they reported, which events are reported/collected, and whether pregnancy reports are collected retrospectively or prospectively (prospective data of exposure during pregnancy are data acquired prior to the knowledge of the pregnancy outcome or prior to the detection of a congenital malformation at prenatal examination, while retrospective data of pregnancy exposure are data acquired after the outcome of the pregnancy is known or after the detection of a congenital malformation on prenatal test).

Two databases were queried:

1. Sanofi PV database

Post-marketing cases reported from EU countries between 2011 to 2021, from HCPs or patients and reporting at least one event coded with a Medical Dictionary for Regulatory Activities (MedDRA) term of the Standardized MedDRA Query (SMQ) « pregnancy and neonatal topics ».

2. FAERS (FDA Adverse Events Reporting System) database

Cases reported to EU countries between 2011 to 2021, from HCPs or patients and reporting at least one event coded with a MedDRA term of the SMQ « pregnancy and neonatal topics » were selected. FAERS database contains all cases occurring in the US but also some cases occurring in other countries worldwide.

### Survey among the TIS centres

A short questionnaire comprising 7 questions using the survey tool SmartSurvey was sent by email to all TIS centres. The email accompanying the questionnaire contained a description of the aims of wp 5.3. Six survey questions were close-ended with fixed answer options:

- Does your TIS have the capacity to take more enquiries/collect more pregnancy outcome data?
- If yes, would you be interested in being provided with information and resources about how to promote your services to clinicians and members of the public?
- Do you currently promote your TIS to general public/HCPs?
- If you promote your TIS, which methods do you use?

In addition, two open-ended questions were included:

- How we can help promote the TIS? What resources, information and advice would be useful?
- Do you signpost any other organisations/reporting systems which collect medicines exposures data in pregnancy? Please give details.

## Results

### Pilot project in the NL

All results can be found in Appendix 1.

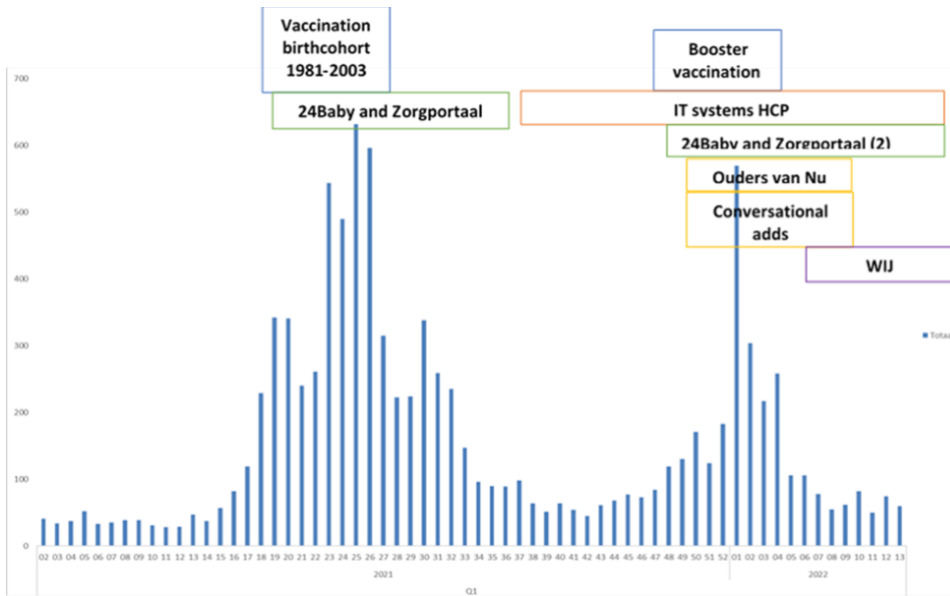
The total number website pages of the Dutch TIS visited increased in 2021 to 1.5 million compared to 1 million the year before (2020).

The three social media campaigns (a total of 6 weeks) led to a total of 36 inclusions

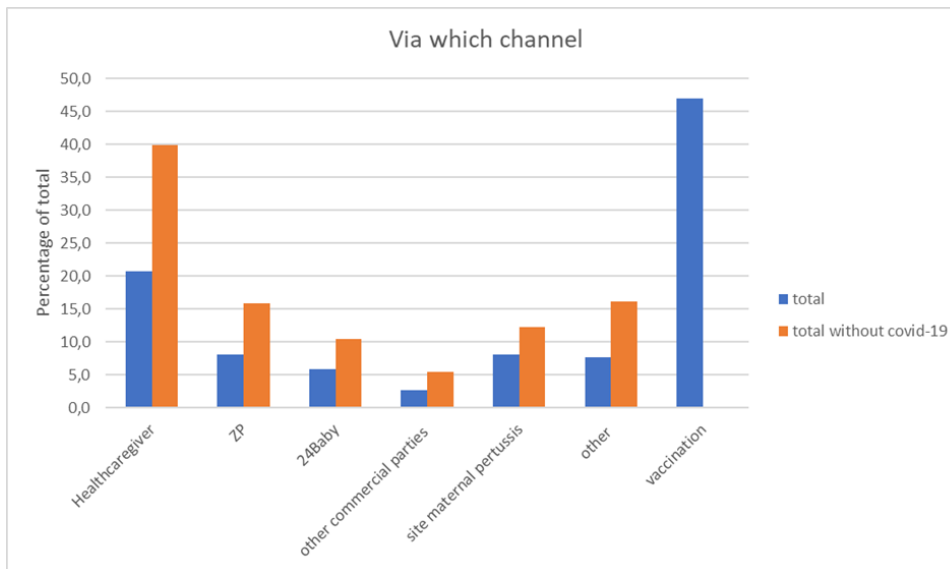
|   | Campaign 1<br>7 – 20 February | Campaign 2<br>4 – 17 April | Campaign 3<br>4 – 17 July | Total |
|---|-------------------------------|----------------------------|---------------------------|-------|
| Website visits from WIJ*                              | 1.451                         | 887                        | 486                       | 2.824 |
| % WIJ visits from total website visits these weeks    | 20.7%                         | 13.6%                      | 12.9%                     | 16.6% |
| Inclusions from WIJ                                   | 16                            | 6                          | 14                        | 36    |
| % WIJ inclusions from total inclusions in these weeks | 8.5%                          | 4.9%                       | 14.3%                     | 8.8%  |
| % Website visits to inclusions                        | 1.1%                          | 0.7%                       | 2.9%                      | 1.3%  |

\*WIJ = one of the (semi-)commercial parties

The total number of inclusions was put in perspective of the time periods of the different campaigns. The total number of inclusions in 2021 was 8000. For comparison in 2020 the number of inclusion was 772, and in 2019: 512.



The percentage of women per channel via which participations could have heard from Moeders van Morgen are presented below. Since the COVID-19 vaccination (i.e. the mentioning on the health statement) had a great impact on the results (blue bars), the orange bars depict the distribution of routes without women who (also) reported the COVID-19 health statement.



Distribution of channels via which women have heard from Moeders van Morgen. ZP = Zwangerenportaal, other commercial parties = Ouders van Nu and WIJ, health care giver = combination of automatic e-mails, distribution of a flyer/ brochure and verbal information

## Pilot project in the UK

All results can be found in Appendix 2.

### Twitter engagement

The @medsinpregnancy twitter account gained 232 followers over the campaign period (current following 1,954). This was not significantly more followers gained than in previous years (149 for 2018, 184 for 2019 and 230 for 2020). Tweets relating to COVID-19 gained the highest number of new followers.

Campaign tweets containing media and hashtags relating to health awareness days and tweets advertising blog posts generally gained more impressions and engagements and had a better engagement rate than

automated tweets about patient information leaflets:

Comparison of tweet engagement

| Type of tweet              | Impressions (±SD)  | Engagement (±SD)  | Engagement rate# (±SD) |
|----------------------------|--------------------|-------------------|------------------------|
| Automated tweet (no media) | 135.25 (±51.87)    | 1.63 (±2.14)      | 1.075 (±1.36)          |
| Awareness day tweet        | 631.93 (±585.13)*  | 15.87(±17.57)*    | 2.43 (±1.08)*          |
| Tweet promoting blog       | 1438 (±403.15)*, ^ | 38.67 (±9.20)*, ^ | 2.8 (±0.71)*           |

\*p<0.01, compared to automated tweets.

^p<0.01 compared to awareness day tweets.

# According to Twitter, average engagement rate for a tweet is 1-3%

Tweets to promote the UKTIS videos hosted on YouTube generated only very small numbers of video views (51 views for 'An Introduction to UKTIS and Teratology' and 18 views for 'How to make a 'My Bumps' record').

Traffic to UKTIS and BUMPs websites

During the campaign period there was a 34% increase in website traffic to the information documents on the UKTIS website and 5.8% increase in traffic to the patient information leaflets on the *BUMPs* website compared to the previous year:

Visits to information leaflets on the UKTIS and *BUMPS* website

| Year    | UKTIS (n) | <i>BUMPs</i> (n) | Total     |
|---------|-----------|------------------|-----------|
| 2020/21 | 894,750   | 1, 848,974       | 2,743,724 |
| 2021/22 | 1,199,357 | 1,955,918        | 3,155,275 |

Website hits for blog posts on *BUMPs* website

The blog posts created for the promotional campaign generated a total of >10,000 hits over the year of the promotional campaign:

Website hits to blog posts on *BUMPs* website

| Blog post                    | Publication date | Total hits 2021/22 | Mean hits/day post publication | Hits in first 7 days |
|------------------------------|------------------|--------------------|--------------------------------|----------------------|
| Introduction to <i>BUMPs</i> | 15/03/21         | 1,881              | Unknown                        | Unknown              |
| MS conversation              | 17/03/21         | 1,819              | Unknown                        | Unknown              |
| IMI ConcePTION               | 26/05/21         | 1,924              | 6.19                           | 500                  |
| Pfizer study launch          | 01/06/21         | 2,000              | 6.54                           | 702                  |
| Pregnancy PV                 | 30/06/21         | 1,420              | 5.11                           | 27*                  |
| COVID-19 in pregnancy        | 22/10/21         | 1,129              | 6.84                           | 55**                 |

\*Hits were higher on week 9 (n=111)

\*\* Hits were higher on week 7 (n=409)

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.

*BUMPs* pregnancy registry participation

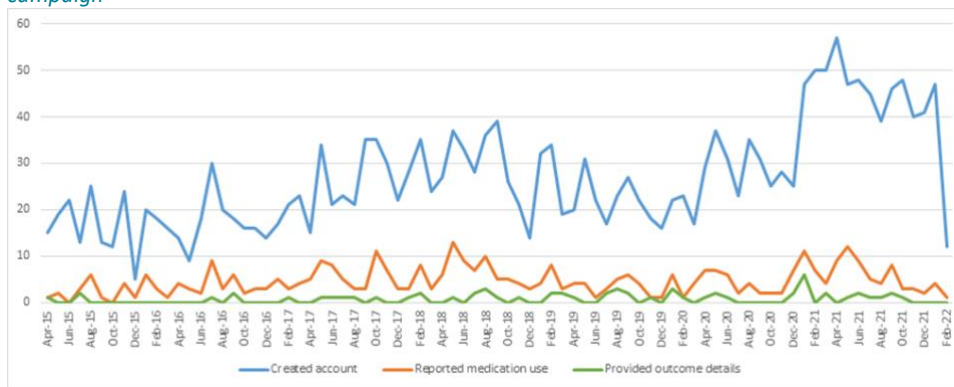
January 2021 onwards saw the biggest increase in monthly registry sign ups which UKTIS have recorded since the registry was created in 2015. This increase was larger than the general increase which has been recorded year on year:

*BUMPs account creation from 2015 to present*

| Year | Median (accounts created* per month) | IQR           | T-test P-Value | Relative Increase |
|------|--------------------------------------|---------------|----------------|-------------------|
| 2015 | 15                                   | 13 to 22      | -              | -                 |
| 2016 | 17                                   | 15.5 to 18.5  | 0.715648497    | 1.133333          |
| 2017 | 22.5                                 | 21 to 31      | 0.007670151    | 1.323529          |
| 2018 | 28                                   | 25.5 to 35.25 | 0.160187751    | 1.244444          |
| 2019 | 22                                   | 18.75 to 28   | 0.056385970    | 0.785714          |
| 2020 | 26.5                                 | 23 to 31      | 0.137854281    | 1.204545          |
| 2021 | 47                                   | 44 to 48.5    | 0.000000014    | 1.773585          |

\*entering pregnancy data

*My BUMP's account creation and outcome collection over time. The purple dashed line indicates the start of the promotional campaign*



There was a strong positive correlation between the number of Tweet impressions and registry account creations which was only measurable of the day of the tweet. This correlation was mainly driven by a tweet promoting the COVID-19 survey which had 13,000 impressions which correlated with 6 new account creations.

