Informed consent and refusal

France report prepared for HRiC Europe Summit 2016, Strasbourg
This report gives an insight on what women are experiencing in France regarding informed consent and refusal in health care facilities. It is authored by Ciane, which is a coalition of users organizations in relation with pregnancy and childbirth.

(1) the sources of the information
(2) informed consents and refusal
   - Women’s experience. Induction, Augmentation, Episiotomy, Pain relief.
   - How to exercise informed consent. Landscape of laws and does it work?
(3) obstetrical violence is becoming a public issue

1. Sources of information

Ciane data collection

Our association, Ciane, is a 13 years old coalition of about 40 ‘users’ organizations concerned with issues related to pregnancy and childbirth.

Ciane was created in order for people involved into “childbirth activism” to gain recognition and to be considered as key representatives of users vis-à-vis the authorities. Its platform of propositions focuses on three main claims: 1) the diversification of maternity services, including the recognition of homebirth and the creation of free standing birth centres; 2) the introduction of practices that pay greater respect to parents and newborn children and that fully acknowledge parents’ ability to make decisions; 3) the provision of rich and comprehensive information on practices and performances of healthcare institutions to the general public, including the production of indicators that are relevant for users. The ultimate principle on which CIANE bases its claims is a principle of self determination and empowerment of parents.

CIANE collects information on women’s experience through two main ‘methods’

Direct Support to women and families

First, all parents/users associations which are part of Ciane are in direct contact with women and families through their various support actions. They meet them through direct contact like “café parents” (parents gatherings), by phone support, or online support, discussion forums. Some of them are also in the position to provide individual support to parents who take action (not necessarily legal actions) steps against the health system or professionals, such as: help them to get access to their health records, stand by them to meet health professional individually or as part of a conciliation commission, and more rarely support and advise them in taking legal steps. For the latest, our associations are generally quite limited in term of knowledge, contacts and financial capabilities.

Permanent online survey on childbirth experience

Ciane set up a permanent online survey meant to collect childbirth experience directly from women.

Since 2012, this survey gathered more than 20 000 responses. Most of them relate to hospital birth (98%). It allows to get fresh data on the real situation as it is in the maternity wards: 1600 are for deliveries in 2014, 700 for deliveries in 2015.

To get access to ‘ordinary’ (as opposed to activist) women, the CIANE set up a partnership with a women’s magazine. Apart from a higher proportion of primiparous women, our population is very similar to the general population as gathered in the National Perinatal Survey, in particular, with respect to rates of medical interventions.
The questionnaire is targeted to different aspects of childbirth experience. Firstly, we gather quantitative data on medical intervention, such as labor induction, episiotomy, oxytocin infusions, possibility to move during labor and delivery, possibility to drink/eat. Secondly, we ask women if they feel they were informed and asked to provide their consent, and in a position to refuse. We also ask them how they felt physically and emotionally... This is a very important part of the survey and it’s quite unique in the maternity survey landscape. Official inquiries tend to seek numbers on interventions and their results, but little attention is paid to women’s experience and informed consents.

Finally, the survey leave a significant place to testimonies, in each section of the survey. Women have the possibility to write about their experience, and more than half of them actually leave at least one testimony during the survey.

How Ciane processes results of online surveys

Ciane is compiling regular reports based on the survey. Each report is targeted on a particular childbirth issue such as: Induction and augmentation of labor; episiotomy; pain relief and epidural; hospital discharge … One report focuses on how women’s wishes and preferences are respected, and how it impacts on their physical and psychological health.

Each of these reports present numbers, with focus on women’s feeling, informed consents and how they feel supported. They also present a collection of testimonies that explain and illustrate our findings.

This report for HRiC 2016 is largely based on the findings and testimonials published in Ciane’s survey reports.

