A quality assessment of patient leaflets on misoprostol induced labour – does written information adhere to international standards for patient involvement and informed consent?

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Objectives:
The need for thorough patient information is increasing as maternity care becomes more medicalised. The aim was to assess the quality of written patient information on labour induction. In most Danish hospitals misoprostol is the first-choice drug for induction in low-risk pregnancies. Misoprostol has been associated with adverse side-effects and severe outcomes for mother and child and is not registered for obstetric use in Denmark.

Setting:
Secondary care hospitals in Denmark.

Data:
Patient information leaflets from all hospitals that used misoprostol as induction agent by June 2015 (N=13).

Design:
Patient leaflets were evaluated according to a validated scoring tool (IPDAS), core elements in The Danish Health Act, and items regarding off-label use and non-registered medication. Two of the authors scored all leaflets independently.

Outcome measures:
Women’s involvement in decision making, and information on benefits and harms associated with the treatment, other justifiable treatment options, and non-registered treatment.

Results:
Generally, the hospitals scored low on the IPDAS checklist. No hospitals encouraged women to consider their preferences. Information on side-effects and adverse outcomes were poorly covered, and information varied substantially between hospitals. Few hospitals informed about precautions regarding outpatient inductions, and none informed about the lack of evidence on the safety of this procedure. None informed that misoprostol is not registered for induction or explained the meaning of off-label use or use of non-registered medication. Elements like inter-professional consensus, long-term experience, and health authorities’ approval were used to add credibility to the use of misoprostol.

Conclusions:
Central criteria for patient involvement and informed consent were not met, and the patient leaflets did not inform according to current evidence on misoprostol-induced labour. Our findings indicate that patients receive very different, sometimes contradictory, information with potential ethical implications. Concerns should be given to outpatient inductions, where precise written information is of particular importance.

Main strengths and limitations specific to the study:
- The study had up-dated and complete data from all Danish hospitals that performed labour induction with misoprostol by the time of data collection.
- Patient leaflets were scored by two of the authors independently.
- Patient leaflets were evaluated against a validated scoring tool and according to national legislation.
- Data included written patient information alone, and so the study cannot conclude on other aspects of patient information.

References: