PHIRI
Population Health Information Research Infrastructure

# Perinatal Health Case Study Report

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# Executive summary

**Context**

The COVID-19 pandemic adversely affects pregnancy outcomes when pregnant women and their newborns are infected by the SARS-CoV-2 virus. Adverse perinatal outcomes may also be indirect and occur because of disrupted healthcare provision and increased stress, anxiety and economic hardship linked to COVID-19 disease or to lockdown and other mitigation measures.

While clinical studies provide reliable evidence of the direct effects of COVID-19 on pregnancy outcomes, surveillance and analysis of maternal and newborn health indicators at the population level are essential for investigating the pandemic's indirect effects. Having comparable data from different countries enhances the relevance and value of a population approach because outcomes can be contrasted by the level of circulation of the virus as well as varying societal mitigation policies. Data from different countries can also be combined to more rapidly detect signals of adverse effects for uncommon outcomes.

As part of the PHIRI (Population Health Information Research Infrastructure) project, we (1) assessed the availability of population data on maternal and newborn health in Europe for the evaluation of the impact of the COVID-19 pandemic; (2) developed a protocol to facilitate the exchange of data in Europe based on a federated analytical model and (3) implemented this protocol to assess changes in perinatal outcomes in 2020 in comparison to previous years.

**Methods**

The Euro-Peristat Network (https://www.europeristat.com/index.php), which includes experts from 31 European countries (clinicians, epidemiologists and statisticians working with routine birth data), carried out two surveys to assess (1) availability and timeliness of population birth data in Europe and (2) relevant indicators for evaluating the indirect effects of the pandemic to determine the overall feasibility of this approach and the availability, quality and comparability of the data.

The results of these two surveys were used to develop a common data model and R scripts to facilitate the rapid exchange of anonymised aggregate tables and analysis results from routine population-based sources for the years 2015 to 2020. The methodology was based on the approach developed for the four use cases in Work Packages 6 and 7 of the PHIRI project. An initial set of core items were tested in this first phase, which was constrained by a total implementation period of 18 months. Aggregated output tables were compiled to produce national and European results on core perinatal health outcomes. Data collection and validation is still on-going in some countries.

Based on these aggregated tables and analytic results, we compared preterm birth, stillbirth, neonatal death and caesarean delivery rates in 2020 to 2015-2019 for 2 periods: full-year (FY) and pandemic (March-September [MS]). Data from October onward were not included in the MS period because potentially declining pandemic-related fertility may affect perinatal indicators. Country-specific relative risks (RR) for the periods, adjusted for linear trends, overall and by socio-economic (SES) group, were calculated and pooled using random effects meta-analysis. Time series models (autoregressive integrated moving average (ARIMA) models) using monthly data were used to validate the FY and MS models for key perinatal outcomes.

**Results**

The first survey on data availability and timeliness (published as an open access commentary in the *BJOG, https://obgyn.onlinelibrary.wiley.com/doi/10.1111/1471-0528.16946*) found high heterogeneity across Europe, with final data for the year 2020 becoming available in March 2021 and only half of countries having final data by September 2021. Preliminary data on the first lockdown period (through April 2020) were available for about half of countries by November 2020. Countries using medical registers as their data source were more likely to have timely access to preliminary data. Codes indicating COVID-19 infection (ICD-10 mainly) were included in population data sources in less than 60% of countries, while 25% could add codes with linkage and 23% could not include them.

The second set of surveys made it possible to select and to define the data items included in the common data model. A core model including 26 variables, based on the Euro-Peristat core indicators and socioeconomic indicators, was specified for the testing phase. Consensus was obtained on 17 additional variables, which were considered important and feasible for a second phase, leading to a final expanded common data model with 39 variables. The definitions for some of the variables in the expanded model require validation before implementation. The core data model and the R scripts for producing the aggregate tables are available as open source files (https://zenodo.org/record/6483177).

The model was implemented in 25 countries that were able to create patient-level data files. Most countries had 20 or more of the data items, whereas 1 had 18, 3 had 16 and 2 had 15 variables. Limiting factors included not having all data in a single database, most often the case for neonatal and infant mortality and mode of delivery, and the diversity or absence of data on socioeconomic status. Setting up the model could be time consuming (up to two weeks of work), but once established, running and updating R scripts was easy and quick (<15 min). The protocol requires the active participation of each country to ensure it is properly applied and several iterations were often required to resolve inconsistencies.

This report provides descriptive data on trends over time between 2015 and 2019 in participating countries and estimates deviations from expected trends in 2020 using various models. While this analysis is still on-going, this report illustrates the wealth of data that can be collected by this protocol. In terms of number of events, at this stage of the data collection process, data are available on over 23 million births, 1.2 million singleton preterm births, 100,000 stillbirths and 30,000 neonatal deaths. These data demonstrate the complexity of analysing the pandemic in Europe, as large variations exist in both the rates of key indicators and the trends over time between European countries. To assess the impact of the pandemic, it is essential to be able to estimate the expected outcomes in the absence of the pandemic, which requires an accurate depiction of underlying trends and involves model building adapted to each country's context.

Preliminary results about perinatal outcomes in 2020 are reassuring in most countries, showing stable trends. However, some results are puzzling and cause for concern. A first finding is that some countries experienced significant declines in singleton preterm birth rates of between 4% and 8%. The second is that stillbirth rates increased in some countries with declining preterm births rates, as well as in other countries with changes of similar magnitude. The next steps of the analyses involve refining these estimates, pooling them using meta-analysis techniques and quantifying between-country heterogeneity. This will be followed by analyses that integrate information on pandemic indicators (hospitalisations, deaths, confinement stringency indices) using meta-regression. Final analyses will compare estimates and models across socioeconomic groups.

**Conclusion and recommendations**

This use case on perinatal health illustrates the feasibility of using federated analysis of anonymous aggregated data tables to facilitate rapid production of data and subsequent analysis of key perinatal health indicators in a large number of European countries. The successful implementation of this model has implications for future pandemic research and provides a roadmap for a health information system to monitor and evaluate the health of European pregnant women and their newborns.

The study's results were reassuring with regard to birth outcomes in 2020 in a majority of countries. Observed decreases in preterm birth rates may be the result of healthcare disruption if medically indicated preterm births for pregnancy complications were not carried out, which could have delayed adverse effects on perinatal mortality and morbidity and therefore continued surveillance is essential. Other hypotheses to explain observed decreases in preterm birth rates focus on potentially positive effects of lockdowns, illustrating the complexity of balancing positive with negative indirect effects of the COVID-19 pandemic mitigation strategies in heath assessments. The high country-level heterogeneity between European countries in perinatal outcomes associated with the pandemic suggests that some government policies to mitigate the pandemic may have been more protective of pregnant women and newborns than others. Understanding these differences and identifying relevant policy determinants of this variation is important for continued management of the COVID-19 pandemic and for future infectious disease outbreaks.

A final set of conclusions and recommendations address preparedness for a future pandemic. This use case developed a set of indicators, including an expanded list of indicators, for a pandemic response system using birth data in Europe which was considered feasible in at least half of participating countries and which would enable a greater focus on healthcare effects. Testing this expanded model is an important next step. Action is also needed to improve national data sources. Despite very promising results regarding the rapid transfer and synthesis of data at the European level in this study, population birth data sources in Europe face major limits in a pandemic due to slow processing and missing data items in some countries. Some countries also experienced institutional constraints which precluded participation in data collection. For this reason, reliable results about the pandemic's impact can only be provided for the period of March to September of the year 2020. Priority areas for improvement include modernising the transfer of birth data, linkage of population birth data sources, including with infectious disease databases, and streamlining processes to allow more timely data production.

## Key points

*This study illustrates the feasibility of a federated approach for the rapid production of data and subsequent analysis of key perinatal health indicators in a large number of European countries.*

*This model provides a roadmap for a health information system to monitor and evaluate the health of European pregnant women and their newborns. These results can also elucidate capacity building priorities in countries that could not provide data or did not have all items in the common data model.*

*Overall, the key perinatal health indicators in many European countries did not show major changes in 2020 despite the disruption to health care and normal daily life due to the COVID-19 pandemic. However, available data only allow reliable analyses of the period from March to September of 2020 and continued surveillance is required.*

*During this period, the preterm birth rates decreased by between 4 to 8% in some countries, which may reflect restricted health care provision and fewer medically indicated births or other potentially positive indirect effects of the pandemic (for example, more rest, less pollution). In contrast, several countries had significant increases in stillbirth rates and slight increases were observed in a larger number of countries. Pooling these effects on the European level and exploring the underlying reasons for the heterogeneity in observed trends in 2020 are planned in future analyses.*

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# PHIRI: Perinatal health use case

## I. Rationale and aims

### A. Context

**Pregnant women and newborns constitute vulnerable populations in an infectious disease pandemic**

During an infectious disease pandemic, pregnant women and newborns are vulnerable because of the specific characteristics of their immune systems, their non-deferrable needs for health services, the effects of environmental factors on their health - notably the influence of social circumstances on morbidity and mortality risks - and the long-term consequences of adverse health events.

The novel coronavirus, SARS-CoV-2, exposed weaknesses in our health systems' capacities to respond to pandemics, as evidenced both in the management of patients with COVID-19, but also, more broadly, in the care of non-COVID-19 diseases. Maternity care, which brings low-risk populations into contact with the health system on a regular basis, is particularly challenging. Quality care relies on regular, routine contacts with health providers because of the difficulties of distinguishing life-threatening complications from unremarkable, everyday symptoms. Further, hospital admission for childbirth, often in emergency conditions, cannot be avoided.

Containment strategies for SARS-CoV-2 resulted in severe restrictions and changes to normal everyday life, raising hardship and anxiety in families related to their personal safety and their economic livelihoods. Family units were called upon to play a central role in the fight against the virus. Beyond the changes in care seeking patterns, stress and anxiety, which have been shown to influence perinatal complications[1], could lead to increases in adverse outcomes such as preterm birth, restricted growth and maternal complications. Economic hardship is associated with indicators such as stillbirth rates and infant death rates,[2] but underlying mechanisms remain poorly understood.

**Population data are required for research on the health of pregnant women and newborns, but are not readily available**

To investigate the direct (due to infection by SARS-CoV-2) and indirect (due to health system or other changes related to the pandemic) effects of the COVID-19 on maternal and newborn health, large, population-based data are needed. Many studies have assessed the impact of COVID-19 on pregnancy complications and newborn health and of maternal-newborn transmission. These have been essential for guiding obstetric and neonatal care during the pandemic.[3] However, these cohorts focus on women and newborns presenting with symptoms of infection or who test positive and therefore cannot respond to broader questions about how the pandemic affects population health.

Data have also been produced on the indirect effects of the COVID-19 pandemic, although because of delays in the production of health data, these were not available for most of 2020.[4] Further delays occur as this information is synthesised in reviews, although this began in the latter part of 2021.[5,6] Assessments from routine birth data are needed to evaluate perinatal risks, including preterm birth, stillbirth and neonatal and infant mortality. Initial synthesis of this evidence has shown high heterogeneity between countries, with some experiencing increases in certain adverse outcomes, such as stillbirth, whereas elsewhere some negative outcomes, such as preterm birth, have decreased.[5,6]

The comparison of geographic and temporal distributions of perinatal health outcomes, taking into consideration differential secular trends, is essential to produce actionable knowledge about the impact of the COVID-19 pandemic on perinatal health. Further, a pan-European approach, assessing effects in multiple settings, enables testing of the association between viral circulation and societal mitigation measures in a wide-range of settings, which is vital for understanding underlying causal mechanisms and the potential effectiveness of social or health service interventions.

**The PHIRI project: an opportunity to bring together data on maternal and newborn health**

PHIRI (Population Health Information Research Infrastructure) is a Health Information project on COVID-19 financed by the European Commission to support research across Europe through the identification, access, assessment and reuse of population health and non-health data to underpin (public health) policy decisions on COVID-19 and future health crises. PHIRI was launched in November 2020 and includes 41 partners in 30 different countries. The aim is to share data and expertise between countries through a Health Information portal on population health in close interaction with key stakeholders in the health information landscape, notably the ECDC, EUROSTAT, JRC, OECD, and WHO.  A broader goal of the PHIRI project is to structure sustainable and reactive health information systems in Europe. Work package 6 within the PHIRI project conducts research of immediate relevance for public health policies and management of the COVID-19 pandemic using a federated model, making it possible to share data rapidly and securely. One of the four use cases in this work package is on “the impact of COVID-19 on perinatal health and perinatal health inequalities” and is piloted by the Euro-Peristat Network.

## B. Aims

The main aim of the use case on perinatal health is to investigate the indirect effects of the COVID-19 pandemic on pregnant women and newborn health using data collected routinely on births in European countries. Secondary objectives are to examine the use of population birth data for assessing the direct effects of infection and to promote sustainable European health information systems by structuring data collection and reporting to improve data availability and timeliness to guide national and European policy.

Principal objectives are to:

1. Investigate principal maternal and newborn health outcomes in relation to population-level temporal and geographic exposure to the COVID-19 pandemic. We will distinguish between countries and time periods by the intensity of viral circulation and the restrictiveness of social measures and confinement orders.
2. Assess the impact of social and geographic factors on these effects by integrating individual or area-based socioeconomic indicators within this broader exposure framework to identify at-risk groups based on social context.

Secondary objectives are to:

1. Assess the timeliness and completeness of routine birth data for evaluating exposures and outcomes relevant for the evaluation of this and future pandemics and make recommendations for how to improve routine birth data to provide actionable data for future epidemics.

2. Assess the capacity of the federated data collection model to improve European-level health information systems and to provide data on perinatal health to inform policy and practice nationally and on the European level.

## C. State of the art

**Despite a vastly expanded evidence-base since November of 2020, many questions remain**

Since the PHIRI project was proposed in November of 2020, the scientific literature about maternal and child outcomes associated with COVID-19 has grown substantially. As an illustration, a PubMed search on terms related to perinatal health and childbirth and the COVID-19 pandemic[1] yields over 13,000 hits of which 10,500 have been published since November 2020. Synthesis of this literature in systematic reviews contributes to an increasingly solid evidence-base about how the COVID-19 pandemic has affected the health of pregnant women and their fetuses and newborns. Yet despite this prolific literature, many questions remain. This literature has also illustrated the methodological challenges involved in accurately identifying health risks due to the pandemic. Population birth data, covering large populations and using harmonised methods, are still urgently needed to understand the impact of this pandemic.

**Direct effects of COVID-19 on maternal and newborn health: research using population birth data is needed, but methodological issues constrain quality and comparability**

Multiple studies show that infection with SARS-CoV-2 can have grave health consequences during pregnancy for both mother and baby, by increasing risks of maternal intensive care admissions, indicated preterm birth and pregnancy complications such as preeclampsia.[7] Stillbirth and infant admission to the neonatal intensive care unit are also higher for pregnancies in which the woman is infected with COVID-19 versus those without COVID-19. Furthermore, this disease burden is unequally distributed, with stark socioeconomic inequalities in infection and disease severity among pregnant women.[8] Thankfully, however, risks to pregnant women are lower than in previous SARS outbreaks,[9] maternal-fetal transmission, although possible, is not common[10] and most babies born to mothers with COVID-19 have good outcomes.[11]

Initially, most knowledge about these risks came from single-centre studies, with small sample sizes and poor external validity, but the number of multi-centre and population-based studies has increased. The regCOV-19 Living Systematic Review Consortium instituted an on-going systematic to evaluate and synthesise this voluminous and growing literature.[3] The most recent update in May 2022 includes 435 studies (293,152 pregnant and recently pregnant women with COVID-19). Bringing together these studies is essential for evaluating less common events, trends and evaluating risk factors. However, limits persist. For instance, the results on stillbirths and neonatal mortality are based on 351 stillbirths and 127 neonatal deaths occurring to women with COVID-19 from 102 and 100 studies, respectively, corresponding to less than 4 stillbirths and about 1 neonatal death, on average, in the exposed group per study.

Most studies in this living review are hospital cohorts, illustrating difficulties in using routine population-based data to describe risks of COVID-19. Routine databases have the potential to be more representative and have greater precision because of large population-based sample, but this

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[1] ((covid OR SARS-Cov-2 OR coronavirus) AND (postpartum OR maternal OR pregnancy OR perinatal OR newborn OR infant OR neonatal OR fetal OR stillbirth OR preterm OR prematurity OR cesarean OR caesarean OR childbirth)). Results: 13,284 of which 10,466 results since November 2020, on prematurity/preterm: 1,408/1,144 since November

depends on the presence and quality of COVID-19 codes. A recent study from a large US data warehouse concluded "that one-in-five COVID-19 cases would be missed by using ICD-coded diagnoses alone to identify COVID-19 during pregnancy".[12] Routine systems linked to other databases can overcome these limits[13] and allow full investigation of short and long-term outcomes.[14] Other issues relate to the presence (or absence) of systematic testing policies for COVID-19 which has a major impact on the number of women coded as having COVID-19. At least three-quarters of infections at delivery were asymptomatic in first assessments of early COVID-19 variants.[7] The high percentage of asymptomatic cases will lead to differential exposure misclassification linked to testing practices. Other methodological issues are also of concern, notably, immortal time bias, i.e. women with a COVID-19 diagnosis after 37 weeks of gestation are no longer at risk of preterm birth, but are often included in studies assessing these risks when time-invariant measures of exposure are used.[15]

**This use case on perinatal health focused principally on the indirect effects of the pandemic because of the complexity of evaluating direct effects in a comparable way using population birth data. However, we gathered information on availability of codes for COVID-19 in these datasets.**

**Research on the indirect effects of the pandemic: essential questions for shaping and evaluating pandemic strategies now and for the future**

Two main pathways exist for potential indirect effects. The first arises from the disrupted provision of antenatal and maternity care. Reluctance to go to the hospital may lead to delayed responses to danger signs during pregnancy, for instance. Use of telemedicine increased with potential (negative and positive) consequences for antenatal care.[16] Furthermore, confronted with uncertainty about the transmissibility of SARS-Cov-2, health providers adopted multiple approaches to reduce risks during childbirth and the postpartum, some of which had adverse psychosocial and health consequences (separation of mothers and babies, restriction of breastfeeding, systematic caesarean).[17]

The second pathway is the impact of societal mitigation measures on wellbeing, the activities of daily life, economic security and the broader environment. These measures could in turn impact outcomes though stress and anxiety, which rose among pregnant women.[18,19] Many perinatal outcomes such as preterm birth have been related to stress and anxiety, making this a plausible concern.[1] The lockdowns may also have had some positive effects for pregnant women, such as more rest and less exposure to pollution. Indirect effects are likely to be socially patterned. In general, most adverse pregnancy outcomes are more common among socially disadvantaged women.[2] The mechanisms underlying these effects are not well understood, but they are dynamic as shown by rises in stillbirth and infant mortality during economic downturns.[20]

**Research on the indirect effects of the pandemic: a natural experiment yielding insight into the causality of perinatal pathology and impact of health services on health outcomes**

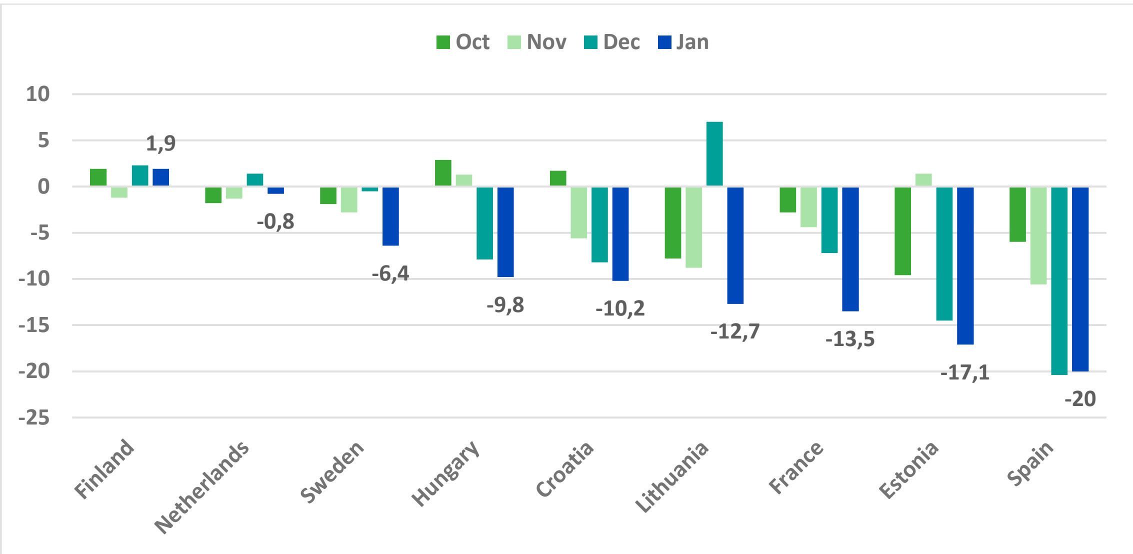
Counter to expectations of adverse effects, studies documented a possible reduction in population preterm birth rates during the lockdown.[6] Starting with small Danish and Irish studies in the fall of 2020,[21,22] the literature on COVID-19 and preterm birth decreases has burgeoned. This interest stems from the major public health impact of preterm birth, linked to three-quarters of infant deaths, and the fact that its aetiology remains largely unknown. Hypotheses to explain a decrease are that restricted access to medical care reduced indicated preterm births (about one-third of the total) or that there was a positive impact of rest or of lessened exposure to environmental pollutants[23] or other viral infections during the lockdowns.

Systematic reviews of these studies have reported ORs for PTB reductions in high-income countries of about 0.91 (95% confidence intervals (CI): 0.84-0.99, 12 studies published before 8 January 2021[5]) and 0.94 (95% CI: 0.91–0.98, 28 studies published before 14 May 2021). However, heterogeneity is substantial in both reviews[6] and the second review found no difference for population-based studies (OR 0.99, 95% CI: 0.95–1.03, 8 studies). Since these reviews, studies continue to report conflicting results, with a majority finding decreases[24-29], but notable exceptions, including for a multi-country Nordic study.[30]

Some studies have reported higher stillbirth rates, which would be expected if preterm birth rates were decreasing because of fewer medical induction, but this research is less extensive and also shows mixed results.[6,29,31-34] Almost no studies have explored neonatal mortality or morbidity.

**Changes in fertility and impact on assessment of perinatal health outcomes**

Literature is starting to emerge on the impact of the pandemic on fertility and childbearing patterns.[35] Understanding changes in fertility is essential for evaluating the impact of COVID-19 on population health outcomes because many of the adverse outcomes in pregnancy occur before term. Therefore, if the number of conceptions decreases, rates will be distorted because the numerator (for example the number of preterm births, early stillbirths and neonatal deaths) will be from cohorts conceived during the pandemic while the denominator (all births) will be from a pre-pandemic cohort. Declining fertility will make it appear as though preterm birth rates are declining or underestimate the impact of increases in stillbirth. This is a complex topic which has not been taken into consideration in most studies and is subject to high inter-country variability, as shown in Figure 1 constructed using data from a recent study.[35] The births in January 2021 principally resulted from conceptions during the lockdowns starting in mid-March. This figure shows striking differences in fertility reduction in Europe, with the largest reduction in Spain and no or minimal reductions in Finland and the Netherlands. The other important message from this recent study is that we are still waiting for 2021 data in many countries and therefore this effect cannot yet be described everywhere.




NOTE: Data from National Statistical Offices, abstracted from Sobotka et. al.[35] (page 33).

*Figure 1 Percent differences in births in 2021 compared with the same months in 2020 for selected European countries*

**The evaluation of adverse perinatal outcomes after October 2020 must consider potential distortions in health indicators due to changes in the number of conceptions. Starting in October, preterm births and early stillbirths (numerator) were conceived during the lockdowns, whereas term births (main component of the denominator) were from pre-pandemic conception cohorts. If fewer babies are conceived, this will lead to lower preterm birth and stillbirth rates, purely because of the pandemic cohort's smaller size.**

# II. Approach

## A. Data sources and hubs: the Euro-Peristat Network

This project differs from the other use cases as it is conducted by the Euro-Peristat Network, a European surveillance and research network. The objective of the Euro-Peristat Network is to establish a high quality, innovative, internationally recognized and sustainable European perinatal information system. This system's goal is to produce data and to conduct analyses on a regular basis for use by national, European and international stakeholders who make decisions about the health and health care of pregnant women and newborns.

Euro-Peristat began in 1999 as part of the EU's Health Monitoring Programme and currently has official representation from 31 countries across Europe, with a large network of contributing experts. The on-going project builds on the Euro-Peristat list of recommended indicators for perinatal health surveillance which have been used to collect data for European Perinatal Health Reports in 2008, 2013 and 2018 and in many scientific publications (see www.europeristat.com). The project is coordinated by Inserm, the French National Institute of Health and Medical Research, in Paris.

The data sources used by the Euro-Peristat network are: birth registers, hospital discharge data, vital statistics, civil registration and cause of deaths statistics. When more than one source includes the data used to construct the indicators, each country team decides which is best able to produce high quality and comparable indicators corresponding to Euro-Peristat definitions.

*Table 1 Principal data sources for the Euro-Peristat network*

| Country | Data sources |
|---|---|
| Austria | Birth statistics (Statistics Austria)<br>Cause of death statistics (Statistics Austria) |
| Belgium | Vital Statistics, Statistics Belgium (Statbel) |
| Bulgaria | Vital Statistics (National Statistics Institute)<br>National birth register (National Center for Public Health and Analysis) |
| Croatia | Croatian Medical Birth Database (Croatian Public Health Institute),<br>Croatian Mortality Database (Croatian Central Bureau of Statistics) |
| Cyprus | Birth register (The Health monitoring Unit, Cyprus Ministry of Health)<br>Death Register (The Health monitoring Unit, Cyprus Ministry of Health) |
| Czech Republic | Institute of Health Statistics and Information of the Czech Republic (national birth register (mothers and newborns) collecting individual perinatal data.) |

| | |
|---|---|
| Denmark | Medical birth register (The Danish Data authority, Danish Ministry of Health)<br>National patient register (The Danish Data authority, Danish Ministry of Health)<br>Danish causes of death register (The Danish Data authority, Danish Ministry of Health)<br>The Centralized Civil Register |
| Estonia | Estonian Medical Birth Register (National Institute for Public Health)<br>Estonian Cause of Death Register (National Institute for Public Health)<br>Report of a health care institution on maternal deaths and child health (Health statistics Unit, National Institute for Public Health) |
| Finland | Medical Birth Register (Finnish Institute for Health Welfare) linked with Central Population Register (Digital and Population Data Services Agency) and Cause of Death Register (Statistics Finland)<br>Register on Induced Abortions (Finnish Institute for Health Welfare) for late terminations 22-24 weeks |
| France | PMSI (ATIH: Technical agency of hospitalization information) |
| Germany | IQTIG (Federal Institute for the Quality of Medical Care)<br>Destatis (Federal Statistical Office) |
| Greece | Hellenic Statistical authority |
| Hungary | Hungarian Central Statistical Office |
| Iceland | The Icelandic Birth Registration Hospital register (National University Hospital) |
| Ireland | National Perinatal Reporting System (the Healthcare Pricing Office) |
| Italy | Birth certificates (Ministry of Health)<br>Causes of deaths (Istat)<br>Terminations of pregnancies (Istat)<br>Miscarriages (Istat) |
| Latvia | Newborn Register of Latvia (Centre for Disease Prevention and Control of Latvia)<br>Register of Causes of Death (Centre for Disease Prevention and Control of Latvia) |
| Lithuania | Medical Date of Births (Institute of Hygiene Health Information Centre)<br>Database of the Demographic Statistics (Central Statistical Office)<br>Causes of Death register (Institute of Hygiene Health Information Centre) |
| Luxembourg | Perinatal Health Monitoring System (Luxembourg Institute of Health) |
| Malta | National Obstetrics Information System (Directorate for Health Information and Research)<br>National Mortality Register (Directorate for Health Information and Research)<br>Disease Surveillance Database |
| Netherlands | Perined (The Netherlands Perinatal Registry) |
| Norway | Medical Birth Register of Norway (The Norvegian Institute of Public Health) |
| Poland | Central Statistical Office<br>Ministry of Health |
| Portugal | Instituto Nacional de Estatística – Portugal (Statistics Portugal)<br>Central Administration of the Health System |
| Romania | National Institute for Public Health Romania |
| Slovakia | National health information center (NCZI)<br>Statistical Office (SR) |

| | |
|---|---|
| Slovenia | Perinatal information system (National institute of public health) |
| Spain | Vital Statistics  (National Statistics Office) |
| Sweden | Medical Birth Register (The National Board of Health and Welfare) |
| Switzerland | BEVNAT, statistics of natural population change - vital statistics (Swiss federal Statistical Office) |
| UK, Northern Ireland | Northern Ireland Maternity System - NIMATS (Department of Health) |
| UK, Scotland | Scottish Morbidity Record 02 (maternity hospital discharge record) National Records of Scotland Stillbirth, live birth, and infant death registrations (statutory vital event registration) |
| UK, England and Wales | UK, Office for National Statistics (Live birth and stillbirth registration in England and Wales, notification of births in England and Wales) |
| UK, England | Maternity Hospital Episode Statistics |
| UK, Wales | Digital Health and Care *Wales* |
| UK, all countries | MBRRACE UK (University of Oxford and University of Leicester) |

**Euro-Peristat (www.europeristat.com) is a network for the surveillance and evaluation of maternal and newborn health in Europe. Started in 2000 as part of the European Health Monitoring Programme, it periodically collects data on 10 core and 20 recommended perinatal indicators. The network includes participants from 31 countries.**

## B. Surveys on the availability of population birth data and relevant indicators

We carried out two surveys with members of the Euro-Peristat Network to establish the study's protocol and the common data model and, more broadly, to describe the capacity of population birth data in Europe for evaluating the SARS-CoV-2 and future pandemics. These surveys differed from those used in the other use cases because the data hubs within the network were already established and information on sources and core indicators was available from previous reports.

