

# Chronic Fetal Exposure to Opioids: National Practices in the Newborn

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## Abstract

**Introduction:** Intrauterine exposure to abuse substances is a growing public health problem, with opioids being the most frequent cause of neonatal abstinence syndrome. The purpose of this study was to report the prevalence of newborns with chronic fetal opioid exposure, and compare the national practices of diagnosis, treatment, and follow-up.

**Methods:** Online questionnaire sent to 43 public neonatology units in Portugal. Descriptive and statistical analysis of the data was done.

**Results:** Replies were received from 21 (49%) units, 11 (52%) were level III. Of the total 32,212 newborns, 39 (1.2 per 1,000) were exposed to opioids, in which 29 (74%) of these required pharmacological therapy. Nine units had their own protocol and the remainder followed the clinical consensus from the Portuguese Neonatology Society for newborns of mothers with substance abuse problems. Rooming-in was never practiced in two units versus was allowed during pharmacological therapy in two units. The minimum age for discharge ranged from three to 10 days for infants at risk of neonatal abstinence syndrome. The Finnegan scale was used by all of the units for the decision to treat or discontinue therapy, whether or not associated with clinical criteria. The most used drugs were opioids and phenobarbital in the treatment of neonatal abstinence syndrome and seizures, respectively. Two units allowed outpatient therapy (weaning of phenobarbital). Breastfeeding was allowed in newborns exposed to various abuse substances in three units. Seven units had no follow-up plan established after discharge.

**Discussion:** The heterogeneity in the approach to neonatal abstinence syndrome is wider regarding the use of rooming-in, age for discharge and follow-up plan. The most significant study limitation was the low response rate.

**Keywords:** Clinical Protocols; Infant, Newborn; Neonatal Abstinence Syndrome/diagnosis; Neonatal Abstinence Syndrome/therapy; Opioid-Related Disorders; Portugal; Surveys and Questionnaires

## Introduction

Intrauterine exposure to drugs of abuse is an alarming worldwide public health problem that has been rapidly growing in the last decade. Some European and American studies have shown a significant increase in the prevalence of opioid use by pregnant women, more than quadrupling in some reports, accompanied by an increment in neonatal abstinence syndrome (NAS) of the same magnitude. According to the kids' inpatient database in the United States of America, there was an increase from 1.19 to 5.63 per 1,000 hospital births from 2000 to 2009, in parallel with a marked rise in NAS from 1.2 to 5.8 per 1,000 hospital births per year, from 2000 to 2012. In Norway 6% of pregnant women had at least one opioid prescription between 2004 and 2006.<sup>1-4</sup>

Chronic fetal exposure to drugs of abuse followed by abrupt cessation after birth may result in NAS, characterized by a variable and complex spectrum of central nervous system hyperexcitation (with excessive release of noradrenaline) and autonomic instability.<sup>5-6</sup> Maternal substance abuse imposes a significant risk for the fetus, newborn, and child neurodevelopment. The constellation of NAS symptoms and signs can range from mild behavior changes to severe complications (Table 1), with an increased risk for preterm birth, low birth weight, stillbirth, microcephaly, sudden infant death and admission to a neonatal intensive care unit, with a risk of long-term morbidity and high health care expenses.<sup>5-7</sup> In preschool and school-age children, intrauterine exposure to opioids may manifest with cognitive and motor deficits, school difficulties, behavioral problems and attention-deficit/hyperactivity disorder.<sup>1</sup>

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Table 1. Clinical manifestations of neonatal abstinence syndrome

Neurological hyper-excitability	Gastrointestinal dysfunction	Autonomic dysfunction
Irritability	Feeding difficulties	Thermal instability
High-pitched crying	Excessive and uncoordinated sucking	Fever
Sleep disturbance	Excessive weight loss	Excessive sweating
Hypertonia	Vomiting	Nasal obstruction
Tremors and myoclonus	Diarrhea	Frequent sneezing
Increased osteotendinous reflexes and Moro	Dehydration	Tachypnea
Seizures (reported in 2%-11%) <sup>6</sup>		Marbled skin

There are several substances that can cause NAS, opioids being the most frequent drug causing manifestation. Neonatal abstinence syndrome occurs in 50% to 95% of newborns exposed *in utero* to opioids, with 42% to 94% of those needing pharmacological therapy.<sup>1,8</sup> This intrauterine exposure of opioids may be due to the consumption of illicit opioids (such as heroin), misuse of legal drugs (analgesics opioids), or opioids used for maternal replacement therapy (methadone or buprenorphine).<sup>5,7-9</sup>

