

Strategy for Assistance at Normal Childbirth in the National Health System

HEALTHCARE 2008

MINISTRY OF HEALTH AND CONSUMERS' AFFAIRS

SPAIN

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Our Birth Association [El Parto Es Nuestro] (EPEN)
Pro-Birth Rights Platform

List of participants in the elaboration of this report

List in Annex VI

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Strategy for Assistance at Normal Childbirth in the National Health System



GOBIERNO DE ESPAÑA
MINISTERIO DE SANIDAD Y CONSUMO

Plan de **Calidad**
para el Sistema Nacional de Salud

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Prologue

This strategy document has been prepared as a response to a demand among social groups, health professionals and regional health authorities which has seen a significant increase in recent years, and which has prompted the Spanish Ministry of Health and Consumers' Affairs to set up a process in which all the affected persons and parties are invited to participate, as a prerequisite for its elaboration and consensus.

The contents of this document are the result of a thorough review of scientific evidence, of the existing research on the subject and the analysis of documented trials, and models of best practice. It has been possible through the combined work of professional bodies, women's groups and regional health authorities.

While the assistance offered at childbirth within the National Health System is based on objectives of safety and quality similar to those of other European countries, there is a widespread feeling that this assistance could be improved by promoting a more caring approach and the participation and protagonism of women themselves in the process of childbirth. This is the fundamental objective of this report.

The Observatory on Women's Health, at the Quality Agency General Directorate at the Ministry of Health and Consumers' Affairs, Spain, has worked to facilitate and compile the efforts of all the persons and institutions who have participated in the elaboration of this document. I would like to emphasize that this has involved the collective commitment of all participants towards an improvement in the assistance offered at childbirth.

The approval that was granted by the Inter-territorial Advisory Board of the National Health System in October 2007, together with the contributions made by its members, support the interest and willingness which has been displayed and the collective commitment to improving health care in this area.

I would like to extend special thanks to all those who have participated in the process of elaborating the Strategy Document for Assistance at Normal Childbirth as a tool to be used for obtaining the recognition of the role that women have played. I would also like to express my thanks to all those who collaborate in its development and practice on a day-to-day basis.

Bernat Soria Escoms
Health Minister

Introduction

The period since the passing of the Act of Parliament 14/1986 on the 25th April, Spain has seen the development of a good public health system, offering a wide range of services with well-distributed universal coverage, which has resulted in positive health statistics.

The Spanish National Health System is characterized by its decentralisation. The Autonomous Communities and Cities with Statute of Autonomy have responsibility for the planning and management of their health services in accordance with their specific character and the requirements of health care in their respective territories.

In common with other neighbouring countries, we are now facing the challenge of quality, working towards a standard of clinical practice based on scientific principles while centred on the model of individualised attention as the basis for the development of new strategies and as a guarantee of improved service. This is what the Quality Plan of the National Health System has envisaged.

The strategies that are being developed contribute to both the legitimacy and social sustainability of the public health systems, for both users and health professionals, and ensure that the financial resources which the state and regional governments assign to health services are used to maximum effect.

The objective of these strategies is to ensure first-class health care which is more personalised and centred on the specific need of individual users. It evidently follows that the efforts should be focused on supporting the health professionals in every way that will contribute to the achievement of that goal. The aspects which are currently of great interest in this respect are those relevant to the continuous and permanent improvement of knowledge, skills and attitudes which are aimed at satisfying the needs of the users, who are continuously becoming better-informed and more demanding.

To help the National Health System respond to this type of challenge, the Spanish Ministry of Health, as coordinator of the service, has the task of boosting cohesion and monitoring equal opportunity of access and service quality in order to safeguard the rights of users in their dealings with the National Health System. Through the Observatory on Women's Health and the National Health System itself, the Ministry has been working with women's groups, professional bodies and regional health departments with responsibilities in the area of pregnancy, childbirth and post-natal care, in a number of different forums and conferences.

Internationally, this issue is subject to wide variations, in terms of practice as well as in levels of assistance and repercussion on health statistics. For this reason, and due to its repercussions in society, it has

been a topic of discussion and study as well as a source of concern among international health organisations and all those involved in the defence of women's rights.

The studies and analyses carried out so far have concluded that the safety indicators for women and children's healthcare provision are positive in comparison with our neighbouring countries. Even so, and leaving aside the objection that things can always be improved, our aim is to be among the highest ranking countries, but there are aspects related to the quality and warmth of reception in assistance that have ample room for improvement.

On the other hand, the Observatory on Women's Health and the National Health System have reviewed the available scientific findings on midwifery, and this review has provided valuable information for updating some current practices to bring them into line with others based on these findings. This mainly involves eliminating certain unnecessary practices and the introduction of new alternatives to those already available. The review of good practice as established in international journals revealed an emphasis on the importance of promoting women's informed participation throughout the process and in deciding the clinical procedures which should be applied. This would lead to an improvement in women's well-being, the relation between doctors and patients and increased satisfaction for all concerned, as well as reducing the number of legal proceedings started for suspected or actual negligence.

This document is based on the processes of change already initiated by professional bodies and the health service administration of regional autonomies, and is intended as a document of consensus and agreement to be adopted by all the parties involved in the process of assistance at childbirth, whether representing associations of health professionals, users or health organizations.

The ultimate aim is that of ensuring quality in the assistance offered at childbirth across the whole territory of Spain, so that women and their partners who make use of the National Health Service at this crucial point in their lives receive the best possible attention and participate actively and informedly in the process.

There are aspects of childbirth assistance which are intimately related to pre-natal and post-natal care (both for the mother and the newborn child), but it has been considered more appropriate to focus this strategy document primarily on the process of childbirth itself. This choice was made for efficiency, given that the level of assistance and the range of professionals involved are specific to this area. The aim is to continue advancing in the future by widening this improved level of quality to the pre-natal and post-natal periods.

1. General aspects

1.1. Justification

Health Services have been progressively acquiring more and more sophisticated means which can guarantee an acceptable level of assistance at childbirth, especially in those cases where there are complications, or the risk of complications. At the same time, assistance at ordinary childbirth has been subject to increasing medicalization in what is fundamentally a physiological process.

Today's health services are aware of the importance of the equilibrium resulting from the greater importance given to women's participation and their opinions. Similarly, they welcome the opportunity to engage in a shared process of reflection, taking the existing models of good practice as a reference with the aim of incorporating a warmer and more caring approach to the quality of assistance at childbirth.

At present there are enormous variations in the assistance at normal childbirth, and public debate being held between differing points of view. Women's groups are increasingly demanding the right to give birth with full respect for privacy, full participation in decision-making and improved conditions for themselves and the children. Similarly, there are an increasing number of health professionals who see this movement as an opportunity for debate and agreement, as an occasion for engaging in reflection and sharing experience and knowledge.