The first survey assessed the timeliness of population birth data in Europe for evaluating the COVID-19 pandemic. An online survey was sent to participating countries asking about the timing for availability of preliminary and verified finalised birth data for constructing the Euro-Peristat core perinatal health indicators (including stillbirth, neonatal mortality, preterm birth, low birthweight and caesarean rates) for births from (1) January to April 2020 and (2) all of 2020. We also enquired about whether codes had been added to birth data to indicate COVID-19 infection. The initial survey was sent to network members over the summer of 2020 (as the PHIRI study protocol was being developed) and then updated in November-December (after the PHIRI study was approved).  In this update, we collected information about data linkage and disruptions to reporting systems.

The second survey was a three-round on-line consensus process to clarify which indicators were relevant for assessing the impact of the COVID-19 pandemic, in particular for assessing health service use. As a starting point for this process, we developed three lists of indicators, those:
(1) utilised in the literature on COVID-19
(2) proposed in recent reviews of indicators for assessing maternal and newborn care
(3) derived from a European study on maternal and newborn health based on WHO standards

For the COVID-19 literature, we based our methodology on a review article (Kotlar and al, Reprod Health, Jan 2021, "The impact of Covid-19 pandemic on maternal and perinatal health: a scoping review") which included all articles through September 2020. We used their search terms to extend the search through January 2021. For the second list, we identified recent systematic reviews of health care indicators for maternity care.[36-38] Finally, the third list was derived from questions included in surveys for women and health care professionals as part of the IMAGINE EURO project (Improving MAternal Newborn carE in the European Region). As part of this process, we invited Marzia Lazzerini from the WHO Collaborating Centre for Maternal and Child Health at the Institute for Maternal and Child Health IRCCS Burlo Garofolo, who was in charge of the IMAGINE EURO project, to speak at a meeting in March 2021.

## C. Use case C protocol for federated analysis

The methodology for the use cases follows the common PHIRI roadmap, which involves processing outputs in an interoperable way by formalising data models, data management processes and analytical pipelines. These are part of the client-server PHIRI federated infrastructure (see: 10.5281/zenodo.6483177). Within PHIRI, WP7 (leader: Enrique Bernal Delgado, Instituto Aragones De Ciencias De La Salud) is responsible for creating and validating this infrastructure.

The full protocol for use case C is provided in Appendix 1.

### 1. Common data model

The common data model was based on Euro-Peristat recommendations for the collection of perinatal health indicators in Europe.

**Study population**: Euro-Peristat uses the following criteria for selecting births for data collection: all births (live, stillbirths and terminations of pregnancy) with a gestational age greater or equal to 22+0 weeks or with a birthweight greater or equal to 500 grams if gestational age is missing. If countries are unable to follow this definition, national definitions can be used and are noted.

**Study period**: The study covers all births from 2015-2020. Having data over several previous years is necessary for assessing changes during the pandemic in 2020, since baseline trends in rates need to be established in order to distinguish differences due to the pandemic. Previous research in the network has documented substantial heterogeneity across Europe in trends over time in key perinatal health outcomes.[39] Collecting data from 2015 onwards also allows cross-checking with the last data Euro-Peristat collection exercise, conducted in 2015. For the present study, data were collected by year and additionally by month, as monthly data were needed to model the exposure periods of interest and to adjust for seasonality in birth outcomes.

**Data items:** A first stage Common Data Model was developed based on the Euro-Peristat core indicators, which are those considered most important for monitoring maternal and newborn health and which are most feasible. By selecting this set, we aimed to test the feasibility of the protocol in the most geographically comprehensive set of countries. An Expanded Common Data Model was defined for development in a future stage based on the results of the second survey on relevant indicators, described above. In addition to the core data items, time stamps (year, month, day) were added to allow for time trend analyses. Socioeconomic variables, which could be provided as individual level data (maternal education or parental occupation) or small area based socioeconomic scores depending on their availability in individual countries, were also included in order to evaluate social disparities, which was a study objective. The protocol stipulated that data on maternal education would be collected if this were available and on either parental occupation or area-based deprivation scores if education was not available. Maternal education is a good marker of socioeconomic status and has been associated with perinatal outcomes in most studies. Previous work in the Euro-Peristat Network has harmonised the coding of this variable.[40] The data items needed to construct the core indicators included in the common data model are listed in Table 2.

All of the Euro-Peristat core indicators, with the exception of maternal mortality, were included in this protocol. Maternal mortality is a very rare outcome (<10/100,000) and therefore is not suitable for this approach. Furthermore, enhanced data collection procedures are needed to ensure data quality.[41]

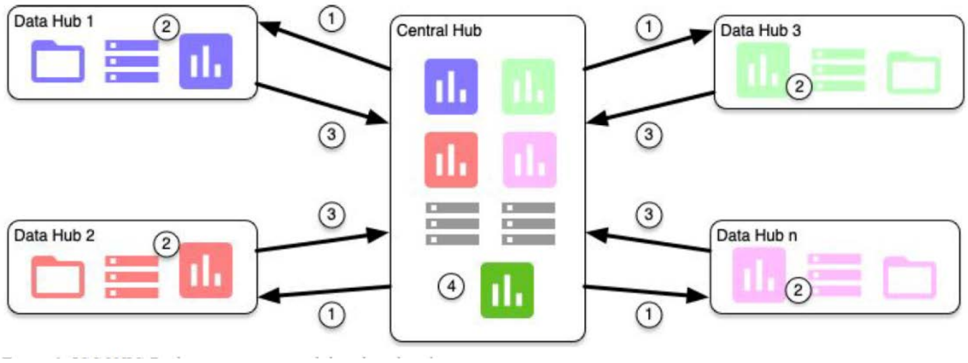
*Table 2 Data items included in the Common Data Model*

| *Label of variable* | **Description** |
|---|---|
| *baby_id* | baby identifier |
| *Mother* | mother identifier |
| *GA* | gestational age |
| *BW* | birthweight at delivery |
| *SEX* | sex of baby |
| *MULT_B* | type of pregnancy |
| *VITAL* | vital status at birth |
| *NNM* | mortality in first month |
| *NNM_pre* | mortality in first week |
| *IM* | mortality in first year |
| *MATAGE_B* | maternal age at the birth of the baby |
| *PARITY_B* | parity |
| *PRES* | presentation of the baby at delivery |
| *PREVCS* | previous caesarean delivery |
| *MOD* | mode of delivery |
| *TYPECESAR* | type of caesarean |
| *INSTRUMENT* | instrumental delivery |
| *ONSET* | mode of onset |
| *COUNTRY* | country |
| *Year* | year of the birth |
| *Month* | month of the birth |
| *Day* | day of the birth |
| *SES_ED* | education of the mother |
| *SES_OccM* | occupation of the mother |
| *SES_OccF* | occupation of the father |
| *SES* | deprivation score of area of residence |

## 2. Framework for federated analysis

The protocol used for data collection and transfer is based on the framework proposed in WP7 and is implemented using R open software. The data collection protocol uses a federated model, whereby individual patient data (personal data), including outcomes and exposures, are not transferred from the institution with authorisation to hold and analyse them. Rather, only anonymous, aggregate data on indicators and results of statistical analyses are collected by each country and then provided to the Euro-Peristat coordination team.

Figure 1 illustrates the data collection process. Data Hubs are the participating institutions in each country which host and curate data and/or obtain access to the individual-level data in accordance with local security and other legislation. To ensure that personal data is not transferred, data providers within Data Hubs (authorised data controllers within their institutions) run the R scripts themselves and inspect the outputs before the files are transferred to the Central Hub (Inserm) or made available in the Docker application. Output files include anonymous aggregate data tables or the results of analyses. The protocol also includes making the data model and scripts (inspected and pre-tested by all participants) publically available.




NOTE: *figure from 1 Gonzalez-Garcia J, et al. Archives of public health. Dec 9 2021;79(1):221.*[42] *(1=the coordination hub sends processing instructions/scripts, 2=the data hubs run the analysis; 3=results are returned to the coordination hub and 4 = these are combined in the final analysis).*

*Figure 2. Architecture for exchanging data - hub-central hub*

To ascertain that the exported aggregate data tables were in line with the GDPR's definition of anonymous data (Recital 26), we assessed "whether a natural person is identifiable" by taking account "of all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly." In the absence of any personal data included in the files, this means ensuring that the data tables should not include any indirectly identifying personal information that would enable identification through linkage to other sources. To ensure this, the following rules are applied: (1) Output files only include aggregate data tables, with a maximum of 3 cross-tabulated variables; (2) Aggregate data files cannot be linked to each other to augment the number of data items available, even in the case of a cell size of 1 individual because the data items included in the tables do not overlap; (3) No dates (except year) or location identifiers (except country) are used in aggregate cross-tabulated tables with small cell sizes (3) Month is only used for aggregated indicators (4) All sociodemographic characteristics (age, parity, socioeconomic status) are exported in grouped categories.

## 3. R scripts and output files

The R scripts produce three main outputs. The first is an HTLM page for internal use and checking of data to control data quality which includes information on the variable types, the missing values, outlying values, duplicated observations and provides the minimum, maximum, mean and quartiles of numerical variables. Each data hub uses this file to verify the data collection process and it is not collected by the central coordinating team.

The second are the outputs files in csv format which are transferred to the central hub and combined for the main analyses. Depending on the availability of the variables in the common data model, 9 or 10 csv files are produced which provide perinatal indicators by sub-group, yearly and by month. These outputs are in the form of aggregate tables (tabulation of cell frequencies) as well as results (coefficients and standard errors) from regression analyses (see annex to protocol for the full list of data tables).

A final output uses R Markdown to produce an HTML page with the summary of the results. These results include the principal perinatal indicators by year over the study period, graphs of trends over time in key indicators by month and outputs of the regression analyses.

The final R-scripts are available at https://zenodo.org/record/6483177

## 4. Data collection and transfer

The federated model for the PHIRI use cases provides two approaches for collecting and transferring data. The first approach involves bilateral, direct communication and exchange between the data hub and the central hub or coordination team, while the second involves installation of a customised application in the national server that produces outputs available to hubs that have installed the application.

**Bilateral exchange between the hub and central coordination team:** Because of the timeline of the PHIRI use cases (data collection was simultaneous with development of the data collection and transfer application) and because many of the Euro-Peristat data hubs are not part of the PHIRI project, this use case mainly utilised the first method, illustrated in Figure 2. This figure describes the process of exchange between Inserm and the data hub. This process was flexible and iterative, allowing for on-going adjustments of the scripts to integrate country-specific considerations as necessary.

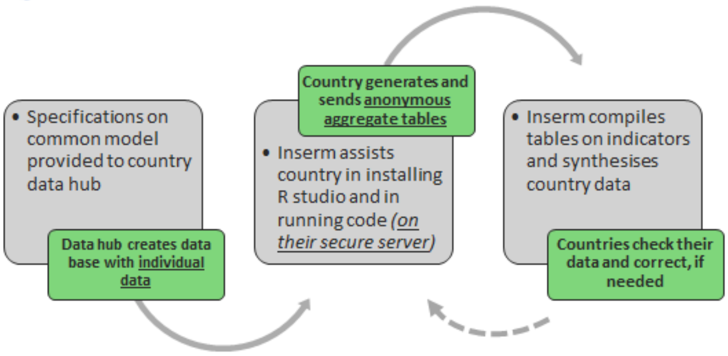



*Figure 3 Federated data collection and exchange between the data hub and coordinating team*

**Use of the PHIRI docker application:** The WP7 team created an application that implements the data collection protocol in a federated environment. This application, installed and tested in several countries, produces the same outputs as the model described above and is illustrated in Figure 3..

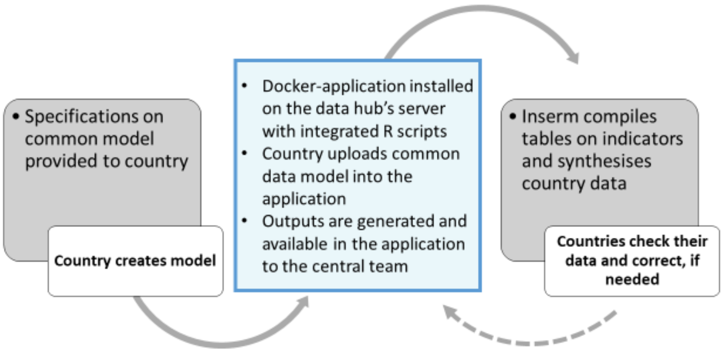



*Figure 4 Federated data collection and exchange using the Docker application*

## 5. Data cleaning and validation

The first step of the data cleaning and validation process is to verify data completeness and accuracy at data collection. An initial data check is completed automatically with the R scripts (HTML page created for quality control; see section C above). The data provider can also check the aggregate data tables (in CSV format) for verification before they are transferred.

After the data are returned to the coordination team, several additional steps ensure data quality. First, the coordination team performs validation checks, including internal validation by verifying the percentage of missing data and consistency across indicators as well as external verification with data collected previously (2015 data) and other sources, notably Eurostat. At this stage, any queries are sent to national teams. Second, summary data tables are sent to the data providers from each country to be checked for accuracy and validated. The consortium's publication guidelines require checking and endorsement of data tables before publication in reports or scientific articles. Finally, during network meetings, data are presented and reviewed to compare results between countries and detect and investigate outliers. During the PHIRI study, 15 meetings (11 plenary meetings and 4 working group meetings) were held to discuss the study protocol and preliminary data. An average of 40 people participated in plenary meetings and 30 people in working group meetings (see Appendix for dates and list of meetings).

## 6. Analysis strategy

The analysis strategy was developed prior to data collection and informed the data collection protocol. It involved the following steps:

1 Analysis of key perinatal health outcomes by year using the Euro-Peristat core output tables to establish whether the year 2020 differs from previous years (2015-2019) and to determine background rates and trends.

- Key outcomes are defined as preterm birth, stillbirth, neonatal death and caesarean delivery rates.
- Euro-Peristat output tables require collecting the Euro-Peristat core indicators by relevant sub-categories
- For key indicators, measuring differences in 2020 using regression analyses, adjusting for age and parity

2 Analyses using monthly rates and specific periods in 2020, including (i) all of the post-pandemic period and (ii) country-specific lockdown periods, if relevant. Lockdown periods will be defined using the ECDC database: (https://www.ecdc.europa.eu/en/publications-data/download-data-response-measures-covid-19 ) and other data available in the public domain on the pandemic and societal mitigation measures.

3 Sub-group analyses to investigate outcomes within specific sub-groups, notably by sociodemographic characteristics to answer the research questions about social disparities in pandemic effects.

# III.Results

## A. Process related results: population birth data availability and indicators

### 1. First survey: data availability and timeliness

Twenty-seven countries and the constituent nations of the UK provided data for the first survey on data availability and timeliness. The results were published as an open access commentary entitled "Population birth data and pandemic readiness" by the Euro-Peristat network in the BJOG,[4] available at https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1111/1471-0528.16946 and is attached as Appendix 3.

This survey revealed difficulties in providing timely population birth data in most countries. Only about half of countries were able to access preliminary birth data relevant to the first lockdown period, which we defined in the survey as January through end of April 2020, by November of 2020. About 40% only had data in March 2021 or later (see Figure 1 in Appendix 3). Final data for the year 2020 was available starting in March 2021, with half of countries having data by September 2021. In the survey, we differentiated between civil registration data and medical registers or hospital discharge databases. For preliminary data, medical registers provided more rapid access that civil registration data. The study also revealed disruptions related to the pandemic in many countries which could impact quality or completeness, particularly for preliminary data. Disruptions mainly resulted from personnel shortages and the prioritization of activities related to the pandemic over routine data tasks.

An update about the availability of 2021 data among 19 contributors to the project presented in Table 3 confirms the estimates of these time lags.

*Table 3 Availability of final population birth data for 2021*

| Country | Timing of availability of finalised data |
|---|---|
| Austria | July 2022 |
| Croatia | Preliminary data by end of June 2022; Final data by end of October 2022 |
| Cyprus | First trimester of 2023 |
| Denmark | End of May 2022 |
| Finland | Preliminary in June 2022; Final data in October 2022 |
| Hungary | By about September 2022 |
| Ireland | Q1 2023 |

| | |
|---|---|
| Italy | TOPS and miscarriages: July 2022 (maybe provisional data); Infant deaths: Dec 2023 (final data); Birth certificates Dec 2022 (final data) |
| Latvia | May 2022 |
| Lithuania | November/December 2022 |
| Luxembourg | September 2022 |
| Netherlands | Exact time to be determined at the beginning of Q4 2022. |
| Norway | Most data available in June 2022; Complete data around September 2022 |
| Scotland | October/November 2022 |
| Slovenia | July/August 2022 |
| Spain | Preliminary data in December 2022; Complete data in March 2023 |
| Sweden | December 2022 |
| Switzerland | Mid-July 2022 for civil registration data; maternal health data in November 2022 |
| UK : MBRRACE | Planned December 2022 |

The other focus of the survey on data availability was the use of COVID-19 codes to identify infections in population birth data. Identifying COVID-19 infection among pregnancy women and their newborns is necessary for monitoring outcomes associated with infection and for exploring indirect effects when the prevalence of infection is high. We found that 16 (53%) of participating countries had ICD or other local codes for COVID-19 already in birth data (either directly or because linkage was carried out). In an additional 5 (17%) countries, linkage was planned to registers containing data of people with COVID-19 infection. Hoiwever, in 9 countries (30%) this was not planned – and was considered impossible in 7 of the 9. COVID-19 codes were more likely to be included in medical registers than civil registration data.

## 2. Second survey: indicators for measuring the pandemic's effects

This survey was accomplished as a three-round consultation process; 44 people participated in the first round, 37 people from 22 countries in the second round and 39 people from 29 countries in the third round. The survey allowed us to identify a set of indicators in addition to the Euro-Peristat Core indicators to be used for evaluating the impact of the pandemic. These include indicators that are already part of the Euro-Peristat recommended indicators or new indicators which were proposed and operationalised as part of the DELPHI process. The results from the three rounds of the survey are provided as Appendix 4.

The set of indicators, core and expanded, is shown in Table 4. This table also shows which Euro-Peristat indicators were not retained in this process and adds indicators related specifically to COVID-19 exposures. The expanded indicators focus on healthcare services and utilisation (transfer of the baby to a neonatal intensive care unit or the mother to an adult intensive care unit), length of postpartum stay and level of care and size of the hospital of birth), morbidities (Apgar, maternal pregnancy complications and morbidities), maternal risk factors such as maternal body mass index and on breastfeeding.

At the end of this consensus process, 17 variables were added to the core common data model to create an expanded version, as shown in Table 5. However, in comparison to the core elements which are available in almost all participating countries, most items are available in about half to two-thirds of countries. Given the short timeline, the group's desire to include as many countries as possible and concerns about resources and time given the absence of funding for this work in most of these countries, a decision was made to implement the core common data model first. However, this process provides a roadmap for a second phase which should be explored in future work.

*Table 4 Euro-Peristat Core and Expanded (recommended and new) indicators for assessment of the COVID-19 pandemic*

| | **PHIRI core common data model** | **Items considered relevant and feasible for an expanded common data model** | |
|---|---|---|---|
| Data category | Core indicators (number) | Recommended indicators (number) | New indicators |
| Newborn health outcomes | Stillbirth (C1)<br>Termination of pregnancy (C1)<br>Neonatal death (C2)<br>Infant death (C3)<br>Birth weight (C4)**<br>Gestational age (C5) | Apgar (R2) | Transfer to NICU<br>Neonatal morbidity<br><br>For C4: it was decided to modify the definition to include small for gestational age (requires data on sex of baby) |
| Maternal health outcomes | | Maternal morbidity (R6* however, individual items are redefined)<br>Hysterectomy associated with obstetrical haemorrhage<br>RBC transfusion associated with obstetrical haemorrhage<br>Eclampsia<br>Transfer to ICU | Gestational diabetes<br>Preeclampsia |
| Population risk factors | Multiple pregnancy (C7)<br>Maternal age (C8)<br>Parity (C9) | Body mass index, BMI (R12)<br>Distribution of mother's place of birth (R8)<br>Distribution of mothers' education (R9)<br>Distribution of households' occupational classification (R10) | SES – deprivation score |
| Health care/medical practices | Mode of delivery (C10) by all sub-groups<br>Induction of labour** | Induction of labour (R15)<br>Place of birth (R16)<br>Breastfeeding at birth (R20) | Postpartum hospital stay (mother) |
| COVID exposures | | | Date of birth (to be linked to information on infection and societal mitigation measures)<br>COVID infection (ICD or other code)<br>Geographic location (NUTS) |
| Euro-Peristat indicators not currently included in data collection | Maternal mortality (C6) | Congenital anomalies (R1)<br>Fetal and neonatal deaths due to congenital anomalies (R3)<br>Cerebral palsy (R4) | |

| | | | |
|---|---|---|---|
| | | Maternal mortality by cause (R5)<br>Tears to the perineum (R7)<br>Mother's country of origin (R11)<br>Pregnancies following subfertility treatment (R13)<br>Timing of 1st prenatal visit (R14)<br>Very preterm infants delivered in units without NICU (R17)<br>Episiotomy (R18)<br>Births without obstetric intervention (R19) | |

*<500g; 500-999g; 1000-1499g; 1500-2499g; 2500-4499; 4500g+; Unknown

**Spontaneous onset of labour ; induction of labour by medical or surgical means prior to the onset of labour; prelabour caesarean; Unknown

*Table 5 Data items in the Expanded Data Model*

| Label of variable | Description |
|---|---|
| APGAR | 5 minute Apgar score by gestational age |
| PREPREG_BMI | Mother's prepregnancy BMI |
| BREASTFED_BIRTH | Breastfeeding at birth |
| COUNTRY OF BIRTH | Maternal country of birth |
| MAT_MORB_HYST | Severe maternal morbidity (hysterectomy associated with obstetrical hemorrhage) |
| MAT_MORB_TRANS | Severe maternal morbidity (red blood cell [RBC] transfusion associated with obstetrical haemorrhage) |
| MAT_MORB_ECLAMPSIA | Severe maternal morbidity (eclampsia) |
| MAT_MORB_ICU | Severe maternal morbidity (transfer to ICU) |
| DEL | Volume of deliveries of the birth place |
| NICU_ADM_TERM | Term babies admitted to NICU |
| NEONAT_MORB | Neonatal morbidity based on ICD-10 codes |
| DIAB_PREG | Diabetes in pregnancy |
| PREECLAMP | Preeclampsia |
| PPSTAY | Length of postpartum stay |
| COVID | Covid infection at delivery (use of ICD or other code) |
| VACCINATION | Whether Covid-19 vaccinations were received |
| NUTS 2 | EU geographic region |

**The second survey, a three-round consultation process with participation of representatives from 30 countries, identified core and expanded data models for evaluating the COVID-19 pandemic. The expanded model includes information on health services use, morbidities and maternal characteristics. The network decided to focus on the core data set for this project because of the short time period and limited resources.**

## 3. Participation in the PHIRI protocol

At the time of the writing of this report, 25 countries had implemented and validated the common data model and data had been provided by 23, as shown in Table 6. Table 7 provides the sources and person responsible for the data collection in each data hub. In the UK, national data as well as data from individual countries of the UK have been provided (Scotland, Wales) or are being prepared (Northern Ireland). All countries, except for two, had data for 2020.

The reasons that countries could not participate are diverse, including limits in terms of time available due to the COVID epidemic and resources. Note that the majority of Euro-Peristat data hubs are not partners to the PHIRI project and did not have person time allocated to this task. In some countries, bringing together all needed data into one database is complex and requires negotiation between institutions. Further, finding a contact in the national data system who can implement the model is a constraint.

*Table 6 Participating countries and availability of 2020 data*

| Data collection status | Data 2020 available | Data 2020 not yet available |
|---|---|---|
| Data tables and results received | Austria<br>Cyprus<br>Croatia*<br>Czechia<br>Denmark<br>Estonia<br>Finland*<br>France#<br>Italy#<br>Latvia*<br>Lithuania<br>Luxembourg<br>Malta<br>Netherlands<br>Norway<br>Portugal<br>Poland<br>Slovenia<br>Spain<br>Switzerland<br>UK: MBRRACE<br>UK: Scotland<br>UK: Wales | Belgium<br>Ireland |
| In progress: testing carried out, individual dataset in preparation | Germany (dataset ready)<br>Sweden (dataset ready)<br>UK-Northern Ireland | |
| Not submitted data (negotiations on-going with institutions to compile data or time or organizational obstacles) | Bulgaria<br>Greece<br>Hungary<br>Iceland<br>Romania<br>Slovakia* | |

NOTE: * institution is participating in the PHIRI project # for France, 2018-2020, other data in progress; for Italy, infant and neonatal deaths are up to 2019

Table 7 Data hubs providing data for the Use Case C

| Country | Data sources | Data provided by |
|---|---|---|
| Austria | * Birth statistics (Statistics Austria)<br>* Cause of death statistics (Statistics Austria) | * Jeanette Klimont/Statistics Austria |
| Belgium | * Vital Statistics, Statistics Belgium (Statbel) | * Gisele Vandervelpen/Statbel |
| Bulgaria | * Vital Statistics (National Statistics Institute)<br>* National birth register (National Center for Public Health and Analysis) | |
| Croatia | * Croatian Medical Birth Database (Croatian Public Health Institute),<br>* Croatian Mortality Database (Croatian Central Bureau of Statistics) - | * Željka Draušnik/Croatian Institute of Public Health |
| Cyprus | * Birth register (The Health monitoring Unit, Cyprus Ministry of Health)<br>* Death Register (The Health monitoring Unit, Cyprus Ministry of Health) | * Theopisti Kyprianou/Health Monitoring Unit, Ministry of Health |
| Czech Republic | * Institute of Health Statistics and Information of the Czech Republic (national birth register (mothers and newborns) collecting individual perinatal data.) | * Jitka Jirova/Institute of Health Information and Statistics of the Czech Republic |
| Denmark | * Medical birth register (The Danish Data authority, Danish Ministry of Health)<br>* National patient register (The Danish Data authority, Danish Ministry of Health)<br>* Danish causes of death register (The Danish Data authority, Danish Ministry of Health)<br>* The Centralized Civil Register | * Anne Vinkel Hansen/ Statistics Denmark |
| Estonia | * Estonian Medical Birth Register (National Institute for Public Health)<br>* Estonian Cause of Death Register (National Institute for Public Health)<br>* Report of a health care institution on maternal deaths and child health (Health statistics Unit, National Institute for Public Health) | * Liili Abuladze/Estonian Institute for Population Studies |
| Finland | * Medical Birth Register (Finnish Institute for Health Welfare) linked with Central Population Register (Digital and Population Data Services Agency) and Cause of Death Register (Statistics Finland)<br>* Register on Induced Abortions (Finnish Institute for Health Welfare) for late terminations 22-24 weeks | * Mika Gissler/National Institute for Health and Welfare (THL) |
| France | * PMSI (ATIH: Technical agency of hospitalization information) | * Annick Vilain/DREES |
| Germany | * IQTIG (Federal Institute for the Quality of Medical Care)<br>* Destatis (Federal Statistical Office) | *…../IQTIG |
| Ireland | *National Perinatal Reporting System (the Healthcare Pricing Office) | * Karen Kearns /Healthcare Pricing Office |
| Italy | * Birth certificates (Ministry of Health)<br>* Causes of deaths (Istat)<br>* Terminations of pregnancies (Istat)<br>* Miscarriages (Istat) | * Marzia Loghi / Italian National Institute for Statistics-ISTAT |

| | | |
|---|---|---|
| Latvia | * Newborn Register of Latvia (Centre for Disease Prevention and Control of Latvia)<br>* Register of Causes of Death (Centre for Disease Prevention and Control of Latvia) | * Irisa Zile / The Centre for Disease Prevention and Control of Latvia |
| Lithuania | * Medical Date of Births (Institute of Hygiene Health Information Centre)<br>* Database of the Demographic Statistics (Central Statistical Office)<br>* Causes of Death register (Institute of Hygiene Health Information Centre) | * Jelena Isakova / Institute of Hygiene, Health Information Centre |
| Luxembourg | * Perinatal Health Monitoring System (Luxembourg Institute of Health) | * Audrey Billy / Department of Population Health, Luxembourg Institute of Health |
| Malta | * National Obstetrics Information System (Directorate for Health Information and Research)<br>* National Mortality Register (Directorate for Health Information and Research)<br>* Disease Surveillance Database | * Miriam Gatt / Directorate for Health Information and Research |
| Netherlands | * Perined (The Netherlands Perinatal Registry) | * Lisa Broeders / Perined |
| Norway | * Medical Birth Register of Norway (The Norvegian Institute of Public Health) | * Rupali Akerkar / The Norvegian Institute of Public Health |
| Poland | * Central Statistical Office<br>* Ministry of Health | * Katarzyna Szamotulska/ National Research Institute of Mother and Child |
| Portugal | * Instituto Nacional de Estatística – Portugal (Statistics Portugal)<br>* Central Administration of the Health System | * Carina Rodrigues / Institute of Public Health of the University of Porto |
| Slovenia | *Perinatal information system (National institute of public health) | * Ivan Verdenik / University Medical Centre, Research Unit |
| Spain | * Vital Statistics (National Statistics Office) | * Adela Recio Alcaide/ Cuerpo Superior de Estadísticos del Estado and Oscar Zurriaga/ Public Health and Addictions Directorate, Generalitat Valenciana |
| Sweden | * Medical Birth Register (The National Board of Health and Welfare) | * Karin Kallen / The National Board of Health and Welfare |
| Switzerland | * BEVNAT, statistics of natural population change - vital statistics (Swiss federal Statistical Office) | * Tonia Rihs / Swiss Federal Statistical Office |
| UK, Northern Ireland | * Northern Ireland Maternity System - NIMATS (Department of Health) | * Sinead Magill / Northern Ireland Maternal And Child Health (NIMACH) |
| UK, Scotland | * Scottish Morbidity Record 02 (maternity hospital discharge record)<br>* National Records of Scotland Stillbirth, live birth, and infant death registrations (statutory vital event registration) | * Kirsten Monteath / Public Health Scotland |
| UK, England and Wales | *UK, Office for National Statistics (Live birth and stillbirth registration in England and Wales, notification of births in England and Wales) | * Hannah McConnell/ Office for National Statistics |
| UK, England | *Maternity Hospital Episode Statistics | *Adam Mitchell / NHS Digital |
| UK, Wales | *Digital Health and Care *Wales* | *Mark Piper /Digital Health and Care *Wales* (*DHCW*) |

| | | |
|---|---|---|
| UK, all | * MBRRACE UK (University of Oxford and University of Leicester) | * Lucy Smith / University of Leicester, MBRRACE collaboration |

## 4. Availability of variables in the common data model

Figure 5 illustrates the availability of data in the common data model for the countries whose data could be assessed. About half of the counties could provide all of the 22 required items in the common data model and a large majority could produce 20 or more of these items. Three types of data were most often missing: neonatal and infant mortality (in blue), mode of delivery (in red) and socioeconomic status (in light green). For neonatal and infant mortality, these data are often in different databases and are not linked. Sometimes some data are available, but they are not comprehensive enough for use in surveillance. Further, these deaths can occur in the following year (after birth) and therefore there is a lag for consolidating and merging death data with birth data. For mode of delivery, different databases are similarly utilized for the surveillance of medical practices versus births and deaths. In these countries with distinct databases for these indicators, it is possible to collect these data separately, but customised scripts need to be developed or tabular data can be provided by the countries on these indicators.

