Informed consent before obstetric analgesia and anesthesia: An institutional perspective

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Presentation Summary

1. Context of informed consent
   . Ethical
   . Legal

2. Informed consent for obstetric anaesthesia: a simple format

3. Ethical & Legal issues of the simple format

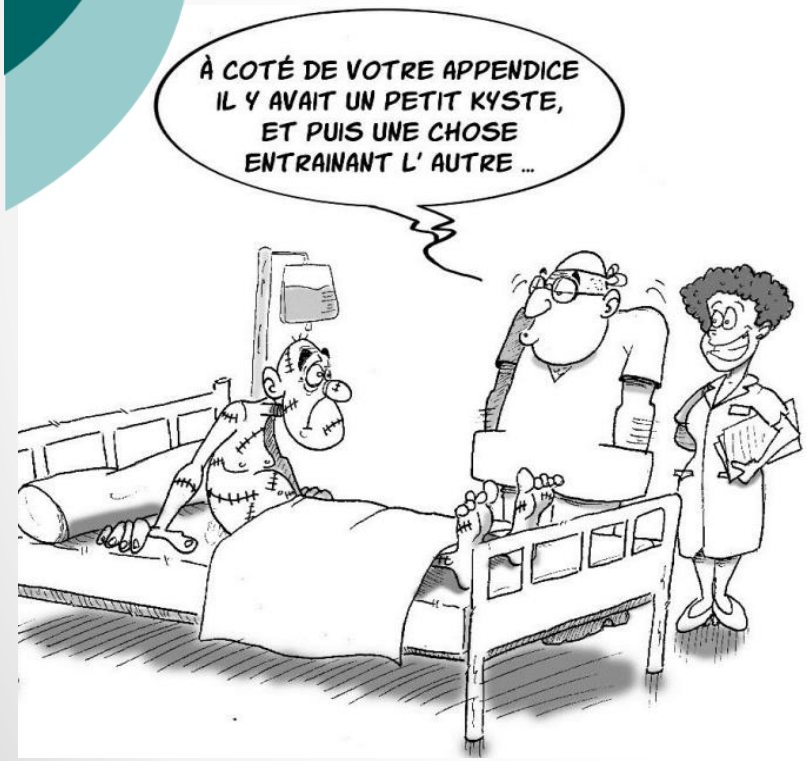
4. Institutional guidances as a help

5. Limitations

6.Conclusion

Ethical Context

Paternalistic Model



- Beneficence
- Nonmaleficence

Patient centred Model

- **Autonomy**
- Justice

Ethical context: autonomy principle

Definition:

The ability to self determine or self-legislate one's own life.
In the context of healthcare it refers to the self-determination of thought, intention, and action when making decisions regarding health or care procedures.

Table 1. The Process of Informed Consent

Threshold Elements (Preconditions)
Decision-making capacity or competency
Freedom or voluntariness and absence of overriding state or legal interests
Informational Elements
Adequate disclosure of material information
Recommendation
Understanding
Consent Elements
Decision
Authorization

Beauchamp T, Childress J, Principles of biomedical ethics, Oxford University Press 2001

Legal context

The right of the person

Art 28 Swiss Civil Code

Art. 28[24]

[1] A person whose personality has been unlawfully infringed may take legal action for its protection against any person involved in the infringement.

[2] An infringement is unlawful unless it is justified by the victim's consent, by an overriding private or public interest, or by law.

[24] Nouvelle teneur selon le ch. I de la LF du 16 déc. 1983, en vigueur depuis le 1er juil. 1985 (RO **1984** 778; FF **1982** II 661)

Legal context

Behaviour of healthcare professionals with patients with full capacity

Loi genevoise (9328) sur la santé (K 1 03)

Art. 45

[1] The patient has the right to be informed in a clear and appropriate manner about :
a) his or her state of health b) possible treatments and interventions, their benefits and possible risks c) means of preventing disease and maintaining health.
[2] The patient may request a written summary of this information.
[3] On admission to a health care institution, patients must receive written information on their rights, on the measures of protection or under guardianship law, their duties and the conditions of their stay. If necessary, the patient's next of kin are also informed.
[4] Within the limits of their competence, all healthcare professionals ensure that the patient has received the information necessary to make an informed decision.
[5] If reimbursement by compulsory health insurance is not guaranteed, the patient is informed.

Art. 46

[1] No care may be provided without the free and informed consent of the discerning patient, whether an adult or a minor.
[2] The patient may withdraw consent at any time.

Legal context for high risk interventions

ATF 28.04.2003

With the exception of emergencies, if the operation is complicated or involves major risks, the time at which information is given must be chosen early enough for the patient to make up his or her mind without being under time pressure.

During this period of reflection, which should in particular allow the patient to seek the advice of relatives or friends, the patient should in principle not already be hospitalized, as the influence, even positive, of the medical and hospital environment is not conducive to the formation of the patient's objective will.

→ Often used is a delay of minimum 3 days between information (not CONSENT) and intervention

Patient should also not be hospitalized (if possible)

Informed consent for obstetric anaesthesia

Let's make it simple !

Labour analgesia

1) Written brochure information on patient rights and hospital rules

2) Face to face patient information right before neuraxial procedure with possible alternatives, benefits and risks of the procedure properly explained and making sure they are understood. Written information if required.

3) Oral consent is the norm

BUT...

Anaesthesia for other interventions

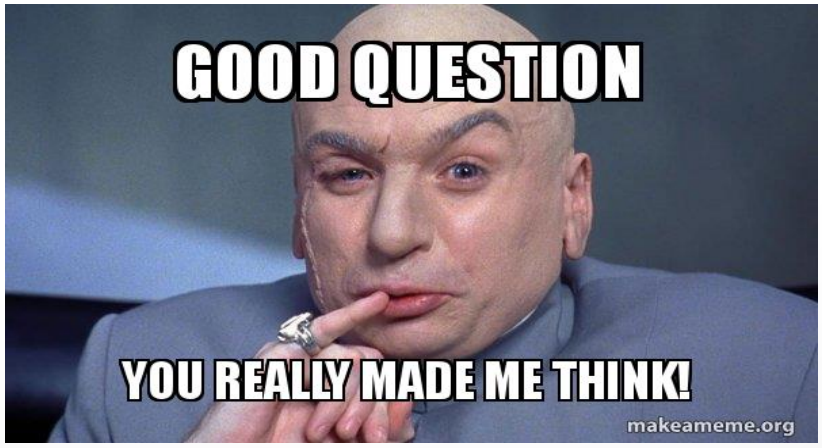
1) Written brochure information on patient rights and hospital rules

2) Face to face patient information during anaesthetic consultation with possible alternatives and risks properly explained and making sure they are understood

