



# Prenatal diagnosis of congenital anomalies and birth institution complexity levels in Argentina

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## Abstract

Patients with major congenital anomalies diagnosed prenatally should be referred to and delivered in institutions with the appropriate level of complexity, as this reduces morbidity and mortality. We aimed to assess the prevalence and prenatal diagnosis proportion of selected congenital abnormalities and the complexity levels of birth institutions in a sample of public maternity hospitals in Argentina. Data sources were (1) National Congenital Anomalies Registry, covering the period from 2013 to 2021; and (2) Categorization of birth institutions according to their complexity (high or low). Newborns with the following anomalies were selected for analysis: spina bifida, hydrocephalus, critical congenital heart defects, diaphragmatic hernia, gastroschisis, and omphalocele. Prevalences at birth and prenatal diagnosis proportions were calculated according to the birth institution complexity level. A total of 2,214,102 births across 131 institutions were evaluated, with 1,202,311 births in high-complexity institutions and 1,011,791 in low-complexity institutions. The prevalences per 10,000 births and the prenatal diagnosis proportions for the entire sample were: spina bifida 5,40(95%CI 5,10–5,71) 68,54%; hydrocephalus 6,96(95% CI 6,62–7,32) 78,92%; critical congenital heart defects 11,05(95% CI 10,62–11,49) 43,21%; diaphragmatic hernia 3,88(95%CI 3,62–4,14) 68,65%; gastroschisis 7,85(95%CI 7,48–8,22) 79,27%; omphalocele 2,01(95%CI 1,83–2,20) 76,18%. Prevalences and prenatal diagnosis proportions were significantly higher in high-complexity institutions. Prenatal diagnosis and perinatal care networks must be improved to ensure that patients with major congenital anomalies are delivered in high-complexity birth institutions. The prevalence and prenatal diagnosis proportion, stratified by the complexity level of institutions, can serve as management indicators to evaluate improvements in care quality.

**Keywords** Congenital anomalies · Prenatal diagnosis · Public health · Perinatal care

## Introduction

Congenital anomalies (CA) in Argentina have a strong impact on infant morbidity and mortality. In 2022, the prevalence at birth of major congenital anomalies was 1,83 per 100 births (RENAC 2023) and this group of pathologies accounts for approximately one-third of deaths in the first year of life in our country (DEIS 2023).

Prenatal diagnosis of congenital anomalies aims to provide the pregnant person with early information on fetal health, as well as timely referral during pregnancy to an institution with the appropriate complexity for monitoring and birth. These measures allow early planning of medical and/or surgical interventions, in some cases, even during pregnancy (Gagnon 2009). Additionally, prenatal diagnosis of CA allows women to make informed and autonomous decisions to terminate or continue the pregnancy. In

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Argentina, the Ministry of Health's "Guide to Practice for Prenatal Care" recommends a minimum of 8 prenatal visits for low-risk pregnancies, as well as a systematic ultrasound examination between weeks 19 and 24, and a routine ultrasound examination between weeks 11 and 13.6 (Dirección de Salud Perinatal y Niñez 2023).

Since 2008, Argentina has initiated a process of regionalization of perinatal care health services, focusing on concentrating births in institutions with a greater number of deliveries that meet essential obstetric and neonatal conditions (CONE, by its acronym in Spanish), establishing a health system with increasing and coordinated complexity. Public sector maternity wards have been classified according to their complexity in three levels according to the CONE (Speranza and Kurlat 2011):

- **Level 2:** Institutions that provide care for low maternal risk pregnancies and include neonatal services for infants who are full term or older than 35 weeks and/or weigh more than 2500 g and do not require special care.
- **Level 3 A:** Institutions with neonatal services capable of providing care for infants requiring short-term special care, such as oxygen therapy. They accept infants who are at least 32 weeks of gestational age or weigh at least 1500 g at birth. The provision of brief mechanical respiratory assistance varies depending on the region where the service is located.
- **Level 3B:** Institutions with the capacity to provide comprehensive neonatal care, including care for extremely premature infants, low birth weight infants, and/or those with congenital anomalies.