At present women are demanding greater participation in the decisions that affect the process of assistance at childbirth. On the other hand, professional medical and nursing bodies directly involved in the process of assistance (Spanish Society of Gynaecology and Obstetrics, Federation of Spanish Midwives' Associations, Midwives' Association of Spain and Autonomous Communities), have recently created protocols and guides for assistance at childbirth which include revisions of some widely accepted practices.

Given the interest within society and the health services of the regional autonomies in developing innovations in assistance at childbirth, part of the budget assigned to health strategies and policies of cohesion in 2006 and 2007 were devoted to implanting them. Specifically, initiatives were undertaken in the Autonomous Communities to set up training courses for health professionals, to adopt protocols based on scientific evidence into improving the assistance offered at childbirth, to starting programmes to promote breast feeding, greater involvement of the fathers and attention to

cross-cultural issues. The total sum spent on these initiatives amounts to more than 4 million euros.

This collaborative process undertaken by the autonomous health services has shown that there is enough interest and maturity to engage in shared programmes aimed at changing the ways in which assistance at childbirth can be changed within the National Health System to obtain greater quality of assistance and recognition of the prominence of women's role.

1.2. Meeting points

Giving birth is a natural practice which has accompanied the evolution of the human species, and has been influenced by the development of the medical profession and its impact on health care. To this we must add the changes in the perceptions, judgements and expectations of the community, and especially those of women, concerning the significance of this unique moment in people's lives. These circumstances have led to the emergence of meeting points where a debate has been taking place between research and know-how.

Among others:

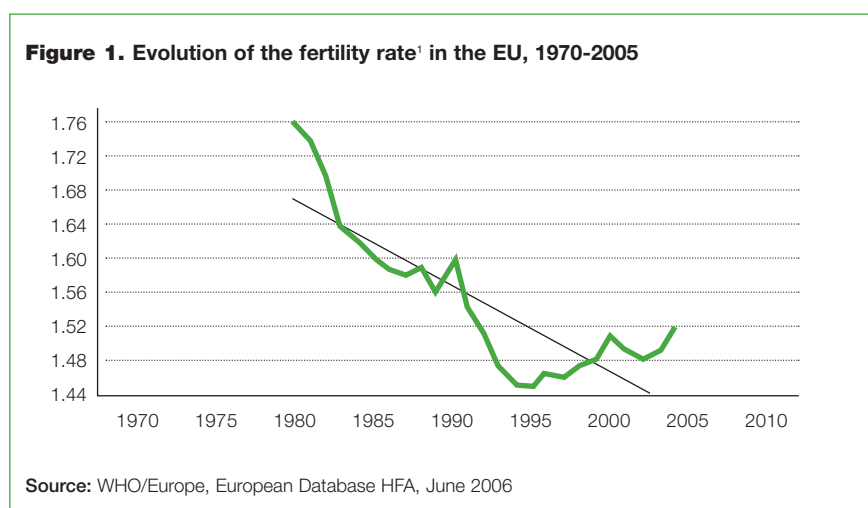
- *Meeting points between different knowledge*, between professional and scientific knowledge and that of women, who are exercising their rights and demanding appropriate healthcare.
- *Meeting points between divergences*, recognising that there are aspects of assistance at childbirth that have not been resolved, and which merit a space for consensual criticism between the world of the health professionals and that of the population of health service users.
- *Meeting points between differing ideas of health*, those which arise from beliefs, myths and inter-generational transmissions concerning health, its significance and how to address it.
- *Meeting points between mothers and their children*, at the end of a gestation period filled with hopes and expectations.
- *Meeting points for women with their partners and family framework*, in the context of a varied network of affection.
- *Meeting points for facing diversity*, in recognition that there is more than one model for the manner in which people relate to each other, and that society is in need of new ways of recognising this changing reality.
- *Meeting points for women-mothers with themselves*, in response to the need to satisfy the requirements of their bodies and minds to enable them to cope with this period calmly and without stress.

For all these reasons, this strategy document reaches far beyond a simple proposal of standards. It recognises the advances made in medicine and proposes new challenges for the heterogeneous processes of maternity and paternity in a context of dynamic transition, in which the roles are reconfigured. It demands that health professionals adopt more and better responses to the demands for the provision of assistance to women during childbirth.

1.3. Analysis of the situation

1.3.1. Evolution of natality

There has been a profound decline in fertility in Europe over the last twenty years. The most common family unit at present is that of a family with one or two children. The slight increase that has been noted between 2000 and 2005 has not been sufficient yet to reach the level of replacement fertility rate¹ (2.1 children per woman; fig. 1).



¹ **Fertility rate:** the average number of children per mother if mothers had lived through their fertile periods and had children in accordance with the fertility rate at a given specific age. It is calculated by adding the fertility rate for a specific age for all age groups and multiplying this by the intervals in which the ages are grouped.

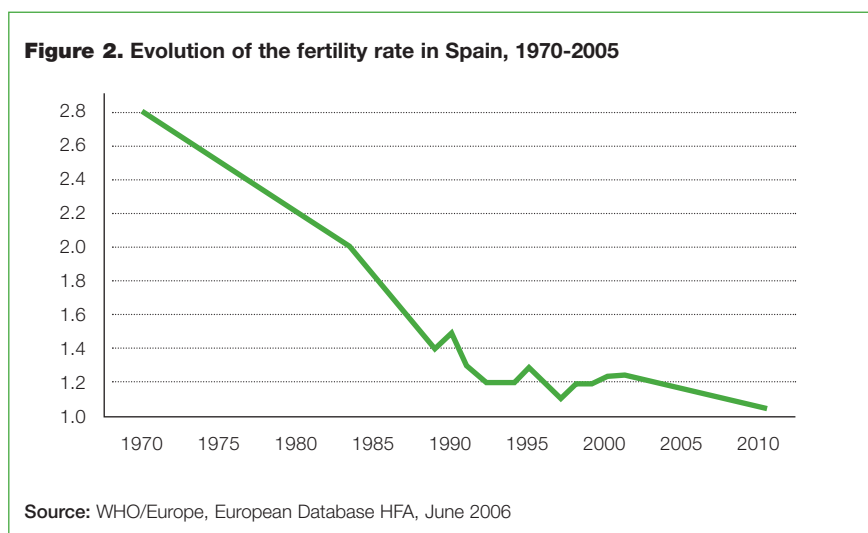
This decline has been most significant in those countries which have traditionally had high birth rates, especially in the southern countries, in contrast with more moderate fluctuations in the countries to the north. At the moment, Spain, Italy and Germany are the European countries with the lowest birth rates.