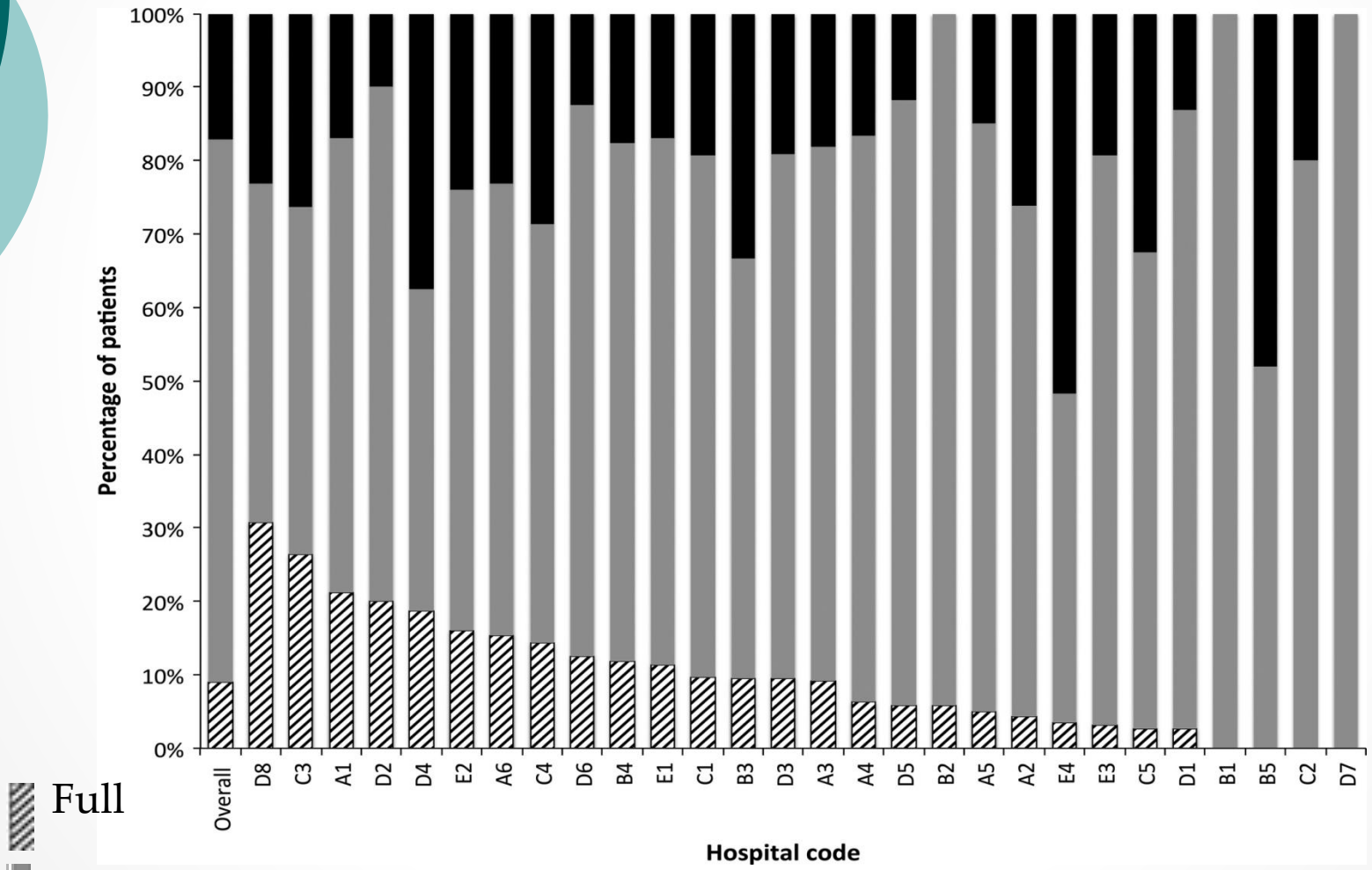
.3) Oral consent reported in medical charts (written if IVG, sterilization, PMA, clinical research). Written information if required.

Ethical & Legal issues of the simple format

1. Information: What is the level of information recall of parturients ?
2. Consent: Is the context of labour rooms facilitating self-determination ?
3. Risk of procedures: Country of origin and native language impact ?
4. Risk of procedures : Is CS section always a low risk procedure?
5. Is it really possible to provide written information in labour room ?



Overall information recall during labour



Brinkler et al. Anesthesia 2019:74; 1101-1111

Type of information recall during labour

Table 2. Percentage of All Patients Recalling a Specific Risk

Risk	Patients with Recall of Risk (%)
Postdural puncture headache	58
Pruritis	26
Nerve damage	33
Nausea/Vomiting	17
Infection	15
Block failure	10
Hypotension	10
Intravenous injection (cardiovascular collapse)	9
Bleeding	9
Local anesthetic toxicity (seizure)	8
High spinal block	7
Urinary retention	2
Respiratory depression	2

Kelly G. Int J Obst Anesth 2004

Autonomy in the context of labour rooms

Patient-led decision making: Measuring autonomy and respect in Canadian maternity care

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Patient Education and Counseling 102 (2019) 586–594

ARTICLE INFO

Article history:
Received 9 February 2018
Received in revised form 23 September 2018
Accepted 26 October 2018

Keywords:
Autonomy
Decision-making
Pregnancy
Patient-oriented
Participatory research
Respectful maternity care
Childbirth
Person-centered
Quality measure

ABSTRACT

Objective: The **Changing Childbirth in British Columbia** study explored women's preferences and experiences of maternity care, including women's role in decision-making.

Methods: Following content validation by community members, we administered a cross-sectional online survey exploring novel topics, including drivers for interventions, and experiences of autonomy, respect, or mistreatment during maternity care. Using the *Mothers Autonomy in Decision-Making (MADM)* scale as an outcome measure in a mixed-effects analysis, we examined differential experiences by socio-demographic and prenatal risk profile, type of care provider, interventions received, and nature of communication with care providers.

Results: A geographically representative sample of Canadian women (n = 2051) reported on 3400 pregnancies. Most women (95.2%) preferred to be the lead decision-maker during care. Patients of physicians had significantly lower autonomy (MADM) scores than midwifery clients as did women who felt pressured to accept interventions. Women who had a difference in opinion with their provider, and those who felt their provider seemed rushed reported the lowest MADM scores.

