National Clinical Guidelines for the management of drug use during pregnancy, birth and the early development years of the newborn
• Funded by the Ministerial Council on Drug Strategy (MCDS)

• Cost Shared Funding Project
1. How did this project come about?

2. How were the guidelines developed?

3. What credibility do the guidelines have, can we rely on them?

4. Who should use the guidelines?
1. How did this project come about?
History of the Project

• 1993 Vic Fogarty Report Child Protection
• 1998-9 NSW Child Death Review
• 2001 nationally based discussions: IGCD (Intergovernmental Committee on Drugs with National Expert Advisory Committees on Alcohol, Tobacco & Illicit Drugs)
• 2002 NSW Health NAS (Neonatal Abstinence Syndrome) Management Guidelines
• 2003 Langton Centre project to review NAS literature

• Proposal submitted to IGCD/MCDS by SA
  • Scope extended to include
    ▪ licit substances (alcohol, tobacco)
    ▪ early childhood

• Late 2003 Proposal accepted

• NSW Health and SA Health lead agencies

• Early 2004 Funding to NSW Health

• Steering Committee
1. How did this project come about?

2. How were the guidelines developed?
The Proposal required that they be:

- Clinical
- National
- Evidence based
- Use Ketttil Bruun process
National: All Jurisdictions

- State
- Territory
- Federal

Steering Committee formed with nominees:

- All jurisdictions
- Relevant professional organisations
Evidence base

• Overall, little reliable evidence on the effects of drug and alcohol use in pregnancy, or on developmental effects

• Highest levels of evidence for tobacco
## Levels of Evidence

*Adapted from NH&MRC 1999*

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from a systematic review of all relevant randomised controlled trials.</td>
</tr>
<tr>
<td>II</td>
<td>Evidence obtained from at least one properly designed randomised controlled trial.</td>
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<tr>
<td>III-1</td>
<td>Evidence obtained from well-designed pseudo randomised controlled trials (alternate allocation or some other method).</td>
</tr>
<tr>
<td>III-2</td>
<td>Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised (cohort studies), case control studies, or interrupted time series with a control group.</td>
</tr>
<tr>
<td>III-3</td>
<td>Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without parallel control group.</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from case series, either post-test or pre-test and post-test.</td>
</tr>
<tr>
<td>CONSENSUS</td>
<td>In the absence of scientific evidence and where the executive committee, steering committee and review groups are in agreement, the term 'consensus' has been applied.</td>
</tr>
</tbody>
</table>
Life stages

• Pre conception
• Pregnancy
• Birth
• Early years of infant
Kettil Bruun Process

- Trigger papers
- Discussant papers
- Expert Workshop
Topics 1

- Opioids
- NAS
- Current protocols
- Current protocols
- NAS

- Alcohol
- Tobacco
- Cannabis
- Benzodiazepines
- Amphetamines
- Cocaine
- Inhalants
Topics 2

- Vertical transmission
- Obstetric complications
- Breastfeeding
- Psychosocial aspects
- Pain management in labour
- Continuing support into the early years
- Indigenous issues
On each topic:

Trigger papers

- Review of evidence by a relevant expert

Discussant papers

- Review of trigger paper by a second expert

Workshop

- 5 min presentations followed by facilitated discussion
Workshop Participants

- Midwives
- D&A physicians
- Drug and alcohol workers
- Psychologists
- Social workers
- General practitioners
- Obstetricians
- Neonatologists
- Nurses
- Psychiatrist
- Policy analysts
- Researchers
• Main workshop & Indigenous workshop

• Drafting of guidelines

• Corrections by authors & workshop groups
Consultation:

Two phases

Phase 1

• Consumers
• Clinicians
• Professional organisations
Consultation:

Phase 2

- Government bodies including
  - Drug and alcohol sections
  - Child protection
  - Justice health
  - Aboriginal and Torres Strait Islander health
Current Progress

- Guidelines approved by IGCD
  September 05

- Endorsed by MCDS out of session 2
  December 05
1. How did this project come about?