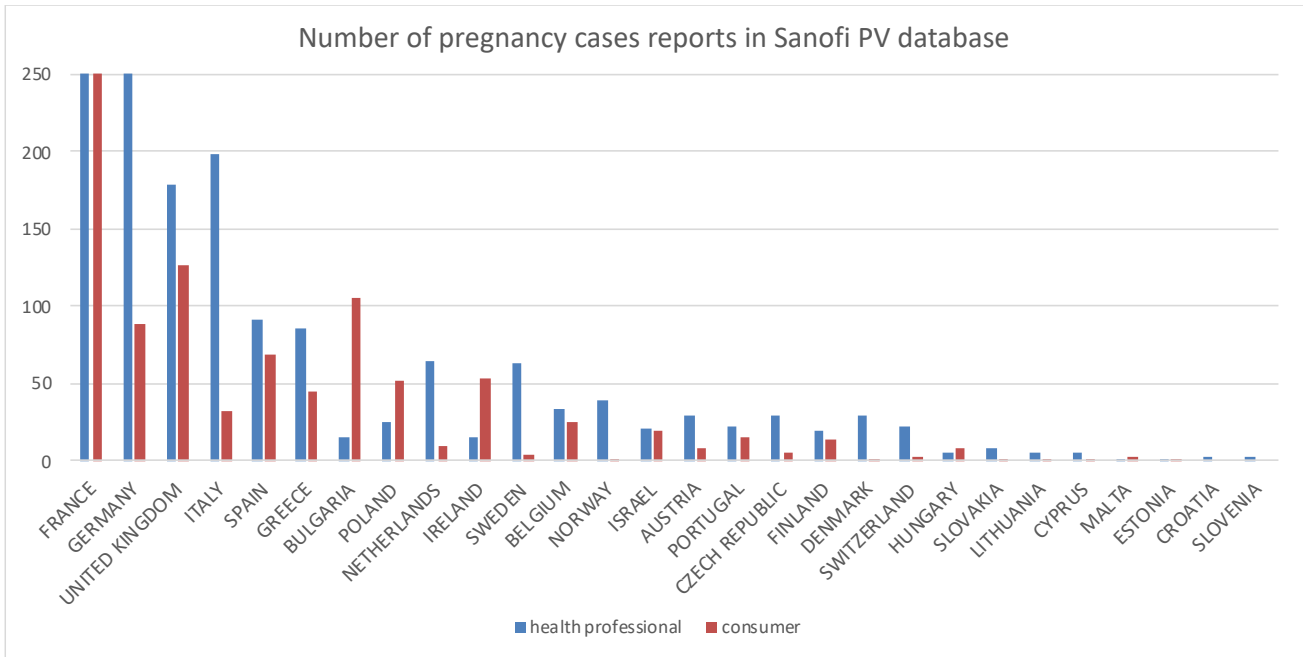
## Landscape analysis

### Landscape analysis of pregnancy case reports

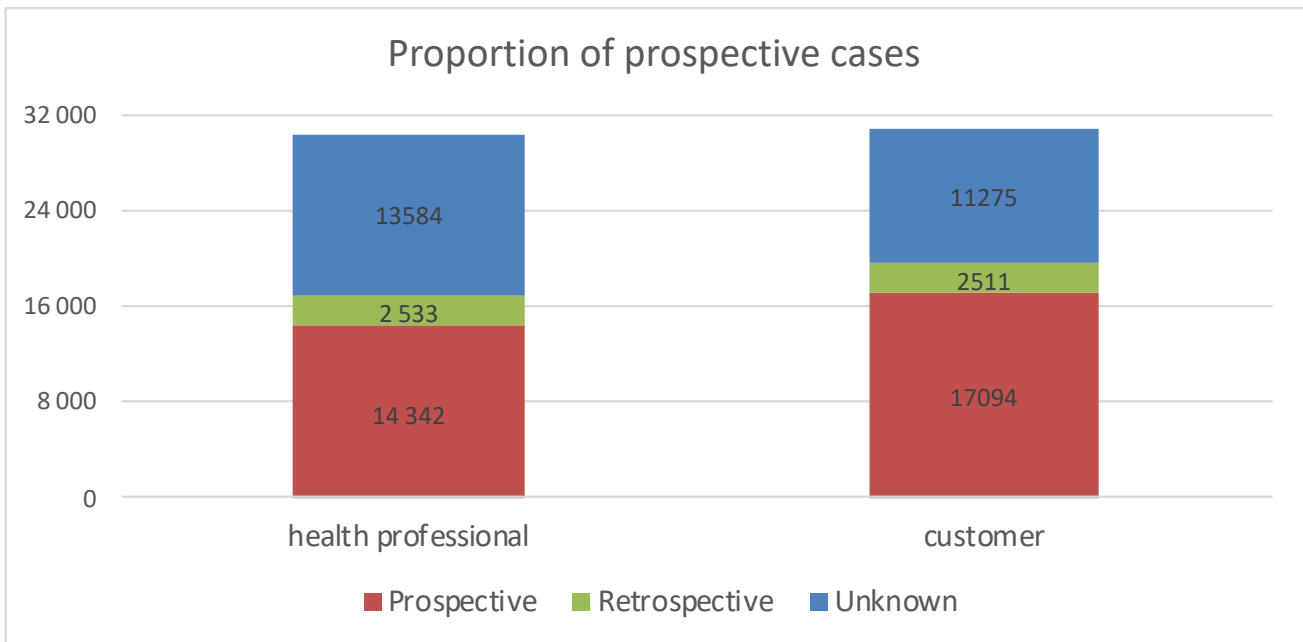
The total counts of cases retrieved were respectively N=12616 cases and N=47282 cases from the Sanofi PV database and FAERS. Different breakdown of cases were considered to further understand the reporting trends.

Counts of Sanofi database cases of pregnancy exposure were presented by

- Country and data sources (HCP or consumer)
- Prospective, retrospective or unknow reporting



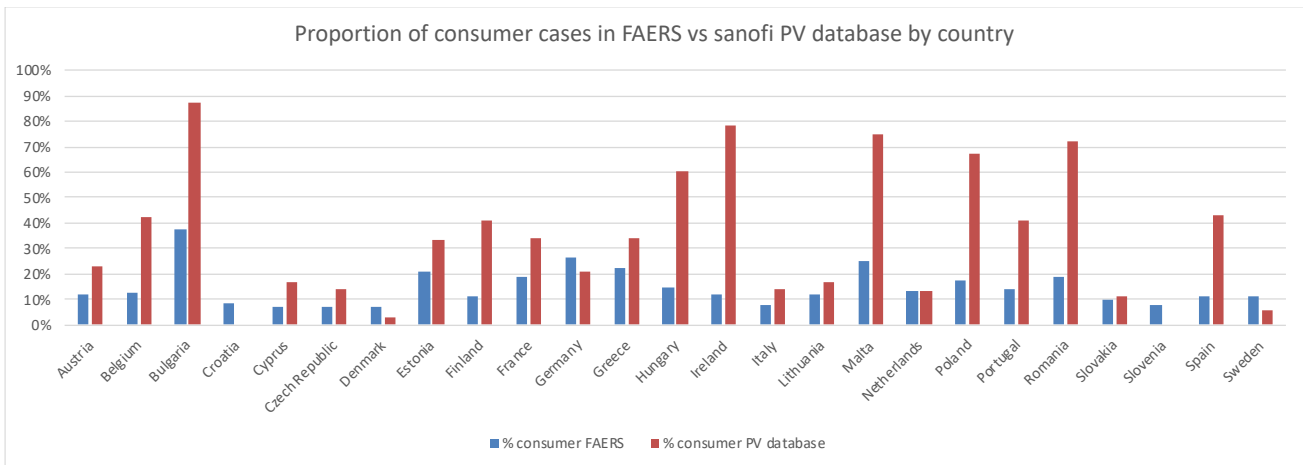
In the Sanofi PV database, both HCPs and women are reporting pregnancy cases. In most of the countries, more reports are from HCPs except in Bulgaria, Poland, Ireland.



In the Sanofi PV database, for both HCPs and women, about half of pregnancy cases reported were identified as prospective, meaning they were initially collected before the outcome is known.

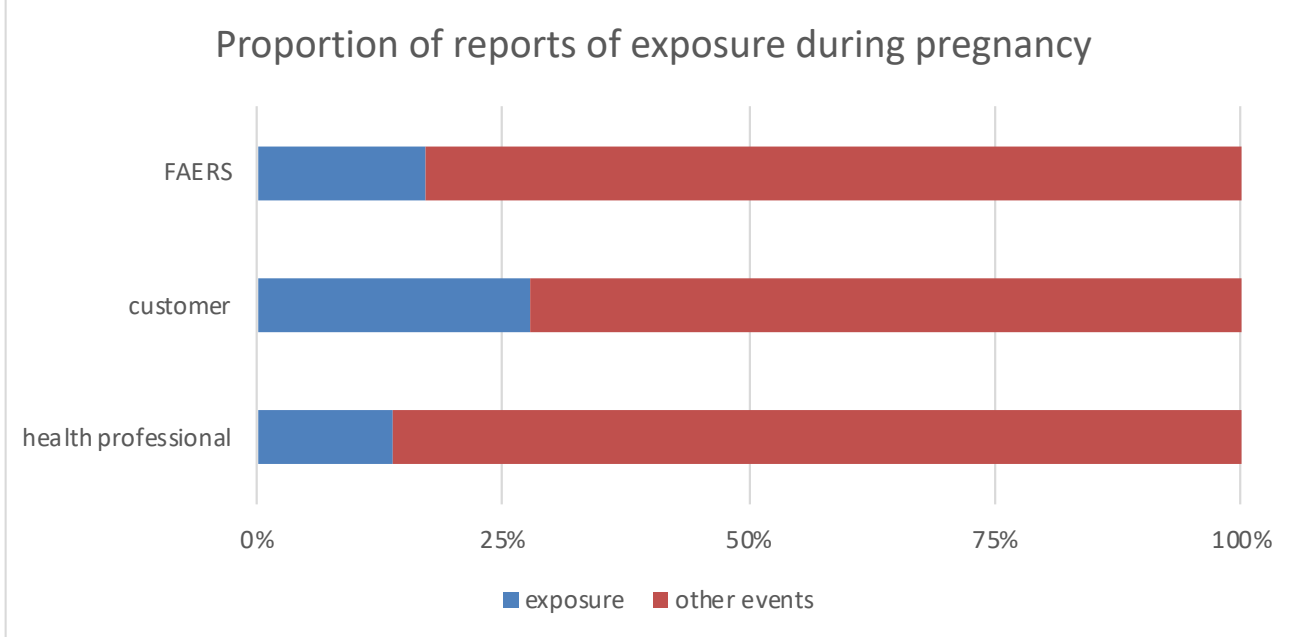
Distribution by country and data sources between cases reported in FAERS and Sanofi PV database cases is presented below.





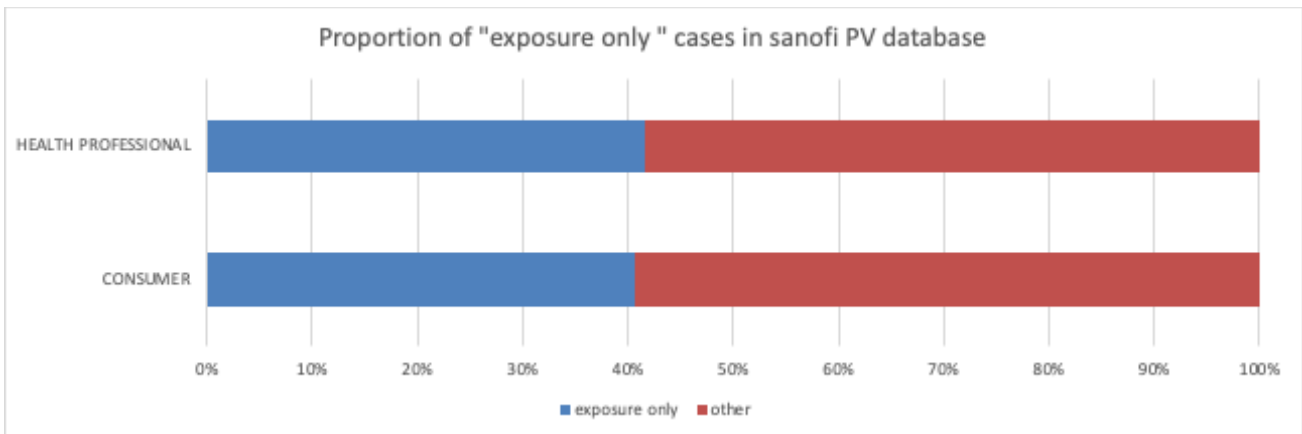
Comparing the Sanofi PV database to FAERS, the proportion of women reporting pregnancy cases is higher in company database.

Proportion of reports of exposure during pregnancy versus other events reported:



Among all pregnancy cases, exposure events « exposure during pregnancy, foetal exposure during pregnancy, maternal exposure during pregnancy » are events the most frequently reported. In total, they represent 14% to 28% of the events reported in pregnancy cases. Other pregnancy cases are very diverse and include either a pregnancy outcome, birth outcome or any information related to pregnancy.

Proportion of exposure during pregnancy without other reported event:



Among all pregnancy cases from the Sanofi PV database, exposure only cases where only exposure events are reported « exposure during pregnancy, foetal exposure during pregnancy, maternal exposure during pregnancy » represent more than 40% of reported cases.

In conclusion:

Across Europe, both HCPs and women report pregnancy cases either to the MAHs or to the national HA with variability across countries

- HCPs are more likely to report cases of exposure during pregnancy
- Women are more likely to report to the MAH (information available in the PIL)
- Proportion of prospective cases (reported before the outcome is known) is high.
- Exposure during pregnancy is the most frequent event reported and is frequently reported as a single event.