Official reports

Enquête nationale périnatale (national perinatal enquiry). Latest publications are on data from 2010.
http://www.xn--epop-inserm-ebb.fr/grandes-enquetes/enquetes-nationales-perinatales

Informed consent and refusal

What are women’s experience

Induction of labor

Ciane’s report (2015)
58% of women whose labour was induced between 2008 and 2014 state they were informed and asked for consent. 15% did not get any information nor were asked for consent,

This report shows a link between induced birth experience and the provision of information/the demand of consent (or not). Women who received information about induction experienced their labour in a very similar way as women who had spontaneous births: 22% had a bad experience against 19% for spontaneous births. On the other hand, 44% of those who were not informed stated they had a bad experience.

Testimonies

They decided to induce labour because my baby was overdue. The doctor was surprised I was asking questions about induction (reasons, consequences, etc)…
I believe I did not get enough information, and, as a consequence, gave an ineffective consent. I was scared about the consequences they (barely) mentioned, but nobody presented me with a balance between the benefits and the risks (deliberately or not). Induction was presented to me as if I did not have the possibility to refuse it.

At first we refused induction, but they told us we were putting our baby at risk, so we had no other choices but to accept it.

Source: Déclenchement: l'importance cruciale de l'information et du consentement (décembre 2015)

Augmentation of labor

For non-induced deliveries, Ciane survey asked women whether or not they were administered oxytocin during labor.

- Administration of oxytocin 34%
- Don’t know 8%
- No administration of oxytocin 58%

However, official surveys (enquête nationale pérenale, 2010) report that oxytocin is used in 58% of non-induced deliveries.

These numbers support the hypothesis that out of 4 women who believe they weren’t administered any oxytocin, one actually was. This demonstrates that information on the procedure, not to speak of consent, hasn’t been provided in a significant proportion of the cases.

Testimonies

I still don’t understand why I received pitocin.

I was never asked for consent, for any procedure, they put products in my drip without even telling me…

The doctor insisted on giving me pitocin, even if we refused… We are more vulnerable during labour, I submitted. I feel guilty now

Source: Déclenchement et accélération du travail : information et consentement à revoir ! Ciane 2012

Episiotomy

Only 15% of episiotomies are done after requesting women’s consents. More consent requests for multiparous than for a first baby (23% vs 13%)

When women are requested their consent, more than 7 out of 10 accept (refusal: nulliparous 23%, multiparous 35%)
The Ciane evaluated trends since 2005. 2005 is a key date in France, when the french college of gynecologists and obstetrician issued some recommendation against systematic episiotomy. The following trends can be observed:

- Clear decrease in the episiotomy rate
- Clear decrease in the proportion of women declaring they have received no information at all: (no information: 43% pre-2005, 29% 2010-2013)
- Unchanged rate of women - 85%- declaring informed consent was not provided/ requested by professionals)

Conclusion: some progress are to be noted regardind episiotomy rate and information, but not regarding consent: the decision remains in professionals’ hands.

Testimonies

The last stage of labour was long (nearly 1.5 hour) and tiring, the midwife suggested a small episiotomy to speed things up, I refused but she insisted

Nobody told me about it. I only realised they performed an episiotomy when they sewed me up.

They did not ask me for consent but it was necessary and was done in a hurry for my baby to come out as the heart’s rate was 30 beats per minute. Needless to say I gave them carte blanche !

I saw the midwife was about to perform an episiotomy and I told her I did not want one. She said we would wait a little longer, but 2 or 3 contractions later she performed it without even asking or telling me.

Source Ciane (2013) Episiotomie: état des lieux et vécu des femmes

Pain relief / epidural

France has a high epidural rate (82% in 2010 according to official report). The Ciane survey asks women about their initial plan regarding pain relief, and whether or not they received appropriate care and support to achieve their plan. Out of 10 women with a first baby (primiparous), 6 responded that they had planned to have an epidural, 3 wanted to wait and see, 1 planned not to have an epidural. For next babies, the pattern is different: 5 out of 10 plan to have an epidural, 2 wait and see, 3 want no epidural

Our focus is on how the maternity units respond to what women ask for in good condition. This applies to women who wanted an epidural, those who wanted to wait and see, and those who wanted no epidural.