2. How were the guidelines developed?

3. What credibility do the guidelines have, can we rely on them?

4. Who should use the guidelines?
Who should use the guidelines?

- All health care practitioners working with pregnant women experiencing a drug or alcohol use problem, particularly drug dependency, but including other drug uses such as bingeing.
• Mothers who are drug dependent should be encouraged to breastfeed with appropriate support and precautions. In addition, it is now recognised that skin-to-skin contact is important regardless of feeding choice and needs to be actively encouraged for the mother who is fully conscious and aware and able to respond to her baby’s needs.

*Level of evidence: Consensus*
Breastfeeding
Harm minimisation

- A harm minimisation approach to breastfeeding is recommended in these guidelines. Encouraging breastfeeding is preferred to avoiding breastfeeding, provided that:
  - the woman is informed about the likely effects on the infant of the drugs she is using (or may use) and
  - the woman is assisted to plan minimum exposure of the infant to the effects of these drugs.

*Level of evidence: Consensus*
Advising women

- In advising drug-dependent women with regard to breastfeeding, the specific potential risks in each woman’s individual circumstances should be weighed against the benefits of breastfeeding, and she should be informed of them.

*Level of evidence: Consensus*
Weaning

- As with all breastfeeding women, drug-dependent women should not wean rapidly.

*Level of evidence: Consensus*
Breastfeeding & alcohol

- The Australian Alcohol Guidelines recommend a prudent approach to breastfeeding if alcohol is consumed:

  ‘Women who are breastfeeding are advised not to exceed the levels of drinking recommended during pregnancy, and may consider not drinking at all’.
... alcohol ...

- If a breastfeeding mother wants to drink alcohol, it is suggested that she breastfeed before drinking alcohol, then wait a minimum of three to four hours after the last drink before breastfeeding again. In the event that the woman exceeds the recommended levels of drinking, it is recommended that the breast milk be expressed and discarded.

*Level of evidence: Consensus*
Breastfeeding & tobacco

- Minimal amounts of nicotine are excreted into breast milk and absorption of nicotine through the infant’s gut is minimal, but tobacco smoking can have other effects on breastfeeding that might indirectly affect the baby.
Women should be informed that:

- milk production may be reduced by as much as 250 mL per day in mothers who smoke

- mothers who smoke are less likely to start breastfeeding than non-smokers

- that mothers who smoke tend to breastfeed for a shorter time.

*Level of evidence: Consensus in BMA 2004.*
Sudden Unexpected Death in Infancy (SUDI) & SIDS

- SUDI is defined as the death of an infant less than 12 months of age, where the death was sudden, and was unexpected at the time. The term ‘unexpected’ indicates that the cause of death was not recognised before the event, although it may be diagnosed at autopsy. SUDI usually includes death due to SIDS and to other ill-defined causes (such as sleeping accidents).
SIDS and tobacco

- Both maternal smoking during pregnancy and environmental exposure of the infant to tobacco smoke (ETS) are associated with an increased risk of sudden infant death syndrome (SIDS).
Environmental tobacco smoke

- Contamination by environmental tobacco smoke is not limited to the indoor air, it includes surfaces and dust in living rooms and bedrooms and on skin. Infants are at risk of exposure to the toxic components of environmental tobacco smoke through these sources, so it is important that parents are given this information.
SIDS & ETS

- Mothers who smoke tobacco (or cannabis mixed with tobacco), or who live with smokers, should be advised of these risks, and specifically:
  - not to smoke during feeding (whether breastfeeding or bottle feeding)
  - not to smoke in the house or the car with the baby
  - that partners, family and friends should not smoke in the house or the car.

- In addition, mothers should be offered support with smoking cessation.