The rapid worldwide increase of NAS prevalence, with high economic and social costs, has stimulated an increase in research in this area in the last decade. Several studies have concluded that the approach to newborns exposed to opioids varies widely within the same country and that standardized protocols reduce the duration of treatment and hospitalization with a reduction of costs. Even in relation to breastfeeding policies, there is a great heterogeneity of attitudes. For instance, many units do not allow breastfeeding by mothers on methadone, although it is proven that the methadone dose transmitted through milk is low and unrelated to maternal dose, helping infants to avoid pharmacotherapy.<sup>1,8,11</sup>

The arguments against the treatment of NAS in neonatal intensive care units have progressively gained strength. Since the focus in neonatal intensive care units is mainly towards pharmacological treatment, many authors consider that the separation of the newborn from the mother and higher costs are unnecessary for most infants who are not severely ill. Increasing evidence suggests that, in most cases, appropriate care can be provided in a rooming-in regime with the mother or even at home, optimizing care and costs.<sup>1,11-13</sup>

The objective of this study was to compare practices at a national level regarding the diagnosis, treatment and follow-up of newborns subject to chronic fetal exposure to opioids, with the national and international recommendations.

## Methods

An anonymous online questionnaire with 21 questions, written in Portuguese, was sent by e-mail to the directors/coordinators of the 43 Portuguese public neonatology units. Each unit was assigned a questionnaire access code, which ensured the anonymity of the collected data. To encourage participation, all units that did not respond to the first submission received a new request every two months during 2017.

Chronic fetal exposure to opioids was defined as *in utero* exposure to morphine, buprenorphine, methadone, or heroin for a period of three or more weeks prior to delivery. Neonatal abstinence syndrome was defined as a set of signs and symptoms that occur in the neonate exposed *in utero* to opioids and attributable to the reduction of the drug in circulation. These definitions were included in the questionnaire.

The data collected was for the year 2016 and included:

- Characteristics of the hospital/perinatal support unit;
- Geographical location of the unit;
- Number of live births, newborns at risk of and diagnosed with NAS;
- Methods for diagnosing and assessing NAS severity;
- Unit policies regarding non-pharmacological and pharmacological measures, discharge of newborns under pharmacological treatment, breastfeeding and follow-up plan after hospital discharge.

A descriptive and statistical analysis of the data was performed using Microsoft Excel<sup>®</sup>.

## Results

Of the 43 units contacted, 21 (49%) completed the questionnaire, yet not all answered all the questions. Units from all over the country responded, in which the majority (52%) were level III neonatal intensive care units. The annual number of live births for 2016 was quite variable among the units, with an average of 1,856. Table 2 presents a summary of the characteristics

Table 2. Characteristics and case summary of the units for 2016

Total number of units contacted, n	43
Total number of units that responded, n (%)	21 (49)
<b>Characteristics of the units</b>	
Type of hospital, n (%)	
Level I and II neonatal care units	10 (48)
Level III neonatal intensive care units	11 (52)
Region of the country, n (%)	
North	5 (24)
Center	6 (29)
South	9 (43)
Portuguese Atlantic islands	1 (5)
<b>Data from all the units (n = 21)</b>	
Number of live births	
Average, range	1,856, 670-2,985
Number of newborns chronically exposed to opioids*	
Total, n (%)	39 (0.12)
Number of chronically exposed newborns treated pharmacologically†	
Total compared to chronically exposed, n (%)	29 (74)

\* Data referring to 18 units (corresponding to a total of 32,212 live births).

† Data referring to 19 units (two did not provide data).

of the units and the data of newborns chronically exposed to opioids.

Of a total of 32,212 live births (according to 18 units that provided data), 39 or 1.2 per 1,000 live births were chronically exposed to opioids, and 29 (74%) of these required pharmacological therapy. The number of neonates chronically exposed to opioids show a weak correlation with the number of live births (Pearson correlation coefficient 0.48,  $p = 0.04$ ).

#### Protocol of care for infants at risk of or diagnosed with NAS

As described in Table 3, only nine units reported having their own protocol, the remaining followed the clinical consensus of the Sociedade Portuguesa de Neonatologia (Portuguese Neonatology Society) for newborns of mothers with substance abuse.

All responding units used the Finnegan scale to diagnose/ assess NAS severity, initiating pharmacological treatment if scoring 8 in 3 or more consecutive evaluations, except for one unit that made the decision to initiate treatment according to clinical examination.