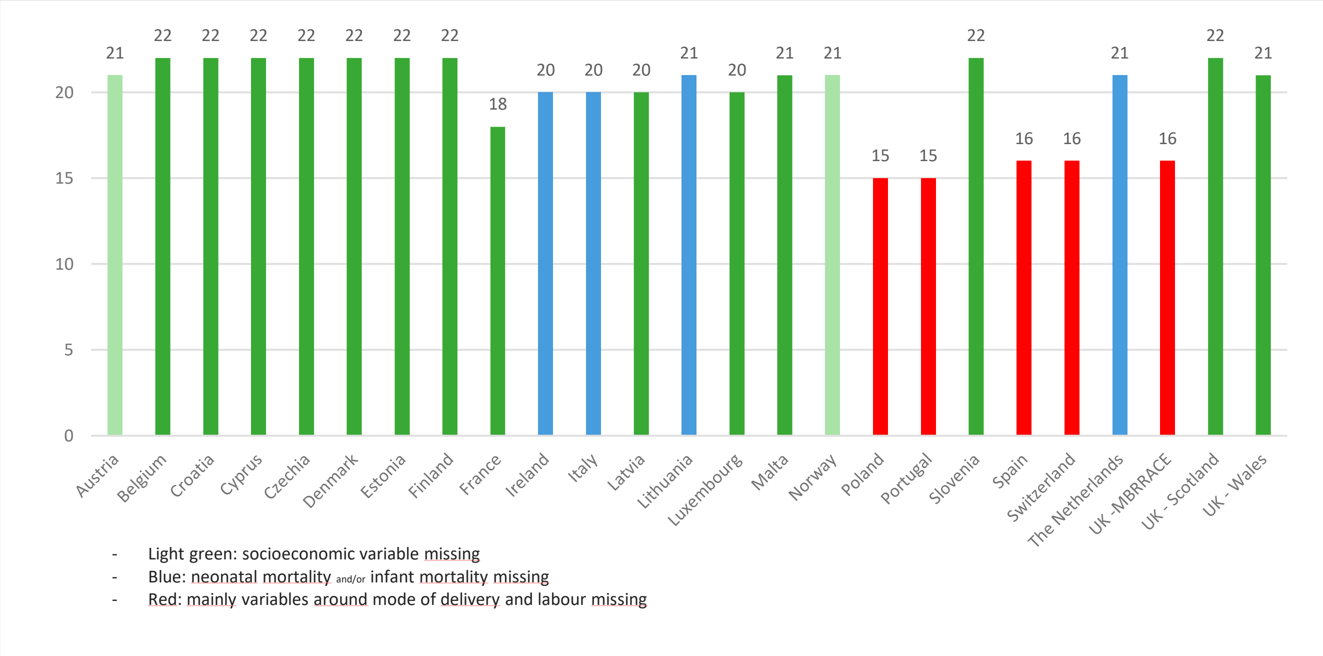



*Figure 5 Number of variables available for data collection by category of missing (out of 22 in aggregate data tables)*

Socioeconomic status was available in most countries but the variable collected differed, as shown in Table 7. The protocol requested data on maternal education when this was available, or occupation and area-based deprivation when education was not available. Fifteen countries were able to provide data by maternal education, whereas 5 countries collected area-based deprivation. Ireland collects data on occupation and Austria and Norway did not have data on socioeconomic status.

*Table 8 Socioeconomic status collected according to country (mother's education was preferred variable, if several)*

| Mother's education | Mother's occupation | Father's occupation | Area-based deprivation score | None |
|---|---|---|---|---|
| Belgium<br>Croatia<br>Cyprus<br>Czechia<br>Denmark<br>Estonia<br>Italy<br>Latvia<br>Lithuania<br>Luxembourg<br>Malta<br>Poland<br>Portugal<br>Slovenia<br>Spain | Ireland | | Finland<br>France<br>Netherlands<br>Switzerland<br>UK-MBRRACE<br>UK-Scotland<br>UK-Wales | Austria<br>Norway |

## B. Perinatal health outcomes: baseline rates, trends and change in 2020

The results presented in this section of the report are based on aggregate data tables and results provided by 23 countries. Germany has implemented the data collection protocol, is still awaiting approval for transfer. French data are currently being verified and are included in overall data counts, but have not been fully analysed. Other data are presented, but are still preliminary. For Sweden, annual aggregate tables have been provided, but monthly tables are being finalised. Data from Netherlands, Norway, Poland and UK (MBRRACE) are still being checked by the providers. Finally, data from Switzerland are being re-run using finalised databases. All countries where data are still considered preliminary are noted in table footnotes.

### 1. Preterm birth

We investigated trends in preterm birth based on the live singleton preterm birth rate (singleton live births before 37 completed weeks of gestation as a proportion of all singleton live births), as done in the majority of studies in the scientific literature on the pandemic's effects on preterm birth. Exclusion of multiple births is justified by different baseline risks of preterm birth among multiples, their distinct risk profiles and varying multiple birth rates across countries in Europe.

**Preterm birth, before 37 completed weeks of gestation, is associated with higher risks of mortality, morbidity and impaired motor and cognitive development in childhood. In high-income countries, about three quarters of neonatal deaths occur in preterm infants**

The analysis was conducted on a total of 886,755 singleton live preterm births and over 19 million live singleton births between 2015 and 2020 in 21 countries, although 2 countries (Belgium and Ireland) have not yet contributed 2020 data and were included for baseline trend analyses only.

Countries contributed varying number of singleton preterm births with annual data ranging from about 4500 to over 400,000 (Table 8).

Figure 6 illustrates the variation in preterm birth rates and trends. The figure is ordered by the countries' preterm birth rates, starting at less than 4.5% to over 7%. Countries with small numbers of births (Malta, Luxembourg, Cyprus) show the most year to year fluctuation, as expected. A final note is that the 2018 dip in Croatia is due to a change in the approach to recording gestational age, resulting in underreporting of preterm birth that year.

*Table 9 Singleton live births and preterm births included in the preterm birth analysis*

| Country | Live singleton births | Min yr | Max yr | Min Mon | Max Mon | Singleton preterm births | Min yr | Max yr | Min Mon | Max Mon |
|---|---|---|---|---|---|---|---|---|---|---|
| Austria | 494118 | 80562 | 84346 | 5993 | 7733 | 29005 | 4431 | 5074 | 327 | 464 |
| Belgium | 577393 | 113540 | 117493 | 8223 | 10307 | 36607 | 7259 | 7395 | 547 | 664 |
| Croatia | 213915 | 34878 | 36391 | 2427 | 3333 | 10654 | 1609 | 1899 | 104 | 187 |
| Cyprus | 54921 | 8901 | 9550 | 613 | 912 | 4535 | 714 | 785 | 43 | 87 |
| Czechia | 655714 | 107284 | 111221 | 7692 | 9997 | 37071 | 5645 | 6523 | 409 | 640 |
| Denmark | 356450 | 57166 | 60626 | 4083 | 5599 | 17345 | 2749 | 2959 | 194 | 282 |
| Estonia | 79638 | 12572 | 13686 | 931 | 1330 | 3448 | 542 | 601 | 30 | 67 |
| Finland | 291836 | 44596 | 54108 | 3209 | 4913 | 12826 | 1885 | 2416 | 134 | 248 |
| France | 2052809 | 671403 | 693308 | 49867 | 62589 | 108934 | 34421 | 37542 | 2640 | 3386 |
| Ireland | 300180 | 57185 | 63158 | 4288 | 5670 | 14421 | 2804 | 2965 | 182 | 273 |
| Italy | 2592707 | 390833 | 468341 | 29009 | 42978 | 147534 | 20994 | 26851 | 1525 | 2495 |
| Latvia | 116022 | 17036 | 21082 | 1271 | 2013 | 5309 | 763 | 1001 | 48 | 110 |
| Lithuania | 154373 | 22521 | 28097 | 1609 | 2636 | 6469 | 900 | 1242 | 63 | 127 |
| Luxembourg | 41001 | 6516 | 7349 | 479 | 670 | 2248 | 347 | 396 | 16 | 49 |
| Malta | 25894 | 4235 | 4393 | 309 | 443 | 1433 | 208 | 260 | 8 | 33 |
| Netherlands | 959073 | 156772 | 163721 | 11305 | 14974 | 49934 | 7989 | 8667 | 564 | 808 |
| Norway | 330206 | 52022 | 57807 | 3578 | 5473 | 15436 | 2440 | 2765 | 162 | 265 |
| Poland | 2205973 | 340291 | 391861 | 18519 | 35072 | 125685 | 18611 | 22276 | 1101 | 2045 |
| Portugal | 502252 | 82344 | 84584 | 5848 | 7904 | 30166 | 4498 | 5275 | 328 | 528 |
| Slovenia | 113372 | 18078 | 19498 | 1254 | 1808 | 6060 | 922 | 1056 | 49 | 101 |
| Spain | 2207556 | 330254 | 401847 | 20241 | 30611 | 106970 | 15489 | 19144 | 1069 | 1798 |
| Switzerland | 502208 | 82896 | 84490 | 6177 | 7739 | 26285 | 4157 | 4514 | 297 | 425 |
| UK: MBRRACE | 4306049 | 665674 | 754777 | 42610 | 64631 | 254748 | 37360 | 44700 | 2559 | 3993 |
| *UK: Scotland* | *297477* | *45352* | *52821* | *3481* | *4745* | *19546* | *2901* | *3427* | *221* | *311* |
| *UK: Wales* | *148917* | *22766* | *27071* | *1556* | *2637* | *8999* | *1366* | *1607* | *89* | *167* |

Note: Data from Netherlands, Norway, Poland, Switzerland, Sweden and UK (MBRRACE) are preliminary

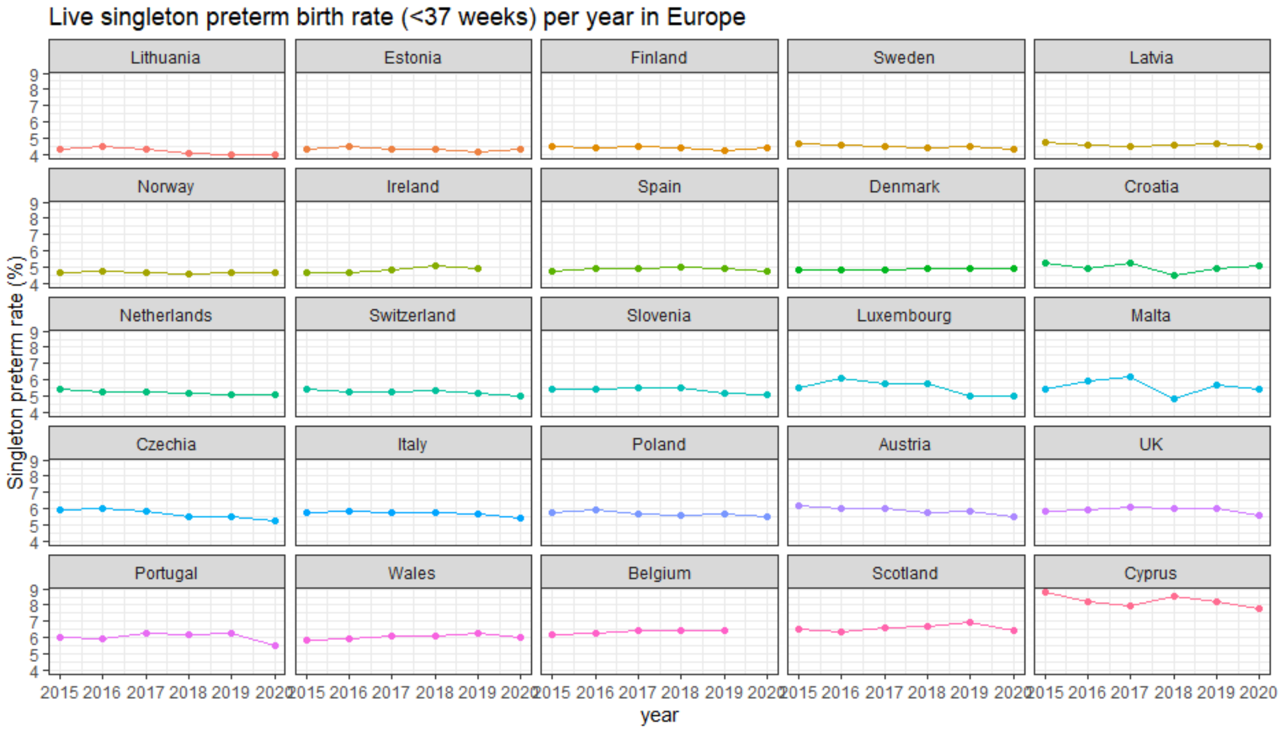



*Figure 6 Singleton live preterm birth rate by country, 2015-2020*

To assess the impact of the pandemic, we first modelled baseline trends from 2015 to 2019 to provide expected values from which to measure a deviation in 2020. We assumed that trends were linear. This was considered a reasonable assumption given the short time period and progressive evolution in the population characteristics that influence preterm birth risks (e.g. maternal age, parity). However, the assumption of linearity was also assessed by modelling monthly data from 2015 to 2019 and by comparing results of time series models using monthly data with annual linear models. In most countries, linear models described trends well, with a few exceptions.

The first column of Table 9 describes the baseline trends based on annual models and provides an assessment of change per year (0.99 = relative decrease of 1% per year). Preterm birth rates declined slightly in most countries over this period (14/20 the relative risks were less than 1), though 6 countries had increases.

The next three columns provide the evaluation of the pandemic's effects. The columns represent, first, the full year 2020, second, the period March to September using an annual model and third, the March to September period evaluated using ARIMA time series models. March to September is considered the period for which evaluation is most appropriate given potential fertility trends which could distort rates starting in October (see explanation in I.C State of the Art).

In general, all three columns provide consistent evaluations of the situation in most countries. Given the potential effects of changing fertility, we would expect the full year estimate to accentuate decreases, as seen in most countries (decreases represent 70% of estimates in 2020 full year models versus 58% in the March-September models). Several countries experienced significant and consistent decreases of their preterm birth rates during the pandemic regardless of the modelling method, including Italy, Portugal and the UK. In Spain and Latvia, decreases were observed, but differed in some models. In contrast, in many other countries there was no overall trend. Based on the ARIMA models of the March to September period, a majority of countries experienced decreases.

Once data from all participating countries have been included, we will undertake meta-analyses to pool effects across countries and use statistical techniques to assess heterogeneity.

*Table 10 Preterm birth: Baseline trends and evaluation of pandemic effects*

| | Baseline Trend | Evaluation of Pandemic effects | | |
|---|---|---|---|---|
| | Linear annual models RR (95% CI)[2] | Full year 2020 Linear annual models RR (95% CI)[2] | March-September Linear annual models RR (95% CI)[2] | March-September ARIMA models RR (95% CI)[2] |
| Austria | **0.99 [0.98;0.99]** | 0.97 [0.92;1.01] | 0.98 [0.92;1.03] | 0.95 (0.89 - 1.01) |
| Belgium[2] | **1.01 [1.00;1.02]** | -- | -- | -- |
| Croatia[3] | -- | -- | -- | -- |
| Cyprus | 0.99 [0.97;1.01] | 0.96 [0.86;1.06] | 0.98 [0.84;1.11] | 0.92 (0.80 – 1.07) |
| Czechia | **0.98 [0.97;0.98]** | 0.98 [0.95;1.02] | 0.98 [0.93;1.02] | ***0.94 (0.88 – 1.00)*** |
| Denmark | 1.01 [0.99;1.02] | 0.99 [0.94;1.05] | 0.98 [0.91;1.04] | 0.99 (0.94 - 1.05) |
| Estonia | 0.99 [0.96;1.01] | 1.03 [0.91;1.15] | 1.12 [0.97;1.27] | 1.02 (0.94 - 1.12) |
| Finland | 0.99 [0.98;1.00] | 1.04 [0.98;1.10] | 1.04 [0.95;1.12] | 0.99 (0.93 - 1.05) |
| Ireland[2] | **1.02 [1.01;1.03]** | **--** | -- | |
| Italy | 1.00 [0.99;1.00] | **0.94 [0.92;0.96]** | **0.96 [0.93;0.98]** | **0.94 (0.92 - 0.97)** |
| Latvia | 1.00 [0.98;1.02] | 0.99 [0.89;1.08] | 0.95 [0.82;1.07] | 0.92 (0.85 – 0.99) |
| Lithuania | 0.98 [0.96;1.00] | 1.01 [0.93;1.10] | 1.02 [0.91;1.14] | 1.03 (0.94 - 1.13) |
| Luxembourg | 0.98 [0.95;1.01] | 0.95 [0.80;1.09] | 0.92 [0.73;1.11] | 0.85 (0.73 - 1.00) |
| Malta | 0.99 [0.95;1.03] | 1.00 [0.82;1.18] | 1.08 [0.85;1.32] | 1.04 (0.86 - 1.27) |
| Netherlands | **0.98 [0.98;0.99]** | 1.02 [0.99;1.05] | 1.02 [0.98;1.06] | 1.00 (0.96 - 1.04) |
| Norway | 0.99 [0.98;1.00] | 1.03 [0.97;1.08] | 1.03 [0.96;1.10] | 1.01 (0.96 - 1.07) |
| Poland | 0.99 [0.99;1.00] | 0.98 [0.96;1.00] | 1.00 [0.97;1.02] | 0.99 (0.94 - 1.03) |
| Portugal | **1.01 [1.00;1.02]** | **0.86 [0.82;0.90]** | **0.86 [0.81;0.92]** | **0.90 (0.85 - 0.95)** |
| Slovenia | 0.99 [0.98;1.01] | 0.96 [0.87;1.05] | 0.98 [0.87;1.10] | 0.99 (0.88 - 1.10) |
| Spain | **1.01 [1.01;1.02]** | **0.93 [0.91;0.95]** | 0.98 [0.95;1.01] | **0.97 (0.95 - 0.99)** |
| Sweden | 0.99 [0.98;1.00] | 0.99 [0.95;1.02] | -- | |
| Switzerland | 0.99 [0.98;1.00] | 0.97 [0.93;1.01] | 0.98 [0.92;1.03] | **0.95 (0.90 – 0.99)** |
| UK: MBBRACE | **1.01 [1.01;1.01]** | **0.92 [0.90;0.93]** | **0.94 [0.92;0.96]** | **0.95 (0.93 - 0.98)** |
| UK: Scotland[4] | ***1.02 [1.01 ; 1.03]*** | ***0.92 [0.97 ; 0.97]*** | ***0.91 [0.95 ; 0.97]*** | ***0.93 (0.86 - 1.00)*** |
| UK: Wales[4] | ***1.02 [1.00 ; 1.03]*** | *0.95 [0.97 ; 1.02]* | *0.95 [0.86 ; 1.05]* | *0.95 (0.86 - 1.05)* |
| Decrease n/N(%) | 14/22 (64%) | 14/20 (70%) | 12/19 (63%) | 14/19 (74%) |
| Increase n/N(%) | 6/22 (27%) | 5/20 (25%) | 6/19 (32%) | 4/19 (21%) |

1) Bold face indicates that the confidence interval does not include 1.
2) Belgium and Ireland do not yet have 2020 data and are included only in the trend analyses
3) In Croatia, changes in instructions for recording GA in 2018 makes it difficult to compute trends
4) Scotland and Wales included in MBBRACE, but data in each country also collected from different source. They are not included in compiled analyses.

Note: Data from Netherlands, Norway, Poland, Switzerland, Sweden and UK (MBRRACE) are preliminary

## 2. Stillbirth and neonatal mortality

Data were provided on 60,548 stillbirths and 36,517 neonatal deaths (Table 10). However, compared to preterm birth which is measured per 100 births, stillbirth and neonatal mortality are infrequent outcomes, representing between 3 and 7 per 1000 total births. For some countries, the numbers of events, even over a 6 year period, can be modest. This can be seen in the minimum monthly numbers of deaths which go below 5 for many of the countries.

**The stillbirth rate is defined as the number of babies born without signs of life (death occurred before or during labour) at 22 weeks of gestational age or over for 1000 total births. The neonatal mortality rate is deaths in the first 27 days of life after live birth per 1000 live births.**

The PHIRI protocol stipulates that these numbers are not presented in publications and a few countries have restrictions for transferring cell sizes under 5, which means these are not available for analysis.

For this analysis we used definitions of stillbirth and neonatal mortality using all births collected in the protocol, meaning those with a gestational age of 22 weeks or more. However, stillbirth rates are often measured using more restrictive lower thresholds to improve comparability of reporting, such as 24 or 28 completed weeks of gestation.[43,44] For comparisons of rates in Europe, Euro-Peristat recommends a 24 week limit[44] and also presents neonatal mortality rates using this same lower threshold. For this analysis, the decision was to use all data (22 week threshold) because we are measuring trends over time within the same country (as opposed to comparing rates across countries) and the study period covers a relatively short period of time during which we would not expect large changes in recording practices within countries. However, sensitivity analyses of final models will be carried out applying more restrictive thresholds.

*Table 11 Numbers of stillbirths and neonatal deaths in participating countries over the periods 2015-2020 or 2015-2019, when 2020 is not available*

| Country | Stillbirths | Min yr | Max yr | Min Mon | Max Mon | Neonatal deaths | Min yr | Max yr | Min Mon | Max Mon |
|---|---|---|---|---|---|---|---|---|---|---|
| Austria | 1690 | 253 | 310 | 12 | 36 | 880 | 130 | 167 | 6 | 23 |
| Belgium | 2876 | 535 | 630 | 28 | 74 | 1392 | 262 | 300 | 53 | 98 |
| Croatia | 971 | 142 | 181 | 6 | 25 | 655 | 96 | 119 | <5 | 24 |
| Cyprus | 272 | 29 | 65 | <5 | 10 | 98 | 8 | 20 | <5 | 7 |
| Czechia | 2418 | 383 | 431 | 16 | 49 | 1086 | 163 | 198 | <5 | 23 |
| Denmark | 1146 | 167 | 226 | 5 | 28 | 799 | 99 | 156 | <5 | 10 |
| Estonia | 251 | 27 | 54 | <5 | 11 | 96 | 12 | 21 | <5 | 6 |
| Finland | 859 | 122 | 171 | 5 | 22 | 425 | 64 | 79 | <5 | 13 |
| France | 10824 | 3526 | 3764 | 247 | 354 | | | | | |
| Ireland | 1268 | 228 | 290 | 8 | 32 | 687 | 116 | 178 | <5 | 24 |
| Italy | 9266 | 1349 | 1769 | 86 | 211 | 4582 | 731 | 1001 | NA | NA |
| Latvia | 629 | 82 | 129 | <5 | 17 | 275 | 31 | 54 | NA | NA |
| Lithuania | 662 | 81 | 133 | <5 | 18 | 358 | 46 | 72 | <5 | 10 |
| Luxembourg | 170 | 23 | 34 | <5 | 6 | | | | | |
| Malta | 127 | 16 | 26 | <5 | 5 | 119 | 15 | 28 | <5 | <5 |
| Netherlands | 4642 | 735 | 824 | 42 | 82 | 3141 | 491 | 561 | 20 | 62 |
| Norway | 1128 | 161 | 213 | 7 | 29 | 488 | 66 | 91 | <5 | 13 |
| Poland | 3669 | 9 | 1269 | 9 | 124 | 6215 | 882 | 1118 | 46 | 113 |
| Portugal | 1758 | 257 | 322 | 13 | 37 | | | | | |
| Slovenia | 356 | 47 | 71 | <5 | 10 | 114 | 14 | 26 | <5 | 5 |
| Spain | 7230 | 1020 | 1326 | 44 | 115 | 4275 | 601 | 772 | 40 | 95 |
| Switzerland | 1884 | 296 | 325 | 15 | 43 | 1361 | 203 | 256 | 7 | 22 |
| UK: MBRRACE | 19204 | 2684 | 3596 | 201 | 334 | 9471 | 1356 | 1717 | 80 | 165 |
| UK: Scotland | 1277 | 191 | 245 | 5 | 32 | 539 | 81 | 102 | <5 | 17 |
| UK: Wales | 785 | 107 | 158 | <5 | 18 | | | | | |

Note 1: the study protocol limits publication of cell sizes under 5. 2. Data from Netherlands, Norway, Poland, Switzerland, Sweden and UK (MBRRACE) are preliminary

Figures 7 and 8 show the rates and evolution of the stillbirth and neonatal mortality rates over the study period. There are marked differences in rates and trends for both of these indicators and there is substantial variability in rates in smaller countries due to a small number of events.