*Level of evidence: Consensus*
Sleeping accidents (SUDI)

- In particular, if an adult has used any form of sedating substance which might result in them sleeping heavily (including prescription medications, methadone and alcohol), there is an increased risk to the infant. A woman who drinks alcohol or takes sedating substances before sleeping should be advised:
  - not to have the baby sleep with her
  - that if she is heavily sedated, she may not wake for the baby’s next feed, or if the baby becomes distressed
  - to consider arranging a ‘safety plan’. That is, to have another responsible adult to take care of the infant if the mother decides to use drugs or alcohol.
Breastfeeding and nicotine replacement therapy (NRT)

- Women who wish to breastfeed while continuing to use nicotine replacement therapy should be advised to breastfeed first, then, as soon as possible after feeding, use one of the intermittent delivery methods of NRT (inhaler, gum, lozenge or sublingual tablet). This will maximise the time between use of NRT and the next feed, and reduce the baby’s exposure to nicotine.

*Level of Evidence: Consensus*
Breastfeeding & opioids

- Mothers who are stable on methadone treatment programs should be supported if they choose to breastfeed.

*Level of evidence: Consensus*
... opioids ...

- Mothers who are unstable, continuing to use short acting opioids such as heroin, or using multiple drugs, should be encouraged not to breastfeed, and attention should be paid to assisting them to stabilise their lifestyle.

*Level of evidence: Consensus*
Buprenorphine

• The safety of buprenorphine is not yet established for breastfeeding. Women who choose to breastfeed while taking buprenorphine, and can make an informed decision, should be informed of the risks and supported in their decision.

*Level of evidence: Consensus*
Breastfeeding & benzodiazepines

- Potential risks should be weighed up against benefits of breastfeeding when the mother is using benzodiazepines. If a woman taking benzodiazepines wishes to breastfeed, she should be advised that she should not stop taking the benzodiazepines abruptly, but should undergo supervised gradual withdrawal if she wishes to cease use.
• Women on short-acting benzodiazepines should be advised not to breastfeed immediately after taking a dose because of the dual risk of her falling asleep, potentially smothering the infant, and of the infant receiving a maximum dose and becoming excessively drowsy. If the mother does breastfeed while she is drowsy, she should be sure she is securely seated in a chair (not lying down), with the baby also well supported, so that if she falls asleep the baby will be safe.

*Level of evidence: Consensus*
Breastfeeding & psychostimulants

• Potential risks should be weighed against the benefits of breastfeeding when the mother is using psychostimulants. A mother who wishes to breastfeed should be supported in that decision, unless she is a regular user and is unstable, in which case she should be advised against breastfeeding.
Breastfeeding mothers who use psychostimulants rarely or in binges

- must be informed of the risks, and
- educated in how to avoid the harmful effects to the baby, that is:
  - to express and discard the breast milk after psychostimulant use (not to simply stop breastfeeding)
  - to have a supplementary feeding plan ready for such eventualities
  - advised not to breastfeed for 24 hours after the use of amphetamines or cocaine.

*Level of evidence: Consensus*
Breastfeeding & cannabis

- Potential risks should be weighed up against the benefits of breastfeeding. There is insufficient evidence to make an evidence-based recommendation about cannabis and breastfeeding. There is some evidence that cannabis is excreted in breast milk, but the effects on the infant are unknown.
...cannabis ...

- Cannabis is a long acting drug, so advice to take the drug after breastfeeding (as for alcohol) is not useful. Current advice given to women ranges from supporting the decision to breastfeed to advising against it. Heavy use of cannabis may pose a greater risk of transmission in breast milk, but this is not known.

*Level of evidence: Consensus*
... cannabis ...

- Advice to mothers and others should be as for tobacco: that is, smoke away from the infant, out of the house, and not in the car.

*Level of evidence: Consensus*
Human immunodeficiency virus

- Breastfeeding increases the risk of transmission of HIV from mother to infant, particularly during the first 6 months. HIV-positive mothers should completely avoid breastfeeding and use formula milk instead. It is important that women who are not breastfeeding be informed of the benefits to the infant of skin-to-skin contact.