#### Non-pharmacological and supportive measures

The non-pharmacological measures are aimed at reducing the physical and sensorial stimulation of the newborn. The measures most frequently adopted were the minimization of sleep disturbance of the newborn (100%), calm and low-light environment (95%), soft and delicate handling (95%) and containment measures (86%). Most of the units also reported adopting policies regarding feeding, including poly-fractionated feeding (76%), breastfeeding (71%) and use of hypercaloric formulas if there was significant weight loss (33%) (Table 4).

Table 3. Units methodology to approach, diagnose, and treat newborns at risk or with neonatal abstinence syndrome

<b>Protocol of care to newborns at risk or with NAS, n (%)</b>	
Existence of internal protocol	9 (43)
Application of Sociedade Portuguesa de Neonatologia clinical consensus	12 (57)
<b>Methods used in the diagnosis and evaluation of NAS severity, n (%)</b>	
Finnegan scale	21 (100)
<b>Decision to start pharmacological treatment, n (%)</b>	
According to the Finnegan score $\geq 8$	20 (95)
According to clinical examination	1 (5)

NAS - neonatal abstinence syndrome.

Regarding the hospitalization policies, rooming-in with the mother was allowed in 29% of infants at risk of NAS and 33% were often maintained in rooming-in; 43% of neonates with NAS who did not need pharmacological treatment were never maintained in rooming-in *versus* 24% who were always kept in rooming-in; only two (10%) units allowed infants undergoing pharmacological therapy to remain in a rooming-in regime during treatment.

Regarding breastfeeding policies for newborns exposed to opioids, 17 (81%) of the units reported allowing/encouraging breastfeeding in newborns exposed only to methadone or buprenorphine. Three units referred allowing breastfeeding even if mother was identified as a user of various drugs of abuse. The majority

(91%) allowed breastfeeding if the mother was hepatitis C virus (HCV) and/or hepatitis B antigen (HBsAg) positive, and none allowed it if the mother was human immunodeficiency virus (HIV) positive.

### Pharmacological treatment

The pharmacological agents used in the treatment of NAS and seizures associated with NAS are detailed in Table 5. An opioid was the drug most frequently used as the first line treatment of NAS (91%), and phenobarbital was the drug most frequently used as the second line (82%). For the treatment of seizures associated with NAS, the most frequently used first line drug was phenobarbital (90%).

**Table 4. Non-pharmacological policies**

<b>Supporting measures used in newborns at risk or with NAS, n (%)</b>	
Minimize sleep disturbance in the newborn	21 (100)
Quiet and dim lighting	20 (95)
Soft and delicate handling	20 (95)
Containment measures	18 (86)
Poly-fractionated feed	16 (76)
Stimulate non-nutritive sucking	16 (76)
Breastfeeding (if appropriate)	15 (71)
Rooming-in	13 (62)
Gloves on the newborn	10 (48)
Massage	10 (48)
Use of hypercaloric formulas (if pronounced weight loss)	7 (33)
<b>Rooming-in policies</b>	
Newborns at risk for NAS kept in rooming-in, n (%)	
Always	6 (29)
Often	7 (33)
Occasionally	6 (29)
Never	2 (10)
Newborns with NAS without pharmacological treatment maintained in rooming-in, n (%)	
Always	5 (24)
Often	4 (19)
Occasionally	3 (14)
Never	9 (43)
Newborns under pharmacological therapy, n (%)	
Hospitalization in neonatology unit	19 (91)
Rooming-in regime	2 (10)
<b>Breastfeeding policies for neonates chronically exposed to opioids, n (%)</b>	
It is encouraged/allowed in infants exposed only to methadone or buprenorphine	17 (81)
Is encouraged/allowed in newborns exposed to various drugs of abuse	3 (14)
Is encouraged/allowed if HIV positive mother	0
It is encouraged/allowed if HCV and/or HBsAg positive mother	19 (91)

HBsAg - hepatitis B antigen; HCV - hepatitis C virus; HIV - human immunodeficiency virus; NAS - neonatal abstinence syndrome.

Table 5. Pharmacologic treatment

Treatment of NAS due to opioids, n (%)		Treatment of seizures, n (%)	
<b>First line</b>	Total of answers: 21	<b>First line</b>	Total of answers: 20
Opioids	19 (91%)	Phenobarbital	18 (90%)
Morphine	17 (81%)	Morphine	2 (10%)
Methadone	2 (10%)		
Phenobarbital	1 (5%)		
Diazepam	1 (5%)		
<b>Second line</b>	Total of answers: 17	<b>Second line</b>	Total of answers: 5
Phenobarbital	14 (82%)	Phenytoin	3 (60%)
Opioids	3 (18%)	Phenobarbital	1 (20%)
Morphine	1 (6%)	Midazolam	1 (20%)
Methadone	2 (12%)		

NAS - neonatal abstinence syndrome.