Women who planned to have an epidural

Among women who wanted an epidural, most of them had it. They have a good satisfaction rate.

Yet 22% of them are unsatisfied and regret painful or badly-processed injection, an inefficient or lateral epidural, a lack of sensation or an epidural done too late. We advocate that there is a need for better information on the limitations of epidural.
Women who asked for an epidural but did not get it
Among women who did not have epidural, 27% asked for it but did not get it. Main reason: birth went too quickly. Still, these women have a good satisfaction rate.

Women who did not want an epidural (1 primiparous and 3 multiparous out of 10) Among women who did not want an epidural, 2/10 had one. High dissatisfaction rate among these ones. They mainly wish they had been better supported through the pain of birth and given a true choice.

I wanted to give birth without the epidural, but the midwife succeeded in scaring me, telling I would feel like “I was hit by a car”, that “I would feel like my bones were being broken” and that “I would want to die”

Women who wanted to wait and see Among women who wanted to wait and see, 8/10 eventually had an epidural. 32% of them are unsatisfied. They think they were not given the choice because they were forced to decide early and they were not supported enough through birth.

I did not get an epidural because of the pain, but because one of the persons who were present at the birth told me that my labour could be 24 hours longer, which scared me because I did not want to end up exhausted. In the end I regret it because 2 hours after they injected it my son was born… I wish I could have had more time without it, especially as the pain was not that bad…

I did not accept to get an epidural, they did not leave me the choice as they forced me to have pitocin to speed up the birth (the heart rate was slowing down a lot every time I had a contraction) and I was told that contractions would become more and more painful, so the epidural was mandatory!

Source: Douleur et accouchement (avril 2013)

See also

How to exercise informed consent: from theory to practice

1 - Law on patients rights (2002)
2002 law on patients’ rights protection sets out patient’s right to decide on what’s best for him/her and prescribes their informed consent to be requested. Summary by Centre for Biomedical Ethics and Law of the Catholic University of Leuven, Belgium on its website on Patient Rights Legislation in EU Member States:

“On 4 March 2002 the Act No. 2002-303 concerning the rights of patients and the quality of the health system (amending among other things the Public Health Code and the Civil Code) was approved by the French Parliament. Patients’ associations were active in promoting this Act. A redefining of priorities by the government places from now on “the individual, the person, in other words the patient or the user, as the focus of concerns, at the centre of legislation: we must move from a system of professionals to a system directed towards the individual”. The Act inserts a preliminary chapter in the Public Health Code entitled “Rights of the Individual”. The Act includes three objectives. The first objective is to enhance patients’ ability...”
to use their “voice” in the health care system. A key emphasis hereby is put on individual rights for the patient. The words of article 1111-1 of the Public Health Code could not be more clear: “There can be no democratic health system without a corresponding legal framework of rights accorded to sick people and users.”

http://europatientrights.eu/countries/signed/france/france.html

2 - A proactive approach to inform consents: birth plans

Birth plans are known since years 2000 in France, coming from the English speaking world. At first, it was mainly used by women among the most informed and generally badly perceived by the medical world.

Current trends can be characterized as follows:

a) An increase of the awareness on birth plans among women

CIANE’s survey suggest that almost one women out of 5 has a birth plan, which is three times more than it was 10 years ago. Regardless of whether they use a birth plan or not, more than half of the women dare to express some particular choice or preference regarding the course of their delivery.