Survey among the TIS centres

In total 12/29 (41%) of the TIS centers answered the questionnaire. Among the respondents, 10/12 (83%) stated that they have the capacity to collect more pregnancy outcome data. A majority, 9/12 (75%) answered that they would be interested in being provided with information and resources about how to promote their services to the general public and HCPs. Currently, 11/12 (92%) do promote their TIS center via the following channels:

| If you promote your TIS which methods do you use? |           |                 |    |
|---|-----------|-----------------|----|
| Answer Choices                                    | Responses |                 |    |
| Twitter   |           | 18.18%          | 2  |
| Facebook  |           | 27.27%          | 3  |
| Instagram   |           | 18.18%          | 2  |
| LinkedIn  |           | 9.09%           | 1  |
| Tik Tok   |           | 0.00%           | 0  |
| YouTube   |           | 18.18%          | 2  |
| TV/Radio  |           | 0.00%           | 0  |
| Leaflets/posters                                  |           | 36.36%          | 4  |
| Internet platform/TIS website                     |           | 72.73%          | 8  |
| Lectures/training for clinicians and prescribers  |           | 90.91%          | 10 |
| Academic publications                             |           | 81.82%          | 9  |
| Newsletters                                       |           | 0.00%           | 0  |
| Other   |           | 18.18%          | 2  |
| Answered: 11 Skipped: 1                           |           | Response Total: | 11 |

The open-end question regarding how we can help to promote the TIS, and what resources, information and advice would be useful yielded the following replies:

“Disseminate our activities in platforms we are not part of”

“How to promote our telephone service to more HCPs. Text for twitter, facebook, instagram, linkedin”

“Our TIS is not familiar with social media activities. Furthermore, we are interested in improved systems of online communication for inquiries and follow-ups. Our privacy policy is a great challenge!”

“Any help especially for adequate use of social media and internet would be welcome.”

“Histopathological, genetic effects”

“Actually, we do not need help as national promotion has been done for many years.”

“Advertising ENTIS, youtube videos on medication in pregnancy/counselling, online tool for exposure data collection”

Finally, several TIS centres answered that they signpost other organisations/reporting systems, such as pharmacovigilance and registration departments at the Health Authorities, births defects registers and pharmacovigilance centres. They also collaborate occasionally with other TIS centres to contribute to multi centre studies.

## Discussion

The results of the pilot campaigns in the NL and UK clearly indicate that communication campaigns tailored to the needs of women, midwives, and physicians are successful to increase the awareness, rate of reporting and can encourage the collection of information on exposures during pregnancy.

### Target audience of a communication campaign:

The target audience for a communication campaign would include both HCPs and pregnant women. To increase the reporting rate in pregnant women, the NL pilot study emphasized that it is important to also involve the HCPs. However, it is essential that HCPs have as little work as possible to invite/ inform a client.

Local stakeholders have the best insight into how to reach both HCPs and pregnant women.

### Distribution pathway:

Based on the UK and NL pilot campaigns, a communication campaign should be undertaken via local stakeholders and be adapted to the situation in the respective countries. The optimal way to increase the rate of reporting of drug exposure during pregnancy, is to target the promotion of existing methods of reporting, including to TIS centres, Marketing Authorization Holders (MAHs) PV department, and Health Authorities. The most reasonable way to do this is to support these stakeholders with a communication tool kit, based on the experiences from the pilot campaigns in the NL and UK, and the results from the landscape analysis.

In the future, alternative methods, for example via an international app linked to a pregnancy register may provide more options for HCPs and women in countries where reporting options are limited, to report pregnancy exposures. Such an app is under development in ConcePTION work package 2.

The TIS centres have a central role to play in the collection of pregnancy exposure data and should be the main beneficiary of a tool kit designed to support increased awareness of data reporting systems. There are already existing communication ways to reach out to the TIS centers via the ENTIS (European Network of Teratology Information Services) network such as mailing lists. The survey among the TIS centres suggested that the majority have the capacity to collect more reports than presently and that they are agreeable to receiving support to facilitate a promotional campaign for their service. Presently, many are using mainly traditional media (e.g lectures and academic publications) to promote their services but they are interested in support with social media campaigns. It should however be noted that the response rate was only 41% in the TIS survey.

In countries lacking a TIS centre, other stakeholders, mainly Health Authorities and other PV-centres (when existing) should be targeted. Even though the homepages of the HAs generally do not seem to be adapted for submitting pregnancy reports, the landscape analyses of reports to HAs and MAHs showed that reports are able to be collected from both patients and HCPs. There is however a need to find pathways to encourage them to use the communication toolkit and initiate promotional campaigns to increase the reporting rate.

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, but with a variability across countries (number and type of reports). This is in line with an exploration undertaken by the 5.3 group of the situation in different countries/regions in Europe (UK, The Netherlands, Nordic countries and Spain) that indicated major differences/challenges: While in some countries there are multiple options for women, midwives, or physicians to report (see pilots), or a well-established channel (Nordic Countries). In other countries (e.g. Spain) it's almost impossible for women to report (neither TIS, nor HAs, nor MAHs have reporting options for women or these, if existing, are not easy to find) and it is unclear how easy it is for physicians or midwives to report.

The NL pilot study also worked with commercial partners to reach its target audience. The Netherlands TIS concluded that working with commercial partners does work, but there are high financial costs related to this. An important lesson from the pilot in the Netherlands is that collaboration with parties exclusively targeting pregnant women, as compared to parties targeting group, like pregnant women and also young parents, is most successful.

#### Communication methods/pathway:

A very efficient pathway used mainly in the UK pilot, was the use of social media such as Twitter. The UK data show that tweets which contain visual content have significantly greater engagement and those which promote other content (such as blog posts) are the most successful (in terms of Twitter impressions and engagement). This is consistent with Twitter's own analysis which showed that tweets with visual content achieve 35% more engagement than those without.

Social media campaigns in the Netherlands rise awareness, and increases website visits, but only a small percentage actually participates in the register.

The social media campaigns in the UK and Netherlands showed that they do generate attention (website visits) and – although not in very high numbers – inclusions. The campaign in the UK shows that this is possible with a low-budget approach.

In the NL, a request to participate in pregnancy registers was sent to pregnant women through the IT-systems used by midwives (or physicians). If applicable, depending on the National Healthcare system specificities, it is of great value to use this communication pathway, however, this may not be applicable in some countries: either there can be no harmonization between the IT tools used by the HCPs involved in pregnant women medical care, or no pregnancy registry is available locally. Another aspect to consider is the local regulation in terms of confidentiality of personal data.

#### Key messages to convey

Following extensive discussions within WP 5.3. and with the support of WP8, there is agreement that we should not be directly asking the public to report exposures during pregnancy unless we can provide the information on how to report it in each individual country. Thereby, communication campaigns should be undertaken via local stakeholders.

When interpreting the results from the pilot studies, it is important to be aware of the activities relating to COVID-19 that was ongoing during the campaign periods. These activities likely had an impact on pregnancy reporting and increased awareness of the Teratology Information Services and suggest that focusing on current 'hot topics' may be an effective way of increasing engagement.

Per NL TIS pilot conclusion, it was clear that everything is a process of giving and taking and that women would like to receive information on safety of drug use in exchange for participating in a registry.

To summarize, a tool kit covering different promotional options with simple messages that could easily be adapted to each country, seems to be the optimal way to proceed at this point.

## Conclusion

Communication campaigns promoting existing reporting systems and validated knowledge databases on the safety of medicine use during pregnancy could increase the pregnancy exposure reporting rate. Low-cost campaigns using social media might be an option for most countries. Support of HCPs of pregnant women, if possible, is important. Presently, a communication toolkit should be directed to local stakeholders such as TIS-centres, HAs and PV-centres, who will need to customize as per National reporting system, communication pathway, and healthcare system specificities.

## Appendices

**Pilot project in the NL – full report**

**Pilot project in the UK – full report**

**Questionnaire and answer options of the TIS survey**

**Introduction**

**The design of the Dutch Pregnancy Drug Registry**

The Dutch Pregnancy Drug Registry (in Dutch brand name 'Moeders van Morgen', literally translated 'Mothers of Tomorrow') belongs, together with the Teratology Information Service of the Netherlands to Pharmacovigilance Centre Lareb.

The Dutch Pregnancy Drug Register was set up to obtain insight into medication use among pregnant and breastfeeding women and potential effects on maternal and fetal/infant health. This systematically documented data on medication use during pregnancy and lactation will contribute to future knowledge on medicines safety. The registry has a prospective cohort design and the population is derived from pregnant women throughout the Netherlands. Data collection started in April 2014 and enrolment of women is continuous. Data on current pregnancy, obstetric history, maternal lifestyle, health and medication use, but also delivery and infant health are collected through web-based questionnaires completed by the participating women (three times during pregnancy and three times during the infant's first year of life).

To have a representative cohort, as many as possible women should participate. Not only chronically ill women or women on (prescribed) medications, but also women only taking for instance vitamins or nothing at all. During the past year, different campaign methods were explored and evaluated in an ultimate goal to draw a conclusion on the most effective and future-proof method. Within the campaigns there were three main goals: 1) increasing the brand awareness, 2) disseminate good information and 3) increase participation in the Dutch Pregnancy Drug Register.

**Methods**

**Campaign activities**

The first step was to change the brand name within the Netherlands from pREGnant to Moeders van Morgen. Next to changing the name, a new website, informative flyer and brochure on drug use for common discomforts during pregnancy and breastfeeding were developed (see Figure 1).

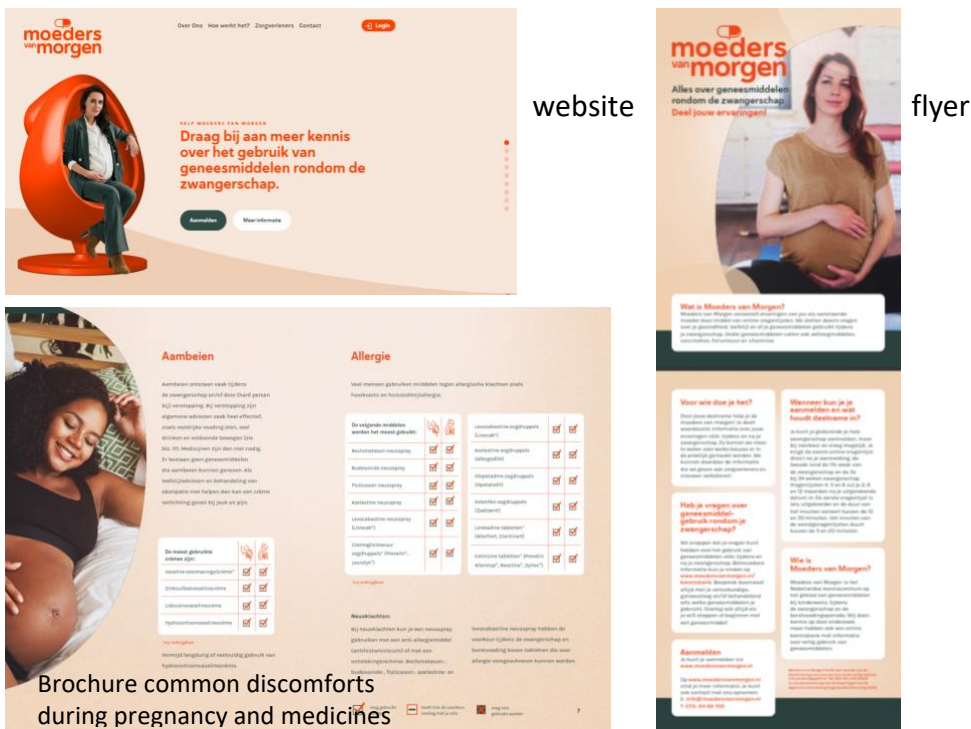


Figure 1; website, flyer and brochure

Next to our campaign activities, a huge but 'unintended/free' amount of publicity was gained due to COVID-19. Partially via media attention, but the biggest part was due to the call on the health statement, which every person in the Netherlands who would like to be vaccinated should fill in. At this statement it was asked if someone is pregnant. If yes, it was first clarified that vaccination is possible with a mRNA vaccine, but also that women can participate in a study about pregnancy and vaccination, with a link to the website. So, in this way, all pregnant women which are vaccinated were made aware of this.

During the campaign period, there was collaboration with several partners, namely health caregivers and (semi-)commercial partners and combinations.

Collaboration health caregivers:

- Automatic e-mail invitation via health caregivers: within the Netherlands, pregnancy care for most women (90%), starts in the first-line care, with midwives. There are roughly 3 IT systems for midwives: Onatal, Orfeus and Vrumun. Incorporation of our register in these systems would be very helpful since health caregivers speak to all pregnant women in an early stage of pregnancy. By incorporation in the systems, an automatic e-mail with information and an invitation to participate can be send to the client within a few clicks, meaning that the amount work for the health caregiver is limited.
  - Onatal: see below, this was incorporated via de semi-commercial partner Zwangerenportaal.
  - Orfeus: within the anamneses page the question for participation was incorporated. If the answer is changed from no to yes, an pop-up will be shown to confirm that the woman will be invited to participate. An automatic e-mail (via a temporary link between Orfeus and our system) is being sent to the woman with information and a link to register. For an example, see Figure 2.
  - Vrumun: within the tab 'research' the health caregiver can give permission to send an e-mail to the women. Technically, this is in the exact same way incorporated as within Orfeus.