Fertility rates in European countries by intervals.		
1.19 to 1.44	between 1.69 and 1.94	above 1.94
Austria, Switzerland, Germany, Spain, Italy and the Czech Republic	France, Denmark, Norway, Sweden, Finland, The Netherlands, Belgium and Great Britain	The Republic of Ireland

Source: WHO/Europe, European Database HFA, June 2006

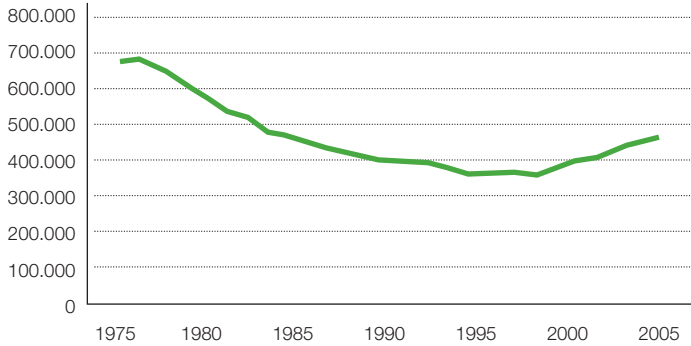
The fertility rate was in steady decline in Spain between 1970 and 1997 (fig. 2). In 2002, the average number of children per mother was 1.26, and this figure was the highest on record since 1993. The fertility rate rose again in 2005 to the level of 1.34 children per mother.

In this way, the fertility rate in Spain continues to recover and has reached its highest point since 1993, but it has yet to reach a level that guarantees replacement (2.1 children per mother).



The number of births per year has increased gradually during recent years. It has risen from 372,749 in 1997 to 459,751 in 2004. In 1997, 75 % of all births took place in state-run hospitals, with the other 25 % taking place in private centres. In 2004, these rates were 26 and 74 % respectively (fig. 3).

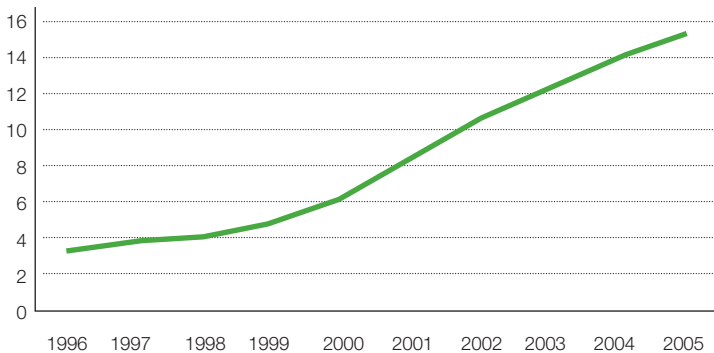
Figure 3. Spain: Births, 1975-2005



Source: National Statistics Institute, Natural Population Growth, 2006

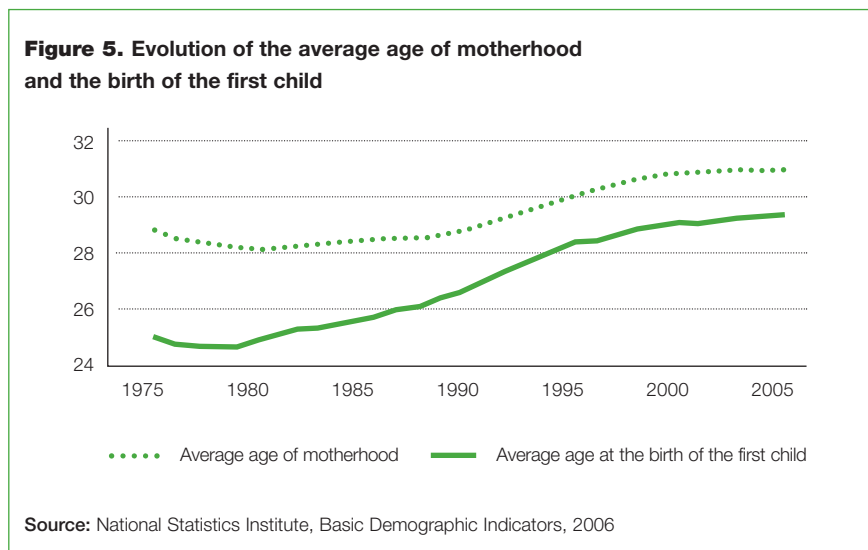
This increase in the fertility rate in Spain is due primarily to the progressive increase in the number of children born to foreign mothers that has taken place in the last decade, and most notably in the last few years. In 2002 they represented 10.4 % of the total, and in 2005 they made up 15 % (fig. 4).

Figure 4. Births to foreign born mothers in Spain, 1996-2005



Source: National Statistics Institute, Natural Population Growth, 2006

The postponement of maternity is another common feature across Europe. In 1983, the average age for a woman to have her first child was around 27.3 years old. At present this figure stands at over 30 years of age. Several European countries have seen a rise in the number of children born to mothers over 35 years old. In Italy, Spain, Switzerland, Ireland, Sweden, Finland and Holland, mothers over 35 years old account for more than 22 % of all births (fig. 5).



1.3.2. Demographic and socio-cultural changes

Recent years have seen a transformation in the attitudes and behaviour of European men and women towards maternity and paternity, and this has been particularly noticeable in Spain. This change is a result of economic development and the political and cultural changes that have taken place in the final years of the 20th century.

Although women have acquired a predominant role at every level of the educational system and are penetrating the most highly-qualified areas of the labour market, these achievements have not been accompanied by a comparable increase of programmes giving support in maternity, nor a greater participation on the part of men in domestic housework, which has restricted the capacity of women to work outside the private sphere, unless by accepting extended working days that are difficult to coordinate.

An important addition to the current situation is the recent approval and application of the Act of Parliament 3/2007, of the 22nd of March, which had as its objective the establishment of effective equality between the sexes in terms of attention and opportunities in order to promote a society that is more democratic, just and cohesive.

These factors, along with others, can explain the process of far-reaching change which has directly and indirectly affected the decisions and capacity for handling the process of maternity, and which will continue to affect them for time to come.

The notable increase in the level of qualifications achieved, especially by women, as well as the social position and degree of independence that they have reached has prompted a parallel increase in the amount of information and expectations demanded of the health system, along with a clearer vision of the conditions in which maternity should be experienced.

One recent study showed that mothers with lower social status demand a lower level of support in the upbringing of their children when compared with mothers of higher status.

According to the latest national fertility survey, the number of children born to each mother diminishes as women acquire a higher level of education. For example, women who demonstrate low levels of literacy have an average of 3.19 children, while those who have higher education have an average of 0.72. To be more specific, women with higher education within the age range of 25-34 years have an average of 0.33 children.

1.3.3. Evolution of the principal birth rate indicators

The principal indicators relating to birth rates in Spain have shown a positive tendency in the last few years. The number of maternal deaths in childbirth dropped during the 20th century as a result of social progress and scientific and technical advances applied to medicine.

Even so, there are some indications that this positive tendency has reached a point of stagnation. On the one hand the number of deaths registered in childbirth has not declined further, but has even seemed to rise slightly since 1998 (fig. 6), although some studies indicate that there are no defined tendencies, or that the overall tendency is to decline. Grouped by medical centres, cases of mortality in childbirth are greater in state-run hospital facilities, which handle a greater number of high-risk cases.

This process is simultaneous with the increase in the average age of the mother and the reduction of infant weight at birth (fig. 7), the increase in premature and multiple births. (fig. 8).

At the same time, the extension of assisted reproduction technology has had an effect on the number of multiple births, and some studies have suggested that cases of multiple gestation resulting from assisted reproduction are more prone to worse obstetric and neonatal results than those occurring naturally.

It is also true that cases of mortality in childbirth are so infrequent (less than seven deaths in a thousand births) that the smallest alteration in the number of deaths causes enormous oscillations in the rates, which reduces their importance as indicators of this tendency. When grouped by catchment areas, it is the public facilities, which deal with the most serious and high-risk cases, which again have the highest rates of mortality in childbirth throughout the years analysed (fig. 9).

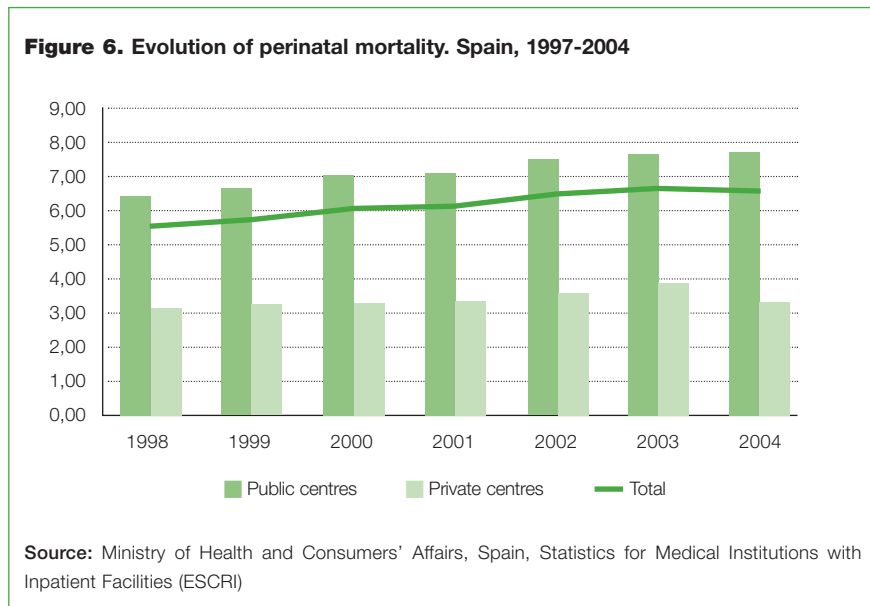
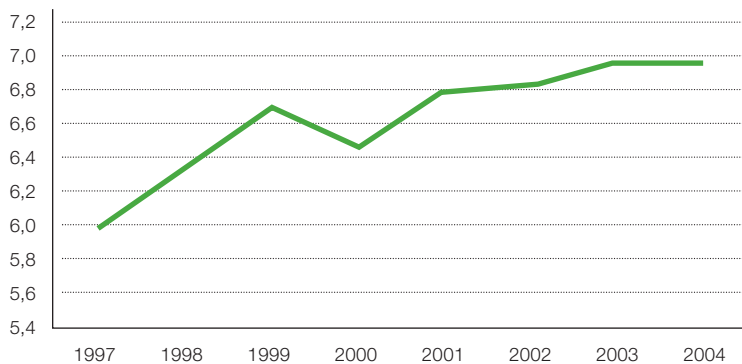
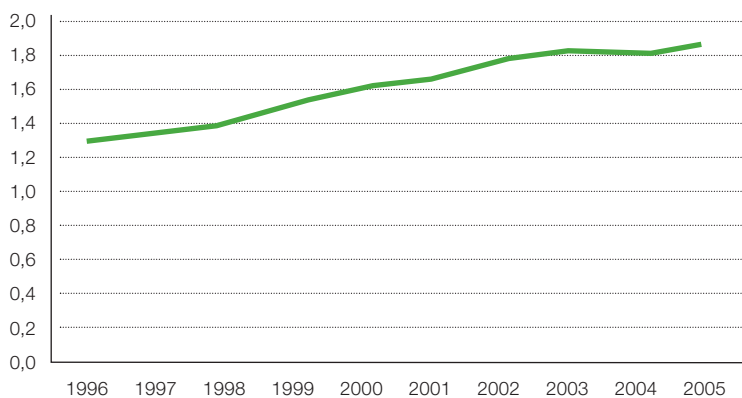


Figure 7. Evolution of infants with low weight at birth (< 2,500 g). Spain, 1997-2004



Source: Ministry of Health and Consumers' Affairs, Spain, ESCRI, 2006

Figure 8. Evolution of multiple births. Spain, 1996-2005



Source: National Statistics Institute, Natural Population Growth, 2006

**Figure 9. Evolution of mortality in childbirth Spain, 1997-2004
(per 100,000 births)**



Source: Ministry of Health and Consumers' Affairs, Spain, ESCRI

1.4. Assistance at normal childbirth in the National Health System

1.4.1. Programmes and services

The Health Programmes of the Autonomous Communities still have little to say on aspects related to the rights of patients to receive quality assistance in sexual and reproductive issues. The sub-programmes of assistance during pregnancy, birth and post-natal period, which are specifically addressed in the Women's Health Plans for the Autonomous Communities, are not available from all of these communities. The Integrated Assistance Processes include the rights of women to demand high standards of care, more information and the right to make decisions during pregnancy and childbirth, but not the shared responsibility of the father. Finally, the Health Care Cards for Expectant Mothers, as documents for channelling communication between health professionals and patients have not been useful for informing and empowering the population with regards to their rights to assistance.

The right to participate in the decision making process has not been fully used because women are not always fully informed about their tests, nor their right to decide about them. Similarly, the expectations of the

patient are not always considered, nor are they always offered advice on the planning of the birth.

