ETHICAL AND POLITICAL DILEMMAS WHEN MAKING NATIONAL GUIDELINES FOR PREGNANT WOMEN IN MEDICATION ASSISTED TREATMENT AND THE FOLLOW-UP OF THE FAMILIES UNTIL SCHOOL-AGE

Gabrielle Welle-Strand, Norwegian Directorate of Health Pompidou Group, Nicosia May 12th
Medication Assisted Treatment (MAT) in Norway

• Started in 1991
• Medication: Methadone or buprenorphine
• Strict inclusion criteria; presently being revised (General guidelines in process)
• By Dec 2008: 5000 patients in MAT-treatment - 1/3 women
• Approx. 200 women in MAT have given birth since 1996
• 25-40 women get pregnant in MAT every year
OPIATE DEPENDENCE AND PREGNANCIES IN NORWAY

- Detoxification/tapering off the women during pregnancy is still common
- Qualified in-patient treatment for pregnant drug users is available (short- or long-term)
- Compulsory treatment of pregnant drug users is possible (Law amendment since 1996)
- Pregnancy is not an indication for MAT
PRESENT NATIONAL RECOMMENDATIONS CONCERNING PREGNANT MAT-PATIENTS

- Family planning is part of the program
- Preganancies are discouraged for unstable patients
- Thorough information to pregnant women/couples - alternatives are discussed
- Methadone/buprenorphine should be continued throughout pregnancy
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PRESENT MAT POLICY FOR PREGNANT WOMEN cont.....

• The lowest efficient dose of the medication should be given
• These women/families need long-time multidisciplinary follow-up
• No illegal drug use is tolerated for pregnant MAT-patients or patients responsible for children
MEDICATION

• Methadone used to be the drug of choice
• The evidence for the safety of buprenorphine is getting better
• If tapering off: Between 14th and 36th gestational week
• The dose should be split towards the end of pregnancy
• If necessary the dose should be increased towards end of pregnancy
FOLLOW-UP OF PATIENTS

- Counselling and coordinating group for each patient; these are supplemented when a woman becomes pregnant
- Pre-natal visits by midwife and/or doctor
- Multidisciplinary follow-up
- Blood concentration for methadone x 1/month
- Urine samples 1-2 x/week (all drugs and alcohol)
- Close co-operation with obstetric and paediatric ward
FOLLOW-UP CONT....

• Primarily out-patient follow-up
• If necessary in-patient treatment (voluntary or compulsory)
• The babies are transferred to a paediatric ward after birth
PRESENT SITUATION

- Present recommendations are not followed nationwide
- Professional, political and general discussion on the topic
- Great variation in the treatment in different parts of the country
  - Dose of methadone/buprenorphine in pregnancy
  - Tapering-off policy
  - In/out patient treatment
  - NAS-treatment
  - Breast feeding
- Lack of knowledge
- Stigmatisation
AIM OF THE GUIDELINE PROCESS

• Give knowledge based recommendations for the treatment and follow-up of pregnant patients in MAT, during the stay at hospital at birth and the follow-up/treatment of the child and the family from birth until school-age
DOUBLE RISK

- The mothers/families – as a group they have medical, psychological and social problems making parenting more difficult
  - Sundfær’s long term study
  - Growing-up with drug abusing parents
- The babies – most of them are born with NAS – a vulnerable start
THE GUIDELINES’ PROCESS

- The Directorate of Health is responsible
- An expert group was appointed in September 2007
- Reference groups
- Seminars on specific topics (treatment of NAS, users’ experiences)
- Transparent process
- Review of the guidelines
- Finalized in 2009
- Dissemination and revision
Knowledge base for guidelines

Users’ knowledge and experience

Knowledge based on research = evidence

Knowledge based on experience = experts

Knowledge based recommendations

Context
EVIDENCE-BASE

- **Group of experts**: Addiction medicine psychologist + MDs, obstetrician, midwife, pediatrician, GP, social service, child protection services, child/youth psychiatrist, child developmental psychologist, research, user’s representative)
- **Search of the literature** – The Norwegian Knowledge Center/other experts – finished by Nov 2008
- **National and international experts’ advisory conference** in November 2007
- **Study trip** to Philadelphia, Baltimore and New York – May 2008
- Separate meetings with pediatricians (NAS-treatment), users
**NORWEGIAN KEY QUESTIONS**

- Should MAT be started during the pregnancy?
- Tapering off during pregnancy
- Buprenorphine or methadone in pregnancy?
- Breast-feeding and substitution treatment
- Diagnosis and treatment of NAS
- What are the long-term results of children born of mothers in substitution therapy?
- Follow-up of the children and families in a Norwegian context
  - Municipality level
  - Specialist level
THE CHALLENGES

• Knowledge-base limited
  • Especially concerning long-term outcomes
  • Available research is not always relevant for Norwegian settings
• Uncertain research findings – interpreted according to professionals’ original point of view
• Get people to think knowledge based
• Highly political issue and press issue
• Implementation of the Guidelines
Bakstad et al, European Addiction Research 2009

- 38 women in MAT giving birth 2005-6
- Only 2 started MAT in pregnancy, average length of MAT 31 month prior to pregnancy
- At birth, methadone dose 90 mg (n=26), buprenorphine dose 13 mg (n=12)
- Almost no drug abuse, all but one smoked
- GA 39,3 weeks, 3140 g birth weight
- NAS:
  - Methadone babies: 57,7 % - 42,2 days of medication
  - Buprenorphine babies: 66,7 % - 37 days of medication
Sandtorv L et al, Journal of Nor Medical Assoc 2009

- Follow-up of 15 children of MAT (1998-2005) mothers until age of 30 months
- 2 pair of twins, one pair born in week 26
- 2 SIDS
- 5 children in foster care
- 6 out of 13 children normal psychosocial development
- 8 children born after week 37: 4 deviant behavior, 2 strabismus, 2 problems with language, 3 problems with motor development, 1 delayed growth
PROFESSIONAL DISAGREEMENT

• Tapering-off policy
  • The knowledge base is limited
• Follow-up after birth
  • How do we in the best way secure the childhood and the well-being of the family?
  • How do these children do?
POLITICAL AND PRESS ISSUES

• The parliament debate 2006
• The minister for children and families
• The health minister and health politicians
• Issues:
  • These women must be tapered off methadone/buprenorphine during pregnancy
  • SIDS
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- Geography
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ON-GOING RESEARCH

- Women and their offspring in MAT 1996 – 2008 – Gabrielle Welle-Strand (160 births)
  - Pregnancies and neonatal outcome – link to the Norwegian birth Registry
  - Follow-up study 2009-2010
- Prospective study 2005 – 2006 cohort - Monica Sarfi/Brittelise Bakstad – 38 MAT babies
  - 2 + 2 groups comparison
  - Pregnancies and neonatal outcome
  - Follow-up of the babies/children+ mother/child interaction (6 wks, 3, 6 and 9 months, 1, 2 and 4 years)
Thank you for your attention!