What are women’s top requests expressed in their birth plans? Nothing extravagant: first, they want to be able to move and chose their position; second, a personalized pain support; and third, refusal of systematic episiotomy.

b) Birth plans becoming a marketing argument for maternity units

The number of birth has recently tended to decrease in France: -5% between 2010 and 2015. Maternity units try to attract women to keep their number of annual birth. They acknowledged the social shift towards the need of humanized care and deflation of medical interventions. On their websites, some maternities claim they are welcoming birth plans. We’re still lacking data to understand to which extend those maternity units are actually welcoming women’s wishes.

c) Women still scared of writing a birth plan - and may have good reasons for that

Regarding how their choices were respected, 6 women out of 10 report that the staff did their best to respect their choices. 3 out of 10 report that they did it partially, and 1 not at all.

Women who did a birth plan report slightly fewer satisfaction with regards to the respect of their choice (-5 pts). This finding is delicate to interpret: it could be the case that birth plans are badly perceived, but also that women who prepare a birth plan are more demanding and have a lower tolerance to breaches, like lack of informed consents or of human support.

Yet some women report their birth plan was not well received by medical staff and resulted in mistreatment.

Testimonies

I politely made some requests and the midwife immediately became defensive. She criticized my choices until the end of my labour!

The medical staff took my birth plan very badly, they even laughed at me.

Source: Respect des souhaits et vécu de l’accouchement (2012)

3 - Reactive approach, when women have faced situations of non informed consents
Our association is engaged in supporting women. The primary objective is to meet women’s personal needs. Secondary, only if relevant for this particular woman, to action on the healthcare and/or legal system to evolve mentalities.

From our experience, women’s need range from:
- need to understand what happened;
- need recognition that their rights have been violated;
- often, need to make sure that this will not happen again to others;
- last, need to see offender is punished

**a. Requesting medical records & understanding it with health professional**

Often, women just need an explanation of what was done or why. Some unexplained treatments are source of anxiety. This is the degree zero of informed consent (information afterwards of what was done and why). Obtaining medical records is often the first step of personal reconstruction, and sometimes it’s enough.

By law in France, hospitals must respond to patients’ requests to consult or get a copy of their medical records. Helping patients to do so is one important activity of our association, and patients’ associations in general.

Does that work well? Most of the time yes. Women who are struggling to obtain a response from the hospital get in contact with associations. That make things move quickly. In some cases, we have to inform women of administrative redress they should use if the hospital does not respond.

The only important gap we’ve seen: some pieces of the medical file disappear/ are never communicated (foetal monitoring) or some information is never recorded (Kristeller manoeuvre). No much can be done in this situation. This happens mainly/ only on issues with possible legal implications (medical malpractice).

**b. Getting a recognition that information should have been provided or that informed consents should have been asked/ respected.**

This can be achieved through
- Direct contact with health professionals: we strongly advise the presence of a friend, or a member of birth associations, or a health professional (midwife) at the appointment
- Reporting to the Users committee (Commission des usagers, formerly Commission de relation avec les usagers et de la qualité de la prise en charge). This is a body, established by law since 2002 in all hospitals, public as well as private. It comprises representatives from the administration, health professional, and users. Its scope encompasses medical and non medical complains. It can only lead to mutual agreement procedures. The aim is to address individual complaints, and to enable improvements at hospital level.

How it’s supposed to work? The commission acknowledges reception of the complaint, the ombudsman meets the plaintiff, the whole commission sends a response letter.

Does it work well? It depends. We observed that its setting up took much time (years). Users representatives are part of patients organisations, some having a general purpose, others targeted on specific conditions: they are often not well aware of maternity specifics, i.e. that pregnancy and delivery are not a disease; most of the time, the plaintiff meets the whole commission, which can be counterproductive, especially when the ombudsman is part of the medical staff: the plaintiff may end up as being placed in a position of defendant.

That is the reason why we recommend to never go unaccompanied but to come with an informed third party, when possible trained to communicate with health professionals.

**Testimony**

H. was pushed to accept an induction for suspicion of diabetes, macrosomia and tachycardia. The benefits were presented to her, not the risks. The induction was
have not yet proven to be successful in obtaining informed consent.

Other procedures for a lack of informed consent.