Campaign activities with (semi-)commercial partners:

- In the Netherlands there are several (semi-)commercial parties to inform pregnant women on all pregnancy and baby related topics:
  - The semi-commercial party Zwangerenportaal: via this channel midwives working with Onatal communicate with their clients. Clients have to create an account within Zwangerenportaal to have insight in their health dossier. Six days after signing up for Zwangerenportaal, they will receive an invitation by e-mail (see Figure 3) to participate in the register. Furthermore, there is marketing via information (i.e. advertorials, see Figure 4A) and advertisement on the website and within e-mails.
  - The commercial party 24Baby: they provide a website, app, forums and a newsletter. We had marketing trough their channels via information, several informative articles (see Figure 4B) were written with the editors of 24Baby. Furthermore, there is for instance bannering (Figure 5) on the online forums of 24Baby.
  - The commercial party WIJ (WE, young parents): the main focus in this collaboration was to explore social media campaigns and advertorials in a magazine (i.e. offline) and the effect of this. Next to this there was a start measurement on brand awareness and after 6 six months of campaign an end measurement (different group of women compared to the start measurement) to see if brand awareness has been increased (results not yet available, campaign is still going on while writing). Ouders van Nu (Parents of Today): a very big commercial brand within a big media group. There are some difference compared to the other commercial parties. For instance Ouders van

Nu works with a lot of commercial parties (with a lot of money) and as a result very often sends direct mails with advertisement. Next to that, they not only focus on pregnancy but also on childhood. During this collaboration for instance a quiz (Figure 6) was set up to check your own knowledge. Furthermore, a direct e-mail to 53,000 pregnant women registered at Ouders van Nu was sent.

- Cavai a commercial party which sends conversational ads, these are computer controlled chats. An example, in Dutch, can be found in Figure 7. These chats are targeted to women in a specific age range. In our case they were partially delivered/targeted via the network of Ouders van Nu.



|    | client e-mail      | ja  | 17-07-2020 | FA |
|----|--------------------|-----|------------|----|
| 20 | apothek            | ja  | 17-07-2020 | FA |
| 20 | zwangerschapsmail  | ja  | 17-07-2020 | FA |
| 20 | Moeders van Morgen | nee | 17-07-2020 | FA |

Beste mevrouw {{context.receivername}},

Als je zorgverlener nodig ik je graag uit om deel te nemen aan Moeders van Morgen ([www.moedersvanmorgen.nl](http://www.moedersvanmorgen.nl)).

#### Wat is Moeders van Morgen?

Moeders van Morgen verzamelt ervaringen van jou als aanstaande moeder door middel van online vragenlijsten. Er worden vragen gesteld over je gezondheid, leefstijl en of je geneesmiddelen gebruikt tijdens je zwangerschap. Onder geneesmiddelen vallen ook zelfzorgmiddelen, vaccinaties, foliumzuur en vitamines.

.....

#### Heb je vragen over geneesmiddelgebruik rondom je zwangerschap?

We snappen dat je vragen kunt hebben over het gebruik van geneesmiddelen voor, tijdens en na je zwangerschap. Betrouwbare informatie kun je vinden op [www.moedersvanmorgen.nl/kennisbank](http://www.moedersvanmorgen.nl/kennisbank) of in deze [brochure](#). Bespreek daarnaast altijd met je verloskundige, gynaecoloog en/of behandelend arts welke geneesmiddelen je gebruikt. Overleg ook altijd als je wilt stoppen of beginnen met een geneesmiddel!

Wil jij je ervaringen delen, en de moeders van morgen helpen? Meld je dan aan door op [deze link](#) te klikken.

Hartelijke groet,

{{context.institution}}

{{context.city}}

Figure 2; incorporation of question tot participate in Moeders van Morgen in Orfeus with some parts of the automatic e-mail

**zwangerenportaal.nl**

Beste Annabel van der Wel,

Je staat er vast niet bij stil, maar ook tijdens je zwangerschap gebruik je misschien wel eens medicijnen. Denk maar eens aan het foliumzuur dat je slikt in de eerste weken van je zwangerschap. Of aan de paracetamol die je kunt nemen omdat je hoofdpijn hebt.

Van deze medicijnen weten we dat ze geen kwaad kunnen. Maar van veel medicijnen weten we helaas niet goed of je ze mag gebruiken tijdens de zwangerschap of borstvoeding. Wat is dan de beste keuze voor jou én je kind, je klacht of ziekte behandelen of niet?

Om daar meer kennis over te krijgen is onderzoek nodig. Moeders van Morgen doet dit onderzoek en heeft jouw hulp daarbij nodig, ook als je nu geen medicijnen gebruikt!

**Deel jouw ervaringen en meld je aan voor Moeders van Morgen**



**Hoe werkt het?**  
Tijdens en na je zwangerschap ontvang je 6 online vragenlijsten.

[Lees meer](#)

Figure 3; example of invitation e-mail via Zwangerenportaal

**Hooikoorts tijdens de zwangerschap**  
 ZPB - Magazine, 14 mei 2020 15:20  
 Laatste update op: 14 december 2021 13:03  
 In samenwerking met: Moeders van Morgen

Van hooikoorts kun je in het hooikoortsseizoen veel last hebben. Zijn er dingen die je kunt doen om hooikoortsklachten te verminderen tijdens de zwangerschap? En mag je als je zwanger bent wel hooikoorts medicijnen nemen?

**Wat is hooikoorts precies?**

Hooikoorts is een allergische reactie voor stofmeel dat van planten, grassen en bomen komt. De klachten merk je vooral in je neus, keel, luchtpijp, mond en ogen, je hebt er vooral last van in het voorjaar en de zomer, wanneer het stofmeel volop door de lucht vliegt. Deze stofmeelkorrels worden ook wel pollen genoemd. Door het stofmeel raken slijmvliezen geïrriteerd, worden ze dikker en gaan ze meer slijm maken. Hooikoorts kan meestal geen kwaad, maar het kan ontzettend vervelend en vermoedend zijn om de hele dag door te niezen en lastiger te ademen, zeker tijdens je zwangerschap.

**Hooikoorts en zwangerschap**

Als je zwanger bent verandert er veel in je afweersysteem en je hormoonhuishouding. Hierdoor kun je anders reageren op allergieën dan normaal. Zo kun je tijdens de

Tijdens je zwangerschap kan je veel last hebben van zwangerschapskwaaltjes. Soms wil je daar het liefst een pijnstiller voor nemen. Maar welke pijnstillers zijn veilig tijdens je zwangerschap? Mag je bijvoorbeeld ibuprofen, aspirine of paracetamol als je zwanger bent?

**In dit artikel**

- Pijnstillers tijdens de zwangerschap
- Paracetamol
- Ibuprofen, naproxen en diclofenac
- Aspirine

**Moeders van Morgen**

De informatie in dit artikel is geschreven in samenwerking met [Moeders van Morgen](#). Dit is het kenniscentrum op het gebied van medicijngebruik vóór en tijdens de zwangerschap en tijdens de borstvoedingsperiode. Door jouw ervaringen tijdens de zwangerschap met hen te delen, kan je helpen met het verbeteren van de voorlichting op dit gebied.

**Pijnstillers tijdens de zwangerschap**

Tijdens je zwangerschap verandert er veel in je lichaam. Dit kan voor verschillende [kwaaltjes](#) zorgen. Denk aan [hoofdpijn](#), [rugpijn](#), [bekkenpijn](#) of [buikpijn](#). Buiten je zwangerschap zou je voor deze klachten misschien een

Figure 4 A and B; advertorials Zwangerenportaal(hay fever) and 24Baby (pain medication during pregnancy)

**Mag ik neusspray bij verkoudheid tijdens de zwangerschap?**

Ja Nee

moeders van morgen.nl

**Mag ik ibuprofen de tweede helft van de zwangerschap?**

Ja Nee

moeders van morgen.nl

**Draag bij aan meer kennis over het gebruik van geneesmiddelen rondom de zwangerschap**

Meld je aan op

moeders van morgen.nl

Figure 5; examples of banners. Left; may I use medicine X during pregnancy. Right; call to action banner

Ouders Inloggen  

Zwanger worden Zwanger Baby Peuter Schoolkind Producten Voordeelpas Forum Meer

Home > Quiz: Wat weet jij over het gebruik van geneesmiddelen tijdens een zwangerschap




Geneesmiddelen en zwangerschap: dit zijn jullie meestgestelde vragen →



### Quiz: Wat weet jij over het gebruik van geneesmiddelen tijdens een zwangerschap

Een paracetamol slikken als je zwanger bent, mag dat? En hoe zit het met verdoving bij de tandarts? Als je zwanger bent, wil je op dit soort vragen zo snel mogelijk antwoord. Voor de gezondheid van je baby en jezelf. Ontdek met deze quiz alles rondom geneesmiddelengebruik tijdens de zwangerschap.

OUDERS VAN NU SAMEN MET MOEDERS VAN MORGEN

De antwoorden in deze quiz worden gegeven door Carlijn Litjens, wetenschappelijk onderzoeker bij Moeders van Morgen, het Nederlandse kenniscentrum op het gebied van geneesmiddelen bij een kindervens, tijdens de zwangerschap en de borstvoedingsperiode.

**1. Is het altijd slecht om medicatie te nemen tijdens je zwangerschap?**

Ja

Nee

[Bevestigen](#)

Figure 6; quiz 'What do you know about the use of medicines during pregnancy? Eight questions on commonly used drugs.



The figure shows a sequence of four conversational ad screenshots from 'moeders van morgen':

- Screenshot 1:** A message bubble says "Hoi, wij zijn Moeders van Morgen, mogen we je een vraag stellen?". Below it are two buttons: "Ja" and "Nee".
- Screenshot 2:** A message bubble says "Gefeliciteerd en bedankt voor je antwoord! Wist jij dat je bij kunt dragen aan meer kennis over het gebruik van medicijnen rondom de zwangerschap. Wil je dat?". Below it are two buttons: "Ja" and "Nee".
- Screenshot 3:** A message bubble says "Bedankt voor je antwoord. Mocht je in de toekomst zwanger (willen) worden, kijk dan eens op moedersvanmorgen.nl voor informatie over geneesmiddelgebruik rondom de zwangerschap.". Below it is a button: "Moeders van Morgen".
- Screenshot 4:** A message bubble says "Ben je zwanger?". Below it are two buttons: "Ja" and "Nee".

Figure 7; example of a conversational ad

## Costs per partner

Despite Lareb is a non-profit organisation, campaigns with commercial partners are not free of charge. The costs per partner can be found in Table 1, with the content of the package and the amount of money and the duration of the campaign.

Table 1; package content of campaign and costs per partner

| Partner          | Package   | Costs                         |
|------------------|---|-------------------------------|
| Orfeus           | Technical realisation in IT system                          | No costs                      |
| Vrumun           | Technical realisation in IT system                          | €4,000 one time               |
| Zwangerenportaal | Email - information - advertorials – banners                | €20,000 / year                |
| 24Baby           | Information - advertorials - banners – newsletter – podcast | €20,000 / year                |
| Ouders van Nu    | Advertorial – banners – information – quiz                  | €40,000 for about half a year |
| Cavai            | Conservational ad   | €10,000 for about half a year |
| WIJ              | Advertorials (socials) – banners – survey – information     | €45.000 for about half a year |

## Measurement of activities

Different methods were used to measure the effect of the campaign activities. First, with all collaboration partners we had regular meetings and/ or received reports to update us on the views our activities have had. Second, the 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-trackingmodule (UTM) codes. The third, more indirect but very important, measure was the number of inclusions. This method is indirect since we do not track women at our website, meaning that we do not know via which route they entered the website before signing up. However, since we would like to know via which route women did hear of our study, in our first questionnaire we ask women via which channel they did hear from us. Analysing this question was the fourth and last measurement method of the campaign.

## Results

### 1. Views on content at websites partner

All partners were very satisfied with the views of the content on their website. Benchmarks were easily achieved in most cases and if not they were met with little extra effort. In their opinion, the content of Moeders van Morgen was very useful and relevant for their readers/ visitors.

## 2. Click through

Figure 8 shows the click throughs to the homepage of Moeders van Morgen between May 2021 and March 2022. These are the total number of visitors, meaning that the number is not only driven by (direct) campaign activities. In Table 2 the number of click throughs per partner can be found. Of note, the number of visitors does not mean that the visitor actual signed up for the study. Furthermore, these numbers do not say anything on the 'quality' of the visit (e.g. duration, number of pages visited, bounce rate).