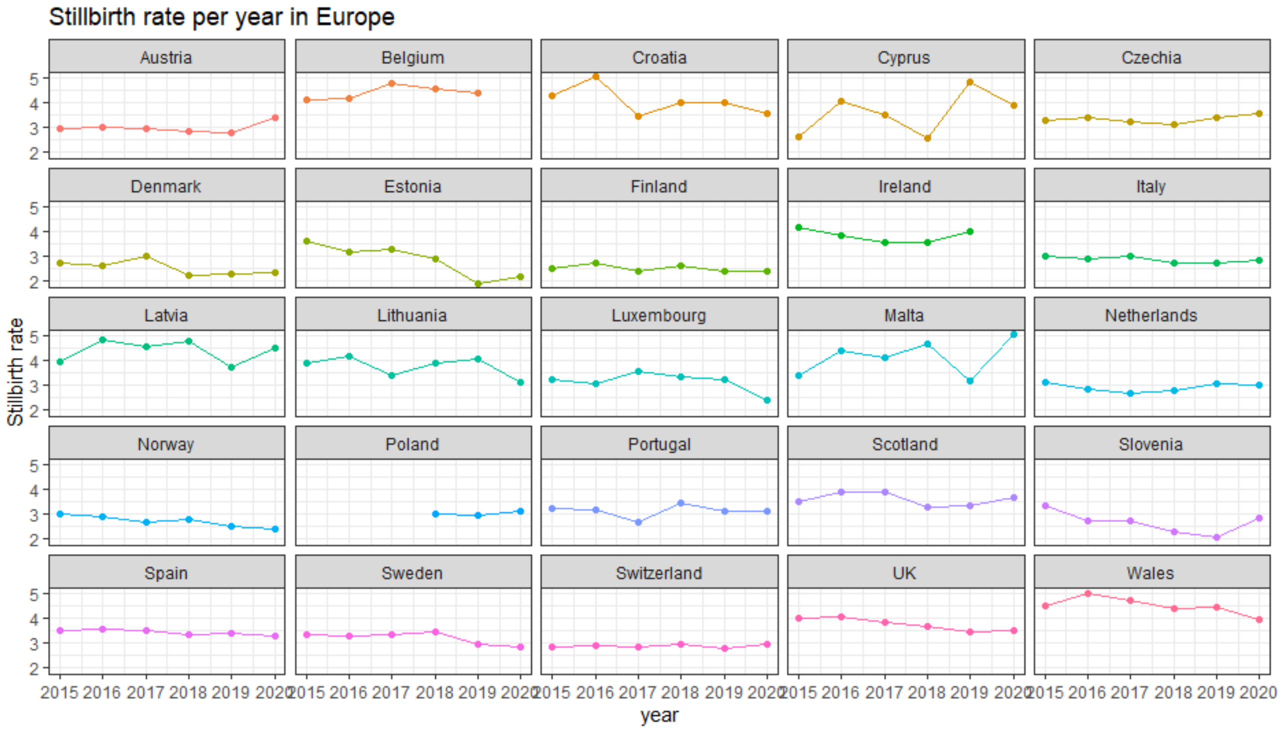



*Figure 7 Stillbirth rate ≥22 weeks of gestation per 1000 total births by country, 2015-2020*

*Table 12 Stillbirth: Baseline trends and evaluation of pandemic effects*

| | Baseline Trend | Evaluation of Pandemic effects | | |
|---|---|---|---|---|
| | Linear annual models RR (95% CI)[2] | Full year 2020 Linear annual models RR (95% CI)[2] | March-September Linear annual models RR (95% CI)[2] | March-September ARIMA models RR (95% CI)[2] |
| Austria | 0.98 [0.94;1.02] | **1.24 [1.07;1.40]** | **1.43 [1.21;1.65]** | **1.24 [1.05;1.46]** |
| Belgium[2] | **1.03 [1.01;1.06]** | | | |
| Croatia[3] | 0.97 [0.92;1.01] | 0.95 [0.72;1.18] | 0.80 [0.50;1.10] | 0.80 [0.63;1.03] |
| Cyprus | **1.09 [1.00;1.19]** | 0.67 [0.25;1.09] | 0.43 [-0.09;0.95] | 0.90 [0.55;1.49] |
| Czechia | 0.99 [0.96;1.02] | **1.15 [1.01;1.29]** | 1.10 [0.92;1.29] | ***1.14 [0.99;1.31]*** |
| Denmark | 0.95 [0.91;1.00] | 1.04 [0.83;1.25] | 0.95 [0.68;1.23] | 0.89 [0.70 1.12] |
| Estonia[4] | **0.88 [0.78;0.97]** | 1.09 [0.60;1.58] | 1.03 [0.45;1.61] | -- |
| Finland | 0.97 [0.92;1.02] | 0.99 [0.74;1.24] | 1.06 [0.73;1.39] | 0.93 [0.73; 1.19] |
| Ireland[2] | **0.**98 [0.94;1.02] | | | |
| Italy | **0.97 [0.95;0.99]** | 1.06 [0.98;1.13] | 1.07 [0.97;1.17] | 1.06 [0.94;1.19] |
| Latvia | 0.97 [0.91;1.03] | 1.11 [0.82;1.40] | 1.24 [0.87;1.60] | 1.15 [0.87;1.50] |
| Lithuania | 1.00 [0.94;1.06] | 0.81 [0.51;1.10] | 0.95 [0.58;1.32] | 0.88 [0.6-9;1.12] |
| Luxembourg[4] | 1.01 [0.89;1.12] | 0.71 [0.15;1.26] | 1.03 [0.32;1.74] | -- |
| Malta[4] | 0.99 [0.85;1.13] | 1.30 [0.70;1.90] | 1.65 [0.87;2.42] | -- |
| Netherlands | 1.00 [0.98;1.02] | 1.02 [0.92;1.12] | 1.08 [0.95;1.21] | 1.04 [0.95;1.15] |
| Norway | 0.97 [0.93;1.02] | 0.98 [0.76;1.19] | 0.84 [0.55;1.13] | **0.80 [0.64;0.99]** |
| Poland[3] | -- | -- | -- | -- |
| Portugal | 1.00 [0.96;1.04] | 1.00 [0.83;1.17] | 0.90 [0.67;1.12] | 0.94 [0.80;1.11] |
| Slovenia | 0.93 [0.84;1.01] | **1.47 [1.10;1.85]** | 1.42 [0.92;1.91] | 1.33 [0.92;1.93] |
| Spain | 0.99 [0.97;1.01] | 0.98 [0.90;1.07] | 1.00 [0.88;1.11] | 0.97 [0.87;1.08] |
| Sweden[5] | 0.98 [0.95;1.01] | 1.04 [0.88;1.20] | -- | -- |
| Switzerland | 0.99 [0.95;1.02] | 0.92 [0.78;1.07] | 0.96 [0.75;1.17] | 0.97 [0.82:1.16] |
| UK: MBBRACE | **0.97 [0.96;0.98]** | 1.00 [0.95;1.05] | 0.99 [0.92;1.06] | 0.97 [0.89;1.05] |
| UK: Scotland[6] | *0,98 [0.94;1.02]* | *1.07 [0.87;1.27]* | ***1.29 [1.02;1.55]*** | *1.04 [0.80;1.34]* |

| | | | | |
|---|---|---|---|---|
| UK: Wales[6] | *0,98 [0.93;1.04]* | *0.88 [0.62;1.14]* | *0.93 [0.58;1.27]* | *0.79 [0.60:1.04]* |
| Decrease n/N(%) | 16/22 (73%) | 8/20 (40%) | 8/19 (42%) | 10/16 (63%) |
| Increase n/N(%) | 3/22(14%) | 10/20 (50%) | 10/19 (53%) | 6/16 (38%) |

1) Bold face indicates that the confidence interval does not include 1.
2) Belgium and Ireland do not yet have 2020 data and are included only in the trend analyses
3) Poland did not have stillbirths over the full period and could not be included
4) Difficulties because of small sample sizes or incomplete collection due to restricted transfer of data
5) Waiting for monthly data from Sweden
6) Scotland and Wales included in MBBRACE, but data in each country also collected from different source. They are not included in compiled analyses.
7) Note: Data from Netherlands, Norway, Poland, Switzerland, Sweden and UK (MBRRACE) are preliminary

When evaluating stillbirth trends (Table 11), most countries experienced decreases over the period 2015-2019, although these were modest. However, some countries experienced increases (Belgium, Czechia) or unchanging rates. In most countries, stillbirth rates did not increase over the year 2020 or in March to September of 2020. However, some countries did have increases and these were significant in Austria, Czechia and Slovenia. The ARIMA models were constituent with the estimates from linear models, but confidence intervals included 1 for Czechia and Slovenia.

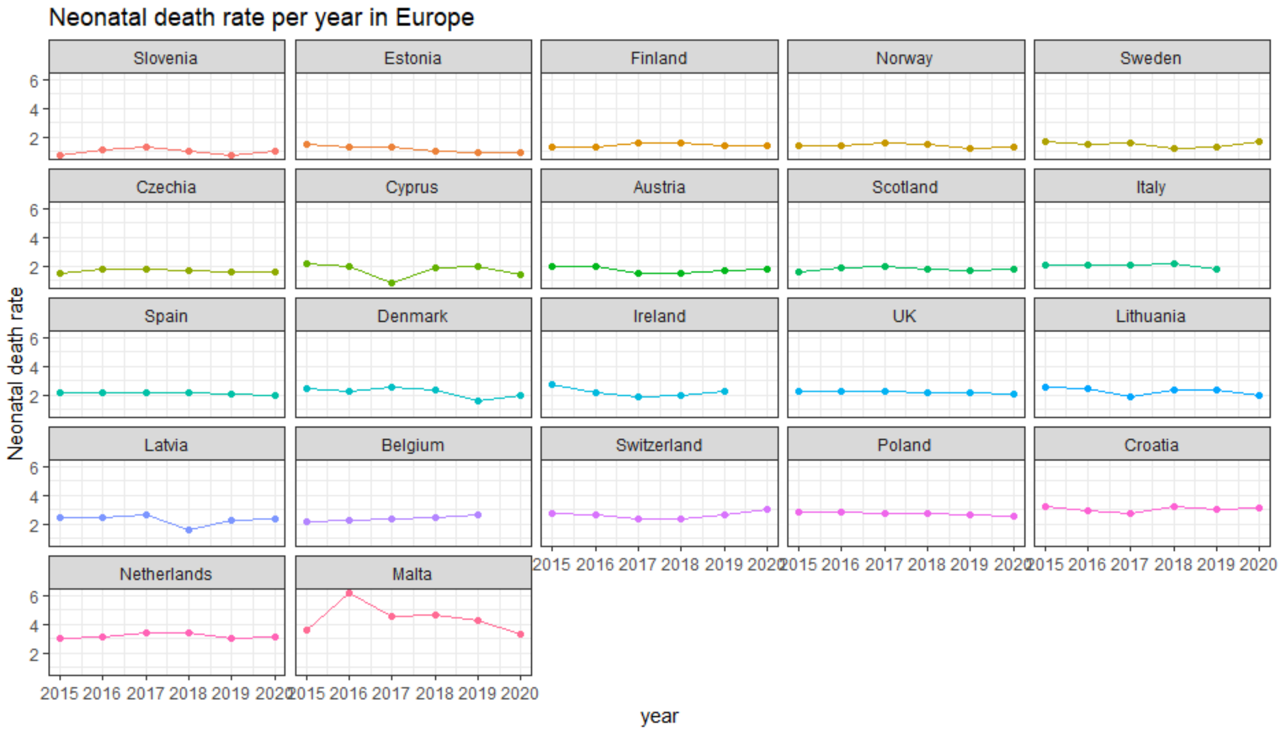



*Figure 8 Neonatal mortality rate ≥22 weeks of gestation per 1000 live births by country, 2015-2020*

Data on trends in neonatal mortality are shown for neonatal mortality. Overall, neonatal mortality rates decreased over this period, although effects were modest. The neonatal mortality data are still being verified in some countries and therefore the pandemic analyses have not been completed.

*Table 13 Neonatal death: Baseline trends*

| | Baseline Trend |
|---|---|
| | Linear annual models RR (95% CI)[2] |
| Austria | 0.95 [0.90;1.00] |
| Belgium | **1.05 [1.01;1.08]** |
| Croatia[2] | 1.00 [0.94;1.06] |
| Cyprus | 0.97 [0.82;1.13] |
| Czechia | 1.01 [0.96;1.05] |
| Denmark | 0.94 [0.88;0.99] |
| Estonia | 0.89 [0.73;1.04] |
| Finland | 1.03 [0.96;1.11] |
| Ireland | 0.95 [0.89;1.00] |
| Italy | **0.97 [0.95;0.99]** |
| Latvia[2] | -- |
| Lithuania | 0.98 [0.90;1.06] |
| Luxembourg | -- |
| Malta | 1.00 [0.86;1.13] |
| Netherlands | 1.01 [0.98;1.03] |
| Norway | 0.99 [0.93;1.06] |
| Poland | 0.98 [0.97;1.00] |
| Portugal[3] | -- |
| Slovenia | 0.99 [0.85;1.13] |
| Spain | 0.99 [0.97 ; 1.02] |
| Sweden | **0.94 [0.89;0.98]** |
| Switzerland | 0.97 [0.93;1.01] |
| UK: MBBRACE | 0.99 [0.97;1.00] |
| UK: Scotland[5] | 1.01 [0.95;1.08] |
| UK: Wales[5] | |
| Decrease n/N(%) | 14/20 (70%) |
| Increase n/N(%) | 4/20 (20%) |

1) Bold face indicates that the confidence interval does not include 1.
2) These countries did not contribute data on neonatal mortality
3) Scotland and Wales included in MBBRACE, but data in each country also collected from different source. They are not included in compiled analyses.
4) Note: Data from Netherlands, Norway, Poland, Switzerland, Sweden and UK (MBRRACE) are preliminary

## 3. Caesarean delivery

**The caesarean delivery rate is the number of stillbirths and live births delivered by caesarean as a proportion of total births. Caesarean delivery can be further divided into caesareans initiated before the on-set of labour (or planned) and those that occur after labour has begun (intrapartum or emergency).**

Fewer countries could provide data on mode of delivery using this protocol because this information was not in the same databases as data on births and perinatal deaths. Twenty countries provided data; notably, information is not available from all UK, but could be provided by Scotland, Wales and Northern Ireland. Some countries could provide overall caesarean section rates, but not by mode of onset. Table 14 gives the number of caesarean deliveries and minimum and maximum values by year and month.

Figure 9 shows trends in caesarean delivery rates over the period covered by the study and highlights the large variation in caesarean delivery rates in Europe. This graph also illustrates differences in the trends over time, with some countries experiencing increases (Wales, Scotland), while others show decreases.

*Table 14 Numbers of caesarean deliveries in participating countries over the periods 2015-2020 or 2015-2019, when 2020 is not yet available*

| Country | N of CD | Min yr | Max yr | Min Mon | Max Mon |
|---|---|---|---|---|---|
| Austria | 151767 | 24889 | 25820 | 1811 | 2371 |
| Belgium | 126641 | 24790 | 25779 | 1807 | 2309 |
| Croatia | 55205 | 8074 | 9956 | 582 | 928 |
| Cyprus | 31665 | 5055 | 5610 | 315 | 530 |
| Czechia | 160262 | 25914 | 28255 | 1850 | 2518 |
| Denmark | 76157 | 12345 | 13096 | 904 | 1208 |
| Estonia | 16629 | 2695 | 2901 | 185 | 275 |
| Finland | 52304 | 8222 | 9186 | 582 | 832 |
| France | 444081 | 146651 | 149577 | 10647 | 13687 |
| Ireland | 103629 | 20323 | 21008 | 1485 | 1985 |
| Italy | 903818 | 129859 | 170274 | 9380 | 15161 |
| Latvia | 26873 | 3964 | 4872 | 293 | 468 |
| Lithuania | 33633 | 4928 | 6342 | 342 | 607 |
| Luxembourg | 13550 | 2203 | 2292 | 137 | 231 |
| Malta | 8659 | 1408 | 1482 | 92 | 158 |
| Netherlands | 163727 | 25795 | 29030 | 1854 | 2680 |
| Norway | 56051 | 8670 | 9915 | 579 | 971 |
| Slovenia | 25614 | 4104 | 4371 | 294 | 429 |
| Spain | 604290 | 87178 | 112339 | 5198 | 8507 |
| UK: Scotland | 104643 | 17151 | 17690 | 1258 | 1615 |
| UK: Wales | 47512 | 6448 | 8494 | 565 | 765 |

Note: Data from Netherlands, Norway, Poland, Switzerland, Sweden and UK (MBRRACE) are preliminary

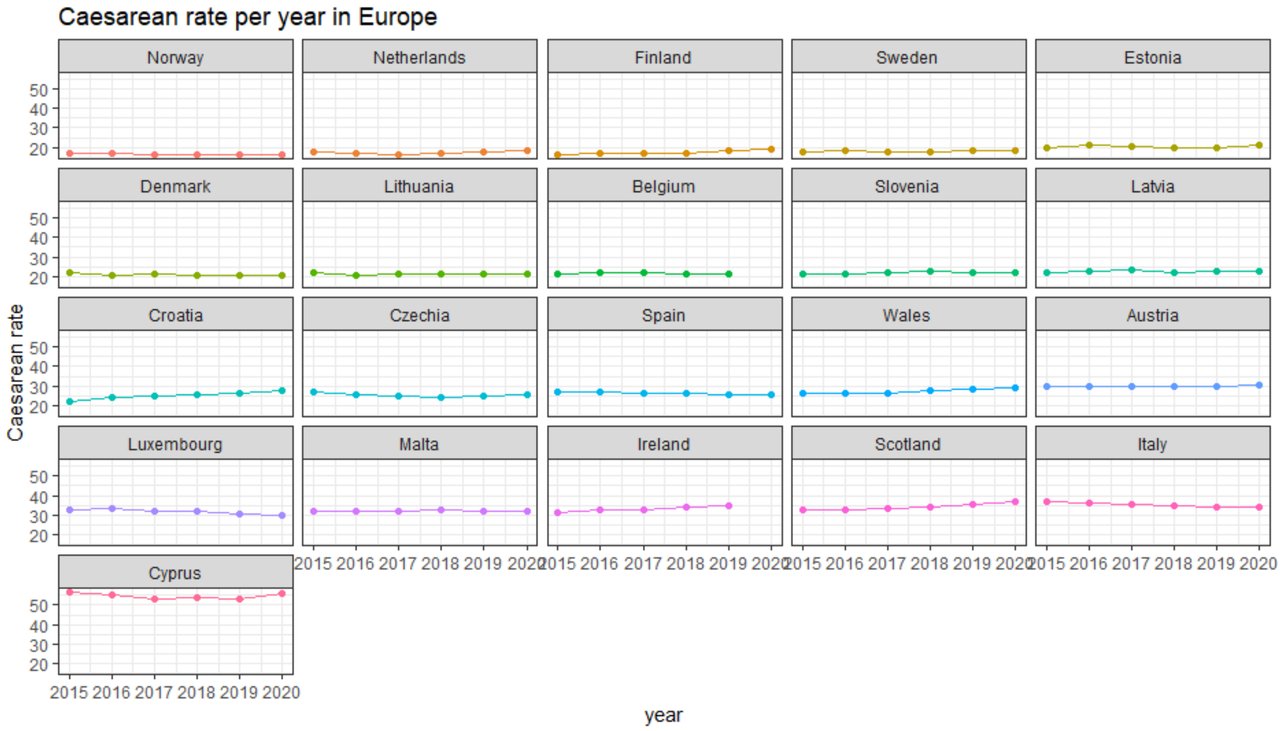



*Figure 9 Caesarean delivery rate per 100 total births, 2015-2020*

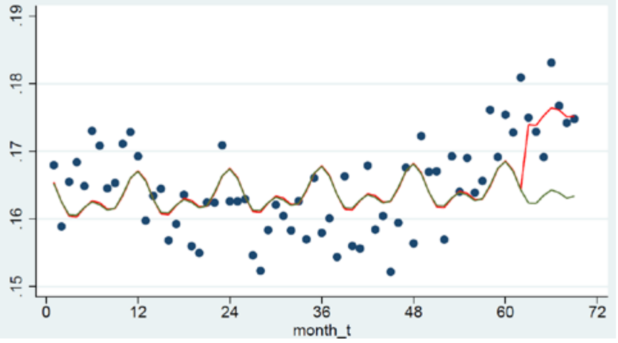
The differences in the trends, estimated in linear models illustrates the heterogeneity in Europe. However, unlike the previous indicators, linear models do not accurately describe the changes over time in caesarean in many countries. This can be observed in the large discrepancies between estimates of change in linear modes (full year and March-September) and the ARIMA model. In 5 cases where significant increases were found in linear models, estimates are much lower and in some countries, inversed. Figure 10 which models caesarean delivery rates for the Netherlands using a linear and non-linear model illustrates why these estimates (1.08 – an 8% increase versus 1.02 – a 2 percent increase) are so different when the linearity assumption does not hold.

*Table 14 Caesarean section: Baseline trends and evaluation of pandemic effects*

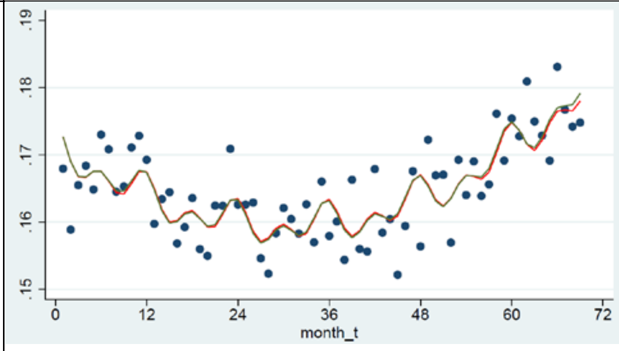
| | Baseline Trend | Evaluation of Pandemic effects | | |
|---|---|---|---|---|
| | Linear annual models RR (95% CI)[2] | Full year 2020 Linear annual models RR (95% CI)[2] | March-September Linear annual models RR (95% CI)[2] | March-September ARIMA models RR (95% CI)[2] |
| Austria | 1.00 [1.00;1.01] | 1.01 [1.00;1.03] | 1.01 [0.99;1.03] | 1.01 [0.99;1.03] |
| Belgium[2] | 1.00 [1.00;1.00] | -- | -- | -- |
| Croatia[3] | **1.05 [1.04;1.05]** | 0.99 [0.96;1.01] | 0.99 [0.95;1.02] | 1.02 [0.93;1.11] |
| Cyprus | **0.98 [0.98;0.99]** | **1.08 [1.05;1.11]** | **1.06 [1.02;1.09]** | **1.05 [1.01;1.08]** |
| Czechia | **0.98 [0.97;0.98]** | **1.07 [1.06;1.09]** | **1.08 [1.05;1.10]** | 0.96 [0.92;1.01] |
| Denmark | **0.99 [0.98;0.99]** | 1.03 [1.00;1.05] | **1.04 [1.01;1.07]** | 0.99 [0.94;1.03] |
| Estonia | 0.99 [0.98;1.00] | **1.06 [1.01;1.11]** | **1.10 [1.04;1.17]** | 1.02 [0.94;1.10] |
| Finland | **1.02 [1.01;1.02]** | **1.04 [1.02;1.07]** | **1.05 [1.01;1.08]** | 0.98 [0.93;1.04] |
| Ireland[2] | **1.03 [1.02;1.03]** | -- | -- | -- |
| Italy | **0.98 [0.98;0.98]** | 1.01 [1.00;1.01] | 1.01 [1.00;1.02] | 0.99 [0.97;1.01] |
| Latvia | 1.00 [0.99;1.01] | 1.00 [0.96;1.04] | 0.96 [0.91;1.01] | 0.99 [0.93;1.05] |
| Lithuania | 0.99 [0.99;1.00] | 1.02 [0.98;1.05] | 1.03 [0.98;1.07] | 0.99 [0.95;1.03] |
| Luxembourg | **0.98 [0.97;0.99]** | 0.98 [0.93;1.03] | 0.99 [0.92;1.05] | 0.97 [0.90;1.04] |
| Malta | 1.00 [0.99;1.02] | 0.99 [0.93;1.05] | 0.98 [0.90;1.06] | 0.98 [0.94;1.02] |
| Netherlands | 1.00 [1.00;1.00] | **1.07 [1.06;1.09]** | **1.08 [1.06;1.1]** | 1.02 [0.97;1.07] |
| Norway | 1.00 [0.99;1.00] | 0.99 [0.97;1.02] | 1.00 [0.96;1.03] | 0.98 [0.94;1.01] |
| Poland[3] | -- | -- | -- | -- |
| Portugal[3] | **--** | -- | -- | -- |
| Slovenia | **1.01 [1.01;1.02]** | 0.97 [0.93;1.01] | 0.97 [0.92;1.02] | 0.98 [0.93;1.04] |
| Spain | **0.99 [0.99;0.99]** | 0.99 [0.98;1.00] | **0.95 [0.94;0.96]** | **0.96 [0.94;0.98]** |
| Sweden[3] | 1.00 [1.00;1.00] | 1.02 [1.00;1.04] | -- | -- |
| Switzerland[4] | -- | -- | -- | -- |
| UK: MBBRACE[4] | **--** | -- | -- | -- |
| UK: Scotland | **1.02 [1.02;1.03]** | 1.02 [1.00;1.03] | 1.02 [1.00;1.04] | 1.00 [0.97;1.02] |
| UK: Wales | **1.02 [1.02;1.03]** | 1.00 [0.98;1.03] | 1.02 [0.99;1.06] | - |
| Decrease n/N(%) | 8/21 (38%) | | | |
| Increase n/N(%) | 6/21 (29%) | | | |

1) Bold face indicates that the confidence interval does not include 1.
2) Belgium and Ireland do not yet have 2020 data and are included only in the trend analyses
3) Still waiting for monthly data
4) These countries did not contribute data on caesarean section
5) Note: Data from Netherlands, Norway, Poland, Switzerland, Sweden and UK (MBRRACE) are preliminary

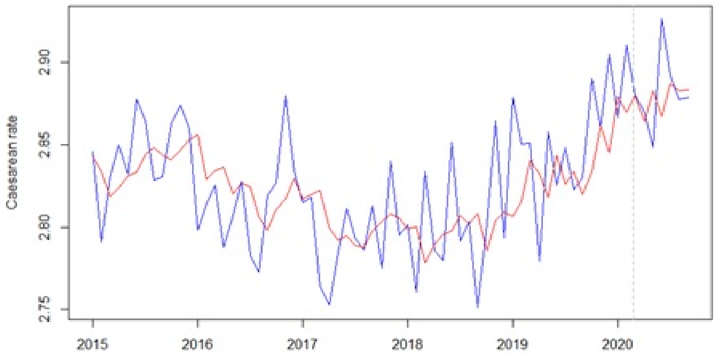
Panel A




Panel B




Trends in caesarean delivery over time using a Poisson model, integrating seasonality. The blue dots are monthly rates, the red line is the deviation in March-Sep. 2020 from the expected trend (in green)
Figure A= trend modelled as linear Figure B= trend modelled using a quadratic term




Arima model showing observed (blue) vs. forecast values (red) for the March-Sep. pandemic period

*Figure 10 Comparing models of time trends in caesarean delivery in the Netherlands*

## 4. Socioeconomic differences

One of the objectives of this use case is to assess whether the indirect effects of the pandemic differed by socioeconomic status. Maternal education was selected as the preferred indicator of socioeconomic status, as it has been used previously by the Euro-Peristat team and has been found by many studies to be highly predictive of perinatal and child outcomes.[40] If countries could not provide education, either parental occupation or area-based socioeconomic was collected. Table 15 shows the distribution of births by the indicator provided by each country. Maternal education has 3 categories and the area-based deprivation indicator is presented in 5 quintiles. Data are also provided on cases with missing socioeconomic status. For maternal education, missing data ranges from 30% in Croatia, to 12% in Belgium and Czechia, between 2 and 6% in most other countries and 0% in Estonia, Latvia and Poland. Missing data are less prevalent for area-based measures (<2%), except for Finland (61.5%). In Finland, the data on socioeconomic status are not used for this reason.

*Table 15 Distribution of socioeconomic status according to country and indicator used*

| COUNTRY | Total births | Primary/lower secondary | Higher Secondary | Tertiary | NA | NA | Missing |
|---|---|---|---|---|---|---|---|
| Belgium | 938299 | 131855 | 309133 | 378970 | | | 118341 |
| Croatia | 217081 | 9000 | 86012 | 56817 | | | 65252 |
| Cyprus | 738098 | 233580 | 239227 | 264969 | | | 322 |
| Czechia | 658963 | 155248 | 194956 | 228634 | | | 80125 |
| Denmark | 851039 | 124425 | 278085 | 416120 | | | 32409 |
| Estonia | 80905 | 9129 | 33334 | 38442 | | | 0 |
| Italy | 2673988 | 703491 | 1138342 | 771310 | | | 60845 |
| Latvia | 119297 | | 0 | 62423 | | | 0 |
| | | 56874 | | | | | |
| Lithuania | 159131 | 11604 | 41263 | 98233 | | | 8031 |
| Luxembourg | 42572 | 7764 | 9614 | 22308 | | | 2886 |
| Malta | 26796 | 8426 | 4772 | 11885 | | | 1713 |
| Poland | 2231849 | 135933 | 936516 | 1159400 | | | 0 |
| Portugal | 516849 | 129860 | 161703 | 194860 | | | 30426 |
| Slovenia | 117556 | 8000 | 47032 | 58824 | | | 3700 |
| Spain | 2019094 | 567705 | 350797 | 922136 | | | 178456 |
| | | 1st quintile (lowest) | 2nd quintile | 3rd quintile | 4th quintile | 5th quintile (highest) | NA |
| Finland | 299089 | 3939 | 19588 | 54367 | 16952 | 20063 | 184180 |
| Netherlands | 989233 | 194535 | 196473 | 198196 | 197584 | 196373 | 6072 |
| UK: MBRRACE | 4274781 | 862665 | 852037 | 853022 | 856389 | 850668 | 0 |
| UK: Scotland | 304958 | 76037 | 64566 | 55158 | 57513 | 51305 | 379 |
| UK: Wales | 170274 | 43547 | 36264 | 33453 | 27293 | 26594 | 3123 |

NOTES 1: data from Finland not used. 2: Data from Netherlands, Norway, Poland, Switzerland, Sweden and UK (MBRRACE) are preliminary

Figure 11 confirms well known disparities in perinatal outcomes by socioeconomic factors, using the association between maternal education and stillbirth rate as an illustration. For the majority of countries, stillbirth rates are higher in the lower educational groups compared to the highest (the red dashed reference line, which is the reference for the risk ratios on the Y axis). This figure also illustrates the challenges in analysing socioeconomic data in a European context, even when the same indicator can be produced, as the proportion of pregnant women in each educational group (displayed in the bars at the bottom of each graph) varies across countries. Harmonising socioeconomic variables across countries is complex, given variations within educational systems.

For the next steps of this analysis, estimates of pandemic-related in the four key indicators in 2020 will be compared between the highest and lowest socioeconomic status groups (defined either by maternal education or area deprivation). As indicators by socioeconomic status were collected only annually, this analysis can only be conducted using the 2020 full year analysis (1st column in the tables presented above). Meta-analysis techniques will be used to derive pooled estimates and to compare them between the two groups.