Conclusion: Women's autonomy is significantly altered by model of maternity care, the nature of interactions with care providers, and women's ability for self-determination.

Practice Implications: If health professionals acquire skills in person-centred decision-making experience of autonomy among pregnant women may improve.

Ethnicity and dural perforation in labour room

Table 3 Characteristics of cases and control patients and crude associations with PDPH following injury of the dural membrane

Risk factors	Case patients (N=154)	Control patients (N=616)	OR (95% CI)	*P*-value
Patient-related factors				
Age				
≤28 years	51 (33.1)	215 (34.9)	1.0 (reference)	0.892
29–33 years	57 (37.0)	227 (36.9)	1.05 (0.69–1.61)	
>33 years	46 (29.9)	174 (28.2)	1.11 (0.71–1.74)	
Marital status				
Single	29 (18.8)	147 (23.9)	1.0 (reference)	0.332
Married	118 (76.6)	435 (70.6)	1.38 (0.89–2.18)	
Divorced/separated	7 (4.5)	34 (5.5)	1.04 (0.39–2.47)	
Profession				
Student/housewife	57 (37.0)	188 (30.5)	1.0 (reference)	0.320
Employee	79 (51.3)	332 (53.9)	0.78 (0.53–1.16)	
Manager	9 (5.8)	57 (9.3)	0.52 (0.23–1.07)	
High-level manager	9 (5.8)	39 (6.3)	0.76 (0.33–1.6)	
Continent of origin				
Europe	104 (67.5)	493 (80.0)	1.0 (reference)	0.006
Africa	19 (12.3)	60 (9.7)	1.5 (0.84–2.58)	
Asia	11 (7.1)	20 (3.2)	2.61 (1.17–5.51)	
South America	19 (12.3)	38 (6.2)	2.37 (1.29–4.23)	
North America	1.0 (0.6)	5 (0.8)	0.95 (0.05–5.96)	

International Journal of Obstetric Anesthesia (2018) 36, 17–27
0959-289X/$ - see front matter © 2018 Elsevier Ltd. All rights reserved.
https://doi.org/10.1016/j.ijoa.2018.05.007

ORIGINAL ARTICLE

ELSEVIER
www.obstetanesthesia.com

Risk factors for post-dural puncture headache following injury of the dural membrane: a root-cause analysis and nested case-control study

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Complications following CS sections

PLOS ONE

RESEARCH ARTICLE

Surgical complications after caesarean section: A population-based cohort study

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Table 3. Complications within 42 days after caesarean section.

	Single birth	Multiple birth	Tot 118 057
Bleeding	203 (0.17)	10 (0.01)	213 (0.18)
Infection	785 (0.66)	28 (0.02)	813 (0.69)
Organ damage	252 (0.21)	5 (0.00)	257 (0.22)
Wound dehiscence	259 (0.22)	13 (0.01)	272 (0.23)
Bowel obstruction	100 (0.08)	9 (0.01)	109 (0.09)
Other	63 (0.05)	1 (0.00)	64 (0.05)

A framework to better adress information and consent issues for obstetric patients is needed

A possible one: institutional ordinances for physicians

Hôpitaux Universitaires Genève	*Type de document* Catégorie législative et réglementaire \ Directive du Comité de direction	*Domaine \ Activité* 2. Patients: médical et soins \ 2.1 Dispositions générales *Instance décisionnelle* Comité de direction	*page* 1/4 *Référence* HUGO.MS.DG.0003
Information et consentement éclairé du patient au traitement		*N° de version 3*	*Portée HUG*
Publié par Instances dirigeantes	*Responsable du document* Directeur des affaires juridiques	*Créé le 16/03/2004* **Mise à jour le** 12/10/2020	*En vigueur à partir du :* 29/09/2020

1. Objectif

La présente directive fixe le cadre institutionnel relatif au devoir d'information du patient et au recueil de son consentement par le médecin. Elle traduit la volonté de :

- s'assurer qu'une information complète et loyale a été fournie au patient afin de lui permettre de donner un consentement éclairé ;
- garantir une documentation adéquate de l'information et du consentement dans le dossier du patient.