The role of the father is barely visible. Many expectant mothers' medical cards which are used within the health institutions continue to consider the fathers as "risk factors" inasmuch as the illnesses in their medical history may have an effect on the foetus, or the effect their presence or absence may have on the patient, or the social context in which the pregnancy takes place. Their participation in the process is seen primarily as a support for the mother, as one of the mother's rights, rather than a right that the fathers can exercise for themselves.

There have been several initiatives specifically aimed at offering assistance for the birth process among immigrant groups, among which the services of "cultural mediators" the publication of information (guides, manuals, health advice pamphlets etc.) translated into different languages should be mentioned. Although studies have been published on the inequalities suffered by groups in risk of exclusion, there has been little work on the few initiatives aimed at resolving them, and fewer still dealing specifically with the topic of assistance in childbirth and after.

In comparison with the other European countries, the assistance offered by the Spanish Health System can be placed within a model of institutionalised interventionism, offering attention from specialized doctors and nurses, as is the case in countries such as Ireland, Russia, the Czech Republic, France and Belgium.

This model coexists with other European countries offering alternative forms of assistance. At one extreme, there is the model proposed by countries such as The Netherlands and Scandinavian countries, which is free from institutional interference and attended by qualified, autonomous midwives. There is also an intermediate model which offers the possibility of institutionalised yet humane treatment, and which can be found in Great Britain or Germany.

1.4.2. Management indicators and results of assistance in public hospitals of the National Health System (MBDS)

The number of patients entering hospitals for maternity constitutes a significant part of the activity of a hospital, accounting for 14 % of all hospitalisations and 7 % of hospital admissions. It is the only area of a hospital's activity which is mostly aimed at a healthy segment of the population, and where the admission takes place in order to undergo an

experience which is biologically natural, and which should terminate in a happy ending, the birth of a son or daughter.

However, along with other events which call for hospital care, assistance at childbirth is subject to many variables which depend on the expectations of the population, changes in the forms of assistance available and variations in the procedures employed in caring.

The studies of these variations are one way of bringing to light the way in which institutions and health authorities differ in their behaviour when offering medical assistance.

When unjustified variations have been observed in the prevalence of certain practices in the perinatal period, each of the factors that contribute to a specific pattern of use should be analysed to gauge its importance. There are questions which are inherent to the provision of services (institutionalised medical culture, professional training, the existence of permanent education programmes and models of quality assessment etc.) or to the demands of the users.

If we know the pattern of variations, this could make a fine starting point for the initiation of corrective action in these practices, whether due to the excessive and unjustified use of inappropriate practices or the unjustified under use of appropriate practices.

The following table is a structured summary of the principal results and indicators for a group of practices relative to assistance at childbirth, with the aim of discovering whether there are differences between groups of hospitals and territorial areas. It also provides information of the level of variation between hospitals for each of the indicators, according to the level of the hospital and its autonomous community.

The data analysed is derived from the minimum basic data set of hospitals that form part of the National Health System, and correspond to the activity of 2005. For the purpose of this study, the hospitals have been classified by level according to the volume of births attended:

Level 1: Centres with fewer than 600 births.

Level 2: Centres with 600 or more births, and fewer than 1,200.

Level 3: Centres with 1,200 or more births, and fewer than 2,400.

Level 4: Centres with 2,400 births or more.

The analysis of variations is comprised of two further analyses: on one hand, there is an exploratory or descriptive analysis, in which the information is summarised numerically and graphically. The second part consists of an evaluation of the statistical significance.

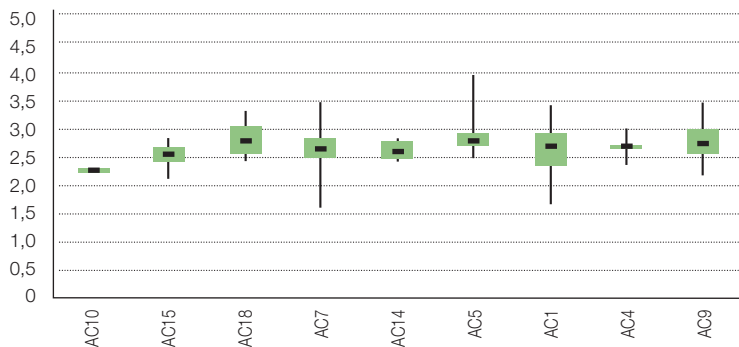
The distribution of each indicator is given in bar graphs. Each bar represents the global value of all the hospitals in each group as defined in

the described levels from 1 to 4. The distribution of each indicator by dimension of analysis is given in box plot graphs. Each box plot contains the maximum and minimum values of the distribution, and the percentiles of 25, 50 and 75 of the distribution. Given that the intention is to show the phenomenon of variability, the data is presented anonymously, grouped by hospital level and by autonomous community.

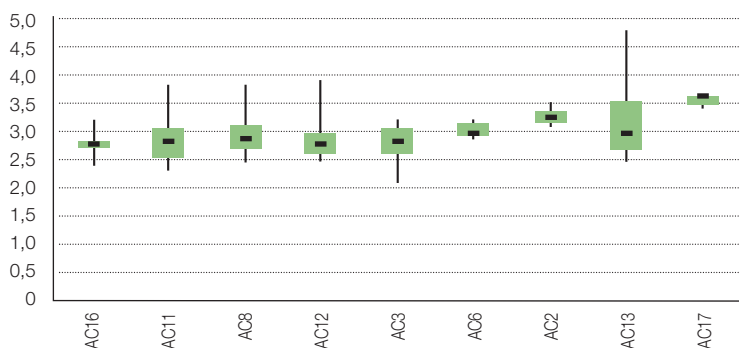
The bar graph (fig. 10) shows us that the average hospital stay for vaginal births displays a variation that ranges from 2.3 to 3.5 days, with a difference of 1 both extremes. When the variation between hospitals within the same autonomous community are compared, we can observe a variability between communities of 2.28 to 3.51 (fig. 11).