These differences in the complexity of institutions have direct implications on prenatal and neonatal care, as higher-complexity services have specialized resources to manage high-risk perinatal conditions, which impacts neonatal mortality. In contrast, lower-complexity institutions may lack the adequate resources for managing these cases, highlighting the importance of early referral for pregnancies diagnosed with CA (Bidondo et al. 2014; Sewell and Keene 2018).

This work aimed to determine the prenatal detection proportion (PDP) of selected fetal abnormalities and the level of complexity of birth institutions in a sample of public maternity wards in Argentina. Furthermore, the study sought to evaluate how the rates of prenatal diagnosis and the prevalence of selected congenital anomalies could reflect the effectiveness of perinatal care services and the regionalization process in Argentina, considering the complexity levels of the birth institutions.

## Materials and methods

### Design and procedures

The present study is a cross-sectional study. The data sources were: (1) The RENAC database (National Network of Congenital Anomalies of Argentina) and (2) The categorization of public maternity wards according to their complexity level (CONE).

RENAC data was used for the period between January 1st, 2013 and December 31st, 2021. RENAC is the national hospital surveillance system for major structural congenital anomalies, which has been operating since 2009 in hospitals with maternity wards across the 24 jurisdictions of the country (Groisman et al. 2013). Cases born in institutions not part of the aforementioned network and cases from institutions in the private or social security subsector were excluded. For this study, newborns with the following anomalies and their respective ICD-10 codes were selected: spina bifida (Q05), hydrocephalus (Q03), critical congenital heart defects (Q20.0, Q20.3, Q20.4, Q21.3, Q21.82, Q22.00, Q22.40, Q22.5, Q23.4, Q25.1–Q25.19, Q25.2, Q26.2, Q26.20), diaphragmatic hernia (Q79.0–Q79.01), gastroschisis (Q79.3), and omphalocele (Q79.2). For the categorization of public maternity wards according to their level of complexity, the criteria of Essential Obstetric and Neonatal Conditions (CONE) were used, as defined by Resolutions 641/2012 and 670/2019 of the National Directorate of Maternity and Childhood of the Ministry of Health of the Nation (Ministerio de Salud de la Nación 2012; 2019) (Fig. 1).

For this study, the complexity level of the birth institutions was analyzed in a dichotomous way: high complexity corresponded to institutions categorized as 3B and low complexity to those categorized as 3A and 2. As shown in Fig. 1 institutions with a high level of complexity are those that provide specialized care necessary for the proper care of newborns with the anomalies analyzed.

- Level 2: Institutions that provide care for low maternal risk pregnancies and include neonatal services for infants who are full term or older than 35 weeks and/or weigh more than 2500 g and who do not require special care.
- Level 3A: Institutions with neonatal services capable of providing care for infants requiring short-term special care, such as oxygen therapy. They accept infants who are at least 32 weeks of gestational age or weigh at least 1500 grams at birth. The provision of brief mechanical respiratory assistance varies depending on the region where the service is located.
- Level 3B: Institutions with the capacity to provide comprehensive neonatal care, including care for extremely premature infants, low birth weight infants, and/or those with congenital anomalies.

**Fig. 1** Categories of essential obstetric and neonatal conditions

## Data analysis

The birth prevalence of each selected anomaly was calculated for the entire country and by the level of complexity of the birthplace. Prevalences were measured as the proportion of cases over the total number of births in the participating facilities, with 95% confidence intervals according to the Poisson distribution, using STATA software version 13.

The prenatal detection proportion was estimated from the quotient between the number of cases with selected CAs detected prenatally (numerator) and the total number of births affected by the selected CAs (denominator).

Statistical analysis was performed using Pearson's chi-square calculation to compare the proportion of prenatal diagnosis between the two levels of complexity.