Example: a decision by the Order of physicians in 2011 in the case of an episiotomy performed against patient’s consent. The court debated on whether the episiotomy was medically indicated or not. The patient’s consent was not even considered by the Court. (source: association AFAR Alliance francophone pour l’accouchement respecté)

4) Compensation commission

The Commissions (régionales) de conciliation et d’indemnisation (former CRCI, now CCI) aim at facilitating financial compensation for medical errors and medical hazards. One of its advantages is that the procedure, including the medical expertises, is free. However, it is highly recommended to be supported by a lawyer.

Although when created (2002) this body was thought to facilitate conciliation as well as financial compensation, it’s now only concerned with the latter. It is not possible to submit information and consents issues to this body, unless they are linked to severe damages.

Examples
Source of information: AFAR, extrait du jugement (2012)

“Doctor Y’s decision to perform an episiotomy in emergency, overriding Mrs. X’s refusal, was medically justified and in accordance with obstetrical practices. A non intervention by Doctor Y. could have been criticised if the child was born with neonatal brain damage. If the need for that episiotomy was not explained by doctor Y to Mrs X, it is justified by the emergency calling for such act to be performed.”


This example concerns a complaint on the use of misoprostol (cytotec) to induce labor. The baby was born with a serious impairment. The court found the gynecologist guilty. The 3 charges recognized by the court were: 1) misoprostol used off label 2) without informing the patient 3) administered at high doses from the outset ; as well as improper use of oxytocin.
local newspaper reported on the conclusion, and it is noticeable that the journalist did not mention the lack of information but focused solely on the medical malpractice.

Article:  [http://www.78actu.fr/cytotec-la-maternite-de-poissy-devra-payer_11864/](http://www.78actu.fr/cytotec-la-maternite-de-poissy-devra-payer_11864/) (in french)

d) Other procedures

Regarding legal actions at Criminal, Administrative or Civil courts. We don't have any example of successful actions at these courts for lack of consents or information in the context of childbirth. However, regarding actions brought by patients in general, recent jurisprudence shows an evolution on court decisions regarding these matters.

Other bodies may be approached in the French legal system. We do not have any return of experience in cases brought by a women on informed consents during pregnancy or delivery. Among these bodies:

- State ombudsman (médiateur de la République),
- Regional health agency (ARS)
- and obviously the European Court of Human Rights.

How obstetrical violence is becoming a public issue in France

a) From Social networks to mainstream media and public authorities

Between 2014 and 2015, no less that 4 media events around medical violence against women occurred in France. All started on social networks and to some extent had an impact on the public as well as on medical bodies and even the Ministry of Health.

The husband stitch
The first event started with a midwife who published on a blog an alert on the “point du mari”, the husband stitch. This consists of the midwife or gynecologist narrowing the vagina when stitching tears or episiotomies, supposedly to improve her partner’s pleasure. The midwife claimed that the practice was rare but that it was taught in some midwifery schools until the 2000s. This created a lot of debates on social networks, professional forums, and reached the national newspaper Le Monde. The president of the National College of Gynecologists and Obstetricians denied that the practice may have existed.

Pay your uterus (Twitter), and I didn’t consent (Tumblr)
The second wave started on Twitter. A pharmacy student launched a hashtag #PayeTonUterus, (Pay your uterus) and called for testimonies of women’s negative experience during gynobs visits. The hashtag was used 7000 times within the first 24h. A number of the testimonies were about pregnancy and childbirth. The high volume of testimonies shows that mistreatment during gynobs consultation is common. Three months later, a Tumblr named ‘Je n’ai pas consenti” (i didn’t consent) was created by three other women. It gathers patients’ testimonies on lack of consents for medical procedures.

Vaginal examination during general anaesthesia
Last but not least, the controversy #TVsousAG (vaginal examination during a general anesthesia). All started with the diffusion of a medical student’s guide - available on a university site - which listed, among items to be validated by students, the performance of vaginal examination in the operating room on asleep patients. Here again, there was an important controversy that took place first on social networks.