Institutional ordinances for physicians

Non-surgical/non-invasive procedures

1.Oral information +/- paper-based- video-training programs

Proof that information has been provided (i.e. note with date and content)

2.Oral consent except for IVG, sterilization, PMA, clinical research.

Written if a risk is clearly identified. Proof that consent has been given written in charts.

Surgical /invasive procedures

1.Written information

Proof that written information has been provided (i.e. patient signature; note)

Minimal delay of 3 days before procedure

2.Written consent with signature

Recorded in hospital IT at latest on day of intervention.

In practice, a possible option for physicians

Labour analgesia

1) Written brochure information on patient rights and hospital rules

2) Written information material sent home +/- videos, training courses, other

Face to face patient interaction before procedure to check understanding of information

Oral consent if non-invasive; otherwise written consent.

In emergency, use of the birth plan, patient or patient relative decision

Anaesthesia for other interventions

1) Written brochure information on patient rights and hospital rules

2) Face to face consultation

Written information material + written consent (at latest on the day of surgery)

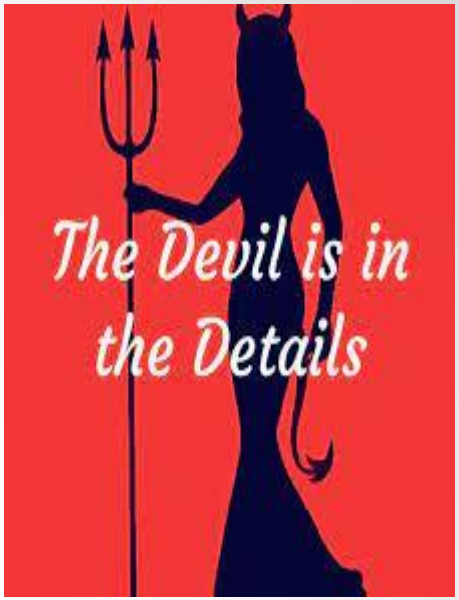
Both information material + consent should be recorded in IT system

>= 3 days delay between information and procedure

Emergency situations

If the patient cannot decide for himself, the physician administers treatment according to presumed wishes of the patient and his best interest, or according to anticipated directives, or official patient representative instructions.

Limitations



The determination of what is an «invasive procedure» is left to healthcare professionals

Obstetrics is often hard to predict: non invasive can become invasive

Not all patients admitted in labour & delivery rooms have been followed by the hospital

Physician consultation & information is not always possible

Recording of written information/consent in IT hospital system can be cumbersome

IF NOT POSSIBLE-→GO FOR THE SIMPLE MODEL

Conclusions

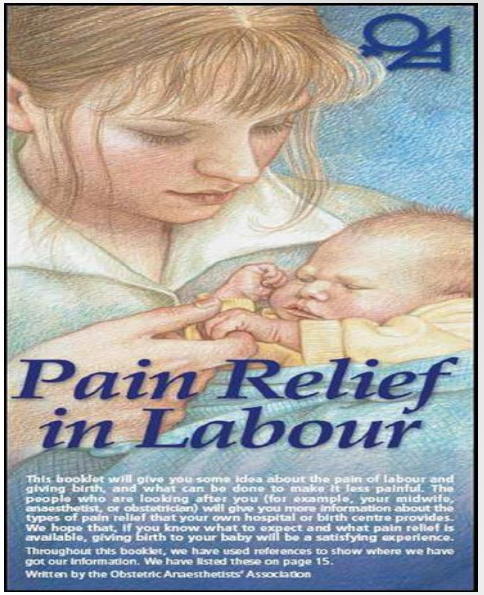
Informed consent is a mandatory part of anaesthesia care

It is supported by both ethical and legal arguments

The law does not consider all case scenarios of informed consent

Hospital based guidances can help but have their limitations

If in trouble, use simple common sense to provide information, gather consent and document it. It is lawful.


Pain Relief in Labour
This booklet will give you some idea about the pain of labour and giving birth, and what can be done to make it less painful. The people who are looking after you (for example, your midwife, anaesthetist, or obstetrician) will give you more information about the types of pain relief that your own hospital or birth centre provides. We hope that, if you know what to expect and what pain relief is available, giving birth to your baby will be a satisfying experience.
Throughout this booklet, we have used references to show where we have got our information. We have listed these on page 15.
Written by the Obstetric Anaesthetists' Association


QUESTIONS