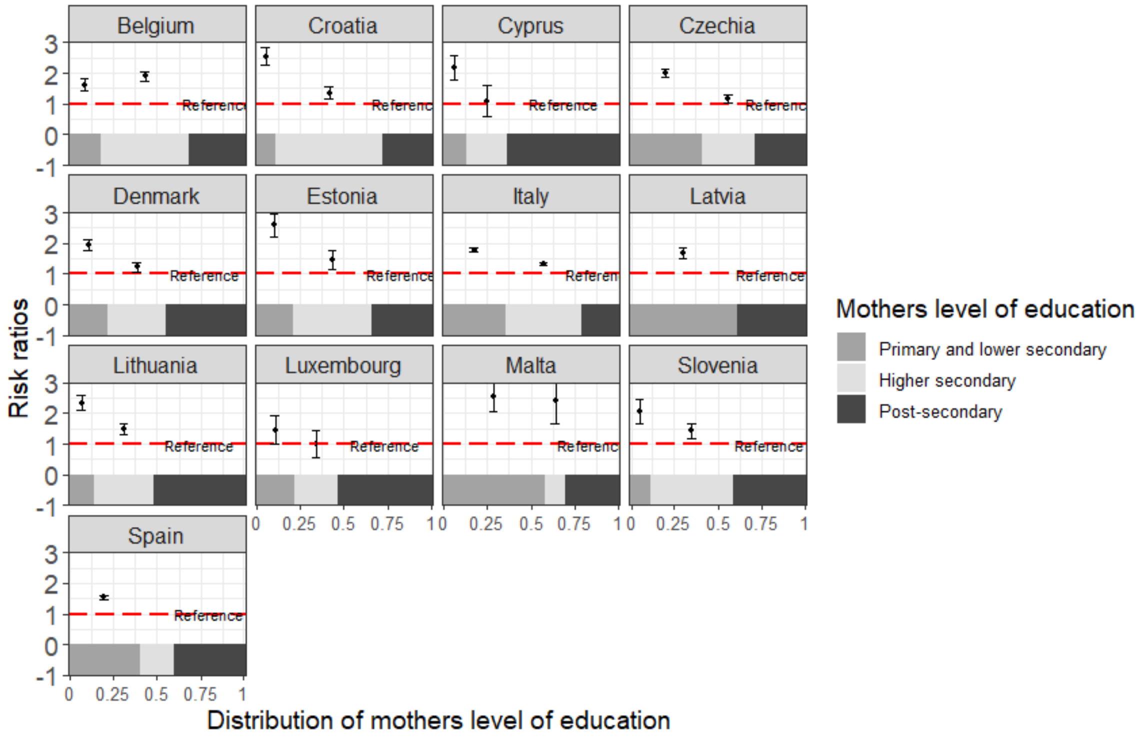



*Figure 11 Relative risk of stillbirth by mother's educational level*

# IV. Implications, limitations and next steps

A successful proof of concept

This deliverable describes the process, implementation and preliminary results of the perinatal health use case. This new protocol was successfully executed in a large number of European countries, considerably simplifying previous processes for collecting, compiling and analysing data. Once setup, these procedures are easy to update and data collection for 2021 using the same procedures is planned for this autumn. The wealth of comparable population birth data that can be collected using this approach is illustrated by the descriptive data presented in this report and opens up myriad possibilities for cross-country investigations to compare perinatal health outcomes and trends. A first major implication is therefore that this model constitutes a successful proof of concept study for a federated perinatal health information system.

Strengths of the approach

Strong points of the protocol are that the data hubs control all personal data which remain on their secure servers and only aggregated anonymous data tables are transferred. The software, model and scripts are open source and transparent. Automatic R Markdown quality checks and outputs are produced for users of the system immediately upon running the scripts. From a quality point of view, the use of an individual dataset leads to better harmonisation at the European level. This approach ensures that all the variables have similar definitions and are coded in an identical manner. The use of common scripts produces indicators computed in a similar manner. This leads to better statistics and comparisons. Another strong point is that this approach returns useful outputs on data quality and summary indicators in a matter of minutes to each data hub. Because feedback is immediate, countries can rapidly identify any mistakes in their original datasets.

Once the system is setup, it can provide a foundation for future work. Adding analyses using the same dataset for all countries or carrying out specific sub-studies among interested countries only requires specifying the scripts and rerunning them using the dataset that is already established and validated. Furthermore, other countries (or data holders in any institution) that would like to compare their data with the Euro-Peristat tables can construct the open source common data model and run the scripts to generate their own tables. Many institutions and hospitals already compare their indicators to those from Euro-Peristat and this would be a way for them to streamline this process and to ensure that their comparisons were valid.

Challenges and limitations

Nonetheless, the approach has constraints and limitations that need to be addressed for successful implementation. First, it requires the participation of (at least one) active and informed member in each country. The process of achieving consensus on the items in the common data model and specifying the procedures for the data collection and checking processes takes time. We held 15 network meetings in the period from November 2020 to June 2022 to discuss these points and review collected data. Data hubs spent between one to two day and several weeks preparing, testing and checking the data. Furthermore, the project's statistician conducted at least one (and often several) one-on-one calls with each data hub to set up the system, to provide guidance for installing R and to run and troubleshoot the scripts. This personalised approach was essential because small problems (formatting issues, use of the wrong code, not having the correct R package) can lead to significant delays, whereas a one-on-one approach can facilitate for their immediate resolution. In sum, the time to get this system to work from the data hub's and the central hub's perspective is significant and must be integrated into plans for sustainability and expansion.

Second, while the system works well once it is set up, the process of developing and troubleshooting the code requires an understanding of national data. In this use case, we benefited from previous work within the network to understand national data availability and limitations as well as from analyses to improve comparability of key indicators.[40,43,45-47] This experience within the Euro-Peristat network made it possible to propose harmonised definitions with a script that functioned well for all 25 countries that implemented the approach thus far. The minor errors discovered in the files or misunderstanding about definitions could easily be corrected. Implementing the expanded data model, however, will require more attention to the harmonization of data because several of the variables have not previously been collected by the network and several use hospital discharge diagnosis and procedure codes which pose challenges for comparisons across countries.[48]

Another challenge inherent in a federated model is that any omission or error in the R-scripts means that all countries have to rerun the corrected programmes. This can constitute a major constraint in a network with many participants who are busy and do not have resources targeted to this task. That being said, the rerunning of R-scripts and sending updating data is quick, less than 10 minutes. In order to reduce the likelihood of errors in the scripts, we pretested new scripts with volunteer countries and using synthetic databases as part of the development process.

Some of the complexity of communication back and forth could potentially be resolved with the PHIRI Docker software application created by WP7. This was developed in parallel to the use cases and therefore when the application was ready, most of the Use Case C data had already been collected. Further, because most of the Euro-Peristat data hubs do not have person months funded in the

PHIRI project, their options for mobilising institutional resources for installing the docker were more limited than in the other use cases where funded person months were available. The installation requires involvement of IT staff and approvals/authorisations for the installation. However, we did test the application in 2 countries participating in the PHIRI project (Croatia, Latvia) and several non-PHIRI countries have expressed interest in installing it. We will pursue this option going forward. While it is clear that there is an added value in facilitating the interface between the coordination hub and the data hubs, an outstanding question is how data transfer and analysis would be managed in a hybrid model.

Orienting capacity building priorities at the national and European levels
In addition to providing and testing a roadmap for a future information system, the second major implication of this work is to identify areas where capacity building in terms of data capture or production at a national level is required. The protocol identifies specific and actionable areas for improvement in countries that cannot implement this model for institutional or data-availability reasons or that cannot provide all elements of the core common data model. The expanded data model was not tested, but countries can use the list of items to prioritise health information upgrades. In many instances, these data exist in databases nationally (or regionally), but they are not combined into one database. Many countries have resolved these problems through linkage of routine data sources, which is known to improve the quality and breadth of data for surveillance and research.[49] There are many examples of successful routine birth data systems in Europe that can provide guidance for those looking for ways to develop better systems.

Finally a common problem is timeliness of data, a significant issue that was highlighted in the Euro-Peristat commentary published in the BJOG.[4] As of now, June 2022, final data from 2021 is available from only several countries. The time demands of current processes for the production of finalised routine birth data is a major constraint for using evidence for decision-making. This is especially acute during new infectious disease emergencies where data from previous years are not informative. The question of how to more rapidly move routine data from collection to analysis is a concern in all countries. Notwithstanding, our approach gave us access to data before official statistics were available and compiled on the European level and could constitute an important step forward in creating a rapid and efficient conduit between evidence and policy.

Next steps for implementation, analysis and dissemination
This report provides the first set of results from Use Case C on perinatal health, but the activities carried out for the Use Case WP6 have not come to an end. Until the end of the PHIRI project in October 2023, work to expand and to refine the protocol, dissemination activities and analyses will be continued.

Work to expand and to refine the protocol involves continuing to assist countries to implement the protocol. Many countries that have not yet contributed data face institutional obstacles that are time consuming to resolve. A difficulty is also identifying the appropriate contact person with direct access to data. We are hopeful that several more countries can test the model before the end of PHIRI. Further, the model will be expanded with the collection of data from 2021, available in most countries later in the year. This will provide a test of the protocols ability to be updated easily and yield valuable data on perinatal outcomes in 2021. There is a general concern that the persisting COVID-19 crisis, with its impact on mental health and wellbeing, may have had a greater negative impact on perinatal outcomes in 2021 than in 2020. Finally, we will also work with WP7 and our partners to install the PHIRI application in interested countries to expand the settings in which this approach is validated.

In terms of dissemination, several activities are planned. Through workshops in scientific conferences and scientific publications, we will present the results of the analyses of perinatal health indicators. Two workshops on the Use Case C results have been accepted at the European Public Health conference in Berlin in November. The first is the “Impact of the COVID-19 pandemic on perinatal health and perinatal health inequalities in Europe” which is part of the WP6/WP7 PHIRI workshop on the use cases and the second is a workshop entitled “Improving perinatal health and reducing inequality: the value of European population comparisons” with 4 presentations on results specifically related to perinatal health. We will also disseminate information about the federated analysis protocol. We have been in touch with UNICEF and WHO about implementing this approach in other countries outside of Europe. We will participate in outreach within PHIRI and in particular the planned stakeholder meeting with representatives of the European Commission to promote implementation of the research infrastructure and support policy making at European and National level.

We will continue the analyses of the data collected, as specified in our analysis plan, by synthesising the results from all countries once all the data have been received and verified and descriptive analyses are complete. This will involve conducting meta-analyses to assess pooled effects within Europe, measure heterogeneity across countries and adding covariables to describe the characteristics of the pandemic and societal mitigation measures in each country. These analyses will also benefit from continued exchanges and discussion with the other participants in WP6 and WP7.

# V. Conclusions and recommendations

This use case on perinatal health illustrates the feasibility of using federated analysis to facilitate rapid production of data and subsequent analysis of key perinatal health indicators in a large number of European countries. The successful implementation of this model has implications for future pandemic research and provides a roadmap for a health information system to monitor and evaluate the health of European pregnant women and their newborns.

The study’s results were reassuring with regard to birth outcomes in 2020 in a majority of countries. Observed decreases in preterm birth rates may be the result of healthcare disruption if medically indicated preterm births for pregnancy complications were not carried out. This may have delayed adverse effects on perinatal mortality and morbidity and continued surveillance is essential. Other hypotheses to explain this result focus on potentially positive consequences of the lockdowns, illustrating the complexity of balancing positive with negative indirect effects of the COVID-19 pandemic mitigation strategies in heath assessments. The high country-level heterogeneity in perinatal outcomes associated with the pandemic between European countries suggests that some government policies to mitigate the pandemic may have been more protective of pregnant women and newborns than others. Identifying potentially relevant policy characteristics is important for continued management of the COVID-19 pandemic and for future infectious disease outbreaks.

A final set of conclusions and recommendations address preparedness for a future pandemic. This use case developed a set of indicators for a pandemic response system using birth data in Europe, including an expanded list of indicators, considered feasible in at least half of participating countries, which would enable a greater focus on healthcare effects. Testing this expanded model is an important next step. Action is also needed to improve national data sources. Despite very promising results regarding the rapid transfer and synthesis of data at the European level in this study, population birth data sources in Europe face major limits in a pandemic due to slow processing and missing data items in some countries. For this reason, reliable results about the pandemic's impact can only be provided for the period of March to September of the year 2020. Priority areas for improvement include modernising and streamlining the processes for the production and transfer of birth data and linkage of population birth data sources, including with infectious disease databases, to ensure that most up-to-date and relevant data are available to inform practice and policy.

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# VII. Appendices

**Provided as a separate document, except for appendix 2**

## 1. Use Case C Protocol

| STUDY PROTOCOL |
| --- |
| The COVID-19 Pandemic and Maternal and Newborn Health: |
| Assessment of indirect and direct effects using routine population birth data |

**A study carried out by the Euro-Peristat Network**

**PHIRI (Population Health Information Research Infrastructure) project**

**Work Package 6, Use Case C**

**Coordination: Inserm, Paris**

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# 1. Background and context

Pregnant women and newborns constitute vulnerable populations in an infection disease pandemic

During an infectious disease pandemic, pregnant women and newborns are vulnerable populations because of the specificity of their immune systems, their non-deferrable needs for health services, the effects of environmental factors on their health - notably the influence of social circumstances on risks of morbidity and mortality-, and the long-term consequences of adverse health events.

The novel coronavirus, SARS-CoV-2, has exposed vulnerabilities in our health system's capacity to respond to pandemics both in the management of patients with COVID-19, but also, more broadly, in the care of non-COVID-19 diseases. This is particularly true for maternity care that brings low-risk populations into contact with the health system for care that cannot be rescheduled or postponed. In addition, care for this generally low-risk population relies heavily on routine and regular contacts with health providers because of challenges in distinguishing life-threatening complications from unremarkable, everyday symptoms.

Containment strategies for SARS-CoV-2 also resulted in severe restrictions to normal everyday life, raising hardship and anxiety in families related to their personal safety and their economic livelihoods. Family units have been called upon to play a central role in the fight against this virus. Beyond the changes in care seeking patterns, stress and anxiety, which have been shown to influence perinatal complications, could lead to increases in adverse outcomes such as preterm birth, restricted growth and maternal complications. In times of economic hardship, indicators such as stillbirth rates and infant death rates rise, but underlying mechanisms remain poorly understood.

Population data are required for research on the health of pregnant women and newborns, but these are not readily available

To investigate the direct (due to infection by SARS-CoV-2) and indirect (due to health system or other changes related to the pandemic) effects of the COVID-19 on maternal and newborn health, large, population-based data are needed. Many studies have assessed the impact of COVID-19 on complications during pregnancy, maternal-newborn transmission and newborn health.[1] These have been essential for guiding obstetric and neonatal care during the pandemic. However, these cohorts focus on women and newborns presenting with symptoms of infection or who test positive and cannot respond to the broader questions about how the pandemic affects population health.

Data have also been produced on the indirect effects of the COVID pandemic, although because of delays in the production of health data, these were not available for most of 2020.[2] Further delays occur as this information is synthesized in reviews, although this has begun to occur in the latter part of 2021.[3,4] These assessments from routine birth data are needed to evaluate perinatal risks, including preterm birth, fetal growth restriction, stillbirth and, neonatal and infant mortality at the populationlevel. Initial synthesis of this evidence has shown high heterogeneity in outcomes by country, with some experiencing increases in adverse outcomes, such as stillbirth, whereas elsewhere some negative outcomes, such as preterm birth have decreased.[3,4]

Given these initial findings, it is important to compare the geographic and temporal distribution of perinatal health outcomes, taking into consideration differential secular trends, in order to produce actionable knowledge about the impact of the COVID-19 pandemic on perinatal health. Further, a panEuropean approach, assessing effects in multiple settings, would make it possible to test the association with viral circulation and societal mitigation measures in a wide-range of settings. This is important for an understanding of underlying causal mechanisms and the potential effectiveness of social or health service interventions.

The PHIRI project: an opportunity to bring together data on maternal and newborn health

PHIRI (Population Health Information Research Infrastructure) is a Health Information project on COVID-19 financed by the European Commission to support research across Europe through the identification, access, assessment and reuse of population health and non-health data to underpin (public health) policy decisions on COVID-19 and future health crisis. The project builds on the BRIDGE Health project and the Joint Action InFact. PHIRI was launched in November 2020 and it includes 41 partners in 30 different countries. The aim is to share data and expertise between countries through a Health Information portal on population health in close interaction with key stakeholders in the health information landscape, in particular with ECDC, EUROSTAT, JRC, OECD, and WHO. One work package within the PHIRI project conducts research of immediate relevance for public health policies and management of the COVID-19 pandemic using a federated model, making it possible to share data rapidly and securely. One of the four use cases in this work package is on “the impact of COVID-19 on perinatal health and perinatal health inequalities” and is piloted by the Euro-Peristat network. Ultimately, PHIRI aims to structure sustainable and reactive health information systems in Europe.

## 2. Objectives

As part of the broader PHIRI project, this study aims to investigate the indirect effects of the COVID-19 pandemic on pregnant women and newborn health using data collected routinely on births in European countries. Secondary objectives are to examine the use of population birth data for assessing the direct effects of infection. Finally, the project aims to promote sustainable European health information systems by structuring data collection and reporting to improve data availability and timeliness to guide national and European policy.

Principal objectives are to:

1. Investigate principal maternal and newborn health outcomes in relation to population temporal and geographic exposure to SARS-CoV-2. We will distinguish between countries and time periods defined by the intensity of viral circulation and the restrictiveness of social measures and confinement orders.
2. Assess the impact of social and geographic factors on these effects by integrating individual or area-based socioeconomic indicators within this broader exposure framework and identify atrisk groups based on social context.

Secondary objectives are to:

1. Evaluate the timeliness and completeness of data in routine birth data for evaluating exposures and outcomes relevant for the evaluation of this and future pandemics. Make recommendations about how to improve routine birth data to provide actionable data for future epidemics.
2. Analyse the codes/variables for COVID-19, their integration into birth registers and their validity and application for research and, if possible, describe direct outcomes for mothers and infants associated with COVID-19 infection.

3. Assess the federated data collection model for its capacity to improve European-level health information systems and to provide data on perinatal health to inform policy and practice nationally and on the European level.

# 3. Methods: data sources, study population and indicators

## 3.1 Euro-Peristat Network

This project is conducted by the partners participating in the Euro-Peristat Network. The objective of the Euro-Peristat Network is to establish a high quality, innovative, internationally recognized and sustainable European perinatal information system. This system's goal is to produce data and analysis on a regular basis for use by national, European and international stakeholders who make decisions about the health and health care of pregnant women and newborns. Euro-Peristat began in 1999 as part of the EU's Health Monitoring Programme and now has official representation from 31 countries across Europe and a large network of contributing experts. The project builds on the Euro-Peristat list of recommended indicators for perinatal health surveillance which have been used to collect data for European Perinatal Health Reports in 2008, 2013 and 2018 and many scientific publications (see www.europeristat.com). The project is coordinated by Inserm, the French National Institute of Health and Medical Research, in Paris.

## 3.2 Data sources

The data sources used by the Euro-Peristat network are:

- birth registers
- hospital discharge data
- vital statistics
- civil registration
- causes of deaths statistics

When more than one source includes the data used to construct the indicators, the country team decides on the source that is best able to produce high quality and comparable indicators. Annex 1 lists the participants and institutions involved in the collection of the Euro-Peristat indicators.

## 3.3 Study population and period

The Euro-Peristat uses the following criteria for defining births for data collection: all births (live, stillbirths and terminations of pregnancy) with a gestational age of 22+0 weeks and over or with a birthweight greater or equal to 500 grams if gestational age is missing.

If countries are unable to follow this definition, national definitions can be used and are noted.

The study period covers all births from **2015-2020.** This is necessary because to assess changes during the pandemic in 2020, we will need to assess trends over previous years. Collecting data from 2015 also makes it possible to cross-check with the last data collection exercise in 2015.

### 3.4 Perinatal health indicators

Infant and maternal outcomes selected for this study are based on the Euro-Peristat core and recommended outcomes as well as a consensus process carried out with the Euro-Peristat network to define other data items of relevance to assessing the impact of the COVID-19 pandemic.

All of the Euro-Peristat core indicators that are feasible are included. One core indicator, maternal mortality, cannot be collected because the outcome is very rare and needs specific collection procedures to be reliable. Recommended indicators are those selected during the consensus process.

Data cover newborn and maternal outcomes, population risk factors, health care and exposures related to COVID.

*Table 1 Perinatal health indicators included in the PHIRI Use Case on Perinatal Health*

| Data category | Core indicators (number) | Recommended indicators (number) | New indicators |
|---|---|---|---|
| Newborn health outcomes | Stillbirth (C1)<br>Termination of pregnancy (C1)<br>Neonatal death (C2)<br>Infant death (C3)<br>Birth weight (C4)**<br>Gestational age (C5) | Apgar (R2) | Transfer to NICU<br>Neonatal morbidity<br><br>For C4: it was decided to modify the definition to include small for gestational age (requires data on sex of baby) |
| Maternal health outcome | | Maternal morbidity (R6* however, individual items are redefined)<br>Hysterectomy associated with obstetrical haemorrage<br>RBC transfusion associated with obstetrical haemorrhage<br>Eclampsia<br>Transfer to ICU | Gestational diabetes<br>Preeclampsia |
| Population risk factors | Multiple pregnancy (C7)<br>Maternal age (C8)<br>Parity (C9) | Body mass index, BMI (R12)<br>Distribution of mother's place of birth (R8)<br>Distribution of mothers' education (R9)<br>Distribution of households' occupational classification (R10) | SES – deprivation score |
| Health care/medical practices | Mode of delivery (C10) by all sub-groups<br>Induction of labour** | Induction of labour (R15)<br>Place of birth (R16)<br>Breastfeeding at birth (R20) | Postpartum hospital stay (mother) |

| | | | |
|---|---|---|---|
| COVID exposures | | | Date of birth (to be linked to information on infection and societal mitigation measures)<br>COVID infection (ICD or other code)<br>Geographic location |
| Euro-Peristat indicators not currently included in data collection | Maternal mortality (C6) | Congenital anomalies (R1) Fetal and neonatal deaths due to congenital anomalies (R3) Cerebral palsy (R4) Maternal mortality by cause(R5) Tears to the perineum (R7)<br>Mother's country of origin (R11) | |
| | | Pregnancies following subfertility treatment (R13)<br>Timing of 1st prenatal visit (R14)<br>Very preterm infants delivered in units without NICU (R17)<br>Episiotomy (R18) Births without obstetric intervention (R19) | |

# 4. Methods: data collection and management

## 4.1 Data collection using a federated model

The data collection process uses a federated model, whereby Individual patient data including outcomes and exposures are not transferred from the institution with authorisation to hold and analyse them. Only aggregate data on indicators are collected and provided to Euro-Peristat coordination team.

The figure below schematises the data collection process. Data Hub are the participating in each country. The datasets with individual data on births are kept in the servers as defined by local security and other specifications. In the schema the central Hub is INSERM.

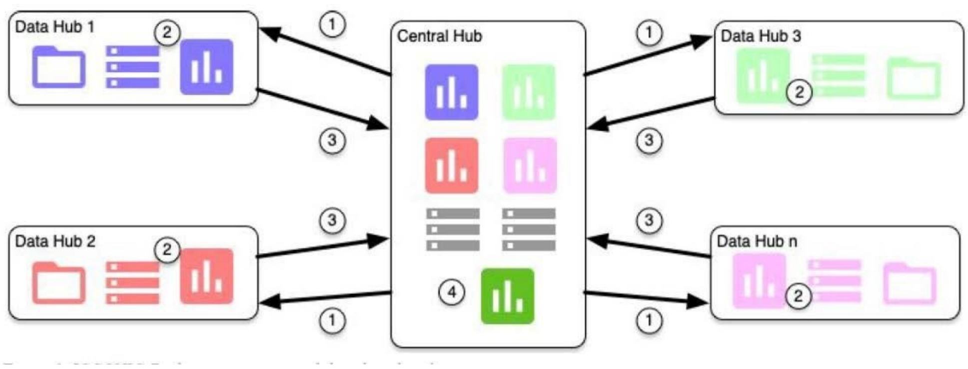

*Figure 1. Architecture for exchanging data - hub-central hub*

Individual-level data does not move outside the each data hub. Only the scripts and results are transferred between the data hub and the central hub. The data hubs host and curate data and/or have "easy" access to data. The coordination hub develops code, coordinates code exchange and provides technical support.

Within the PHIRI project, WP7 (leader: Enrique Bernal Delgado, Instituto Aragones De Ciencias De La Salud) is responsible for creating and validating this federated research infrastructure. Data collection and transfer procedures, based on open software, including R, will be updated as this system is refined and validated.

## 4.2 Common data model

The study will be carried out in two steps – the first using a Core Common Data Model and the second using an Expanded Common Data Model including variables based on the indicators described above. The second stage will require additional project support and is not planned until 2023-2024. Although we present the expanded version of the variables, the data collection procedures descried here only to the first stage. Another data collection protocol will be developed and approved for the second stage if further support is ascertained.

The tables below list the variables in the first data collection step and those that will be considered for the second step.

The Core and Expanded Common Data Models are provided in Annex 2.

**The first phase data list** includes the data from the core data collection list in addition to time stamps (year, month, day) to allow for analysis of data over time and socioeconomic variables, which can be provided as individual level data (maternal education or parental occupation) or small area based socioeconomic scores as available in individual countries.

*Table 2 Data items included in the Core Data Model*

| *Label of variable* | **Description** |
|---|---|
| *baby_id* | baby identificator |
| *Mother* | mother identificator |

| | |
|---|---|
| *GA* | gestational age |
| *BW* | birthweight at delivery |
| *SEX* | Sex of baby |
| *MULT_B* | type of pregnancy |
| *VITAL* | vital status at birth |
| *NNM* | mortality in first month |
| *NNM_pre* | mortality in first week |
| *IM* | mortality in first year |
| *MATAGE_B* | maternal age at the birth of the baby |
| *PARITY_B* | parity |
| *PRES* | presentation of the baby at delivery |
| *PREVCS* | previous caesarean delivery |
| *MOD* | mode of delivery |
| *TYPECESAR* | Type of caesarean |
| *INSTRUMENT* | Instrumental delivery |
| *ONSET* | mode of onset |
| *COUNTRY* | Country |
| *Year* | year of the birth |
| *Month* | month of the birth |
| *Day* | day of the birth |
| *SES_ED* | education of the mother |
| *SES_OccM* | occupation of the mother |
| *SES_OccF* | occupation of the father |
| *SES* | deprivation score of living area |

**<u>The data item or the second phase</u>** will be based on the following short list established after two rounds of a Delphi consensus. Selection will be based on feasibility and data quality. *Table 3 Data items included in the Expanded Data Model*

| Label of variable | Description |
|---|---|
| **APGAR** | 5 minutes APGAR score by gestational age |
| **PREPREG_BMI** | mother's prepregnancy BMI |
| **BREASTFED_BIRTH** | breastfeeding at birth |
| **COUNTRY OF BIRTH** | Maternal country of birth |
| **MAT_MORB_HYST** | severe maternal morbidity (hysterectomy associated with obstetrical hemorrhage) |
| **MAT_MORB_TRANS** | Severe maternal morbidity (RBC transfusion associated with obstetrical hemorrhage) |
| **MAT_MORB_ECLAMPSIA** | Severe maternal morbidity (eclampsia) |
| **MAT_MORB_ICU** | Severe maternal morbidity (transfer to ICU) |
| **DEL** | volume of deliveries of the birth place |
| **NICU_ADM_TERM** | Term babies admitted to NICU |
| **NEONAT_MORB** | Neonatal morbidity based on ICD-10 codes |
| **DIAB_PREG** | Diabetes in pregnancy |
| **PREECLAMP** | Preeclampsia |
| **PPSTAY** | Length of postpartum stay |
| **COVID** | Covid infection at delivery (use of ICD or other code) |
| **VACCINATION** | Whether vaccinations were received |
| **NUTS 2** | EU geographic region |

## 4.3 Data exchanges

The schema below describes the procedures for the pretest and first phase of the data collection process. A similar schema will be used for subsequent waves of data collection. The R scripts will be determined for each country.

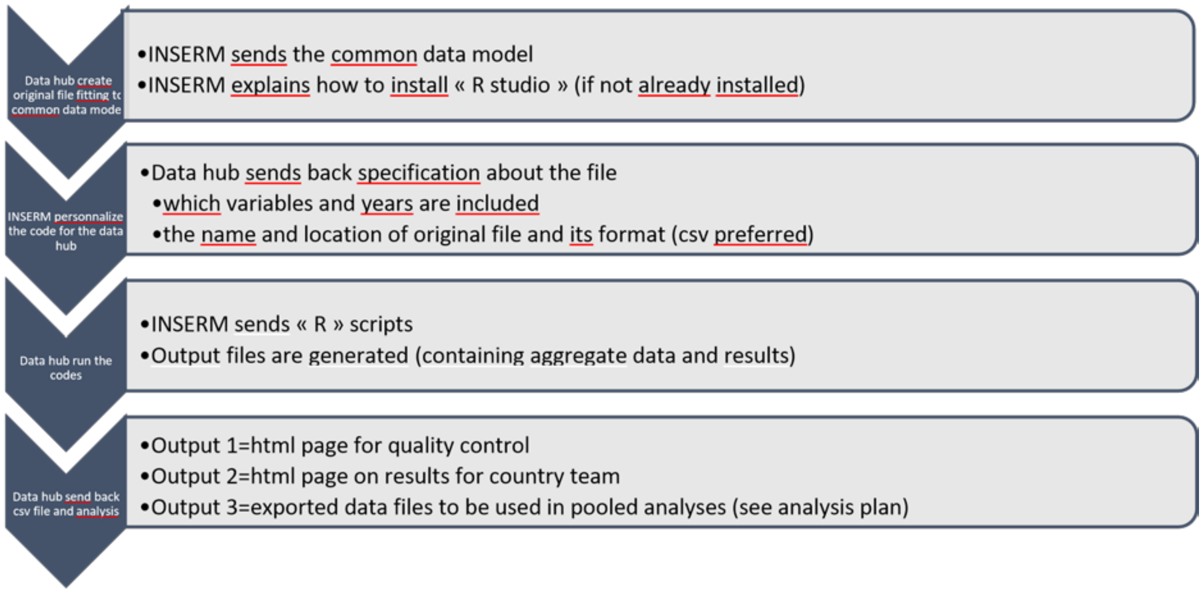


*Figure 2 Schema for data collection*

## 4.4 Protection of personal data and transfer and storage procedures

**Measures to ensure that personal data is not transferred:**

- No personal data are included in the common data model (names, addresses, other directly identifying information).
- The data providers, who are authorized data controllers within their institutions, run all of the R scripts and inspect the outputs before the files are transferred to the central hub.
- Output files include only aggregate data tables which are designed to be anonymous (see below).
    - The data model and scripts are publically available

**Ascertaining that transferred data are anonymous**

To ascertain that the exported data were in line with the GDPR's definition of anonymous data (Recital 26), we assessed "whether a natural person is identifiable" by taking account "of all the means reasonably likely to be used, such as singling out, either by the controller or by another person to identify the natural person directly or indirectly." In the absence of any personal data included in the files, this means ensuring that the data tables should not include any indirectly identifying personal information that would enable identification through linkage to other sources. To ensure this, the following rules are applied:

- Output files only include aggregate data tables, with a maximum of 3 cross-tabulated variables.
- Aggregate data files cannot be linked to each other to augment the number of data items available, even in the case of a cell size of 1 individual because the data items included in the tables do not overlap.
- No dates (except year) or location identifiers (except country) are used in aggregate crosstabulated tables which can have small cell sizes.