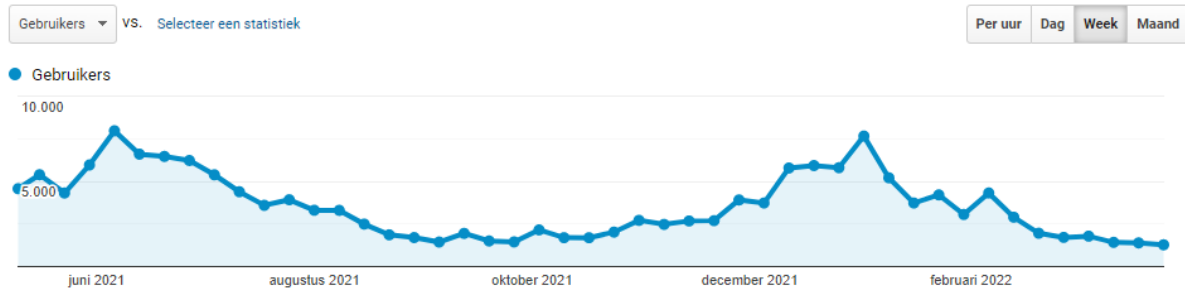


Figure 8; website visitors at Moeders van Morgen

Table 2; number of visitors per collaboration partner

| Partner           | Number of visitors |
|-------------------|--------------------|
| 24Baby            | ~3850              |
| Zwangerenportaal  | ~4600              |
| Ouders van Nu     | ~4275              |
| Conversational ad | ~4000              |
| WIJ               | ~3000              |
|                   |                    |

Figure 9 shows the number of visits of the website of the register vs. campaign timing

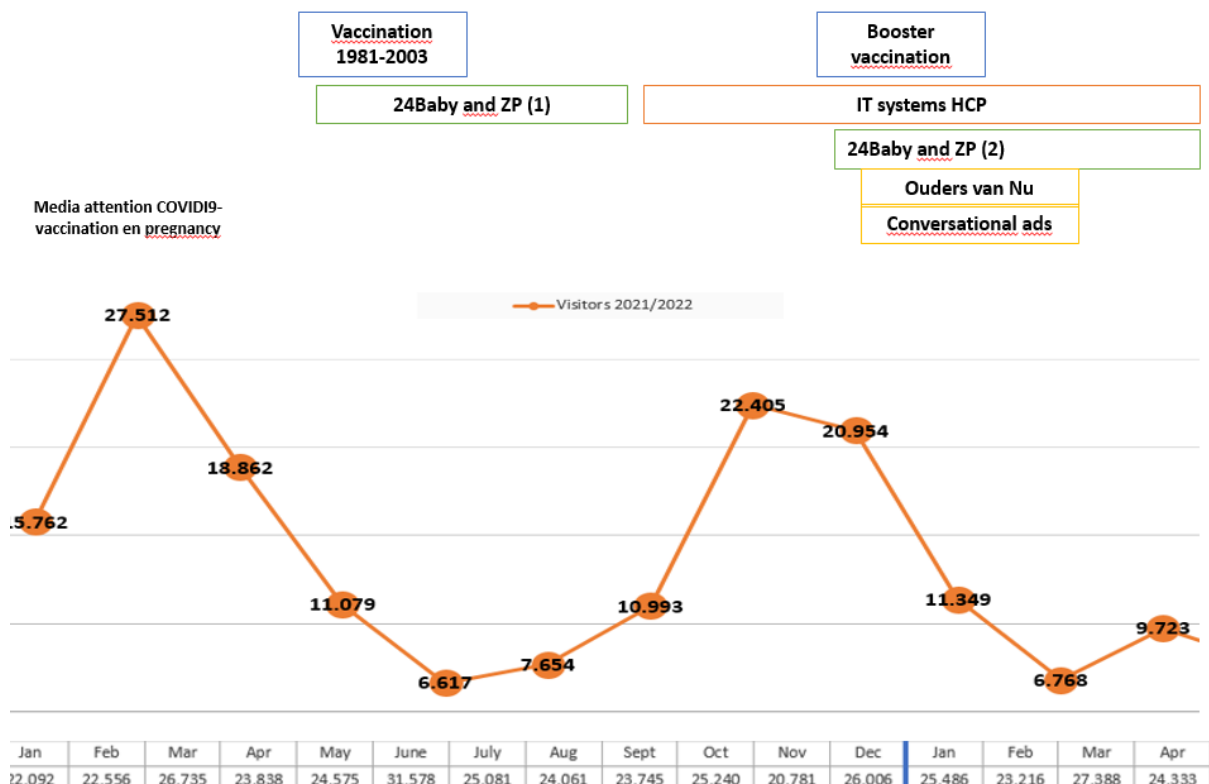


Figure 9; number of visits website of the website of the register moedersvanmorgen.nl vs. campaign timing

Figure 10 shows the total numbers of knowledge pages visited the Dutch TIS during the campaign

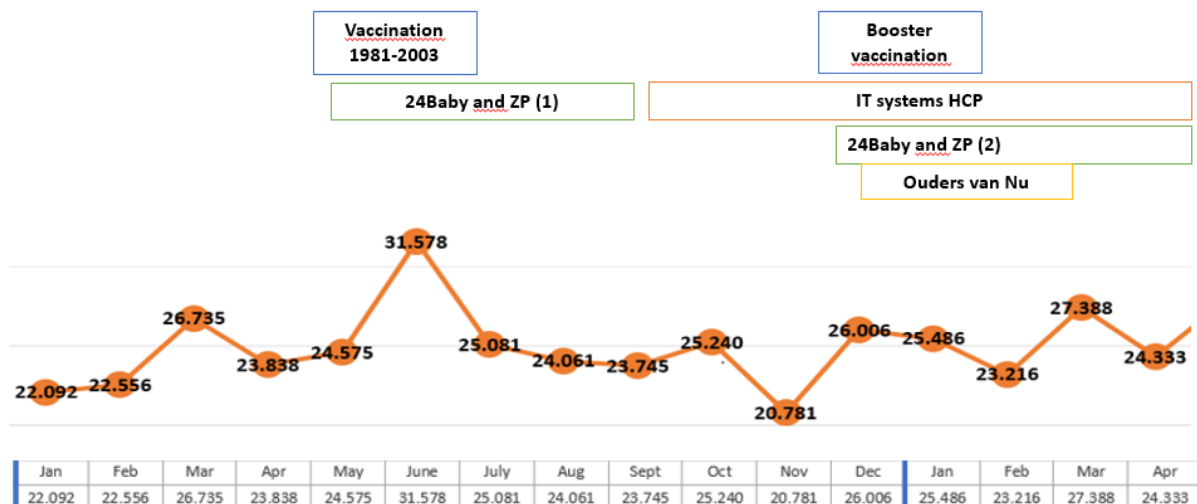


Figure 10; total numbers of knowledge pages visited the Dutch TIS during the campaign

### 3. Number of inclusions

Figure 9 shows the number of inclusions, together with the time periods of the different campaigns. The total number of inclusions in 2021 was 8000. For comparison in 2021 the number of inclusion was 772, an in 2020 512.

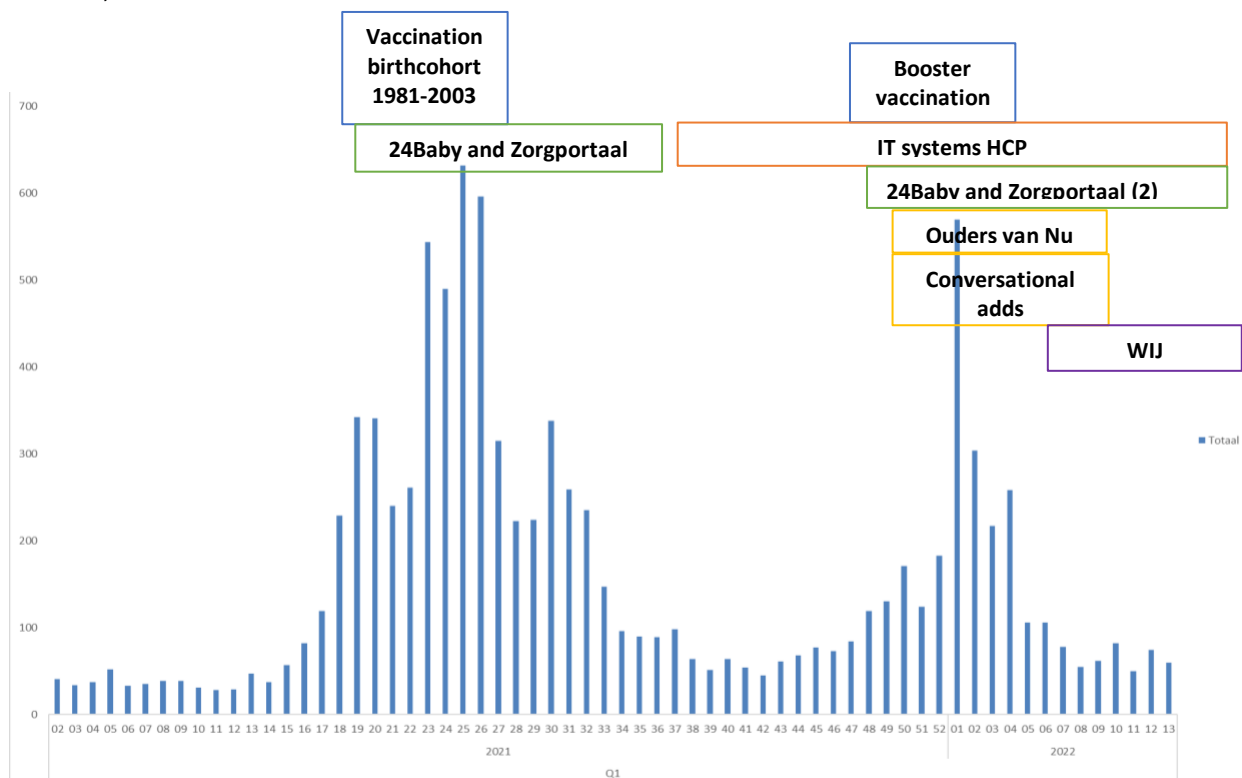


Figure 9; number of inclusion and the time periods of the different campaigns.

Figure 10 shows the percentage of women per channel via which participations could have heard from Moeders van Morgen. Since the COVID-19 vaccination (i.e. the mentioning on the health statement)

had a great impact on the results (blue bars), the orange bars depict the distribution of routes without women who (also) reported the COVID-19 health statement.

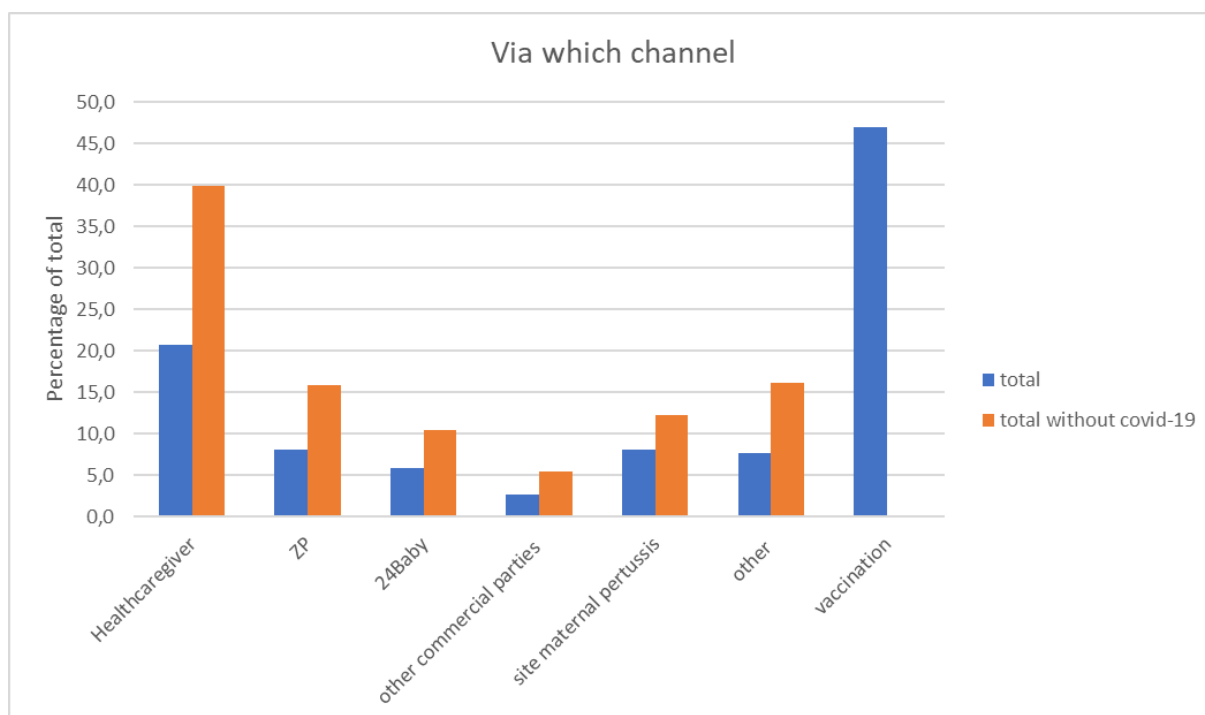


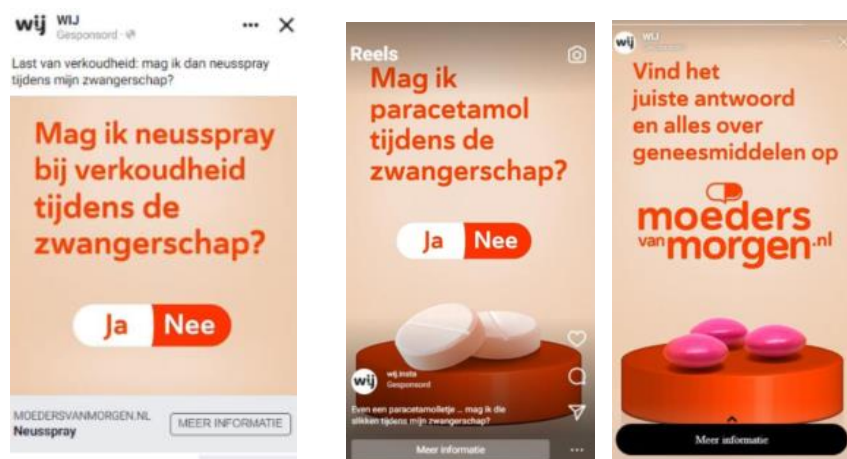
Figure 10; distribution of channels via which women have heard from Moeders van Morgen. ZP = Zwangerenportaal, other commercial parties = Ouders van Nu and WIJ, health caregiver = combination of automatic e-mails, distribution of a flyer/ brochure and verbal information.

#### 4. Social media campaign evaluation

A separate evaluation was conducted on the social media campaign in the period February – July 2022. Using varying (commercial) channels we promoted Moeders van Morgen through social media. Our main channel for recruiting participants through social media was with a commercial partner called WIJ (We, young parents). In cooperation with WIJ we organised three separate social media campaigns, lasting 14 days in February, April and July of 2022. Using the social media accounts of WIJ ( $\approx$  32.2K Instagram followers and 133K likes on Facebook) we especially aimed to reach the target population with four different advertorials (examples are shown below) encouraging women to visit our website. On average the campaigns resulted in over 200.000 views per campaign. The three campaigns led to a total of 2.824 additional website visits from the WIJ social media advertorials, varying from 1.451 visits in the first campaign to 486 visits in the last campaign.