Figure 11. Average hospital stay for vaginal births by Autonomous Community (AC)



Hospitals	2	12	7	10	2	6	32	5	46
Average	2,28	2,54	2,74	2,64	2,62	2,77	2,69	2,65	2,74
Percentile 25	2,28	2,45	2,62	2,48	2,52	2,71	2,38	2,64	2,57
Percentile 75	2,28	2,68	3,01	2,85	2,72	2,90	2,92	2,74	2,99



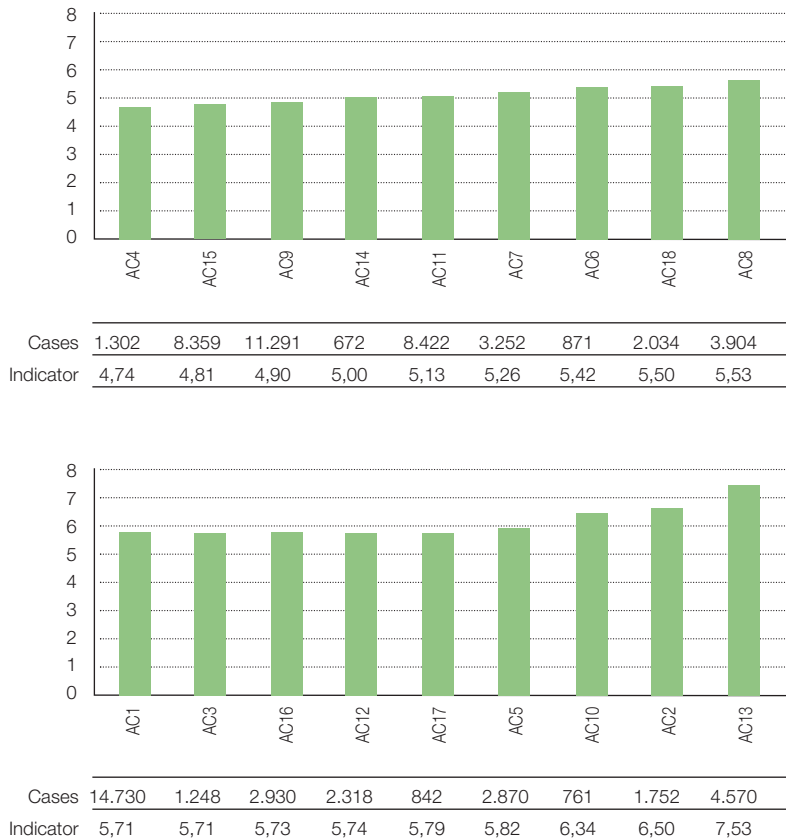
Hospitals	6	21	14	8	8	2	8	15	3
Average	2,68	2,82	2,89	2,70	2,75	2,95	3,23	2,93	3,52
Percentile 25	2,64	2,50	2,69	2,60	2,61	2,88	3,11	2,66	3,45
Percentile 75	2,72	3,00	3,06	2,80	3,00	3,02	3,28	3,41	3,53

Analysis of the variability (Box-plot)

In contrast with the situation of vaginal births, the average hospital stay for caesarean sections (fig. 12) shows not only a higher number of days, but also a greater variability between autonomous communities, with a range stretching from 4.74 days to 7.5, which is almost 3 days difference between the maximum and minimum. A similar variability of this indicator is registered in the interior of each autonomous community (fig. 13).

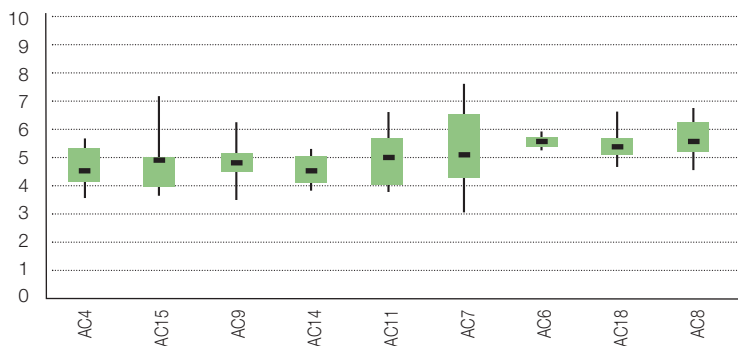
Unlike the previous indicators, the variation in high-risk births with assistance grouped by autonomous community shows an ample variability, with a range that oscillates between 28.4 % and 52.3 % (fig. 14).

Figure 12. Average hospital stay for caesarean sections

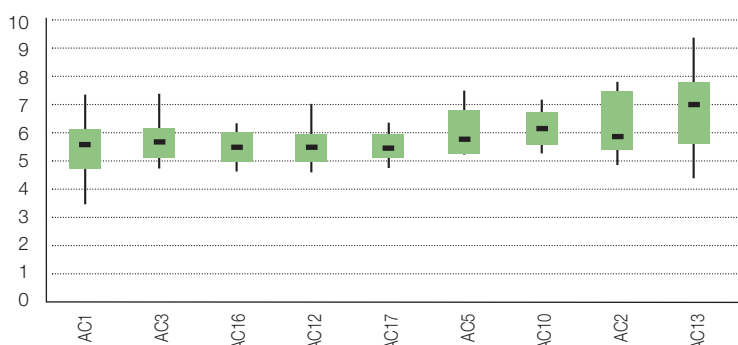


Distribution of the indicator by Autonomous Community (AC)

Figure 13. Average hospital stay for caesarean sections by Autonomous Community (AC)



Hospitals	5	12	46	2	21	10	2	7	14
Average	4,35	4,75	4,69	4,51	4,89	5,03	5,56	5,24	5,53
Percentile 25	4,06	3,90	4,42	4,11	3,96	4,34	5,46	5,08	5,29
Percentile 75	5,16	4,91	5,05	4,91	5,65	6,41	5,66	5,60	6,05



Hospitals	32	8	6	8	3	6	2	8	15
Average	5,56	5,44	5,41	5,58	5,30	5,74	6,12	5,94	6,99
Percentile 25	4,68	5,08	4,87	4,83	4,96	5,30	5,65	5,36	5,62
Percentile 75	5,99	5,86	5,68	5,82	5,74	6,67	6,60	7,29	7,64

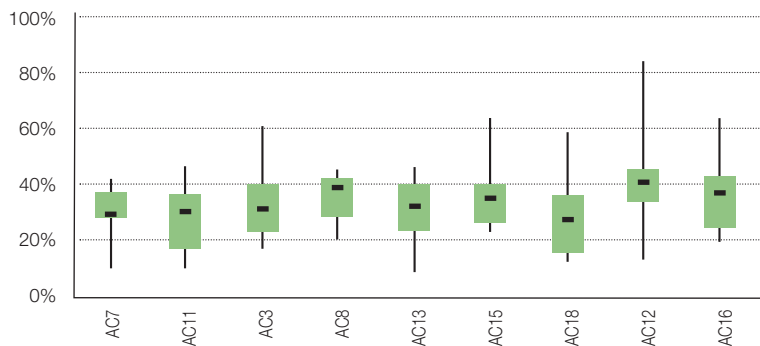
Analysis of the variability (Box-plot)

In this context, it is worth analysing the extent to which this variation can be explained by multiple causes, which can be linked to the definition of what constitutes “high risk”, and the different kinds of medical attention that the different medical facilities offer their users.