### Hospital discharge and follow-up policies

There was a wide variation in the number of days of in-patient observation for infants chronically exposed to opioids without need for pharmacological treatment (three to 10 days). However, the majority (67%) reported a minimum period of observation of 5-7 days. Regarding discharge from the hospital, most units reported keeping newborns hospitalized for at least 72 hours after two consecutive days without therapy, symptom-free, without feeding difficulties, and with weight gain. Pharmacological treatment as an outpatient was only offered by two units, exclusively for newborns undergoing phenobarbital weaning. The follow-up plan for these children on home medication was not discussed in this questionnaire.

Although two-thirds of the units had an established plan for the follow-up of newborns with NAS, the plans were highly variable between the units. A first follow-up visit one week after discharge was the most frequently reported follow-up plan (71%). Some units also indicated that they arranged follow-up under other specialties, including general pediatrics, development, pediatric neurology, among others (Table 6). One unit reported the existence of a specific follow-up outpatient clinic for children of drug-dependent mothers.

### Discussion

This was the first national study on practices in the diagnosis, treatment and follow-up of newborns with chronic fetal exposure to opioids, which is a growing public health problem. The prevalence of intrauterine exposure to opioids observed in this study is significantly lower than that reported in American studies (1.2 vs. 5.63 per 1,000 live births).<sup>2</sup>

Although this study is limited by a low response rate (49%), making it impossible to study the policies of half of the Portuguese perinatal units, the balanced geographical distribution is one of the strong points. Not all the units answered to all the questions, further limiting the sample size. We cannot conclude that the units that did not respond had systematically similar policies to the ones that did and, therefore, we cannot generalize the data collected. The fact that the questionnaire was completed by only one member of the unit, generally the coordinator or doctor with the most experience and knowledge in this area, also raises the possibility that the practices described in the questionnaire are not generalized to all the clinicians at that particular unit. Moreover, the study had the limitation of being based on an unvalidated questionnaire, with no confirmation of the practices applied, making it possible that the answers may represent the ideal, rather than the actual, practices of each unit.

Although most of the units state that they follow the recommendations of the clinical consensus of the Sociedade Portuguesa de Neonatologia, this study highlights a marked heterogeneity in management across the various aspects studied, most marked in the use of rooming-in, age at discharge and follow-up plan (which was non-existent in seven units). Interestingly, two units reported the use of morphine as a first line to control NAS seizures, which is not recommended and raises the question of whether the question was misinterpreted.

We suggest a review of the national policies according to best practice in this area, acknowledging it will be a challenge, given the lack of scientific evidence and inconsistencies in several practices widely used in the management of newborns in risk or with NAS. However, proven best practice measures should be implemented in a standardized way, including:

Table 6. Hospital discharge and follow-up policies

<b>Discharge of newborns at risk of NAS without pharmacological therapy</b>	
5-7 days, n (%)	14 (67)
Range, days	3-10
<b>Clinical criteria used to decide discharge, n (%)</b>	
≥ 72 hours without therapy and symptom	19 (91)
Newborn without feeding difficulties, with weight gain in at least two consecutive days	14 (67)
Social service clearance	2 (10)
More than 4-5 days	1 (5)
<b>Discharge with outpatient pharmacological therapy, n (%)</b>	
Yes	2 (10)
<b>Established plan for the follow-up of newborns with NAS, n (%)</b>	
Yes	14 (67)
<b>If yes, what kind of follow-up consultation?</b>	
Neonatology	10 (71)
General pediatrics	3 (21)
Development	2 (14)
Social worker	3 (21)
Pediatric neurology/neonatal risk/mother with drug addiction	1 (7) each
Home visit and connection with a health center	1 (7)
<b>If yes, what periodicity?</b>	
1st visit one week after discharge	4 (29)
Weekly in the first month, monthly up to 4 months, at 6, 9, 12, 15, 18, 24, and 36 months	1 (7)
Weekly in the first month, monthly up to 3 months, at 5, 7, 9, 11, 14, 17, 20, 23, 29, and 36 months	1 (7)

NAS - neonatal abstinence syndrome.