- Month is only used for aggregated indicators which do not have a small cell sizes. Monthly rates of indicators are needed for time series analyses (see analysis plan).
- All sociodemographic characteristics (age, parity, socioeconomic status) are exported in grouped categories.

**Measures to ensure security and integrity of data**

To ensure the security and integrity of the data, transfers will use INSERM's file transfer system with data encryption (RENATER, www.renater.fr) or another secure method proposed by the partner or by WP7 which is developing the architecture for the data hub within PHIRI.

Data stored at Inserm are kept on a secure server (NAS). Backups are performed every week. Access to the office is restricted to those with personal badges; all users have a personal password, sign an agreement with Inserm regarding security procedures, and only have access to parts of the server for which they are explicitly authorised. An antivirus is installed on all computers.

Because the data are assessed to be anonymous, as explained above, aggregate results returned by countries will not be subject to suppression of small cell sizes, unless this is required by the institution's or the country's regulations. Having granular details is essential to permit accurate totals when subgroups are combined and to define comparable indicators. This has been shown in previous EuroPeristat publications which have used the same data collection protocol since 2000.[5-9]

For the publication of results, however, details on cell sizes under 5 will not be included in reports, web tables or scientific papers. In addition, attention will be paid to providing estimates of uncertainty (confidence intervals) in order to make sure that indicators based on small sample sizes are interpreted correctly. Note that if an institution or a country has more stringent requirements (i.e. cell sizes of 10), this will be respected for publication of data from that country. If some institutions have more stringent disclosure rules for the transfer of data with small cell sizes, data transfer agreements can be established with the coordination team at Inserm.

### 4.5 Data collection calendar

Data collection will begin in July of 2021 and continue until March 2022. Inserm will work with each country to customize the data collection protocol to each country.

## 5. Methods: Data analysis and dissemination

The analysis will proceed in iterative steps.

### 5.1 Data cleaning and validation

A first step involves verifying data quality and completeness. This is first done automatically with the R scripts (html page created for quality control by package "dlookr").

**After the data are collected, the following Euro-Peristat operational guidelines on data quality apply:**

- Network meetings discuss quality of data and review preliminary results.
- Data providers from each country are involved in assessing data quality and checking tables.

- All submitted data are checked by the coordinating team (s) and a report with discrepancies returned to the participating country.
- Data should also be checked with previous years and other sources (Eurostat) in order to detect discrepancies and errors.
- Data from 2015 will be compared with European Perinatal Health Report on 2015 data

## 5.2 Analysis strategy

1 We will first analyse the perinatal health indicators included in phase 1 of the study by year to establish whether the year 2020 differs from previous years and to determine background rates and trends. This analysis will be based on the Euro-Peristat output tables which will be produced for each year.

   - This will require collecting the Euro-Peristat core indicators using appropriate subcategories as done in previous data collection exercises.
   - For key indicators, measures of trend using regression analyses, adjusting for age and parity, will be produced and the results of these analyses will be exported.

2 More specific analyses will be undertaken using monthly rates and specific periods in 2020, including (i) all of the post-pandemic period and (ii) country-specific lockdown periods. Lockdown periods will be defined using the ECDC database: (https://www.ecdc.europa.eu/en/publicationsdata/download-data-response-measures-covid-19 ). The table below describes the hypotheses to be tested, the indicators used and the analysis methods and sub-group analyses which are planned.

*Table 4 Research Questions and indicators for the analysis by month and COVID-19 period*

| Research question related to the COVID-19 Pandemic | Outcome measure and definition | Rationale for question and outcome |
|---|---|---|
| Was there an evolution in birth rates during the pandemic? | • Number of births per month | Many countries have observed a decline in births. When fertility changes, this can affect the risk level of the childbearing population, which can affect health outcomes. |

| | | |
|---|---|---|
| Was there a trend in the stillbirth rate during the pandemic? | • Stillbirth rate ≥22 weeks<br>• Stillbirth rate ≥24 weeks<br>• Stillbirth rate ≥28 weeks | There is a concern that stillbirth rates rose during the pandemic, reflecting restricted access to health services. We will use several outcomes. While the stillbirth rate using the 24 week threshold is considered optimal in EuroPeristat studies, not all countries can produce it. Further, adopting a 28 week threshold will permit comparisons with other studies using WHO guidelines |
| Was there a trend in neonatal mortality during the pandemic? | • Neonatal mortality rate (NMR) ≥22 weeks<br>• NMR rate ≥24 weeks<br>• Early NMR rate ≥22 weeks<br>• Early NMR rate ≥24 weeks | Some countries do not have data on all neonatal deaths and therefore a decision was made to produce the early NNR separately. Similar reasons, described above, exist for the gestational age thresholds. |
| Was there a trend in perinatal mortality during the pandemic? | • Perinatal mortality rate (PMR): stillbirths ≥22 weeks and early neonatal mortality<br>• PMR: stillbirth ≥24 weeks and early neonatal mortality | By combining data from stillbirths and early neonatal deaths, the PMR may be a more robust indicator to detect changes given the short time periods covered. |
| What was the trend in preterm birth during the pandemic | • Live singleton preterm birth rates (<37 weeks)<br>• Live singleton very preterm birth rate (<32 weeks) | Contrary to expectations, decreases in preterm birth rates have been observed in some, but not all contexts. Some have claimed that this decrease is primarily among very preterm births. |

| | | |
|---|---|---|
| Was there a trend in fetal growth? | • Live singleton low birthweight rates (<2500 g)<br>• Live singleton small for gestational age (SGA) rates<br>• Live singleton SGA rates for term births (≥37 weeks)<br>• Live singleton SGA rates for preterm births (<37 weeks) | This will assess whether any changes to preterm birth rates also affected fetal growth during pregnancy. This analysis uses a traditional measure of fetal growth (births <2500) which is less specific and can include preterm births with normal growth as well as a new indicator for Euro-Peristat based on recent work on the assessment of fetal growth. [10] |
| Were there changes in the child bearing population linked to declining fertility? | • % of births to mothers <24 years of age and ≥35 years of age<br>• % of primiparous births<br>• % of multiple births<br><br>By preterm/term | The change in fertility during the pandemic may have led to changes in the composition of the childbearing population at the end of 2020 (for term births in Nov/Dec and for preterm births starting in Sept). |
| Did obstetrical practices related to mode of delivery change during the pandemic? | • Caesarean delivery (CD) rate<br>• Prelabor CD rate<br>• Intrapartum CD rate<br>• Indicated CD rate (taking into consideration inductions) • Spontaneous CD rate (considering inductions)<br>• Induction rate<br>• Instrumental delivery rate | Changes in obstetrical practices may reflect attempts to minimize infection risks during the pandemic. |

a. 3/ Sub-group analyses and other perinatal outcomes: We will investigate trends within specific sub-groups, including by sociodemographic characteristics (maternal age, parity, BMI and SES groups) and by infant characteristics (sex). The first set of analyses will focus on the SES groups and infant sex, as below. These analysis will compare the whole pandemic period and the first two months of the pandemic.

*Table 5 Sub-group analyses*

| Sub-group | Outcomes | Rationale |
|---|---|---|
| Socioeconomic differences in outcomes | SB, NNM, PNM, live singleton PTB, live singleton SGA, CD, prelabor CD and intrapartum CD (as described above) | Women with lower socioeconomic status may be more vulnerable to the negative impact of the pandemic. |

| | | |
|---|---|---|
| Sex of baby | SB, PNM, live singleton PTB, live singleton SGA | An exploratory analysis as males may be more vulnerable to negative external impacts during pregnancy. |

4/ In a second phase, the set of recommended and new indicators will be added, including COVID-19 codes. An extension to this protocol will be produced, including a detailed analysis plan that will be developed after finalisation of data definitions and assessment of data completeness.

## 5.3 Publication and dissemination of results

**Purposes for which data will be used**

The data provided will be used solely within the Euro-Peristat project to analyse and report on nationallevel perinatal health indicators and to achieve the objectives as defined in this protocol.

Access to the data by researchers outside of the Inserm coordination team will be conditional on approval by all members of the Euro-Peristat scientific committee and signature of a data use agreement by the researcher.

**Data validation and publication**

- All data tables are checked and endorsed by SC members before publication in a scientific article or being made public in a report or on the Euro-Peristat website.

- The Euro-Peristat group fixes a set of analysis priorities and establishes working groups to work on these analyses and produce publications in accordance with Euro-Peristat authorship guidelines (attached).

**Annex: Description of the data outputs collected**

| Variable description | Time period requested | Geography to which data relate |
|---|---|---|
| | **YEAR** indicate **each** year from 2015 to 2020 | |
| Number of live births **by gestational age (in completed weeks)** and **multiplicity (singletons vs multiple births)** | YEAR | National level |
| Number of live births **by birth weight (in 500g categories)** and multiplicity | YEAR | National level |
| Numbers of stillbirth by gestational age and multiplicity | YEAR | National level |
| Numbers of stillbirth by birth weight (in 500g categories) and multiplicity | YEAR | National level |
| Number of early and late neonatal deaths by gestational age and multiplicity | YEAR | National level |
| Number of early and late neonatal deaths by birth weight (500g categories) and multiplicity | YEAR | National level |
| Number of infant deaths by gestational age and multiplicity | YEAR | National level |
| Number of infant deaths by birth weight (500g categories) and multiplicity | YEAR | National level |
| Number of multiple births by number of foetus | YEAR | National level |
| Number of births **by maternal age (5years categories)** and multiplicity | YEAR | National level |
| Number of births **by parity of the mother (nulliparous vs multiparous)** and multiplicity | YEAR | National level |

| Variable description | Time period requested | Geography to which data relate |
|---|---|---|
| Number of births by mode of delivery, by gestational age and multiplicity | YEAR | National level |
| Number of births by mode of delivery and by parity | YEAR | National level |
| Number of births by mode of delivery and by presentation of the child at birth | YEAR | National level |
| Number of births by mode of delivery and by previous caesarean section | YEAR | National level |
| Number of births small for gestational age | YEAR | National level |
| Number of births large for gestational age | YEAR | National level |
| Number of births by Robson groups by mode of delivery (CS vs all births) | YEAR | National level |
| Mean, Median, Q1, Q3 and SD of birthweight by GA and by sex | All years 2015-2020 (not by year) | National level |
| | **MONTH** indicate **each** month of the period 2015 to 2020 | |
| Number of live births ≥22 weeks (wks), ≥24wks , ≥28wks | a) MONTH<br>b) By YEAR and by maternal SES<br>c) By YEAR and by sex of the baby | National level |
| Number of stillbirths ≥22wks, ≥24wks , ≥28wks | a)MONTH<br>b)By YEAR and by maternal SES<br>c)By YEAR and by sex of the baby | National level |
| Number of births <37wks and <32wks | a)MONTH<br>b)By YEAR and by maternal SES | National level |

| Variable description | Time period requested | Geography to which data relate |
| --- | --- | --- |
| | c)By YEAR and by sex of the baby | |
| Number of births <2500grams | MONTH | National level |
| Numerators and denominators for rate maternal age <25 years and ≥35 years | MONTH | National level |
| Numerators and denominators for rate primiparity | MONTH | National level |
| Numerators and denominators for rate multiple births | MONTH | National level |
| Numerators and denominators for rate caesarean delivery (CD), CD prelabor, CD intrapartum | a)MONTH<br>b)By YEAR and by maternal SES<br>c)By YEAR and by sex of the baby | National level |
| Number of CD prelabor, and CD intrapartum | MONTH | National level |
| Number of CD with spontaneous labor and with induced labor | MONTH | National level |
| Number of instrumental deliveries | MONTH | National level |

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## 2. Meetings held during the project

| Type of meeting | Date of meeting | Number of participants |
|---|---|---|
| Plenary meeting | 03/12/2020 | 41 |
| Plenary meeting | 15/01/2021 | 34 |
| Plenary meeting | 26/03/2021 | 51 |
| Plenary meeting | 03/06/2021 | 50 |
| Plenary meeting | 02/09/2021 | 43 |
| Plenary meeting | 21/10/2021 | 38 |
| Plenary meeting | 16/12/2021 | 36 |
| Plenary meeting | 13/01/2022 | 34 |
| Plenary meeting | 23/02/2022 | 40 |
| Plenary meeting | 23/03/2022 | 38 |
| Plenary meeting | 27/04/2022 | 30 |
| Working group meeting | 13/01/2022 | 34 |
| Working group meeting | 03/02/2022 | 29 |
| Working group meeting | 03/03/2022 | 20 |
| Working group meeting | 17/03/2022 | 19 |

## 3. Results of first survey: Commentary published by in the BJOG

BJOG An International Journal of Obstetrics and Gynaecology
Royal College of Obstetricians & Gynaecologists

DOI: 10.1111/1471-0528.16946
www.bjog.org

Commentary

# Population birth data and pandemic readiness in Europe

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## Introduction

The SARS-CoV-2 pandemic exposed multiple shortcomings in national and international capacity to respond to an outbreak of infectious disease. It is essential to learn from these deficiencies to prepare for future epidemics. One major gap is the limited availability of timely and comprehensive population-based routine data on the impact of COVID-19 on pregnant women and babies. As part of the Horizon 2020 Population Health Information Research Infrastructure (PHIRI) project on the use of population data for COVID-19 surveillance, the Euro-Peristat Research Network investigated the extent to which routine information systems could be used to assess the effects of the pandemic by constructing indicators of maternal and child health and COVID-19 infection. The Euro-Peristat network brings together researchers and statisticians from 31 countries to monitor population indicators of perinatal health in Europe, and periodically compiles data on a set of ten core and 20 recommended indicators.[1]

## The effect of the pandemic on the health of pregnant women and babies

At the onset of the pandemic, single-centre hospital studies and rapidly mounted population-based studies provided vital information to guide clinical care and policy by documenting the greater risks of admission to intensive care and of pregnancy complications, such as preterm delivery and pre-eclampsia, among pregnant women with COVID-19.[2] They also showed generally good outcomes for most infected pregnant women and babies.[2] Systematic reviews of this growing body of work have provided more robust guidance, but are limited in their ability to capture key population outcomes such as stillbirth and neonatal death, which occur too infrequently to be included as outcomes in most single- and even multi-centre studies. The most recent update of a living systematic review, based on 192 studies of pregnant women with COVID-19, with 97 studies investigating perinatal outcomes, included only 72 stillbirths and 41 neonatal deaths.[3]

Research has also accumulated on the effects of the pandemic on the general population of pregnant women. These indirect effects may result from changes in health care access or quality, through health-system failures, policies to reorganise care, such as moving to telemedicine consultations, or women's reluctance to seek care for fear of infection, as well as from economic adversity and increased stress. A recent systematic review provides a valuable overview of 40 studies on the indirect effects of the pandemic on multiple maternal and perinatal outcomes, but also reveals the lack of research using population birth data.[4] For example, some very small studies reported unexpected decreases in preterm birth rates during the first lockdown in March and April 2020.[5,6] Ten further studies on preterm birth in high-income countries were identified by the review, yielding an overall pooled effect in favour of a decrease in preterm birth, but with substantial heterogeneity.[4] However, only three studies were population-based regional or national studies. Only one of the eight studies on stillbirth included in the review was population based.

## Surveillance of perinatal health during a pandemic requires population-based data

As pregnant women and newborns are generally in good health, studies to monitor their health require large population-based samples. Further, trend data from previous years

*For a list of members of the Euro-Peristat Research Network, see the Appendix.

are required for reliable assessments of change because seasonal effects, secular trends in birth rates and pandemic-related changes in fertility, as observed during CoV-SARS-2,[7] can impact on perinatal outcomes. A population approach is also essential because single- and multi-centre studies may not detect systemic changes that result from disruption to the organisation of healthcare services. They may also be unreliable if population movements affect their activity levels and patient case mix. For instance, 17% of residents of the Parisian region moved to other parts of France during the first lockdown.[8] Finally, comprehensive coverage, including disadvantaged populations, is needed because perinatal outcomes are sensitive to changes in socio-economic circumstances, and social disadvantage increases vulnerability to infection and its consequences.[2]

## Population birth data in Europe: a survey of the availability and timeliness of key indicators

To assess the availability of population birth data in Europe, the Euro-Peristat network developed an online survey for participating countries asking about the availability of preliminary and verified finalised birth data for constructing core perinatal health indicators, including stillbirth, neonatal mortality, preterm birth, low birthweight and caesarean rates for births from (i) January–April 2020 and (ii) all of 2020. We also enquired about whether codes had been routinely added to birth data to indicate COVID-19 infection. The initial survey was completed in June–July 2020 and updated in November–December 2020 to include information on linkage and disruptions to reporting systems after a discussion of preliminary results by the country teams. Twenty-seven countries and the constituent nations of the UK provided data (Table S1).

Some countries used several data sources, including birth and death certificates, birth notification systems, or stillbirth and abortion registers, to generate the full set of core indicators. In these cases, we asked for information about the availability of data to generate stillbirth, preterm birth, low birthweight and caesarean rates, as they are often available earlier than data on neonatal or infant deaths.

## Timeliness of data

Figure 1 presents the estimated timing for accessing preliminary and final population data on births in 2020 and illustrates the considerable heterogeneity between countries. About half of the countries had preliminary data on the first lockdown period by November of 2020, with half having the final data by May 2021. Final data for the year 2020 started to become available in March 2021, with half of the countries having data available by September 2021. Figures distinguishing between sources that rely solely on civil registration data and those using medical registers or hospital discharge databases show that, especially for preliminary data, medical registers provided more rapid access.

Some countries reported disruptions or changes of data procedures related to the pandemic that may impact on quality or completeness, particularly for preliminary data. These were mainly as a result of personnel being repurposed for other data or clinical duties, resulting in backlogs in processing, mentioned by eight countries. Several countries mentioned delays to birth registration. For instance, in the UK the civil registration of live births was paused for several months during the first lockdown. It was then continued in Scotland and Northern Ireland, but varied locally in England and Wales, during subsequent lockdowns. Other changes to procedures, such as in France, where the hospital budgets for 2020 and 2021 will not be determined by activity measures from hospital discharge data, may affect the coding of complications or outcomes.

## Integrating COVID-19 codes into birth sources

Specific codes indicating COVID-19 infection are necessary for monitoring outcomes associated with infection, but also for exploring indirect effects where and when the prevalence of infection is high. Only two of the 11 countries that use civil registration sources have the option of adding COVID-19 codes from the tenth revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) to birth data, as shown in Table 1. In contrast, 17 out of 19 countries that use sources based on clinical or medical databases reported that this code is already or will be added to birth data. In some countries, there is a potential to link COVID-19 codes to birth data, but this is not currently planned. Overall, 23% of the countries cannot add COVID-19 codes to routine birth data.

## Remaining questions for European data systems

This overview focused on the availability and timeliness of key data items, but other questions remain. For instance, it is important to evaluate whether disruptions to data procedures affected the quality or completeness of the data. Verifying the coding of key variables or trends over time in numbers of births by hospital or region could reveal system dysfunctions; these quantitative assessments could be complemented by qualitative studies. Further research is also needed on the quality and reliability of COVID-19 codes. At the onset of the pandemic, the World Health

 

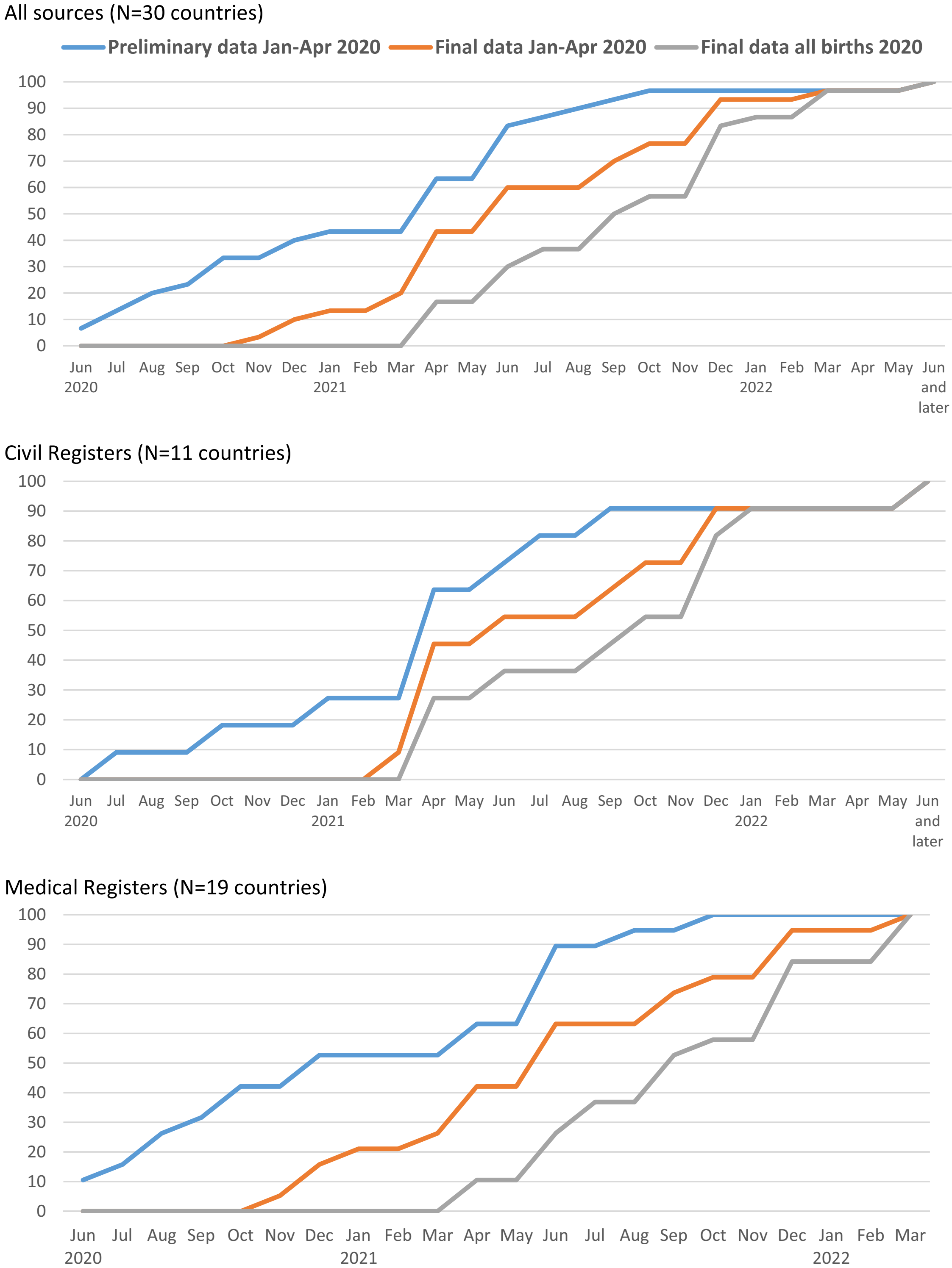


**Figure 1.** Availability of core perinatal health indicators in European countries overall and by source. When several sources were used to generate Euro-Peristat data, we requested information on birth data that could be used to generate stillbirth, preterm and low birthweight rates (as opposed to neonatal or infant deaths, which may become available later). See Table S1 for data by country.

**Table 1.** Capacity to identify confirmed or suspected COVID-19 infections using ICD codes in routine birth data

| | Civil registration only | Clinical/ hospital discharge databases | Total | % |
|---|---|---|---|---|
| ICD codes for COVID-19 included in birth data (directly or by linking to another source) | 2[a] | 14[b] | 16 | 53 |
| Linkage is planned to another source with COVID-19 codes | 2[c] | 3[d] | 5 | 17 |
| Potential to link to other source, but not planned | 2[e] | | 2 | 7 |
| Not possible to include COVID-19 codes | 5[f] | 2[g] | 7 | 23 |
| Total no. of countries responding | 11 | 19 | 30 | 100 |

Refers to data on births used to compute stillbirth, preterm birth and low birthweight rates, using several data sources (using COVID-19 codes for deaths only was not counted as a 'yes').
[a]Czech Republic, Romania.
[b]Croatia, Denmark, England and Wales, Finland, France, Germany, Iceland, Latvia, Luxembourg (code is present, but not based on ICD codes), Malta, Norway, Sweden, Northern Ireland, Scotland.
[c]Belgium, Cyprus.
[d]Estonia, Lithuania, the Netherlands.
[e]Poland, Portugal.
[f]Austria, Bulgaria, Italy, Spain, Switzerland.
[g]Ireland, Slovenia.

Organization (WHO) issued guidelines for coding confirmed COVID-19 infection using ICD codes; these were updated to include guidelines for suspected infection and specific guidelines were developed for mothers and babies. Studies are beginning to address the issue of coding quality as applied generally, finding good results overall,[9] but this is likely to differ across countries and hospitals and has not been assessed for pregnant women and babies. Unique questions exist for the mother–child dyad: for instance, although it may be easy to identify babies with a symptomatic mother testing positive for COVID-19 at delivery, identifying children born to mothers with a resolved or asymptomatic COVID-19 infection during pregnancy is more challenging. The ability to link hospital testing strategies will be crucial for the interpretation of positivity rates as it is estimated that about three-quarters of infections at delivery are asymptomatic.[3]

A final question concerns the data in population data sources beyond the core perinatal health outcomes discussed here. The Euro-Peristat indicator set has a limited number of health service measures, in part because of the complexity of defining comparable indicators between health systems. In line with broader WHO initiatives to develop population health indicators in the context of COVID-19,[10] countries should assess whether they are able to report on population health service indicators to enable rapid feedback on problems with access or quality of care that can affect women and babies during a pandemic.

## Larger lessons and strategies for change

This overview draws attention to the delays in the availability of population birth data; in general, finalised data from the first lockdown period were not available until the spring of the following year. However, there was marked heterogeneity, suggesting that workable solutions to producing more rapid data already exist. Some of the variation was linked to the types of data systems, with a generally longer lag for preliminary information when countries derive birth data from civil registration rather than from clinical databases or hospital discharge systems. This illustrates the importance of using these medical databases for reporting on perinatal indicators at a population level, if this is the case. Many countries relied on linkage to obtain information on COVID-19. Linkage of routine data, underused in many countries, emerges as a central component of a strategy to improve the pandemic readiness of population birth data. It is being exploited in some countries to make further investigations possible,[11] and ambitious initiatives to provide longitudinal maternal–newborn databases for routine surveillance could provide a road map for the future.[12] Finally, a future plan should include procedures for the rapid international synthesis of data. Compiling data at a European level, a central objective of the PHIRI project, permits insight into the generalisability of national trends and generates knowledge to inform European policy.

This overview of information systems in Europe, highlighting the limits of routine birth data, calls for urgent attention to population monitoring capacity to improve preparedness for a future pandemic. The SARS-CoV-2 virus has been most deadly for older people and adults with respiratory and other comorbidities. In contrast, a future pandemic could be more dangerous for pregnant women and newborns who remain uniquely vulnerable to major adverse effects from viral infections and are at risk when health systems are disrupted because of their non-deferrable need for health services during pregnancy, childbirth and the postpartum period.

### Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information.

## Contribution to authorship

All members of the Euro-Peristat network, listed as a group author, participated in the design of the study, provided data for their country, assisted with interpretation of the data and revision of the article and approved the final version. Several online meetings were held to discuss this study. From the Institut national de la santé et de la recherche médicale (Inserm) team, MD and MP designed the data collection instrument and carried out the data analyses. JZ drafted the article.

## Details of ethics approval

Not required.


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## Data availability statement

Data are provided in Table S1.

## Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

**Table S1.** Data sources, type, data available and new ICD codes for COVID-19. ■

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## Appendix

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## 4. Results of second survey on relevant indicators

**Selecting healthcare indicators for use with population data sources in Europe:**
**A consensus process**

**FIRST ROUND**

## Introduction

The Euro-Peristat perinatal health indicator list includes 10 core and 20 recommended indicators. These were established in 2000, updated in 2004 and again in 2015. Few healthcare indicators are included in the list, principally because many indicators could not be generated in a comparable manner across countries. The healthcare indicators are:

- C10: Mode of delivery by parity, plurality, presentation, previous caesarean section, gestational age
- R13: Percentage of all pregnancies following treatment for subfertility
- R14: Distribution of timing of first antenatal visit
- R15: Distribution of births by mode of onset of labour
- R16: Distribution of place of birth by volume of deliveries
- R17: Percentage of very preterm infants born in units without a neonatal intensive care unit (NICU)
- R18: Episiotomy rate
- R19: Births without obstetric intervention
- R20: Percentage of infants breast fed at birth
- New indicator: Caesarean birth by Robson ten group classification system

With the PHIRI project's perinatal use case on COVID-19, it may be necessary to add other healthcare indicators to assess the pandemic's effect on pregnancy, childbirth and the post-partum. This is also an opportunity to update the Euro-Peristat list as indicator availability and feasibility may have improved.

