

# EVAPRIMA - Management of threatened preterm delivery in France : a national practice survey

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Recherche clinique U953 Recherche épidémiologique en santé périnatale et santé des femmes et des enfants Équipe/activité : Épidémiologie clinique et organisation des soins

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| General                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Identification                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Detailed name                                                                                                            | Management of threatened preterm delivery in France : a national practice survey                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Sign or acronym                                                                                                          | EVAPRIMA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | N° d'autorisation CNIL 905388 (07/09/2005)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| General Aspects                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Medical area                                                                                                             | Gynecology/ obstetrics<br>Pediatrics                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Health determinants                                                                                                      | Genetic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Keywords                                                                                                                 | threatened preterm delivery, Abortion, Threatened/diagnosis, Threatened/prevention & control, Adrenal Cortex Hormones/therapeutic use, Cross-Sectional Studies, Female, Hospitalization/statistics & numerical data, Hospitals, Maternity/statistics & numerical data, Humans, Maternal Age, Obstetric Labor, Premature/diagnosis, Premature/prevention & control, Perinatal Care/standards, Physical Examination, Pregnancy Trimesters, Professional, Practice/standards, Random Allocation, Tocolytic Agents/therapeutic use, MAP, France, Pregnancy |
| Scientific investigator(s)<br>(Contact)                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Name of the director                                                                                                     | Goffinet                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
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| Unit         | CIC901 CIC - GH NECKER-COCHIN-PARIS CENTRE<br>DESCARTESÉquipe/activité : Recherche clinique<br>U953 Recherche épidémiologique en santé<br>périnatale et santé des femmes et des enfants<br>Équipe/activité : Épidémiologie clinique et<br>organisation des soins |
| Organization | Assistance Publique - Hôpitaux de Paris Hôpital<br>Cochin - AP-HP ; Institut national de la santé et de la<br>recherche médicale -                                                                                                                               |

## Collaborations

## Funding

|                |         |
|----------------|---------|
| Funding status | Private |
|----------------|---------|

|         |                         |
|---------|-------------------------|
| Details | Ferring Pharmaceuticals |
|---------|-------------------------|

## Governance of the database

|                                           |                                                                   |
|-------------------------------------------|-------------------------------------------------------------------|
| Sponsor(s) or organisation(s) responsible | Assistance Publique - Hôpitaux de Paris Hôpital<br>Cochin - AP-HP |
|-------------------------------------------|-------------------------------------------------------------------|

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|---------------------|--------|
| Organisation status | Public |
|---------------------|--------|

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|-------------------------------------------|-----------------------------------------------------------------------|
| Sponsor(s) or organisation(s) responsible | Institut national de la santé et de la recherche<br>médicale - INSERM |
|-------------------------------------------|-----------------------------------------------------------------------|

|                     |        |
|---------------------|--------|
| Organisation status | Public |
|---------------------|--------|

## Additional contact

## Main features

## Type of database

|                  |                 |
|------------------|-----------------|
| Type of database | Study databases |
|------------------|-----------------|

|                           |                                                                       |
|---------------------------|-----------------------------------------------------------------------|
| Study databases (details) | Not-repeated cross-sectional studies (except case<br>control studies) |
|---------------------------|-----------------------------------------------------------------------|

|                                                        |                                                 |
|--------------------------------------------------------|-------------------------------------------------|
| Database recruitment is carried out by an intermediary | A selection of health institutions and services |
|--------------------------------------------------------|-------------------------------------------------|

|                                                                        |    |
|------------------------------------------------------------------------|----|
| Database recruitment is carried out as part of an interventional study | No |
|------------------------------------------------------------------------|----|

| Database objective                           |                                                                                                                                                                                                 |
|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Main objective                               | To describe the management of threatened preterm delivery (TPD) in France 3 years after publication of the French guidelines and to analyse the factors of variation of the practices observed. |
| Inclusion criteria                           | Women hospitalised for TPD (22-36 weeks of amenorrhea) during May 2005.                                                                                                                         |
| Population type                              |                                                                                                                                                                                                 |
| Age                                          | Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)                                                                                                                                        |
| Population covered                           | General population                                                                                                                                                                              |
| Gender                                       | Woman                                                                                                                                                                                           |
| Geography area                               | National                                                                                                                                                                                        |
| Detail of the geography area                 | Representative sample of French maternity units. The study included 107 hospitals, accounting for 20% of all French maternity units.                                                            |
| Data collection                              |                                                                                                                                                                                                 |
| Dates                                        |                                                                                                                                                                                                 |
| Date of first collection (YYYY or MM/YYYY)   | 05/2005                                                                                                                                                                                         |
| Size of the database                         |                                                                                                                                                                                                 |
| Size of the database (number of individuals) | [500-1000[ individuals                                                                                                                                                                          |
| Details of the number of individuals         | 734                                                                                                                                                                                             |
| Data                                         |                                                                                                                                                                                                 |
| Database activity                            | Data collection completed                                                                                                                                                                       |
| Type of data collected                       | Clinical data<br>Declarative data                                                                                                                                                               |
| Clinical data (detail)                       | Medical registration                                                                                                                                                                            |
| Declarative data (detail)                    | Paper self-questionnaire                                                                                                                                                                        |
| Presence of a biobank                        | No                                                                                                                                                                                              |

|                                                                                       |                                                                                                                                                                                                                   |
|---------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Health parameters studied                                                             | Health event/morbidity<br>Health event/mortality                                                                                                                                                                  |
| Procedures                                                                            |                                                                                                                                                                                                                   |
| Participant monitoring                                                                | No                                                                                                                                                                                                                |
| Links to administrative sources                                                       | No                                                                                                                                                                                                                |
| Promotion and access                                                                  |                                                                                                                                                                                                                   |
| Promotion                                                                             |                                                                                                                                                                                                                   |
| Link to the document                                                                  | <a href="http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2008.01929.x/full">http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2008.01929.x/full</a>                                                   |
| Link to the document                                                                  | <a href="http://www.ncbi.nlm.nih.gov/pubmed/?term=EVAPRIMA+AND+Goffinet+F+[Author]">http://www.ncbi.nlm.nih.gov/pubmed/?term=EVAPRIMA+AND+Goffinet+F+[Author]</a>                                                 |
| Link to the document                                                                  | <a href="https://hal.archives-ouvertes.fr/search/index/?qa[text][]=EVAPRIMA&amp;submit_advanced=Rechercher">https://hal.archives-ouvertes.fr/search/index/?qa[text][]=EVAPRIMA&amp;submit_advanced=Rechercher</a> |
| Access                                                                                |                                                                                                                                                                                                                   |
| Terms of data access (charter for data provision, format of data, availability delay) | Contact scientific investigator                                                                                                                                                                                   |
| Access to aggregated data                                                             | Access on specific project only                                                                                                                                                                                   |
| Access to individual data                                                             | Access on specific project only                                                                                                                                                                                   |