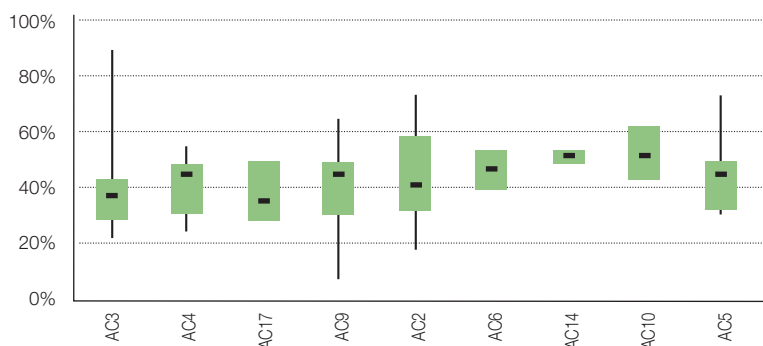
The same phenomenon can be observed within the autonomous communities (fig. 15).



Figure 15. Variation in the proportion of high risk births by Autonomous Community (AC)



Hospitals	10	21	8	14	15	12	7	8	6
Average	29,6	30,6	31,0	38,0	31,4	34,3	26,9	40,0	37,0
Percentile 25	28,0	17,8	22,8	28,2	24,0	27,0	16,6	34,5	25,9
Percentile 75	36,0	35,5	39,4	40,6	39,8	39,8	35,8	44,7	41,5



Hospitals	32	5	3	46	8	2	2	2	6
Average	35,8	44,1	34,1	43,0	40,5	45,3	50,0	50,9	43,7
Percentile 25	28,8	29,8	27,9	30,6	32,6	39,7	47,8	42,1	32,9
Percentile 75	41,8	47,0	47,5	48,0	56,1	50,9	52,2	59,8	48,6

Analysis of the variability (Box-plot)

1.5. Frame of reference

1.5.1. Quality Plan of the National Health System

The Quality Plan of the National Health Service (QPNHS), of the Spanish Ministry of Health and Consumers' Affairs is responsible for articulating the coordination of the NHS with the aim of promoting greater cohesion and higher standards of service, guaranteeing the rights of the citizens and the users of the NHS.

The QPNHS places the general population at the centre of the modern health service, giving rise to a new model of health assistance focused on the patients and users. This change of focus is the basis for the development of new strategies.

The strategies which are included in the QPNHS constitute a firm commitment to achieving greater levels of legitimacy and social sustainability within the public health system between the users and the health professionals. It also pursues improvements in efficiency so that the economic resources which the state and the autonomous communities devote to health care enjoy the best use possible.

The QPNHS also takes into consideration the demands placed upon health professionals to keep their knowledge up-to-date, and to face the challenge of deciding in the light of scientific evidence which aspects should be incorporated into clinical practice, and which time-honoured practices should be declared obsolete in the interests of the patients and users of the service.

The essential objective of the QPNHS is to ensure an optimum level of health care which is tailored to the individual, centred on the specific requirements and expectations of the patients and users, and it is therefore necessary to lend support in the drive to update the skills and knowledge available.

Therefore in strategy point 3: "Encouraging health policies based on the best practices", it states that health policies should be based on knowledge that is useful in practice, setting out specific processes to be used in producing data, and that the great diversity among the different actions adopted by the Autonomous Communities forming part of the National Health System offers many opportunities for mutual learning and collaboration in the common pursuit of quality.

In strategy point 4: "Analysing health policies and proposing action to reduce inequalities in health with emphasis on gender differences", it underlines that one of its objectives is to raise awareness of gender

inequalities in health, and to reinforce the attention given to gender issues in health policy and in the training offered to health personnel.

This objective highlights the fact that gender inequalities in health and in the assistance provided by health services affect both men and women, but have a greater negative impact on women, not only for social reasons, but because of the way that the service is organized.

1.5.2. Transversal sections of equity

The objectives and recommendations of this strategy document have been formulated and should be read with the following transversal sections of equity in mind:

- Diversity of ability.

The assistance offered in health care should take into account the varying requirements that users have, depending on their physical, intellectual and sensorial capacities. When handicapped women are admitted to hospital for assistance at childbirth, they may require specific and differentiated treatment which is adapted to their needs.

- Multicultural issues.

The immigrant population has grown and also displays a greater level of fertility. Immigrants may find obstacles that impede their access to health services that call for specific responses and actions. The hospitality offered and the presence of intercultural elements acquire even greater significance in this context, both from a social and economic standpoint. The proportion of births delivered to immigrant parents in public hospitals as a percentage of total births varies between 20 and 50%.

- Gender perspectives.

From the point of view of gender, it can be seen that the protagonism that women acquire during the birth process, with the support, experience and companionship provided by friends and health professionals, has been diminished in proportion to the increasing intervention of specialised medical professionals.

The participation of the partner in the process in order to facilitate the development of the father's rights and responsibilities has not been established as a matter of course by the majority of health administrations.

2. General and specific objectives

2.1. General objective of the strategy

The general objective is to advance the assistance for ordinary births in the National Health System, by improving the quality of the service offered while maintaining current levels of safety.

The assistance offered in childbirth should be considered in the light of the underlying concept that birth is a physiological process which should only require intervention to correct deviations away from normality, and that the medical professionals who assist in the process must create a climate of trust, safety and intimacy, with full respect for the privacy, dignity and confidentiality of the women they treat.

2.2. Specific objectives

- Promote use of clinical practice based on the best knowledge available.
- Encourage the consideration of birth as a physiological process while at the same time recognising its uniqueness and importance in the lives of women, their families and their relationships.
- Include active participation of the mother-to-be in the process of informed decision making regarding the assistance at birth, so that woman become protagonists and feel responsible for their delivery.
- Offer personalised care based on the needs of each woman, respecting their decisions whenever they do not place the safety and well being of mother or child at risk.
- Restructure the training of medical and care personnel (in specialization and continuing training) involved in assisting at birth, so they can include the contents of this strategy into their work.
- Encourage the development of research aimed at improving the models of service provided for assistance at birth.

3. Development of strategy lines

It is vital to begin by emphasising the importance of caring for the mother-to-be during her pregnancy so that she can reach the point of birth in the best possible conditions, both for herself and for the child that is to be born.

From the very beginning of pregnancy, women and their partners must be informed about the physiological process of giving birth, and the natural capacities that women develop during it. This is one way to dispel any uncertainties and fears, and encourage a satisfactory way of experiencing the pregnancy while preparing the couple for normal labour and childbirth, and diverting demands away from an unjustified intervention.

It is also important that the mothers-to-be and their partners are fully informed of the health services available from the place where the baby is to be delivered, and that they make contact with the team of professionals who coordinate between primary and specialised health care services.