The three campaigns (a total of 6 weeks) led to a total of 36 inclusions, varying from 4.9% of the total inclusions in that period to 14.3% of the total inclusions that could be accounted from WIJ. Since the beginning 2022, we received 142 inclusions through activities from WIJ, representing only 5% of our inclusions in 2022. In the social media campaign weeks, this was an average of 6.0 inclusions per week compared to an average of 4.8 inclusion per week in the non-campaign weeks. Remarkably, the final campaign proved to be most effective campaign since 2.9% of the women visiting our website due to the social media campaign actually participated in the study, compared to an average of 1.3%. Possibly, the more women see and hear about Moeders van Morgen over a course of time (not only on social media), they might be more inclined to participate. In conclusion, the boundary between visiting a study website and actually participating in the study is substantial, therefore, distributing information through various channels over a long period of time could aid to create more awareness.

|   | Campaign 1<br>7 – 20 February | Campaign 2<br>4 – 17 April | Campaign 3<br>4 – 17 July | Total |
|---|-------------------------------|----------------------------|---------------------------|-------|
| Website visits from WIJ                               | 1.451                         | 887                        | 486                       | 2.824 |
| % WIJ visits from total website visits these weeks    | 20.7%                         | 13.6%                      | 12.9%                     | 16.6% |
| Inclusions from WIJ                                   | 16                            | 6                          | 14                        | 36    |
| % WIJ inclusions from total inclusions in these weeks | 8.5%                          | 4.9%                       | 14.3%                     | 8.8%  |
| % Website visits to inclusions                        | 1.1%                          | 0.7%                       | 2.9%                      | 1.3%  |



### Conclusions / lesson learned

The COVID-19 pandemic, or more specific, vaccination against COVID-19 resulted in a huge number of new participants (Figure 9), slightly less than 50% of the women reported (also) to have heard from Moeders van Morgen via the health statement before COVID-19 vaccination (Figure 10).

This means that about 4000 participants entered the study via other routes among which commercial parties. Working with commercial does work, however there are some important points to keep in mind. First, there are high costs related to these parties (see Table 1). Second, direct measuring the effect of campaigns is difficult. For instance a campaign can increase brand awareness, but this is hard to measure, and if a health caregiver subsequently asks a woman to participate she might be more inclined to participate because she already knows the name/ concept. Third, in the Netherlands there are parties exclusively related to pregnancy and newborns but also a party proceeding in childhood (i.e. Ouders van Nu). It seems that collaboration with parties exclusively targeting pregnant women is more successful, probably because less commercial mails with advertisement is send by these parties. Furthermore and probably most important, it seems that everything is a process of giving and taking. Women would like to get information (back) on drug use during pregnancy in exchange for/ before their participation.

Social media campaigns rise awareness, and increases website visits, but only a small percentage actually participates in the register.

Lastly and probably as expected, you need the support of health caregivers. As Figure 10 shows, 40% of the women heard from Moeders van Morgen via their health caregiver, which in the Netherlands are mostly the midwives. Together with (online) marketing this could be the last/ decisive push. It is essential that health caregiver have as little work as possible to invite/ inform a client. This was realized in Moeders van Morgen by embedding semi-automatic invitations within the IT systems. Furthermore health caregiver have free access to information material for the pregnant women



(both recruiting material (flyer) as well as informative material (brochure with common illnesses and allowed/ forbidden drugs). Mainly the brochure answers questions from clients, meaning that these are not asked to healthcare providers. Lastly, they have access to our knowledge bank. All in all, also for health caregivers the process of giving and taking is important to keep in mind.

## Appendix 2

### Introduction

The UK Teratology Information Service (UKTIS) is commissioned by the UK Health Security Agency (UKHSA) to provide expert clinical teratology advice to National Health Service (NHS) healthcare professionals and their patients. This teratology information advice is now primarily provided to service users through online patient information leaflets which are based upon systematic evidence reviews written for healthcare professionals. In addition to this written guidance, the service also operates a telephone advice service through which health professionals can contact experts trained in teratology information counselling for more specific advice.

Healthcare professionals who contact UKTIS may do so for a variety of reasons. These most typically involve discussions of the possible fetal effects of planned or ongoing gestational exposures, usually involving prescription medication use, radiological diagnostic tests or occupational chemicals. Less frequently, healthcare professionals may also contact the TIS to discuss cases where fetuses, neonates or infants are either displaying or have had symptoms consistent with congenital illnesses, attempting to identify or refute casual associations with confirmed gestational exposures. UKTIS also collects data directly from pregnant women via a patient portal that allows women to create a pregnancy record (My *BUMP's* record). The UKTIS teratogen surveillance system therefore consists of three datasets, the first assumes the primary contact scenarios of planned or ongoing gestational exposures and allows for the prospective longitudinal follow-up of pregnancy exposures and outcomes. The second dataset assumes the alternative contact scenario and retrospectively records adverse pregnancy outcomes following documented gestational exposure events. The third is a patient-reported dataset which may contain prospective or retrospective data. For the purpose of this pilot campaign we focused on increasing utilisation of the latter, the *BUMPS* record, as this is a relatively new feature and had limited promotion previously.

### Aims

The key objectives for the external communications (as described in deliverable D5.2) during this pilot campaign were to:

- 1) Raise awareness of UKTIS and *BUMPS* among HCPs
- 2) Increase patient reporting of exposures to UKTIS through a My *BUMP's* Record and HCP reporting via enquiry line
- 3) Increase use of UKTIS and *BUMPS* medicines in pregnancy resources

## Methods

### Audience

Pregnant women were the main target audience for the *BUMPs* promotional campaign (data regarding numbers of pregnant women, at any one time, in the UK is unavailable but there are approximately 700,000 live births/year<sup>1,2,3</sup>) and healthcare professionals who care for pregnant women. Pregnancy is a transient state and therefore we theorised that a dedicated promotional campaign predominantly targeting healthcare professionals who care for pregnant women would be most effective, with the aim that they themselves would report ongoing pregnancies of their patients and/or pass on the information about *BUMPs* and the importance of the registry to their patients.

The HCPs of interest included pharmacists, general practitioners (GPs), midwives and obstetricians. Numbers of each in the UK are difficult to obtain, but figures from the last few years suggest that there are approximately 53,000 midwives, 8,540 obstetricians, 60,630 GPs (those registered on the GMC website) and 72,000 pharmacists registered in the UK.

### Platform for promotion

The *BUMPs* website and patient registry is an established platform launched in the UK in 2014. The website was created due to increasing demand for patient friendly information on the use of medicines in pregnancy and to attempt increased prospective pregnancy data collection.

Written information is provided on the platform as patient leaflets which summarise the scientific literature on individual medicines/vaccines/occupational and environmental chemical exposures that women of childbearing age may be exposed to in pregnancy.

The *BUMPs* website also houses a pregnancy registry which is an online reporting facility which offers all pregnant women (not just those taking certain medicines or whose pregnancies did not result in a healthy baby), or women who have been pregnant in the past, the option to create their own password protected 'My *BUMP*'s Record'. The information requested from women includes medications they were exposed to in pregnancy and at what stage of gestation. Information about their lifestyle, previous pregnancies and any maternal health conditions is also requested.

The *BUMPs* website was designed to be 'sticky'- women search for medicine and chemical information, find the *BUMPs* website patient information leaflets, then hopefully register their pregnancy by signing up for a 'My *BUMP*'s Record'.

### Types of promotion

Drawing on previous experience (PROTECT IMI) we did not attempt to promote and potentially recruit to the *BUMPs* platform using direct-to-participant advertisement methods due to the costs involved and poor take up.<sup>4</sup> The promotional campaign was designed to be no cost to be replicated in full or part by other Teratology Information Services. Such organisations are most commonly government or University funded and employ only a small team of trained experts in the field of teratology. As such there is little budget or staff time for service promotion. International data suggest that 83% of 18-29-year-old people use social

networking sites<sup>5</sup> and therefore a primarily social media focused campaign was undertaken.

The BUMPs/UKTIS Twitter account was chosen as the target social media platform to build awareness of the BUMPs website and patient registry as it is our most well-established social media channel and many HCPs, of the type we were interested in targeting, have active accounts. Automated tweets (posted using a free software account 'Social Oomph' <https://www.socialoomph.com/>) and *ad hoc* Tweets regarding topical issues keep followers engaged with the work of UKTIS. 'Traffic' to the @medsinpregnancy Twitter account has been relatively stable in the years preceding the pilot campaign and therefore provided us with benchmark statistics against which the impact of the campaign could be measured. The UKTIS Twitter account has a mixture of HCPs and patient/general public followers providing a wider audience base than Facebook and Instagram which is predominantly used by patients.

Examples of the types of Tweets used throughout the campaign are shown in Figure 1. These are referred to 'automated', 'Awareness Day' and 'Blog promotion' in the results section.

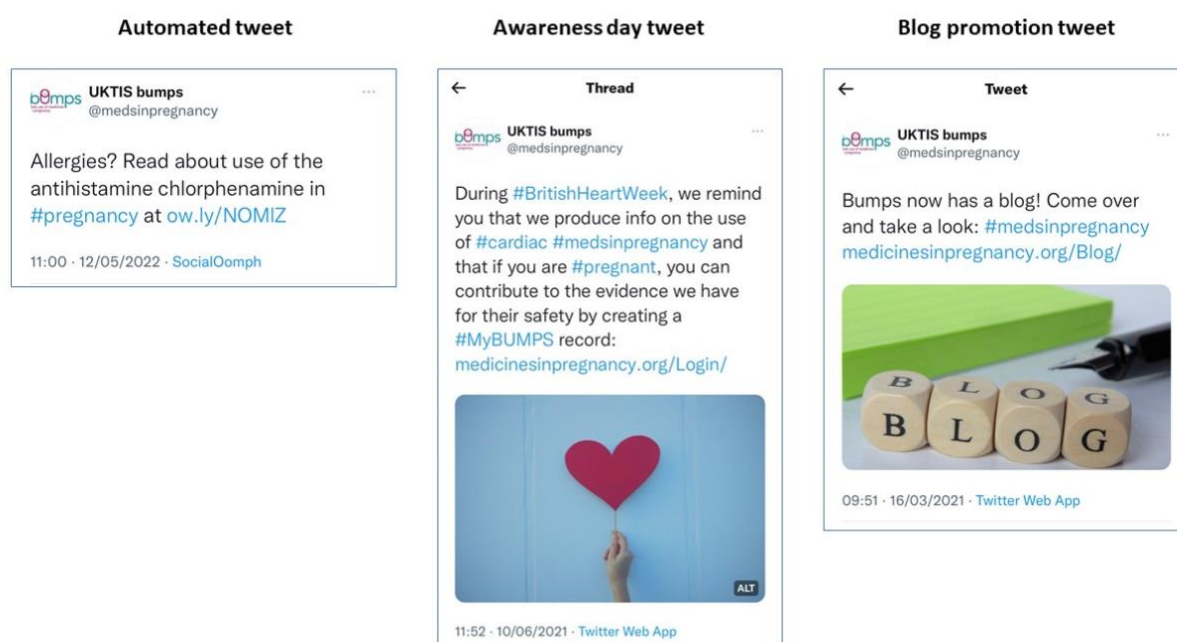


Figure 1: Types of tweet used during campaign.

## Themes

Health awareness days were utilised as 'hooks' for the UKTIS campaign. UK and International awareness days were reviewed in advance and those suitable (health conditions where medicines are used to treat and occur in women of childbearing age) were highlighted for tweets using official hashtags (Table 1). Each tweet included a free image (most of these were obtained from Unsplash <https://unsplash.com/>) and a call to action to register a pregnancy, to read information on the BUMPs website or to watch a video (Figure 2). Where possible we sought involvement from women who had experience of making decisions about medicine use in pregnancy and we acknowledge the help of Katrin and Nikki who provided patient input for the promotional campaign.

Table 1: Health awareness days used in campaign

| Health Awareness days                    | Hashtags used                                   |
|--|---|
| International epilepsy day               | #Internationalepilepsyday, #epilepsy            |
| CHD awareness week                       | #CHDAwarenessWeek, #CHD                         |
| World Birth Defects Day                  | #WorldBDday, #WBDDay, #ManyBirthDefects1Voice   |
| International Women's day                | #BreakTheBias, #InternationalWomensDay2021      |
| World Kidney Day                         | #worldkidneyday                                 |
| British Science Week                     | #BSW21  |
| MS Awareness Week                        | #MSweek, #LetsTalkMS, #MSAwarenessWeek2021, #MS |
| MS Awareness Month                       | #31daysofMS, #MSAwarenessMonth, #MS             |
| UK Maternal Mental Health Awareness week | #maternalmhmatters                              |
| International day of the midwife         | #InternationalDayoftheMidwife, #midwives        |
| Mental Health Awareness week             | #MentalHealthAwarenessWeek                      |
| British Heart Week                       | #BritishHeartWeek, #cardiac, #medsinpregnancy   |
| Diabetes Week                            | #DiabetesWeek2021 #Diabetes                     |
| World Patient Safety Day                 | #WorldPatientSafetyDay2021                      |
| World Prematurity Day                    | #WorldPrematurityDay2021                        |
| World Immunisation week                  | #WorldImmunisationWeek, #vaccines               |



Figure 2: Example of a tweet leveraging health awareness days. Tweet is accompanied by an image and a call to action.