*Level of evidence: III-2*
Hepatitis C virus

- There is no evidence that breastfeeding increases the risk of transmission of hepatitis C from mother to infant. Women should be informed of the theoretical risks and discard breast milk if it may be contaminated with blood, such as by cracked, abraded or bleeding nipples.

*Level of evidence: III-2*
Hepatitis B virus

- There is no evidence that breastfeeding increases the risk of transmission of Hepatitis B from mother to infant. To protect against transmission it is extremely important that all infants of HBsAg (hepatitis B surface antigen) positive mothers receive active and passive immunisation within 12 hours after birth.

*Level of evidence: III-2*
Role of lactation advice

- Advice should be sought from a child and family health nurse, a lactation consultant or a midwife with drug and alcohol experience where there is uncertainty about how to advise the drug-dependent mother with regard to breastfeeding.

Level of evidence: Consensus
Child Protection

State and Territory legislation
• An assessment of risk to the fetus or infant should be made by the health care professional working with the family, according to the mandated notification system in each State or Territory.

• This assessment should be made early in the pregnancy and continue throughout the pregnancy and postnatally.
• Can be a significant obstacle to willing participation in antenatal and postnatal care

• Honest reassurance where possible
• Although drug and alcohol use alone may not be an indicator for a child protection report or notification, child protection is a consideration in all drug and alcohol interventions for pregnant women.

• Legislation requires that the safety and well-being of the child is a paramount consideration.
Reasons to notify

“When there is risk of harm or neglect to [foetus in jurisdictions where legislation supports reporting before birth] or infant.”

Includes:

- Late presentation for antenatal care
- Polydrug use (including women not using any illicit drugs, but risky levels of tobacco and alcohol)
- Ongoing drug and alcohol use with severe mental illness
- Unstable living arrangements or homelessness
- Suspected abuse
- Suspected domestic violence.
Pattern of drug use

- It is important to establish the pattern and frequency of use, determining whether each substance is used:
  - occasionally,
  - on a regular recreational or
  - non-dependent basis or whether there is
  - habitual,
  - regular or
  - dependent use.

- From a child protection perspective, regular, daily or near daily use and binge use are of most concern

- Document actual effects on parenting
• If the statutory child protection agency is notified of a child at risk, the health care team should liaise closely with the agency throughout the pregnancy and the postnatal period.

• The mother should be informed of the notification unless doing so would increase the risk of harm to the infant.
• At appropriate points (such as before discharge), case meetings should be conducted.
• These meetings will aim to establish an agreed plan of care for the infant, and will include the mother/parents and their advocates (such as an Aboriginal health worker), as well as the child protection worker, health care providers, and representatives of all agencies involved in the care of the family.
• At each meeting, a time frame for review of the plan should be determined.
Statistics

2004 National Drug Strategy
Household Survey Results

Australian Institute of Health and Welfare
Ever used – whole community

- alcohol = 91%
- tobacco = 47%
- any illicit drug = 38%.
Illicit drugs - ever

- Cannabis = 33%
- Heroin =
- Psychostimulants
- Benzodiazepines
Illicit drugs

- **Ever**
- **Cannabis**

- **Last 12 months**
- **Cannabis**
Commonest illicit drugs

<table>
<thead>
<tr>
<th>Ever</th>
<th>Last 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannabis</td>
<td>33%</td>
</tr>
</tbody>
</table>
During pregnancy or breastfeeding – last 12 mths

<table>
<thead>
<tr>
<th>Generally</th>
<th>During …</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol =</td>
<td>85%</td>
</tr>
<tr>
<td>Tobacco =</td>
<td>22%</td>
</tr>
<tr>
<td>Illicit =</td>
<td>17%</td>
</tr>
<tr>
<td>Cannabis =</td>
<td>11%</td>
</tr>
<tr>
<td>Other =</td>
<td>10%</td>
</tr>
</tbody>
</table>
Commonest illicit drugs