## Results

During the study period, RENAC evaluated a total of 2,214,102 births in 131 maternity wards within the public subsector across all jurisdictions in the country. From this sample, 1,202,311 births were examined in 3B maternity

wards (high complexity), while 1,011,791 births were examined in 2 and 3 A maternity wards (low complexity).

The anomalies analyzed with the highest prevalence were critical congenital heart defects, while omphalocele was the least frequent defect (Table 1). When analyzing the prevalence by the complexity of the birth institutions, it was observed that all the selected anomalies exhibited a significantly higher prevalence in high-complexity maternity wards (Table 1).

When evaluating the PDP, it was observed that gastroschisis was the most frequently detected defect, while critical congenital heart defects showed the lowest percentage. All anomalies showed a significantly higher percentage of PDP in the more complex institutions (Table 2).

## Discussion

This study is one of the first investigations carried out in Argentina aimed at understanding the relationship between the prevalence of congenital abnormalities, the proportion of prenatal diagnosis of fetal abnormalities, and the level of complexity of public birth institutions.

**Table 1** Prenatal diagnosis proportion of selected congenital anomalies according to level of complexity, public subsector, RENAC, period 2013–2021

Congenital anomalies	Total		High complexity		Low complexity	
	<i>N</i>	Prevalence per 10,000 (IC 95%)	<i>N</i> (%)	Prevalence per 10,000 (IC 95%)	<i>N</i> (%)	Prevalence per 10,000 (IC 95%)
Spina bifida	1195	5,40 (5,10–5,71)	932 (77,99)	7,75 (7,62–8,27)	263 (22,01)	2,60 (2,30–2,93)
Hydrocephalus	1542	6,96 (6,62–7,32)	1261 (81,78)	10,49 (9,92–11,08)	281 (18,22)	2,78 (2,46–3,12)
Critical congenital heart defects	2446	11,05 (10,62–11,49)	1777 (72,65)	14,78 (14,10–15,48)	669 (27,35)	6,60 (6,12–7,13)
Diaphragmatic hernia	858	3,88 (3,62–4,14)	653 (76,11)	5,43 (5,02–5,86)	205 (23,89)	2,02 (1,76–2,32)
Gastroschisis	1737	7,85 (7,48–8,22)	1447 (83,30)	12,04 (11,42–12,67)	290 (16,70)	2,87 (2,55–3,22)
Omphalocele	445	2,01 (1,83–2,20)	371 (83,37)	3,70 (3,37–4,06)	74 (16,63)	0,73 (0,57–0,92)

**Table 2** Prenatal diagnosis rate (PDR) of selected congenital anomalies according to level of complexity, public subsector, RENAC, period 2013–2021

Congenital anomalies	Total		High complexity		Low complexity		<i>P</i> ( $\chi^2$ )
	Total cases	Prenatal diagnosis <i>N</i> (%)	Total cases	Prenatal diagnosis <i>N</i> (%)	Total cases	Prenatal diagnosis <i>N</i> (%)	
Spina bifida	1195	819 (68,54)	932	691 (74,14)	263	128 (48,67)	<0,001
Hydrocephalus	1542	1217 (78,92)	1261	1009 (80,02)	281	208 (74,02)	0,026
Critical congenital heart defects	2446	1057 (43,21)	1777	900 (50,65)	669	157 (23,47)	<0,001
Diaphragmatic hernia	858	589 (68,65)	653	468 (71,67)	205	121 (59,02)	0,002
Gastroschisis	1737	1377 (79,27)	1447	1190 (82,24)	290	187 (64,48)	<0,001
Omphalocele	445	339 (76,18)	371	293 (78,98)	74	46 (62,16)	0,002