## Objectives

To identify relevant and feasible indicators:

- to assess the impact of the COVID-19 pandemic on maternal and newborn outcomes
- to improve routine surveillance of maternal and newborn health and care

## Methodology

As a starting point, we identified candidate indicators:

(1) used in the literature on COVID-19
(2) proposed in recent reviews of maternal and newborn indicators
(3) proposed in a WHO report on population indicators for COVID pandemic surveillance
(4) from a European study on maternal and newborn health based on WHO standards.

For the COVID-19 literature, we based our methodology on a review article: Kotlar and al, Reprod Health, Jan 2021, « **The impact of Covid-19 pandemic on maternal and perinatal health: a scoping review**". This article reviewed all article through September 2020. Using their search terms, we extended the search through January 2021 (see Appendix for details). We also extracted healthcare indicators relevant to pregnant women and newborns from the WHO report "MONITORING THE WIDER EFFECTS OF THE COVID-19 PANDEMIC ON POPULATION HEALTH: Strengthening monitoring of population health to signal and address the wider effects of the COVID-19 pandemic" [1]

From the non-COVID-19 literature, we included results from two recent systematic reviews of health care indicators for maternity care: Bunch and al, BJOG, Nov 2018, Developing a set of consensus indicators to support maternity service quality improvement: using Core Outcome Set methodology including a Delphi process and Rich and al. Int J Circumpolar Health, Dec 2016, Performance indicators for maternity care in a circumpolar context: a scoping review.

Finally a separate list was derived from questions included in surveys for women and health care professionals as part of the IMAGINE EURO project (Improving MAternal Newborn carE in the European Region), based on the WHO standards.[2] As these indicators were developed for a questionnaire, we first aimed to assess if they were suitable for population databases.

➢ ***Some of the indicators proposed for the evaluation of healthcare services are health outcomes. Indicators already included in the Euro-Peristat list were removed.***

**Selection process**

I. **First phase (choices to be made during in our meeting on Friday)**
   - **Identify a short-list of indicators:**
     - **Most relevance for evaluating impact of COVID-19**
     - **Most relevance for general surveillance**
     - **Most feasible**
   - **Suggest new indicators**

II. **Second phase: assess new indicators for relevance and feasibility, validate and further refine the short list (this will be in our next meeting or by questionnaire)**

III. **Third phase: make a final selection for data collection**

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[1]https://www.euro.who.int/__data/assets/pdf_file/0011/469523/WHO_Strengthening_monitoring_population_health_COVID19.pdf

[22] https://www.who.int/maternal_child_adolescent/documents/improving-maternal-newborn-care-quality/en/

# FIRST PHASE: CONSULTATION ON HEALTHCARE INDICATORS

**List 1: Healthcare indicators**

Instructions: please select the indicators that are (1) very important/essential for evaluating the impact of the COVID-19 pandemic (direct or indirect effects), (2) very important/essential for general surveillance of maternal and newborn health (3) feasible to construct from routine population sources

| Health care indicators | Topic area | Very important/ essential for COVID-19 Indicate with "X" | Very important/ essential for monitoring indicate with "X" | Feasible from routine sources Indicate with "X" |
|---|---|---|---|---|
| Spontaneous abortions during the 1st trimester | Reproduction/abortion | | | |
| Number of induced abortions | Reproduction/abortion | | | |
| Availability of contraceptives for adolescents and women of reproductive age | Reproduction/abortion | | | |
| Spontaneous abortions | Reproduction/abortion | | | |
| Ectopic pregnancies | Reproduction/abortion | | | |
| Number of antenatal visits per pregnant women | Antenatal | | | |
| Use of remote consultations methods/ institution | Antenatal | | | |
| Antenatal care coverage | Antenatal | | | |
| Number of vaginal births for COVID-19 women | Delivery | | | |
| Number of elective C-sections postponed or cancelled | Delivery | | | |
| Deliveries conducted in health facilities | Delivery | | | |
| Coverage of postnatal visits to newborns and mothers | Postnatal | | | |
| Length of stay in facility after birth | Postnatal | | | |
| Number of postnatal appointments per pregnant women | Postnatal | | | |
| Breastfeeding rate at 6–8 weeks | Breastfeeding | | | |

**List 2: Health indicators**

Instructions: please select the indicators that are (1) very important/essential for evaluating the impact of the COVID-19 pandemic (direct or indirect effects), (2) very important/essential for general surveillance of maternal and newborn health (3) feasible to construct from routine population sources

| Health care indicators | Topic area | Very important/ essential for COVID-19 Indicate with "X" | Very important/ essential for monitoring indicate with "X" | Feasible from routine sources Indicate with "X" |
|---|---|---|---|---|
| Prevalence of pneumonia among pregnant women | Maternal health | | | |
| Prevalence of women admitted to the intensive care unit | Maternal health | | | |
| Case Fatality Rate in Intensive Care Unit for COVID-19 | Maternal health | | | |
| Anxiety during pregnancy[1] | Maternal health | | | |
| Late complications of pregnancy (pre-eclampsia, eclampsia) | Maternal health | | | |
| Urinary tract infection in pregnancy | Maternal health | | | |
| Anaemia during pregnancy | Maternal health | | | |
| Diabetes in pregnancy | Maternal health | | | |
| Post-partum depression | Maternal health | | | |
| Prevalence of COVID-19-related admission to the neonatal intensive care - positive for SARS-CoV-2 RNA at birth | Neonatal health | | | |
| Proportion of term babies with an Apgar score <7 at 5 minutes | Neonatal health | | | |
| Proportion of babies born at term admitted to the neonatal intensive care unit | Neonatal health | | | |
| Proportion of babies readmitted to hospital at <30 days age | Neonatal health | | | |
| Severe neonatal morbidity (composite outcome) | Neonatal health | | | |
| Congenital anomalies | Neonatal health | | | |
| Small for Gestational Age (<10$^{th}$ percentile) | Neonatal health | | | |

Note (1) measured using various instruments (measurements used: Spielberger State-Trait Anxiety Inventory (STAI), pregnancy-related anxiety scale (PRAS), Generalised Anxiety Score 7 (GAD-7), National Stressful Events Survey (NSESSS) for posttraumatic stress disorder (PTSD))

**List 3: from IMAGINE EURO project**

**Instructions: please select all indicators that you believe could possibly be collected using routine population sources**

| Indicators | Possible to collect from routine sources Indicate with an "X" |
|---|---|
| Difficulties attending routine clinical visits | |
| Time to admission | |
| Mobility during labour – ability to move around | |
| Constant presence of a companion of choice | |
| Pain relief during labour and childbirth | |
| Ability to choose position for childbirth | |
| Episiotomy | |
| Instrumental delivery | |
| Skin to skin with baby after birth | |
| Breastfeeding immediately after birth | |
| Rooming-in with baby | |
| Breastfeeding (exclusive, mixed) | |
| Immediate attention from healthcare providers to be assisted when needed | |
| Provision of information about baby and post-partum | |
| Treatment by personnel in hospital (including abusive treatment) | |
| Bribes or payments requested | |
| Information readily available on COVID-19 precautions (infographics, written material) | |
| COVID-19 tests available for routine/selective use | |
| Appropriate distances could be maintained between patients in the maternity unit | |
| Handwashing facilities/hydrogel available | |
| Sufficient PPE (personal protective equipment) | |
| Dedicated pathways and spaces for women with COVID-19 | |
| Protocols/guidelines for managing COVID-19 made available to all health professionals | |
| Change in staffing/reduced personnel | |
| Reduced quality measures (audits, MMRs, etc.) | |
| Reduced attention to data entry and quality | |
| Reduced opportunities for training | |

Other questions

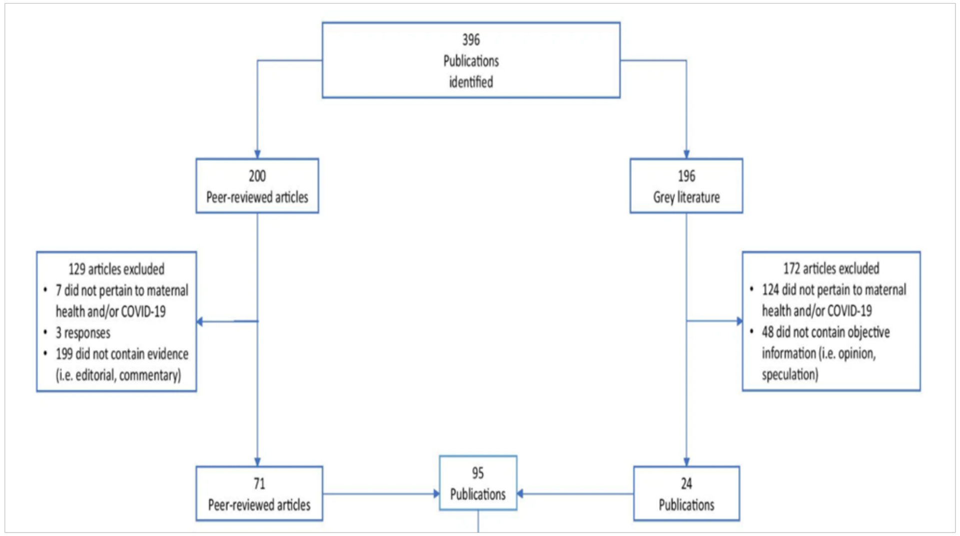
1. Please list indicators that are not included above, but could be relevant:

2. We did not include indicators on domestic violence in the review as this was not considered to be feasible from population sources – do you agree with this decision? Yes/No

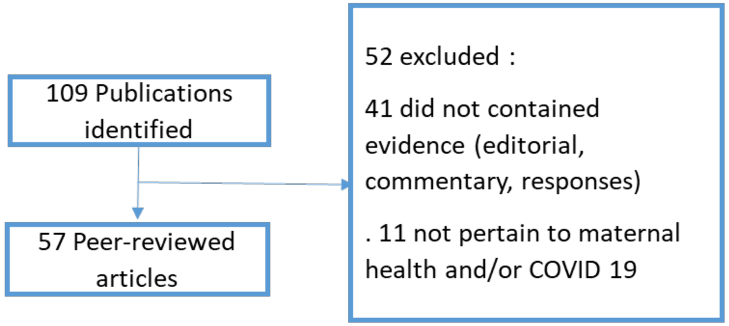
3. Other comments about this consultation

Appendix

Articles from Kotlar and al, Reprod Health, Jan 2021, « The impact of Covid-19 pandemic on maternal and perinatal health: a scoping review”. Search from **01/01/2020 until 11/09/2021**

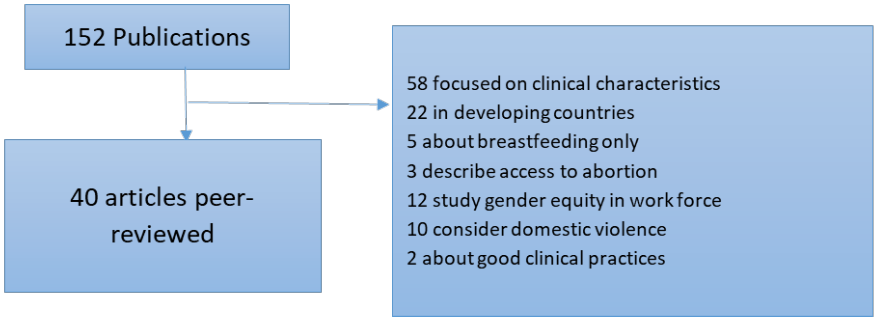



Search with same algorithm for publications from **12/09/2021 to 15/01/2021**




*Algorithm from the Maternal Health Task Force’s Buzz (a biweekly e-newsletter presenting current research relevant to maternal health). The searches were conducted in PubMed using MeSH terms, along with broader searches of “COVID” and “corona” followed by the terms: “pregnant”, “maternal”, “women”, “reproductive”, “economic”, “social”, “indirect”, “direct.”*

**Final set of articles used to identify indicators**



PHIRI
Population Health Information Research Infrastructure

EURO PERISTAT

**Selecting indicators to monitor perinatal health status and service use from population data sources in Europe: *SECOND Round* of consultation**

**YOU CAN ANSWER THIS QUESTIONNAIRE on paper (below) or on-line**

Link to be provided during our meeting

**Before responding on line, please read the options below**

Overall objectives of the consultation and those specific to the second round

- The overall objective is to identify relevant and feasible indicators (1) to assess the impact of the COVID-19 pandemic on maternal and newborn outcomes and (2) to improve routine surveillance of maternal and newborn health and care.
- As the Euro-Peristat list was last updated in 2012, the aim is to scope for new indicators to fill in potential gaps in perinatal health reporting and to identify indicators that are relevant/feasible to collect across countries, as well as the time horizon for collecting these new indicators.
- In the **second round**, our aim is to:
    - Agree on the indicators eliminated in Round 1 (see results attached)
    - Assess new indicators suggested in Round 1
    - Assess additional indicators added from the literature (see attached pdf)
    - Establish whether new indicators should be collected for the PHIRI project on COVID-19
- For the next round, we will finalize the lists and specify the indicator definitions

1. Elimination of indicators in the first round

Do you agree to eliminate the following indicators that had < 50% of respondents replying that they were important/essential and < 30% rating them as feasible? Yes/No

If no, please specify indicator to keep and why:______________________________________________

1. Spontaneous abortions during the 1st trimester
2. Availability of contraceptives for adolescents/women of reproductive age
3. Ectopic pregnancies
4. Use of remote consultations methods/ institution
5. Number of elective C-sections postponed or cancelled
6. Coverage of postnatal visits to newborns and mothers
7. Number of postnatal appointments per pregnant women
8. Breastfeeding rate at 6–8 weeks
9. Prevalence of pneumonia among pregnant women
10. Anxiety during pregnancy
11. Urinary tract infection in pregnancy
12. Anaemia during pregnancy
13. Post-partum depression

2. Updating definition for **R6. Prevalence of severe maternal morbidity**: In Round 1, several investigators suggested including the indicator of Severe Acute Maternal Morbidity from the validation study with Euro-Peristat investigators (attached article). We propose updating R6 to use this definition (see Appendix 1 for proposed definition and Appendix 2 for the current definition).
   Do you agree Yes/No, If no please explain why?

3. New indicators have been added in the third column to the Euro-Peristat indicator table (below, pages 3-5):
   a. Please select (CHECK) up to 10 indicators (i.e. your TOP ten) that you would like us to consider for inclusion in the Euro-Peristat indicator list
   b. Please indicate if you think we should collect them in the PHIRI project to investigate the impacts of COVID-19 on maternal and child health and care.

4. For the PHIRI project, we are going to collect the Core Euro-Peristat indicators, but we could also add the some recommended Euro-Peristat indicators (page 6)
   a. Please indicate which indicators should be collected as part of the PHIRI project to monitor the impacts of SARS-CoV-2 on maternal and child health and care (leave blank if you think the core indicators are sufficient)

5. The main focus of this consultation is to agree on indicators to measure the indirect and overall effects of the SARS-CoV-2 epidemic. Nonetheless:
   a. Should we collect information on COVID codes in the PHIRI collection when it is possible to identify COVID-19 in birth data? Yes/No

# Euro-Peristat list of indicators and potential additions

| Category | Core | Recommended | Suggestions made by the SC members or *from the literature* | Top 10 to add to the Euro-Peristat list | Include in PHIRI |
|---|---|---|---|---|---|
| Neonatal Health | C1-Fetal mortality rate<br>by gestational age, birth weight, plurality<br>C2-Neonatal mortality rate<br>by gestational age, birth weight, plurality<br>C3-Infant mortality rate<br>by gestational age, birth weight, plurality<br>C4-Birth weight distribution<br>by vital status, gestational age, plurality<br>C5-Distribution of gestational age<br>by vital status, plurality | R1-Prevalence of selected congenital anomalies<br>R2-Distribution of APGAR score at 5 minutes *for term and preterm infants*<br>R3-Fetal and neonatal deaths due to congenital anomalies<br>R4-Prevalence of cerebral palsy | Proportion of babies born at term admitted to NICU or neonatal special care | ☐ | ☐ |
| | | | Small for Gestational Age (<10th percentile) | ☐ | ☐ |
| | | | Proportion of babies readmitted to hospital at <30 days age | ☐ | ☐ |
| | | | Severe neonatal morbidity (composite using ICD codes)<br>**Appendix 1 for presentation** | ☐ | ☐ |
| | | | *Infants with RDS* | ☐ | ☐ |
| | | | *Infants requiring mechanical ventilation at birth* | ☐ | ☐ |
| | | | *Neonatal seizures within 7 days* | ☐ | ☐ |
| | | | *Healthcare-associated infections in children in neonatal care* | ☐ | ☐ |
| | | | Number of induced abortions (reproduction) | ☐ | ☐ |
| Maternal health | C6-Maternal mortality ratio<br>by maternal age | R5-Maternal mortality ratio by cause of death | Late complications of pregnancy (pre-eclampsia, eclampsia) | ☐ | ☐ |

| | | | | | |
|---|---|---|---|---|---|
| | | R6-Prevalence of severe maternal morbidity<br>R7-Prevalence of tears to the perineum | Diabetes in pregnancy (insulin/non-insulin dependent) | ☐ | ☐ |
| | | | Prevalence of women admitted to the intensive care unit | ☐ | ☐ |
| | | | *Emergency post-natal admission of mother/ readmission within 30 days of delivery,* | ☐ | ☐ |
| | | | *Nosocomial infection of surgical site* | ☐ | ☐ |
| Population characteristics or<br>risk factors | C7-Multiple birth rate by number of fetuses<br>C8-Distribution of maternal age<br>C9-Distribution of parity | R8-Percentage of women who smoke during pregnancy<br>R9-Distribution of mothers' education<br>R10-Distribution of households' occupational classification<br>R11-Distribution of mothers' country of origin<br>R12-Distribution of mothers' body mass index (BMI) | *Sex of baby* | ☐ | ☐ |
| | | | *Area-based deprivation score (as defined locally) in quintiles or deciles* | ☐ | ☐ |
| | | | *Alcohol consumption* | ☐ | ☐ |
| | | | Number of antenatal visits per pregnant women | ☐ | ☐ |
| Health care services | C10-Mode of delivery by parity, plurality, presentation (of fetus), previous caesarean section | R13-Percentage of all pregnancies following subfertility treatment<br>R14-Distribution of timing of 1st natal visit<br>R15-Distribution of births by mode of onset of labour<br>R16-Distribution of place of birth | Pain relief during labour and childbirth | ☐ | ☐ |
| | | | Number of ultrasounds | ☐ | ☐ |
| | | | First trimester ultrasound | ☐ | ☐ |
| | | | Screening for T21 | ☐ | ☐ |
| | | | Length of post-partum stay | ☐ | ☐ |
| | | | Hospitalisation during pregnancy | ☐ | ☐ |

| | | | | | |
|---|---|---|---|---|---|
| | | by volume of deliveries *including out of hospital births*<br>R17-Percentage of very preterm infants delivered in units without a NICU<br>R18-Births without obstetric intervention<br>R19-Episiotomy rate<br>R20-Percentage of infants breast-fed at birth (by exclusive or mixed feeding) | *General anaesthesia for caesarean section* | ☐ | ☐ |
| | | | *Antibiotic prophylaxis at the time of caesarean section,* | ☐ | ☐ |
| | | | *Detection and treatment of rhesus iso-immunisation in pregnancy,* | ☐ | ☐ |
| | | | *Antenatal steroids,* | ☐ | ☐ |
| | | | *Density of nursing and midwifery personnel (per 10 000 population),* | ☐ | ☐ |
| | | | *Density of physicians (per 10 000 population),* | ☐ | ☐ |
| | | | *Continuous support for women in the delivery room,* | ☐ | ☐ |
| | | | *Establishment of skin-to-skin contact between mother and the newborn infant,* | ☐ | ☐ |
| | | | | | |

| Category | Core | Recommended | Include in PHIRI |
|---|---|---|---|
| Neonatal health | C1-Fetal mortality rate by gestational age, birth weight, plurality<br>C2-Neonatal mortality rate by gestational age, birth weight, plurality<br>C3-Infant mortality rate by gestational age, birth weight, plurality<br>C4-Birth weight distribution by vital status, gestational age, plurality<br>C5-Distribution of gestational age by vital status, plurality | R1-Prevalence of selected congenital anomalies | ☐ |
| | | R2-Distribution of APGAR score at 5 minutes *for term and preterm infants* | ☐ |
| | | R3-Fetal and neonatal deaths due to congenital anomalies | ☐ |
| | | R4-Prevalence of cerebral palsy | ☐ |
| Maternal health | C6-Maternal mortality ratio by maternal age | R5-Maternal mortality ratio by cause of death | ☐ |
| | | R6-Prevalence of severe maternal morbidity | ☐ |
| | | R7-Prevalence of tears to the perineum | ☐ |
| Population characteristics or risk factors | C7-Multiple birth rate by number of fetuses<br>C8-Distribution of maternal age<br>C9-Distribution of parity | R8-Percentage of women who smoke during pregnancy | ☐ |
| | | R9-Distribution of mothers' education | ☐ |
| | | R10-Distribution of households' occupational classification | ☐ |
| | | R11-Distribution of mothers' country of origin | ☐ |
| | | R12-Distribution of mothers' body mass index (BMI) | ☐ |
| Health care services | C10-Mode of delivery by parity, plurality, presentation (of fetus), previous caesarean section | R13-Percentage of all pregnancies following subfertility treatment | ☐ |
| | | R14-Distribution of timing of 1st antenatal visit | ☐ |
| | | R15-Distribution of births by mode of onset of labour | ☐ |
| | | R16-Distribution of place of birth by volume of deliveries *including out of hospital births* | ☐ |
| | | R17-Percentage of very preterm infants delivered in units without a NICU | ☐ |
| | | R18-Births without obstetric intervention | ☐ |
| | | R19-Episiotomy rate | ☐ |
| | | R20-Percentage of infants breast-fed at birth (by exclusive or mixed feeding) | ☐ |

# Selecting indicators to monitor perinatal health status and service use from population data sources in Europe:

## RESULTS
## SECOND Round of consultation

<u>Overall objectives of the consultation and those specific to this first round</u>

- The overall objective is to identify relevant and feasible indicators (1) to assess the impact of the COVID-19 pandemic on maternal and newborn outcomes and (2) to improve routine surveillance of maternal and newborn health and care.
- In the <u>second round,</u> the aim is to:
    - Agree on the indicators eliminated in Round 1
    - Assess new indicators suggested in Round 1
    - Assess additional indicators added from the literature
    - Establish whether new indicators should be collected for the PHIRI project on COVID-19

<u>Participants</u>

This consultation was principally done during an on-line meeting using an on-line LimeSurvey questionnaire. Participants were sent a paper version of the questionnaire in advance.

33 people participated in the poll during the meeting and another 4 who could not attend the meeting responded afterwards, making a total of 37 people from 22 countries.

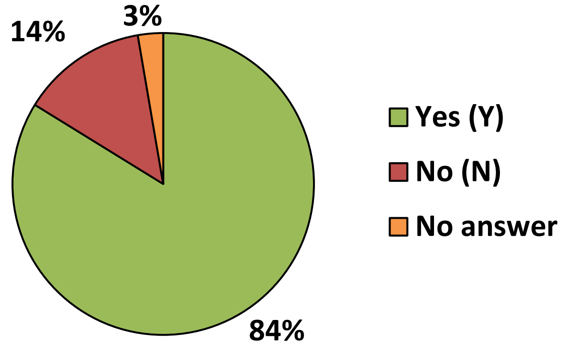
This was less than the 44 people participating in Round 1.

<u>Results</u>

6. <u>Elimination of indicators in the first round</u>

Most of the participants agreed to eliminate the indicators below that had < 50% of respondents replying that they were important/essential and < 30% rating them as feasible

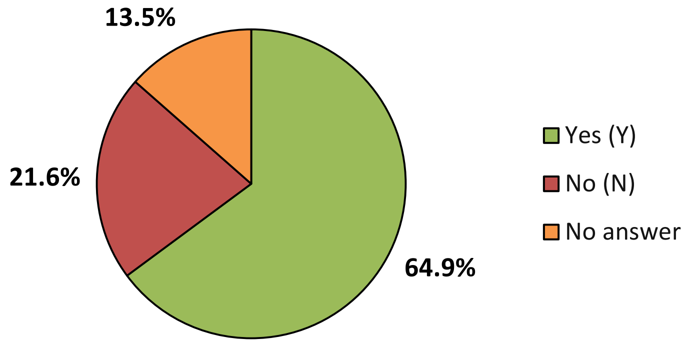
14. Spontaneous abortions during the 1st trimester
15. Availability of contraceptives for adolescents/women of reproductive age
16. Ectopic pregnancies
17. Use of remote consultations methods/ institution
18. Number of elective C-sections postponed or cancelled
19. Coverage of postnatal visits to newborns and mothers
20. Number of postnatal appointments per pregnant women
21. Breastfeeding rate at 6–8 weeks
22. Prevalence of pneumonia among pregnant women
23. Anxiety during pregnancy
24. Urinary tract infection in pregnancy
25. Anaemia during pregnancy
26. Post-partum depression




Several respondents expressed concerns about removing breastfeeding at 6-8 weeks (2 people), spontaneous abortions in the first trimester, remote consultations and the indicators linked to maternal mental health (post-partum visits, anxiety and post-partum depression.

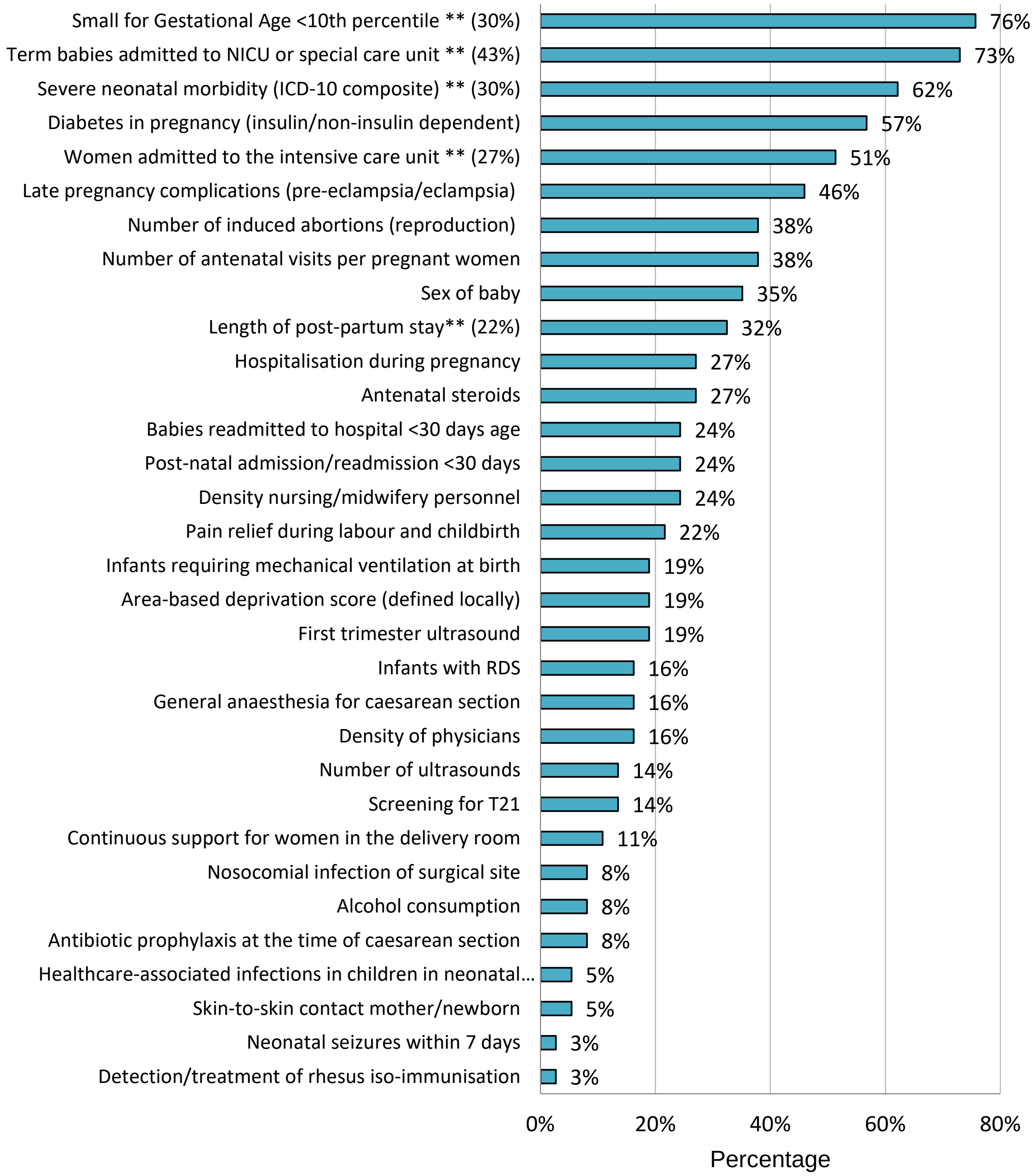
7. Updating definition for "R6. Prevalence of severe maternal morbidity":

A majority of respondents agreed with the suggestion to replace the current definition of maternal morbidity with the proposal from the Euro-Peristat study Severe Acute Maternal Morbidity. However, 21.6% said no and 13.5% did not answer.