- Prenatal counseling, providing information to all mothers at risk, as the best way to prevent and reduce the complications associated with NAS. Pregnancy is a time of great motivation to change risky behaviors, which should not be overlooked<sup>3,12</sup>;
- Adopt observation times for newborns at risk of NAS, depending on the type of opioid (long *versus* short acting) and its pharmacokinetics, and standardized pharmacological treatment initiation and weaning policies, to reduce the hospitalization time<sup>1,12</sup>;
- Adopt guidelines on breastfeeding, including allowing and encouraging breastfeeding of newborns of mothers on methadone or buprenorphine and HCV and/or HBsAg positive mothers (provided that the newborn received vaccine and immunoglobulin for hepatitis B postpartum)<sup>1,12</sup>;
- Encourage the mother's continuous presence and rooming-in accommodation, throughout the observation and pharmacological treatment process<sup>11-13</sup>;
- Develop outpatient treatment programs. This approach is still a rarity in Portugal and not recommended by the clinical consensus of the Sociedade Portuguesa de Neonatologia, which states that rooming-in is only recommended for NAS without the need for

pharmacological therapy, as opposed to several countries that have already proved its efficacy in reducing the need for and duration of pharmacological treatment.<sup>7,11-12</sup>

#### WHAT THIS STUDY ADDS

- This is the first national study on practices in the diagnosis, treatment and follow-up of newborns with chronic fetal exposure to opioids.
- The prevalence of intrauterine exposure to opioids is much lower than that reported in American studies (1.2 vs. 5.63 per 1,000 newborns).
- Most neonatology units use an opioid for neonatal abstinence syndrome treatment.
- The study points out a marked heterogeneity in the approach across the various aspects studied, which is clearly visible regarding the use of rooming-in, age for discharge and follow-up plan.
- Outpatient pharmacological treatment seems to be rare in Portugal, even though it is widely used in country's with high prevalence of NAS.

#### Conflicts of Interest

The authors declare that there were no conflicts of interest in conducting this work.

#### Funding Sources

There were no external funding sources for the realization of this paper.

**Protection of human and animal subjects**

The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

**Provenance and peer review**

Not commissioned; externally peer reviewed

**Confidentiality of data**

The authors declare that they have followed the protocols of their work centre on the publication of patient data.

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**Awards and presentations**

This study was presented as an oral communication in the XLVII Jornadas Nacionais de Neonatologia, Braga, November 15, 2018.

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## Exposição Fetal Crônica a Opióides: Práticas Nacionais em Recém-Nascidos

**Resumo:**

**Introdução:** A exposição intrauterina a drogas de abuso é um crescente problema de saúde pública, sendo os opiáceos a causa mais frequente de síndrome de abstinência neonatal. O objetivo deste estudo foi conhecer a prevalência, comparar as práticas nacionais no diagnóstico, tratamento e seguimento de recém-nascidos com exposição fetal crônica aos opiáceos.

**Métodos:** Um questionário *online* anônimo foi enviado às 43 unidades de neonatologia públicas de Portugal. Foi realizada análise descritiva e estatística dos dados.

**Resultados:** Responderam 21 unidades, 11 (52%) de apoio perinatal diferenciado. Em 32 212 nados-vivos, 39 (1,2 em 1000) foram expostos aos opiáceos, 29 (74%) destes necessitaram terapêutica farmacológica. Nove unidades têm protocolo de atuação próprio, as restantes seguem o consenso clínico Sociedade Portuguesa de Neonatologia para recém-nascidos de mãe toxicodependente. O *rooming-in* nunca foi praticado em duas unidades e outras duas unidades permitiram *rooming-in* durante a terapêutica farmacológica. A idade mínima para alta variou entre três e 10 dias para recém-nascidos em risco de

síndrome de abstinência neonatal. A escala de Finnegan, associada ou não a critérios clínicos, foi utilizada por todas as unidades na decisão de tratar ou desmame terapêutica. Opiáceos e fenobarbital foram os fármacos mais utilizados no tratamento da síndrome de abstinência neonatal e de convulsões, respetivamente. Duas unidades permitiram terapêutica em regime de ambulatório (fenobarbital em desmame). Amamentação foi permitida em recém-nascidos expostos a várias drogas de abuso em três unidades. Sete unidades não tinham plano de seguimento estabelecido após a alta.

**Discussão:** A heterogeneidade na abordagem da síndrome de abstinência neonatal foi mais clara em relação ao uso de *rooming-in*, idade para alta e plano de acompanhamento. A limitação mais significativa do estudo foi a baixa taxa de resposta.

**Palavras-Chave:** Inquéritos e Questionários; Portugal; Protocolos Clínicos; Recém-Nascido; Síndrome de Abstinência Neonatal/diagnóstico; Síndrome de Abstinência Neonatal/terapia; Transtornos Relacionados ao Uso de Opióides