As well as tweets which were related to health awareness days we produced tweets to give information and raise educate and raise awareness of pregnancy pharmacovigilance and teratology (Figure 3). We also used 'hot topics' such as COVID to increase the visibility of our service (Figure 4) . An overview of the timing of tweets (not including automated tweets) is given in Figure 5.

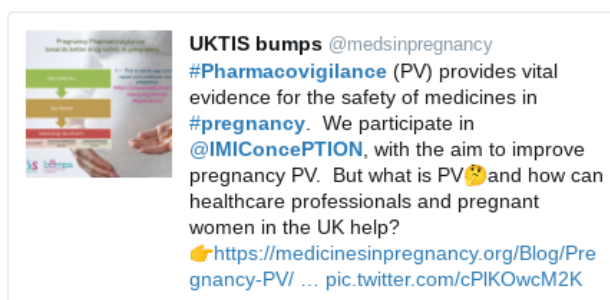


Figure 3: Example of an educational tweet.



Figure 4: Use of 'hot topics' to increase awareness of UKTIS.

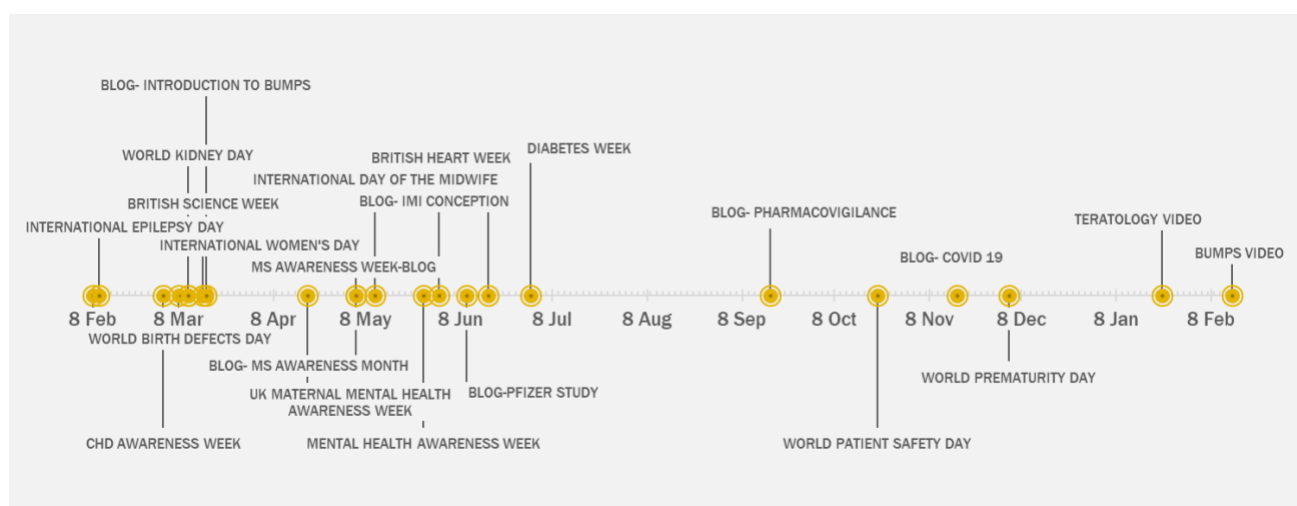


Figure 5: Timeline of Tweets

### Blog posts on BUMPs

Six blog posts (Table 2) were published on the *BUMPs* website over the 12 month promotional period. These were designed to generate awareness of and increase the general knowledge about the safety of medicines used during pregnancy. The blog posts highlighted the work that UKTIS do, the importance of medicines in pregnancy data collection and provided an interview with a woman discussing the experience of having a chronic condition in pregnancy that required drug treatment. Where appropriate, blogs provided details on how to make a My Bump’s Record.

Table 2: Blog posts published on BUMPs website

| Title  | URL   |
|--|---|
| <b>COVID-19 vaccination in pregnancy - 22nd October 2021:</b>  | <a href="https://www.medicinesinpregnancy.org/Blog/COVID-19-vaccination-in-pregnancy/">https://www.medicinesinpregnancy.org/Blog/COVID-19-vaccination-in-pregnancy/</a> |
| <b>Pregnancy Pharmacovigilance: gathering evidence for medicine safety in pregnancy - 30th June 2021</b> | <a href="https://www.medicinesinpregnancy.org/Blog/Pregnancy-PV/">https://www.medicinesinpregnancy.org/Blog/Pregnancy-PV/</a>   |

|   |   |
|---|---|
| <b>Covid-19 vaccine study for pregnant women launches in the UK - 1st June 2021</b>           | <a href="https://www.medicinesinpregnancy.org/Blog/Pfizer-study/">https://www.medicinesinpregnancy.org/Blog/Pfizer-study/</a>   |
| <b>UKTIS participates in collaborative research projects: IMI ConcePTION - 26th May 2021:</b> | <a href="https://www.medicinesinpregnancy.org/Blog/UKTIS-participates-in-collaborative-research-projects-IMI-ConcePTION/">https://www.medicinesinpregnancy.org/Blog/UKTIS-participates-in-collaborative-research-projects-IMI-ConcePTION/</a> |
| <b>Multiple Sclerosis Conversation- 17<sup>th</sup> March 2021</b>                            | <a href="https://www.medicinesinpregnancy.org/Blog/MS-Interview/">https://www.medicinesinpregnancy.org/Blog/MS-Interview/</a>   |
| <b>Introduction to BUMPS- 15<sup>th</sup> March 2021</b>                                      | <a href="https://www.medicinesinpregnancy.org/Blog/15th-March-2021/">https://www.medicinesinpregnancy.org/Blog/15th-March-2021/</a>   |

### Use of Infographics

An infographic (Figure 6) was developed to explain in plain language what pharmacovigilance is. 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 organisations.

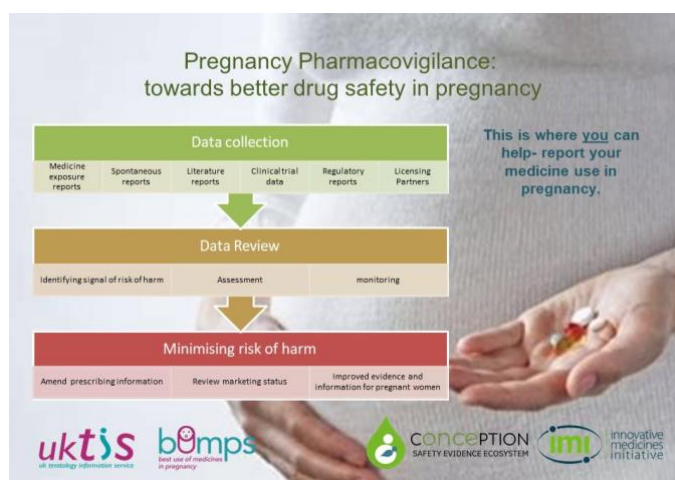


Figure 6: Pharmacovigilance infographic

### YouTube video

A YouTube channel was created for UKTIS ([UKTIS - YouTube](#)) (Figure 7) and a short video was scripted and recorded to explain the purpose of UKTIS and PV reporting and how women can be involved. Another video was recorded showing women how to use the BUMPs pregnancy registry to record their pregnancy. The videos were promoted via Twitter (Figure 8). Both videos were made using free video editing software and used no specialist equipment.

**An introduction to UKTIS and Teratology:** <https://www.youtube.com/watch?v=A8HikhGVHhg>  
**How to make a 'My Bumps' record:** <https://www.youtube.com/watch?v=e3vn2vLu2wQ>

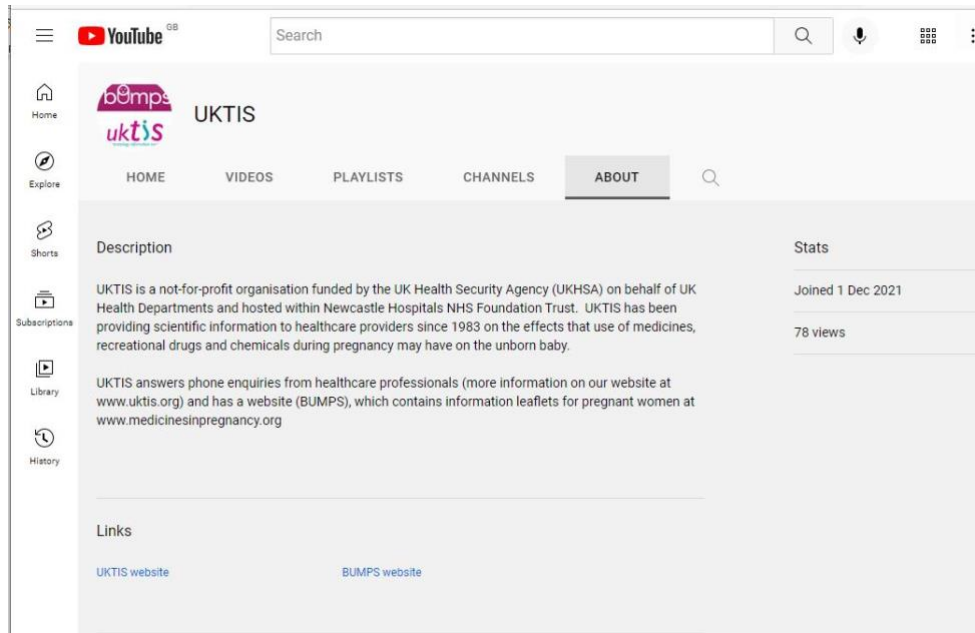


Figure 7: UKTIS YouTube Channel with logo, description and links to UKTIS and BUMPs websites.



Figure 8: Promotion of video on Twitter

#### Adaption of BUMPs leaflets Q&A to promote BUMPs registry

A change to the standard format of our patient information leaflets was made to highlight the BUMPs registry. The following Q. and A. was added to some of the BUMPs leaflets, specifically newer medications, those for which there are limited pregnancy outcome data or conflicting safety information. The Q&A was added in real time as each leaflet was updated and published. Example of the text:



***How can I help to improve drug safety information for pregnant women in the future?***

Our online reporting system offers all pregnant women, and women who have been pregnant in the past, the opportunity to create their own digitally secure ‘my *bumps* record’. You will be asked to enter information about your health, whether or not you take any medicines, and your pregnancy outcome. You can update your details at any time during pregnancy or afterwards. This information will help us better understand how medicines affect the health of pregnant women and their babies. Please visit <https://www.medicinesinpregnancy.org/Login/> to register.

**Acknowledgement of IMI ConcePTION**

The new UKTIS blog and UKTIS videos acknowledged the support of IMI ConcePTION using agreed wording and logos. Where deemed appropriate to the message of the tweet, the IMI ConcePTION Twitter account was tagged (Figure 9).



Figure 9: Example of tweet linking campaign to IMI ConcePTION project.

**COVID-19**

During the promotional campaign UKTIS were involved with the national collection of COVID-19 vaccination exposure in UK pregnant women as part of a UK national surveillance programme, carried out in collaboration with other UK organisations. It was decided not to utilize the *BUMPs* patient reporting portal as this added another layer of complexity to the data collection process, at a time when we needed to analyse data in real time. Women and healthcare professionals were asked to use the UKTIS dedicated telephone line to report COVID-19 vaccine exposures instead.

However, we did increase the traffic to UKTIS and the *BUMPs* websites by the COVID-19 related work that was carried in 2021. This included systematic evidence reviews for the treatment of COVID-19 infection in pregnancy and COVID-19 vaccinations in pregnancy. We also collaborated on a number of infographics directed at pregnant women regarding the risks and benefits of COVID-19 vaccination in pregnancy, and UKTIS created an infographic/flowchart to help HCPs navigate the treatment options available for pregnant women with COVID-19 infection. These products were heavily promoted on Twitter and by other organisations.

We participated in a European study on the effects of the pandemic on pregnant women and promoted the study via our own twitter account. The Royal College of Obstetricians and Gynaecologists (RCOG) agreed to promote this study on our behalf and tagged us in the promotion. This stimulated almost 200 women to participate in the study and it is likely that this also raised awareness of our twitter account, and potentially, our service as a whole.

COVID-19 also led to UKTIS being commissioned by the MHRA to hold an antivirals in pregnancy registry. The UKTIS website and telephone number was heavily advertised, which may also have driven traffic to the *BUMPs* website.

### Measuring Impact of the Promotional Campaign- Key performance indicators

It was envisaged that the promotional campaign would have the effect of raising general awareness of our Twitter account and service as well as a more direct effect of increasing participation in the *BUMPs* pregnancy registry.

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.

## Results

### Twitter engagement

The @medsinpregnancy twitter account gained 232 followers over the campaign period (current following 1,954). This was not significantly more followers gained than in previous years (149 for 2018, 184 for 2019 and 230 for 2020).

The account gained the highest number of new followers (58) in December 2021. The top tweet that month was one promoting data collection for nMABs (now used in the treatment of COVID-19). In addition, our head of service (@ken\_hodson) tagged the account when tweeting about a new quick reference clinical guide for COVID-19 treatment in pregnant women and earned us 4614 engagements.

We also gained a high number of new followers in January 2021 and July 2021(34 and 28 followers, respectively). In both these months we received mentions in relation to COVID-19 from followers with large accounts (in terms of follower number).

Campaign tweets containing media and hashtags relating to health awareness days and tweets advertising our blog posts generally gained more impressions and engagements and had a better engagement rate than automated tweets about patient information leaflets (Table 3). Blog tweets gained more impressions and engagement than awareness day tweets, however there was no increase in engagement rate (number of engagements divided by impressions). According to Twitter, average engagement rate for a tweet is 1-3% and therefore all types of Tweet had an engagement rate within this average range.