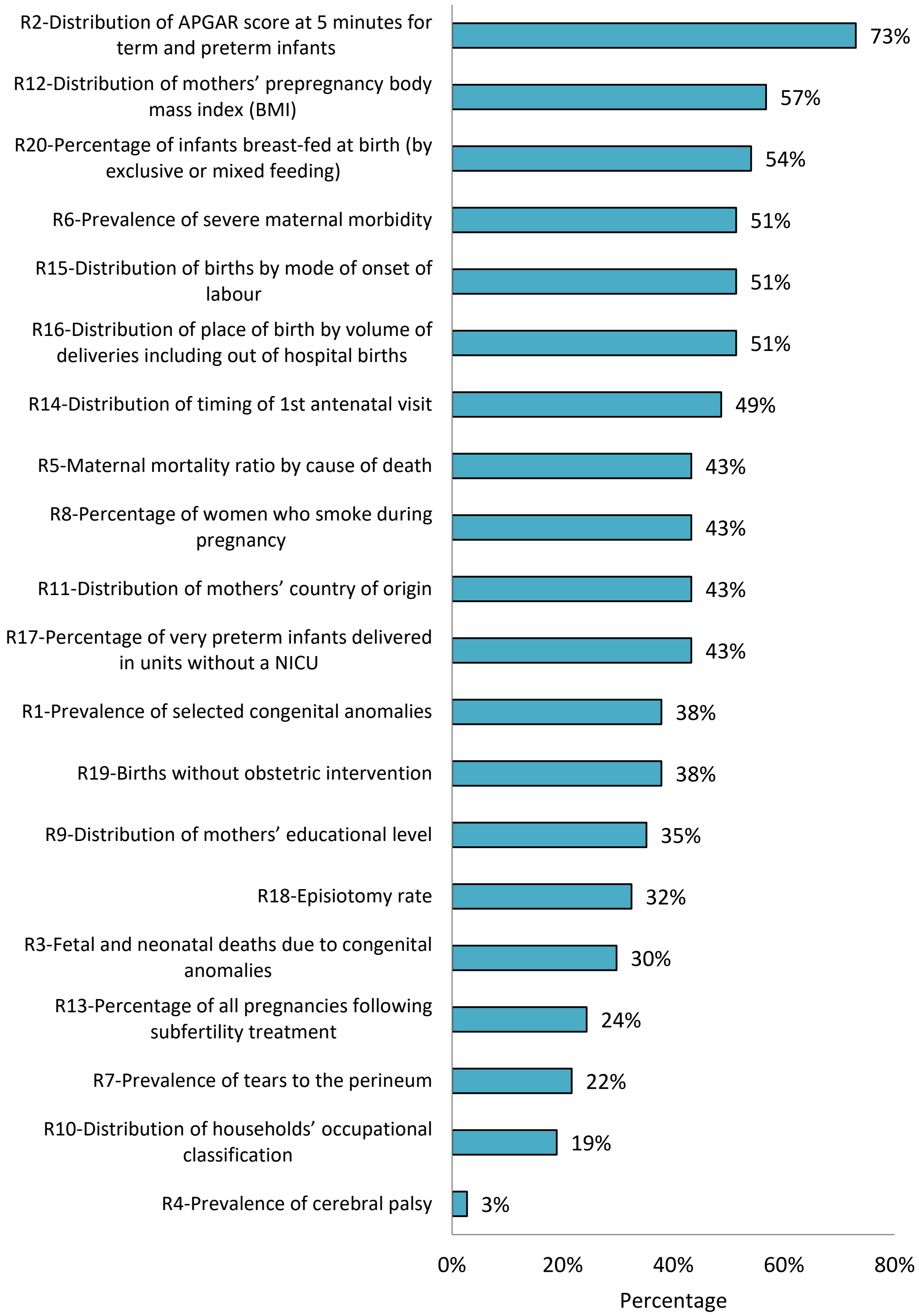



Most respondents said no or did not answer because they wanted more time to evaluate the proposition or "I need more time to look at this". "Probably yes, but I did not review the new definition yet." But there was also concern about feasibility: "It is difficult to assess…if they are feasible in the country. Not against in principle". Concerns related, in particular, to the red blood cell transfusion associated with obstetric hemorrhage. "I am not very sure the accuracy of the coding of obstetric hemorrhage and fear that even transfusions of 1 or 2 units packed cells (which are not infrequent) might be counted towards SAMM." and "I would be surprised if operationalizing the new definition (on red cell transfusion) was possible in many countries."

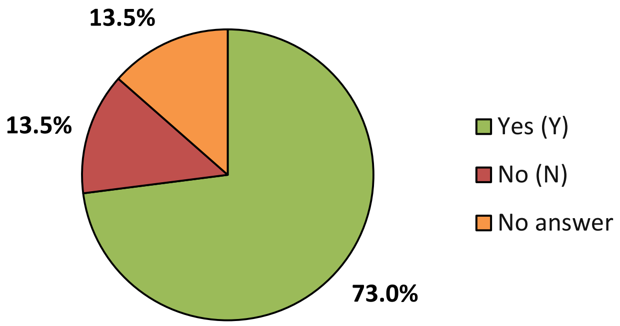
8. From the possible new indicators, five indicators were selected as "TOP ten" by at least half of the panel and 10 were selected by more than 30%. Those starred were selected by 20% or more of respondents for possible inclusion in the PHIRI data collection (% shown in parentheses)



9. More than half of respondents identified 6 recommended Euro-Peristat indicators that should be considered for inclusion in the PHIRI data collection, but several were very close – and if a 40% cut-off were selected, that number would be 11.



10. The main focus of this consultation is to agree on indicators to measure the indirect and overall effects of the SARS-CoV-2 epidemic. Nonetheless, a majority agreed that we should collect information on COVID codes in the PHIRI collection when it is possible to identify COVID-19 in birth data.




5. Comments

Many people provided comments about the survey and their selection. Most explained that they had prioritized feasibility in their country in decision-making. Many comments also concerned definitions and stated that more clarity about definitions/feasibility for some indicators would change their choices. For instance, more information was requested on the definition for the neonatal morbidity composite. As stated by one respondent:

"it is important that indicators that are selected by this consensus method get a more detailed and more precise definition and operationalization. After that these operationalization and definitions still have to be agreed upon and checked by the member states for the feasibility of their collection. A minimum number of countries (to be decided) should be able to deliver."

One comment was that this consensus primarily reflects the perspective of data providers and that we should consider input from other health professionals and involved stakeholders.

In terms of content, one respondent remarked that cause of death is an important indicator for assessing outcomes and that these data might be possible to collect using a common classification.

Finally, regarding maternal intensive care admission, while this might not be a good comparable measure of maternal morbidity (given differences in the organization of care), it is an important aspect of health care for pregnant women and new mothers, especially in the context of the COVID-19 crisis.

**Consultation process for September 2nd (meeting EuroPeristat)**

Country:

Name of respondent:

1. In the second round of the consultation process, there was good agreement (50% or more of respondents replying that they were important/essential and 30% or more rating them as feasible) on the following indicators. The question now is whether these should be included in the data collection for PHIRI. To make this decision, we would like to assess the feasibility of collecting these data.
    - For each indicator, please indicate availability, as specified in the check list. If it is available, we would like to know if it is in the same dataset as the other variables in the common data model.
    - Also, we have included the preferred definition for Euro-Peristat, when one exists or proposed a definition if one does not exist. Please let us know if you have a comment about the definition

| Indicator | Definition | Data availability (please check) | | | | Comment on definition |
|---|---|---|---|---|---|---|
| | | Yes in same dataset | Yes, but different source | Not Available | Don't know/ unsure | |
| Distribution of APGAR score at 5 minutes for term and preterm infants | Distribution of APGAR score at 5 minutes (0-10) for live births for term and preterm infants separately. | | | | | |
| Distribution of mother's prepregnancy body mass index (BMI) | Distribution of pre-pregnancy body mass index for women delivering live or stillborn babies before pregnancy or at the first antenatal visit. BMI is defined as the pre-pregnancy weight in kilograms divided by the square of the height in meters ($kg/m^2$) | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Prevalence of infants breast-fed at birth (by exclusive or mixed feeding) | The proportion of babies who are partially breastfed (infant receives breast milk and the infant is allowed any food or liquid including non-human milk) and the proportion who are exclusively breastfed (infant receives breast milk and is allowed to receive drops and syrups) throughout the first 48 hrs of age as a proportion of all newborn babies. (Definitions from WHO Indicators for Assessing Breastfeeding Practices. Report from meeting 11-12 June 1991. Geneva, 1991.) | | | | | |
| Severe Maternal Morbidity: prevalence of hysterectomy | Hysterectomy (surgical remove of the uterus (partial or total, body and/or cervix) for stopping the untreatable post partum haemorrhage)–(Definition from Monitoring severe acute maternal morbidity across Europe: A feasibility study. Chantry A and al. Paediatr Perinat Epidemiol. Jul 2020) | | | | | |
| Severe Maternal Morbidity prevalence of red blood cell transfusion associated with obstetrical haemorrhage | Transfusion of red blood cells (Definition from Monitoring severe acute maternal morbidity across Europe: A feasibility study. Chantry A and al. Paediatr Perinat Epidemiol. Jul 2020) | | | | | |
| Severe Maternal Morbidity: eclampsia | Eclampsia (includes convulsion following specified or unspecified hypertensive disorders (that are not due to unknown | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | epilepsy) during pregnancy, delivery or the puerperium (ICD-10 code O15.0) | | | | | |
| Severe Maternal Morbidity: prevalence of women admitted to the Intensive Care Unit | ICU >24 hours (admission during pregnancy, delivery or the puerperium to any facility or unit providing intensive or acute care or resuscitation-whether inside or outside of the maternity unit for > 24 hours) | | | | | |
| Distribution of place of birth by volume of deliveries including out of hospital births | Number of births occurring at home or in maternity units defined by the number of annual births, with the following groups: home, <300, 300-499, 500-999, 1000-1499, 1500-1999, 2000-2999, 3000-3999, 4000-4999, ≥5000 | | | | | |
| Sex of baby | sex of the child: male, female, undetermined, unknown | | | | | |
| Proportion of babies born at term admitted to NICU or neonatal special care | New indicator, to be defined | | | | | |
| Any diabetes in pregnancy (pre-existing diabetes and gestational diabetes) | New indicator, to be defined | | | | | |
| Late complications of pregnancy (preeclampsia) | New indicator, to be defined | | | | | |
| Length of stay for childbirth (mother) | The OECD definition: Average number of days that patients spend in hospital following a delivery. OECD only includes normal deliveries, defined by the ICD 10 | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | code: O80 (Encounter for full-term uncomplicated delivery) | | | | | |
| Covid infection at delivery (use of ICD or other code) | New indicator, to be defined | | | | | |
| Whether vaccinations were received | New indicator, to be defined | | | | | |
| EU geographic region | NUTS 2 : https://eur-lex.europa.eu/legal-content/FR/ALL/?uri=CELEX:02003R1059-20180118&qid=1519136585935 | | | | | |

2. The following recommended indicators were not retained using our selection criteria. Do you agree with *__NOT__* collecting the recommended indicators that did not reach the selection threshold?

*R1-Prevalence of selected congenital anomalies*
*R3-Fetal and neonatal deaths due to congenital anomalies*
*R4-Prevalence of cerebral palsy*
*R5-Maternal mortality ratio by cause of death*
*R7-Prevalence of tears to the perineum*
*R8-Percentage of women who smoke during pregnancy*
*R9-Distribution of mothers' education*
*R10-Distribution of households' occupational classification*
*R11-Distribution of mothers' country of origin*
*R13-Percentage of all pregnancies following subfertility treatment*
*R14-Distribution of timing of 1st prenatal visit*
*R17-Percentage of very preterm infants delivered in units without a NICU*
*R18-Births without obstetric intervention*
*R19-Episiotomy rate*

**Yes / No**

If No, list indicator that you believe we should retain:

……………………………………………………………………………………………………………………………………………………………………………………………………………………
…………………………………………………………………………………………………………………………………………………………………………………………………………………

3. Participants agreed that an indicator of neonatal morbidity based on ICD-codes would be useful. However, this has not been tested in Europe.
    a. Do you have data on ICD-10 codes describing neonatal diagnoses available in your database? Yes/No
    b. Would you be interested in participating in a sub-study to assess this indicator? Yes/No

**Inclusion of recommended and new indicators in the PHIRI data collection**
**3rd round of the consultation process**

**Preliminary draft of results**

#### Countries responding to the survey

**We had responses from 39 participants corresponding to 29 countries (with UK/England/Scotland=3**). Most people responded to the questionnaire on-line only, while some provided paper questionnaires with more comments.

Austria (Jeannette Klimont)
Belgium (Gisèle Vandervelpen, Wei Hong Zhang and Marie Delnord)
Bulgaria (Rumania Kolarova)
Croatia (Urelija Rodin and Zeljka Drausnik)
Cyprus (Theopisti Kyprianou)
Czech Republic (Peter Velebil)
Denmark (Laust Mortensen)
Estonia (Luule Sakkeus)
Finland (Mika Gissler)
France (Anne Chantry and Catherine Deneux-Tharaux)
Germany (Günther Heller)
Ireland (Izabela Sikora)
Italy (Marzia Loghi and Serena Donati)
Latvia (Irisa Zile-Velika)
Lithuania (Jelena Isakova)
Luxembourg (Aline Lecomte and Guy Weber)
Malta (Miriam Gatt)
Netherlands (Peter Achterberg)
Norway (Kari Klungsoyr)
Poland (Katarzyna Szamotulska and Ewa Mierzejewska)
Portugal (Henrique Barros and Carina Rodrigues)
Slovakia (Jan Cap)
Slovenia (Ivan Verdenik)
Spain (Oscar Zurriaga)
Spain – Catalonia (Maria Jose Vidal)
Sweden (Karin Källén)
Switzerland (Tonia Rihs)
UK (Lucy Smith)
UK – England (Alison Macfarlane)
UK – Scotland (Kirsten Monteath and Rachael Wood)

**Indicator availability**

Ten of the 15 indicators included in the short list from the first two rounds, were present in the databases used for constructing the common data model in 50% of the countries. All 15 indicators were available in at least half of the countries when availability in another source was also considered, with the exception of the indicator measuring receipt of Covid-19 vaccinations among pregnant women. These numbers could be slightly higher, as the proportion reporting that they were unsure was about 5% for the different indicators. Sex of the baby, place of birth, Apgar and geographic region were the indicators with the best availability.

**Comments on definitions**

We received many comments about the definitions which are summarized in the table below. Some related to providing added detail on the way the indicators should be presented (i.e. Apgar and BMI). This information should be added to the indicator definitions in our list (see the list of indictors on the website for more detail: https://www.europeristat.com/images/doc/updated%20indicator%20list.pdf ). Some raised issues related to standardized ascertainment (when should breastfeeding be measured, how to define NICU, etc), which need to be taken into consideration.

**Other recommended indicators**

55% (N=16 countries) believe we should collect at least one other recommended indicator that did not reach the selection threshold for the short list after round 2. Figure 2 provides the percentage of respondents who would like to keep retain each indicator. Percentages were 50% or over for four indicators: mother's country of origin, maternal mortality ratio by cause of death, fetal and neonatal death due to congenital anomalies and prevalence of selected anomalies.

**Participation in a sub-study to develop a composite indicator of neonatal morbidity**

Among the respondents, 62% (N=18 countries) have data on ICD-10 codes describing neonatal diagnoses available in their database. 48% (N=14 countries) would be interested in participating in a sub-study to assess this indicator.

**Summary**

This consultation provides a good overview of key points needed for deciding on the expansion of the core common data model.

1. There is fairly good availability of the short list of recommended indicators, even though more work will be needed to create common definitions.
2. For some of these indicators, it will be necessary to have a parallel data collection system since all the information is not available in one source.
3. We should reconsider adding some of the other recommended indicators in to the short list. Mother's country of origin is the easiest of those receiving the most votes, as the other 3 are complicated to collect using birth data.

**Figure 1. Availability of recommended and new indicators**

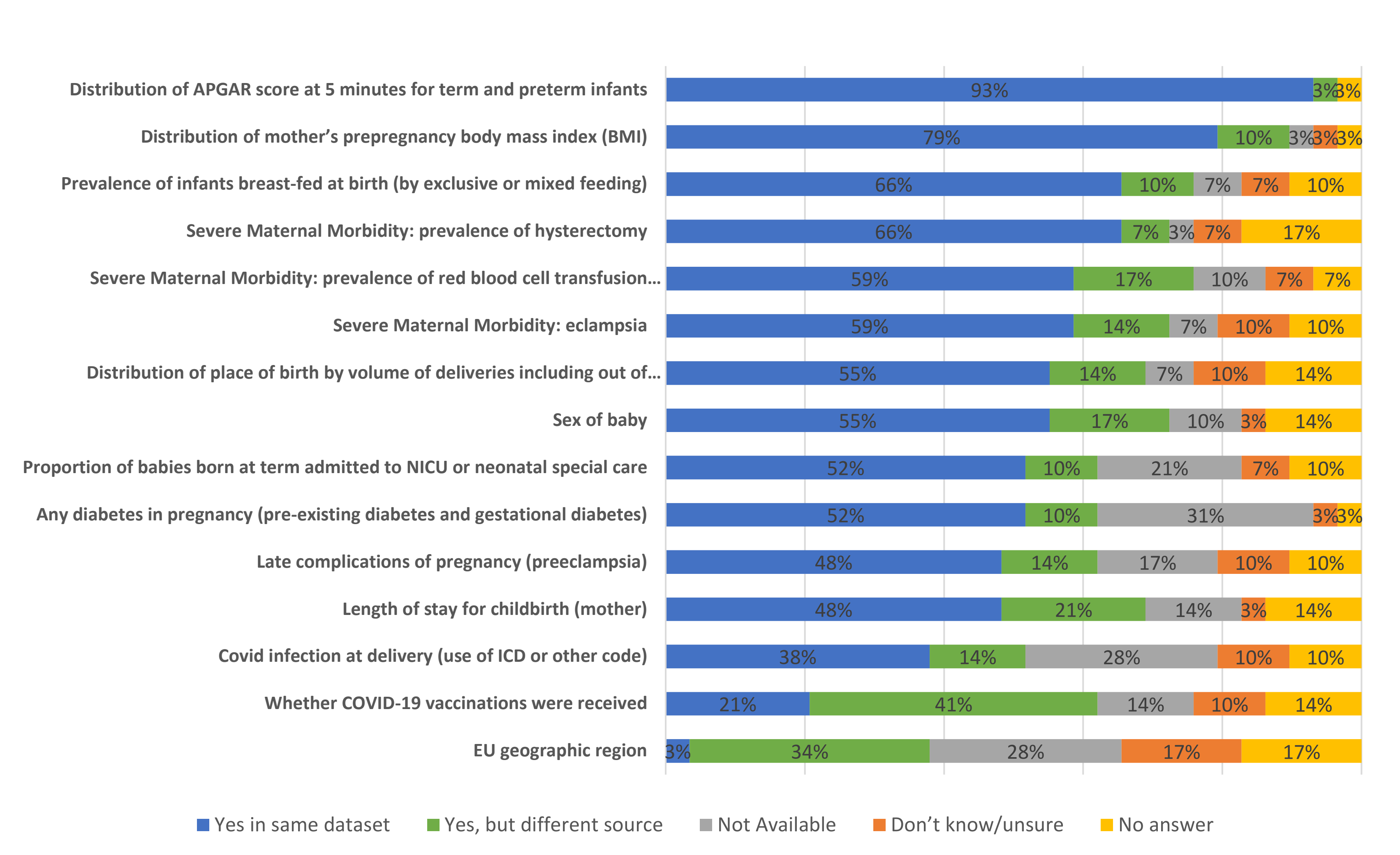



**Table 1. Comments about indicators definition:**

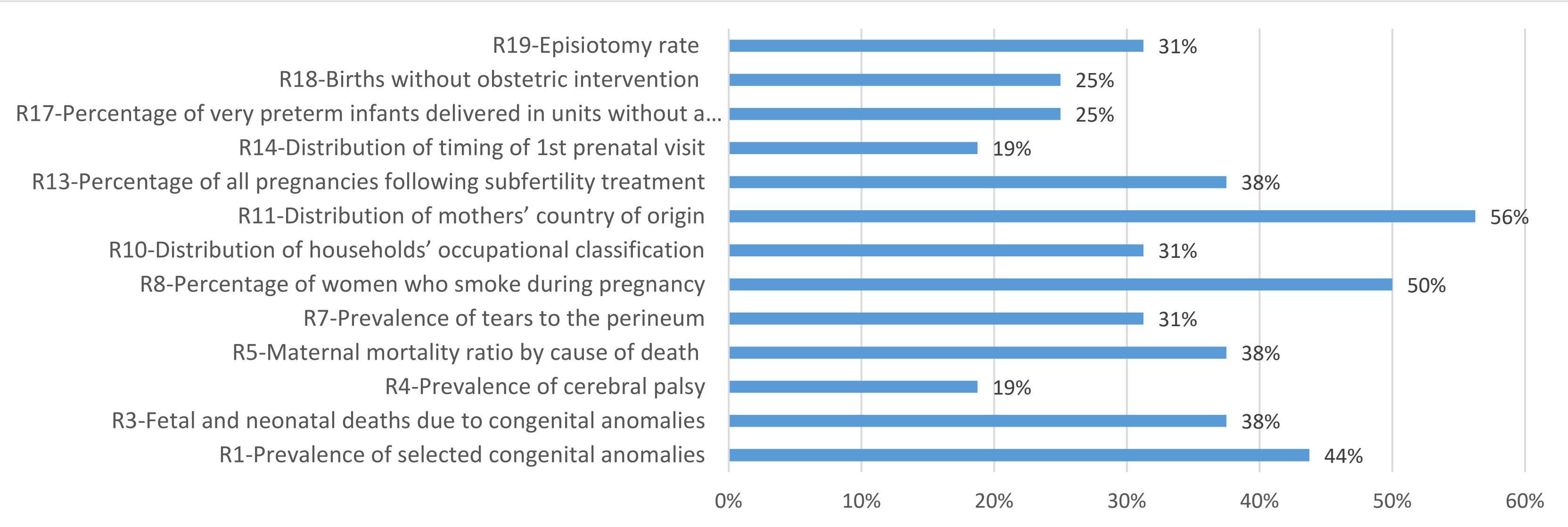
| Indicator | Definition | Comments |
|---|---|---|
| Distribution of APGAR score at 5 minutes for term and preterm infants | Distribution of APGAR score at 5 minutes (0-10) for live births for term and preterm infants separately. | - the indicator should probably include a cut-off point, usually <7 for liveborn children ≥ 22 weeks of gestation<br>- If 1 minute APGAR scores are high, 5 minutes APGAR scores are not given and/or recorded.<br>- select a cut-off point as indicator (lower than 7) for liveborn children of over 22 or 24 (?) weeks of pregnancy duration. Between 22 and 24 wks, 90% or more will die. Or give the distribution per week e.g. starting from 24.0 until 42.6 |
| Distribution of mother's prepregnancy body mass index (BMI) | Distribution of pre-pregnancy body mass index for women delivering live or stillborn babies before pregnancy or at the first antenatal visit. BMI is defined as the pre-pregnancy weight in kilograms divided by the square of the height in meters ($kg/m^2$) | - the indicator should probably include a cut-off point for obesity, usually >30 kg/m2<br>- define maximum (before 8 wks?) for first antenatal visit or (better) ask for prepregnancy weight? Define normal, overweight and obesity (serious overweight) as indicators<br>- prepregnancy is different to first antenatal visit. It is not reliable to record self-reported weight. I prefer to unify the condition for the first visit and suspend the prepregnancy weight |
| Prevalence of infants breast-fed at birth (by exclusive or mixed feeding) | The proportion of babies who are partially breastfed (infant receives breast milk and the infant is allowed any food or liquid including non-human milk) and the proportion who are exclusively breastfed (infant receives breast milk and is allowed to receive drops and syrups) throughout the first 48 hrs of age as a proportion of all newborn babies. (Definitions from WHO Indicators for Assessing Breastfeeding | - all newborn but exclude NICU babies (<28wks?) and possibly define a second and/or third time point after birth (check international indicators)<br>- newborns who receive breast milk after birth (in first 48h).<br>- on the whole stay in the maternity and not only during the first 48 hrs of age.<br>- the breastfeeding information is at the moment of leaving the hospital or at 7 days of age if the baby is still hospitalized<br>- information on breastfeeding at discharge, which is not exactly the same as breastfeeding at birth (but close enough). |

| | | |
|---|---|---|
| | Practices. Report from meeting 11-12 June 1991. Geneva, 1991.) | |
| Severe Maternal Morbidity: prevalence of hysterectomy | Hysterectomy (surgical remove of the uterus (partial or total, body and/or cervix) for stopping the untreatable post partum haemorrhage)–(Definition from Monitoring severe acute maternal morbidity across Europe: A feasibility study. Chantry A and al. Paediatr Perinat Epidemiol. Jul 2020) | - this indicator could be renamed as "prevalence of peripartum hysterectomy for obstetric haemorrhage". Also specify the denominator (number of women and not births) and the postpartum delay<br>- i would prefer a measure of fluxus as that would be registered at the time of birth by the attending caretaker….the surgery would be in another place and possibly not recorded…<br>- it is measure of perinatal care quality but (fortunately) very rare postpartum procedure, about 0,1-0,3/1000 deliveries. Like maternal deaths it is not a major health problem in European countries, maybe it is not necessary to collect this data?<br>- ICD code to determine |
| Severe Maternal Morbidity prevalence of red blood cell transfusion associated with obstetrical haemorrhage | Transfusion of red blood cells (Definition from Monitoring severe acute maternal morbidity across Europe: A feasibility study. Chantry A and al. Paediatr Perinat Epidemiol. Jul 2020) | - specify the denominator (number of women and not births) and the postpartum delay<br>- is it 'just' transfusion or transfusion over a certain amount of blood? |
| Severe Maternal Morbidity: eclampsia | Eclampsia (includes convulsion following specified or unspecified hypertensive disorders (that are not due to unknown epilepsy) during pregnancy, delivery or the puerperium (ICD-10 code O15.0) | - specify "late complications"<br>- specify the puerperium: up to 7 days postpartum? 42 days?<br>- if point "Eclampsia" is marked in the newborn sheet. I don't known about including convulsion following specified or unspecified hypertensive disorders<br>- why only O15.0 (Eclampsia in pregnancy)? Probably we need all O15 codes |
| Severe Maternal Morbidity: prevalence of women admitted to the Intensive Care Unit | ICU >24 hours (admission during pregnancy, delivery or the puerperium to any facility or unit providing intensive or acute care or resuscitation-whether inside or outside of the maternity unit for > 24 hours) | - specify the puerperium: up to 42 days postpartum?<br>- "any facility or unit providing intensive or acute care or resuscitation": not easy to identify |

| | | |
|---|---|---|
| Distribution of place of birth by volume of deliveries including out of hospital births | Number of births occurring at home or in maternity units defined by the number of annual births, with the following groups: home, <300, 300-499, 500-999, 1000-1499, 1500-1999, 2000-2999, 3000-3999, 4000-4999, ≥5000 | - I would suspend the weight groups |
| Sex of baby | sex of the child: male, female, undetermined, unknown | - born? Live born? Still born? |
| Proportion of babies born at term admitted to NICU or neonatal special care | New indicator, to be defined | - % of babies who after birth admitted perinatal care center; Childrens hospital<br>- transfer to other hospital (unit)<br>- proportion of all babies born to NICU<br>- ask neonatologist for precise operationalisation. Avoid…admitted to hospital under supervision of a paediatrician…that is not a good indicator |
| Any diabetes in pregnancy (pre-existing diabetes and gestational diabetes) | New indicator, to be defined | - ICD-x codes for pre-existing diabetes: O24.0; O24.1; O24.2; O24.3; for gestational diabetes O24.4; also we should include diabetes without specification, ICD-x code O24.9 and without 4th character subcategory – O24<br>- ICD codes to determine |
| Late complications of pregnancy (preeclampsia) | New indicator, to be defined | - difficult to identify stage of pregnancy for complications<br>- specify "late"<br>- ICD-x codes: O14.1 (severe preeclampsia) and O14.2 (HELLP sy) or all codes which include preeclampsia (O14; O14.0; O14.9: O11)?<br>- ICD codes to determine |
| Length of stay for childbirth (mother) | The OECD definition: Average number of days that patients spend in hospital following a delivery. OECD only includes normal deliveries, defined by the ICD 10 code: O80 (Encounter for full-term uncomplicated delivery) | - should assisted deliveries and all c-sections be excluded?<br>- specify "normal deliveries"<br>- exclude home births and policlinic births in hospitals…this does not work for some countries…(NL)<br>- OECD definition of length of stay assumes it is normally distributed. It isn't in the UK so possibly not elsewhere. Suggest using median |
| Covid infection at delivery (use of ICD or other code) | New indicator, to be defined | - COVID infection during episode of care<br>- the indicator should include a common definition of infection (test, timing…) |

| | | |
|---|---|---|
| | | - Covid infection of the mother (tested and with specific relevant signs…or….)<br>- exposure to SARS-CoV-2 at any time during pregnancy, by trimester (not only infection at delivery as stated now) would be relevant.<br>- ICD codes to determine |
| Receipt of COVID-19 vaccinations | New indicator, to be defined | |
| EU geographic region | NUTS 2: https://eur-lex.europa.eu/legal-content/FR/ALL/?uri=CELEX:02003R1059-20180118&qid=1519136585935 | - it is not clear whether EU geographic regions pertain to place of delivery or to place of residence |

**Figure 2. Including other recommended indicators**



## Disclaimer

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