Critical congenital heart defects had the lowest proportion of prenatal diagnosis, with only one in four affected children diagnosed prenatally in cases born in low-complexity institutions. The prenatal diagnosis of heart defects should be performed primarily by detailed morphological ultrasound, which should be performed in all pregnancies between weeks 19–24 (Dirección de Salud Perinatal y Niñez 2023). A study that included data from 15 registries across different countries around the world reported that the PDP of critical congenital heart defects varied between 13% and 87% (Bakker et al. 2019). Prenatal screening for congenital heart defects has been shown to have a direct impact on perinatal health, as evidenced by a reduction in infant mortality due to heart disease in Denmark following the implementation of this public health measure (Lytzen et al. 2019). The low proportion of prenatal diagnosis of congenital heart defects observed in our study could mainly be attributed to difficulties in accessing the health system for pregnant women and a lack of training for sonographers in evaluating the fetal heart, which is a complex anatomical structure. Spina bifida is usually detected by specific ultrasound signs in the second trimester of pregnancy (Nicolaidis et al. 1986; Meller et al. 2021) and according to some authors, ultrasound could detect almost all cases of spina bifida (Lennon and Gray 1999). In the European Network of Congenital Anomalies Registries (EUROCAT), the PDP of spina bifida in the period 2017 to 2021 was greater than 75% in 28 of the 31 registries (EUROCAT 2024). The overall PDP in our study was 68.54%, however, in low-complexity institutions the percentage was only 48.67%. Unlike other congenital anomalies, the surgical approach to spina bifida can be started in the prenatal stage, which reduces neurological sequelae. Although the upper limit has been extended to 27–28 weeks, this fetal intervention is usually performed before the 26th week of gestation (Meller et al. 2021; Adzick et al. 2011). For this reason, it is necessary to improve the PDP and ensure that detection is performed at an early stage.

The PDP for congenital diaphragmatic hernia and congenital hydrocephalus observed in our study was similar to the proportion reported in registries from other countries. As with spina bifida, in congenital diaphragmatic hernia, there is a prenatal intervention that has been shown to increase survival after birth (Deprest et al. 2021; Van Calster et al. 2022). Therefore prenatal diagnosis and referral to a more complex center would be beneficial.

The proportion of prenatal diagnosis of gastroschisis and omphalocele varies by country. In 26 of the 31 registries that comprise the EUROCAT network, the percentage of diagnosis was higher than 90% of cases (EUROCAT 2024). These proportions were higher than those observed in our study. However, research conducted in developing countries shows percentages still below those reported in our work (Bilibio et al. 2019; Muniz et al. 2023; Amado et al. 2023).

In a previous study by RENAC, which included all the institutions in the network, it was observed that the PDP in public institutions was lower than in private and social security hospitals (Bidondo et al. 2020). Conversely, another study conducted by the Latin American Collaborative Study of Congenital Malformations (ECLAMC), which included 13 hospitals in Argentina found no differences in the PDP between public and non-public institutions; however, in public institutions, the diagnosis was made at a significantly later gestational age (Campaña et al. 2010).

From a health perspective, prenatal care is considered efficient when it meets certain basic requirements: it should begin early in gestation, be periodic throughout pregnancy, be comprehensive, and have broad coverage within the population. The guidelines of the Ministry of Health of Argentina recommend a minimum of 8 prenatal consultations, however in 2021, only 10.9% of pregnant women attended more than 9 consultations, 61.9% attended between 5 and 9 consultations and 27.2% made fewer than 5 consultations. Furthermore, regarding gestational age at the first prenatal visit, it was observed that only 38.8% consulted in the first trimester (Dirección de Salud Perinatal y Niñez 2023). This situation indicates that there are still barriers to accessing the health system, which, among other implications, affects the potential for early diagnosis of fetal abnormalities. Pregnant women face social, cultural, and economic barriers, as well as challenges related to domestic responsibilities and the care of children or dependent individuals at home. Additionally, there are barriers within the health system itself; in this regard, a study conducted in a maternity ward in the city of Buenos Aires showed that the main barrier to access for pregnant women in the first trimester of pregnancy was the inability to secure an appointment for care at the establishment (Pécora et al. 2008).