Table 3: Comparison of tweet engagement

| Type of tweet              | Impressions (±SD)  | Engagement (±SD)  | Engagement rate# (±SD) |
|----------------------------|--------------------|-------------------|------------------------|
| Automated tweet (no media) | 135.25 (±51.87)    | 1.63 (±2.14)      | 1.075 (±1.36)          |
| Awareness day tweet        | 631.93 (±585.13)*  | 15.87(±17.57)*    | 2.43 (±1.08)*          |
| Tweet promoting blog       | 1438 (±403.15)*, ^ | 38.67 (±9.20)*, ^ | 2.8 (±0.71)*           |

\*p<0.01, compared to automated tweets.

^p<0.01 compared to awareness day tweets.

# According to Twitter, average engagement rate for a tweet is 1-3%

Tweets to promote the UKTIS videos hosted on YouTube generated only very small numbers of video views (51 views for 'An Introduction to UKTIS and Teratology' and 18 views for 'How to make a 'My Bumps' record').

### Traffic to UKTIS and BUMPS websites increased over the campaign period

During the campaign period there was a 34% increase in website traffic to the UKTIS website and 5.8% increase in traffic to the BUMPS website compared to the previous year (Table 4).

Table 4: Visits to UKTIS and BUMPS website

|                | UKTIS     | bumps      |                  |
|----------------|-----------|------------|------------------|
| <b>Year</b>    | <b>n</b>  | <b>n</b>   | <b>Total</b>     |
| <b>2020/21</b> | 894,750   | 1, 848,974 | <b>2,743,724</b> |
| <b>2021/22</b> | 1,199,357 | 1,955,918  | <b>3,155,275</b> |

### Website hits for blog posts on BUMPs website

The blog posts created for the promotional campaign generated a total of >10,000 hits over the year of the promotional campaign (Table 5). 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.

Table 5: Website hits to blog posts on BUMPs website

| Blog post             | Publication date | Total hits 2021/22 | Mean hits/day post publication | Hits in first 7 days |
|-----------------------|------------------|--------------------|--------------------------------|----------------------|
| Introduction to bumps | 15/03/21         | 1,881              | Unknown                        | Unknown              |
| MS conversation       | 17/03/21         | 1,819              | Unknown                        | Unknown              |
| IMI ConcePTION        | 26/05/21         | 1,924              | 6.19                           | 500                  |
| Pfizer study launch   | 01/06/21         | 2,000              | 6.54                           | 702                  |
| Pregnancy PV          | 30/06/21         | 1,420              | 5.11                           | 27*                  |
| COVID-19 in pregnancy | 22/10/21         | 1,129              | 6.84                           | 55**                 |

\*Hits were higher on week 9 (n=111)

\*\* Hits were higher on week 7 (n=409)

### BUMPS pregnancy registry participation increased over the campaign period

January 2021 onwards saw the biggest increase in monthly registry sign ups which we have recorded since the registry was created in 2015 (Table 6 and Figure 10). This increase was larger than the general increase which has been recorded year on year.

Table 6: BUMPs account creation from 2015 to present

| Year | Median (accounts created per month) | IQR      | T-test P-Value | Relative Increase |
|------|-------------------------------------|----------|----------------|-------------------|
| 2015 | 15                                  | 13 to 22 | -              | -                 |

|      |      |               |             |          |
|------|------|---------------|-------------|----------|
| 2016 | 17   | 15.5 to 18.5  | 0.715648497 | 1.133333 |
| 2017 | 22.5 | 21 to 31      | 0.007670151 | 1.323529 |
| 2018 | 28   | 25.5 to 35.25 | 0.160187751 | 1.244444 |
| 2019 | 22   | 18.75 to 28   | 0.056385970 | 0.785714 |
| 2020 | 26.5 | 23 to 31      | 0.137854281 | 1.204545 |
| 2021 | 47   | 44 to 48.5    | 0.000000014 | 1.773585 |

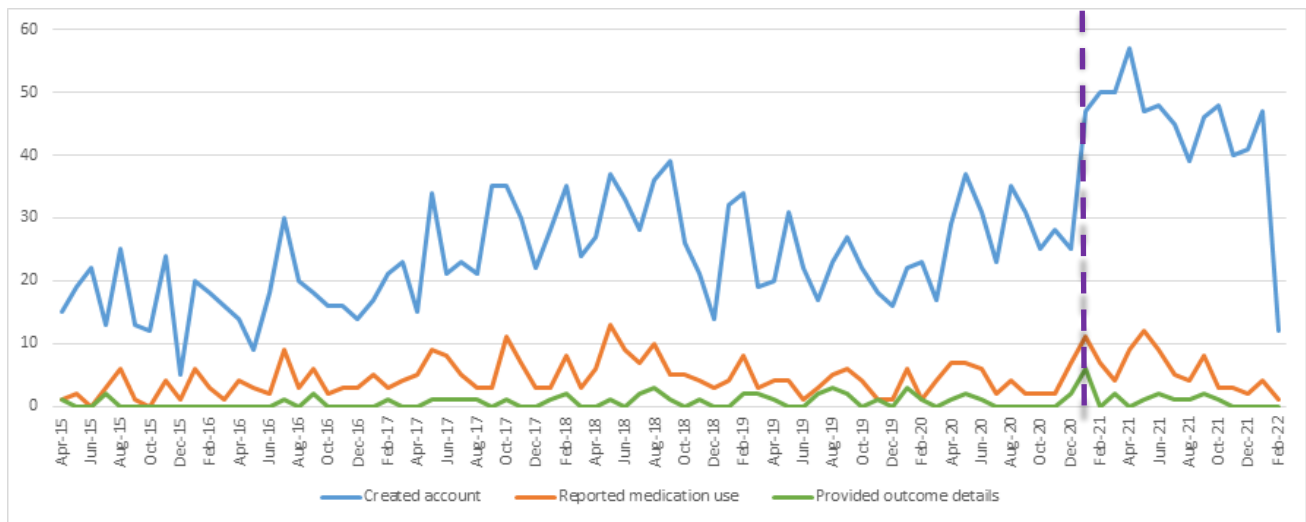


Figure 10: My BUMP's account creation and outcome collection over time. The purple dashed line indicates the start of the promotional campaign

There was a strong positive correlation between the number of Tweet impressions and registry account creations which was only measurable of the day of the tweet (Table 7). This correlation was mainly driven by a tweet promoting the COVID-19 survey which had 13,000 impressions which correlated with 6 new account creations. If these data are excluded, the correlation decreases considerably (Figure 11a&b)

Table 7: Correlation between tweet impression and account creations (within x days of tweet)

|                             | 1d       | 2d       | 5d       | 7d      | 10d      | 14d      |
|-----------------------------|----------|----------|----------|---------|----------|----------|
| Correlation coefficient (r) | 0.352374 | 0.061836 | -0.13867 | -0.0923 | 0.003673 | -0.01095 |

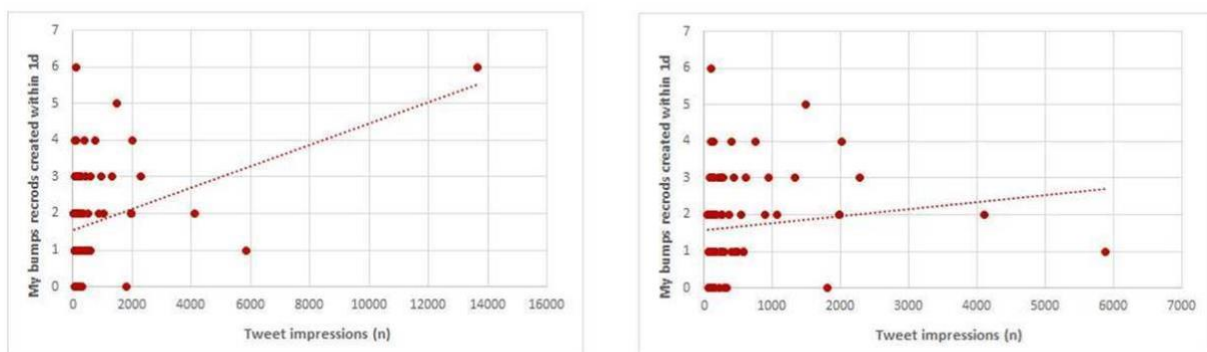


Figure 11. Correlation between tweet impressions and account creations a) with and b) without Covid survey tweet included.

## Discussion

We conducted a low-cost social media-focused campaign which could be replicated in other low-resource settings. Over the duration of the campaign, there was an increase in the level in the rate of engagement with UKTIS resources as well as an increase in the rate of participation in the *BUMPs* pregnancy registry with only a modest increase in Twitter engagement.

Our data show that tweets which contain visual content have significantly greater engagement and those which promote other content (such as the blog) are the most successful (in terms of impressions and engagement). This is consistent with Twitter's own analysis of tweets which showed that tweets with visual content achieve 35% more engagement than those without. Engagement rate for all types of tweet was within the average engagement rate measured by twitter.

While the campaign appears to have been successful in increasing awareness of and interaction with UKTIS, interpretation of the data from this pilot is challenging. COVID-19 represented a significant external factor which may have increased the visibility of UKTIS to HCPs and the general public, independently of the promotional campaign. Nevertheless, our tweets relating to COVID-19 were among the most successful and most widely shared, suggesting that tweeting about current 'hot topics' may be an effective way of increasing engagement.

The video content produced for this campaign could be reproduced in other low resource settings. Although the videos did not achieve many views during the campaign, they represent a lasting resource which may be linked to in the future. Embedding the videos in the *BUMPs* website and further advertisement of the videos on twitter and other social media platforms such as Facebook or TikTok may increase the number of views.

Had more time been available, there are a number of strategies which could have been used to further increase the effectiveness of the campaign and increase engagement with the service as a whole. More effective use of Twitter analytics may have provided us with ways to optimise our campaign. For example, Twitter analytics provides monthly data on the new top follower (new follower with highest number of followers). One strategy to increase visibility might be to directly engage with top followers by tweeting directly at them, thanking them for following, for example.

Throughout the campaign, tweets were generally tweeted only once from the UKTIS Twitter account and then retweeted once from a UKTIS scientist's personal Twitter account. Tweets could have been retweeted more often and at different times of the day (to engage people with different routines). More than one tweet with different messaging could have been utilised for each of the awareness days. We also did not use any paid features of Twitter, paying for certain posts to be promoted could be a way of achieving more impressions and potentially gaining new followers.

Around 24% of people (primarily those aged 25-34 years) in the UK use Twitter therefore more broad use of social media could have been considered. Use of Facebook, Instagram, and newer platforms such as TikTok may have improved the reach of our messaging and helped us reach people of different age demographics. Use of LinkedIn may also have increased our engagement with healthcare professionals.

## Conclusion

A low-cost promotional campaign may be useful to increase awareness of teratology information services

and increase participation in reporting. Whilst COVID-19 represented a major global event which may have independently contributed to the increase in engagement with UKTIS, it also represented an opportunity to our promotional campaign. A number of lessons have been learnt regarding optimal use of social media and these insights will contribute to development of the promotional toolkit for dissemination to other organisations.

## References

1. [Births in England and Wales - Office for National Statistics \(ons.gov.uk\)](https://ons.gov.uk)
2. [Births in Scotland | National Records of Scotland \(nrscotland.gov.uk\)](https://nrscotland.gov.uk).
3. [Monthly Births | Northern Ireland Statistics and Research Agency \(nisra.gov.uk\)](https://nisra.gov.uk)
4. Richardson et al, 2016. [An International Study of the Ability and Cost-Effectiveness of Advertising Methods to Facilitate Study Participant Self-Enrolment Into a Pilot Pharmacovigilance Study During Early Pregnancy. - Abstract - Europe PMC.](#)
5. Duggan M, Brenner J. *The Demographics of Social Media Users*. Vol. 14. Washington: Pew Research Center's Internet and American Life Project; 2012; 2012. Suite 800. [[Google Scholar](#)]

### Appendix. 3. Survey among the TIS centres for wp 5.3

Question 1. Which TIS are you associated with? - required

- Buenos Aires
- Sydney
- Graz
- Porto Alegre
- Rio de Janeiro
- Zagreb
- Odense
- Helsinki
- Lyon
- Paris-CRAT
- Paris-HSVP
- Berlin
- Ravensburg
- Jerusalem
- Zerifin
- Bergamo
- Firenze
- Padova
- Roma
- Tokyo
- Saint Petersburg
- Barcelona
- Madrid
- Lausanne
- 's-Hertogenbosch
- Istanbul
- Izmir
- Trabzon
- UK Newcastle upon Tyne

Question 2. Does your TIS have the capacity to take more enquiries/collect more pregnancy outcome data? - required

- Yes
- No

Question 3. If yes, would you be interested in being provided with information and resources about how to promote your service to clinicians and members of the public? - required

- Yes
- No
- Not applicable

Question 4. Do you currently promote your TIS to general public/healthcare professionals? - required

- Yes
- No

Question 5. If you promote your TIS which methods do you use?

- Twitter
- Facebook
- Instagram
- LinkedIn
- Tik Tok
- YouTube
- TV/Radio
- Leaflets/posters
- Internet platform/TIS website
- Lectures/training for clinicians and prescribers
- Academic publications
- Newsletters
- Other



Question 6. How can we help you promote your TIS? What resources, information and advice would be useful?

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Question 7. Do you signpost any other organisations/reporting systems which collect medicines exposure data in pregnancy? Please give details.

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