Several medical professionals claimed that this is a normal practice and that they don’t have to ask for consents - as soon as a patient enters a public hospital, some of them say, he/she implicitly agrees. When asked by a journalist whether it wouldn’t it sound normal to ask for consents, the president of the National College of Gynecologists and Obstetricians answered “this is going too far in prudishness”. (“c’est aller trop loin dans la pudibonderie”)
This was obviously not the position of all health professionals. A tribute entitled “patient consents, the blind spot of medical studies” was signed by 72 persons and organisations, including some health professionals and the Order of midwives.

Eventually, public authorities had to take a position. The Minister of Health ordered a report on the issue. It came out with the estimation that 20-33% of vaginal examinations during anesthesia were performed without preliminary consent. The Minister published a statement that she firmly condemns these illegal practices.

Reference
Master thesis « Violence obstétricale » Emergence d’un problème public en France, Nastassia Audibert (2016) https://www.academia.edu/29049665/Violence_obst%C3%A9tricale_-_%C3%A9mergence_dun_probl%C3%A8me_public_en_France

Links
Tumblr http://jenaipasconsenti.tumblr.com/

b) Where we are now in 2016, and where we go

We're in 2016 and, in our opinion, there is a clear shift in France towards awareness and recognition of obstetrical violence, in the public opinion as well as in the medical world and public authorities. The challenge now is: how can we, childbirth activists, leverage this momentum to spread the culture of good care, in particular (but not limited to) informed consent? The aim is to get this culture adopted by each and every healthcare professionals, so that each and every women and pregnant / birthing persons gets treated as they should be.

From our standpoint, the objective should be to transfer the burden of fighting medical violence to the health care institutions: health policy makers, teaching system, health facilities. users and lawyers shouldn't be obliged to fight against the healthcare institution and their staff and the eradication of medical violence in health organisations should be taken up as a priority for the medical institution itself.

c) Research and medical education

The diffusion of women’s and patient testimonies has an important role to call for action. Besides, there is a need of academic reports, research and evaluation of interventions.

Earlier this year, CIANE and one of its member association (AFAR) have compiled a bibliography on obstetrical violence and communicated largely about i in order to act upon not only activists but also on institutional and medical actors. Around 60 studies - medicine, midwifery, law, anthropology … - were selected and classified. To facilitate a rapid identification of the topics that might interest the reader, summaries have been translated into French and commented; hyperlinks allowing to find the complete study have been added.

There was no similar compilation available so far in France and very scarce literature coming from the European French speaking countries. The only articles published in French we kept in this compilation were: a report ordered by a healthcare agency on abuse in healthcare, name “ordinary violence”: It was not specific to obstetrics - and actually it didn’t mention gynecology, obstetrics or women’s health; a paper has been published by an activist of an association member of the CIANE (Cesarine), in an open minded professional journal; and a last one has been published in a law journal about violence in hospitals.

The lack of publications from the European French speaking world is not to remain. A Master thesis (Master in International Development, Science Po) was issued in 2016 « Violence obstétricale » Emergence d’un problème public en France, (“Obstetric violence”, emergence of a public issue in France). Nastassia Audibert
Some indications that medical research and education may be starting to move

CIANE has been approached to participate in a university programme on violence in obstetrics, for local healthcare professionals. The cursus addresses all violence against women. Rape, intimate partner violence,... but medical abuse / obstetric violence are fully considered. Users experiences are integrated from the start.

CIANE has been also approached by students in midwifery and in medical ethics who are considering doing their master thesis on obstetric violence. Expectedly, some of them are having a hard time having the thesis board accepting their subject. However, to our knowledge, some of them have not given up.

CIANE received a call for intervention for a training event organized by a perinatal network and gathering, 500 health professionals. Original ask was clearly focused on obstetrical violence. The controversies in social networks and national media originated this ask.

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