In perinatology, poor organization is considered to be as significant a factor as the lack of clinical competence in the origin of morbidity and mortality for both mothers and children (Schwarcz 2011). For several years, Argentina has organized perinatal care to reduce maternal and neonatal morbidity and mortality. To this end, essential obstetric and neonatal conditions (CONE) were established, along with a regionalization and classification system based on complexity (Speranza and Kurlat 2011). Regionalization implies a coordinated system between institutions and health teams. The prevalence of the selected congenital anomalies was significantly higher in institutions of greater complexity, which likely reflects the effectiveness of prenatal diagnosis and timely referral to these centers for follow-up and care at birth. However, a significant percentage of cases were born in low-complexity institutions despite being detected prenatally. This situation may be attributed to deficiencies in the referral and counter-referral system for pregnant women with a prenatal diagnosis of CA to higher-complexity centers.

## Limitations

Our study has some limitations. The analysis was restricted to public institutions, however, it is important to note that in Argentina, the non-public health system (social security and prepaid health plans), where 38.7% of births in the country occur (DEIS 2023), does not have a perinatal organization based on levels of complexity. Additionally, the study covered a period of 9 years and we cannot therefore rule out changes in trends over the time analyzed. Finally, in 2020, abortion was legalized up to the 14th week of gestation in Argentina, which could have affected the prevalence of congenital anomalies at birth. Future research will help us evaluate changes in the proportions of prenatal diagnosis and prevalence of these anomalies.

## Conclusion

In our study, we observed that the six major congenital anomalies selected had higher proportions of prenatal diagnosis and prevalence in the most complex public institutions. The anomalies studied require specific, highly complex perinatal management, which is why birth should occur in maternity wards categorized as 3B. For this reason, it is necessary to improve, among other aspects, the early prenatal diagnosis of CAs as well as the referral system and perinatal care networks.

The regionalization of perinatal health services based on levels of complexity requires the implementation of prenatal ultrasound screening during the first and second trimester of pregnancy as a fundamental pillar at a national level. This strategy enables early diagnosis and timely referral of pregnant women to centers of adequate complexity; Universal screening has been shown to have a direct impact on reducing perinatal mortality (Sewell and Keene 2018).

To achieve this goal, Law No. 27,611 was passed in Argentina in 2020, promoting nationwide access for pregnant individuals to fetal morphology studies via ultrasound between 18 and 22 weeks of gestation to identify major congenital malformations. However, to implement this public health measure effectively, it is necessary to advance various actions, including promoting early initiation of prenatal check-ups among the population; improving access to health services; training health professionals in the diagnosis of CA; increasing the availability of prenatal studies at all levels of care; generating a prenatal diagnosis network with different levels of complexity that facilitates consultation and/or referral between institutions and improving equipment in cases that require it, among other measures.

Early diagnosis also allows pregnant women to decide whether to continue with the pregnancy or opt for termination at an earlier gestational age.

Another conclusion that emerges from our study is that a proportion of patients with the congenital anomalies studied are born in low-complexity maternity wards, even in cases where there was a prenatal diagnosis. To address this situation, it is necessary not only to improve prenatal diagnosis, as previously mentioned; but also to optimize the functioning of perinatal care networks to ensure timely referral to more complex centers is made during pregnancy.

Although this was not the primary objective of the study, our findings suggest that the PDP and the prevalence of major congenital anomalies, stratified by the complexity of the birthing institution, could serve as valuable management indicators for evaluating improvements in perinatal care. These indicators may also help assess the impact of public health policies in this area of perinatal health.

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**Author contributions** All authors have contributed equally to the work and jointly supervised the work.

**Data availability** The epidemiological data that support the findings of this study were sourced from the databases of the congenital anomalies surveillance system of Argentina (RENAC) and have been published in annual reports available at: <https://ine.gov.ar/index.php/otrasareas/renac>.

## Declarations

**Ethical approval** The authors declare that there are no ethical conflicts to disclose.

**Consent to participate** The study was conducted using non-nominalized data, and comparisons were made based on aggregate data. These data fall within the exceptions outlined in Resolution 1480/2011 of the National Ministry of Health, which provides guidelines for research involving human subjects.

**Competing interests** The authors declare no competing interests.

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