3.1. Study of clinical practice based on the best knowledge available

3.1.1. Shaving of the perineum

Available evidence (see details in Annex I):

A systematic review of the Cochrane database and the recommendations of the WHO were analysed. Two clinical trials that evaluated the effect of the routine procedure of shaving the perineum on maternal infection were included. There is insufficient evidence to recommend the shaving of the perineum for women in delivery in order to prevent perineal infection. It is considered an unjustified practice due to the inconvenience caused.

Recommendations:

- Avoid the shaving of the perineum as a routine procedure for women in childbirth.
- If it is necessary to apply a suture, a part of the pubic hair may be shaved, in accordance with the wishes of the patient.

Indicators:

The number of maternity wards including these recommendations in the protocol of assistance at childbirth.

3.1.2. Enema

Available evidence (see details in Annex I):

A randomized clinical trial was included, with a systematic review of the Cochrane database and the recommendations of the WHO. They evaluated the effects of routine administration of an enema in the first phase of childbirth and its relevance to rates of maternal and neonatal infection, duration of birth and dehiscence of episiorhaphy.

Recommendations:

- Discourage the routine administration of an enema in childbirth.
- Optional application, after informing, should the patient request it for any reason.

Indicators:

The number of maternity wards including these recommendations in the protocol of assistance at childbirth.

3.1.3. Accompaniment during the process

Available evidence (see details in Annex I):

A systematic review of the Cochrane database was included, with the recommendations of the WHO and a review of publications that evaluated the effects of continuous and personalised support during pregnancy and birth on mothers and infants compared with standard assistance. The spread of medicine and its institutions were determining factors in the initial separation of the family at the moment of childbirth. The physical structure of these institutions and hospital routine were established to meet the requirements of the medical profession rather than those of women in labour or their families. There is a clear contradiction between what our evidence indicates and the way in which medical assistance is organised.

Accompaniment during childbirth forms an essential part of the strategy of humanizing assistance. Women who received continuous support were less likely to:

- Receive local analgesia/anaesthesia (RR: 0.90; CI 95 %: 0.81-0.99)
- Receive any form of analgesia/anaesthesia (RR: 0.87; CI 95 %: 0.79-0.96)
- Have instrumental vaginal births (RR: 0.89; CI 95 %: 0.83-0.96)
- Have caesarean sections (RR: 0.90; CI 95 %: 0.82-0.99)
- Express dissatisfaction with their experience during childbirth (RR: 0.73; CI 95 %: 0.65-0.83)

In an analysis of sub-groups, continuous support during childbirth is associated with greater benefits if the companion does not form part of the

hospital staff and is associated with the mother at an early stage. No adverse effects have been noted.

Recommendations:

- Permit and encourage all women, if they so desire, to seek support from companions during the process without interruption, enabling any companion to participate from the earliest possible moment.
- Promote a policy within the institution that allows the mother-to-be to choose her companion freely and have their company during the whole birth process.

Indicators:

The number of maternity wards including these recommendations in the protocol of assistance at childbirth.

3.1.4. Period of dilation

Available evidence (see details in Annex I):

Systematic review of the Cochrane database, the WHO Reproductive Health Library, RCTs (randomized clinical trials) and recommendations of the WHO were included.

Recommendations:

- Instruct the mother-to-be so that she can recognise the onset of labour, thereby avoiding a number of consultations for false alarms.
- Make it easier for the mother to move freely and choose her position in accordance with her needs and preferences.
- Allow the intake of food, especially liquids, according to the needs of the mother.
- Encourage a welcoming atmosphere (natural, architectural and psycho-social environments) which helps to establish the best possible attitude and experience.
- Use the partogram as a way of evaluating the progress of labour.
- Monitor and control foetal well-being in accordance with the guidelines laid down by the WHO.
- Do not carry out routine amniotomy.
- Do not use peripheral venous prophylaxis as a matter of routine.
- The use of oxytocin should be limited to cases where it is necessary. It is not considered to be necessary if labour progresses correctly.
- Limit the number of vaginal examinations to the minimum required.

Indicators:

The number of maternity wards including these recommendations in the protocol of assistance at childbirth.

3.1.5. Pain management during birth

Available evidence (see details in Annex I):

The most widespread and most studied method of pain relief is epidural analgesia. Some countries use it as an alternative to the administration of inhaled 50 % nitrous oxide. Other non-pharmacological methods have been studied, such as: company and support, immersion in water, acupuncture and rubber balls. An evaluation was made of randomized clinical trial, systematic reviews of the Cochrane Database to assess the effectiveness of different methods of analgesia during labour and childbirth on parturients and newborn children.

Epidural analgesia appears to be the most effective method of pain relief during childbirth. However, women who give birth using this method have a higher risk of instrumental birth and failure at breast-feeding.

Nitrous oxide is not a powerful analgesic during childbirth, but it appears to be safe for both parturient and newborn child. Women who receive treatment with nitrous oxide should be provided with a pulse oxymeter and the additional application of local anaesthetic in case it is necessary to perform an episiotomy.

Recommendations:

- Ensure that women are informed beforehand of the different methods of pain relief, their benefits and potential risks.
- Inform women that the brain has the capacity to produce analgesic substances (endorphins) during childbirth in conditions of privacy.
- Provide information about the risks and consequences of epidural analgesia for mother and child.
- Consider the application of epidural anaesthesia without inhibiting movement.
- Do not carry out analgesia as routine.
- Offer women the possibility of choosing one or more, should they so desire.
- Those women who do not want to use pharmacology during labour should be informed of the evidence concerning alternative methods available.
- Allow women to be accompanied continually during the whole process.

Indicators:

- Percentage of births with epidural anaesthesia.
- The number of maternity wards including these recommendations in the protocol of assistance at childbirth.

3.1.6. Maternal positioning during the expulsive phase

Available evidence (see details in Annex I):

One systematic review of the Cochrane Database and recommendations from the WHO were included which evaluated the benefits and risks of different maternal positioning during labour. Clinical investigations comparing different positioning adopted by the parturients and comparing them with the prone position were evaluated. In general, the quality of the methodology employed in the 19 clinical trials included in the review was deficient, and as a result, the conclusions cannot be said to be definitive.

Recommendations:

Given that the published results available cannot be relied upon, and until more reliable data is provided by more rigorous clinical studies, the recommendations should be regarded as tentative. Bearing in mind the potential benefits, it is recommended that:

- Women should be allowed to adopt the position that they spontaneously prefer.
- They should be allowed to decide which posture they adopt during the whole process, including the expulsive phase.
- Train the professional staff who give assistance at childbirth to work with the different positions.
- Investigate women's perceptions and the factors that influence their choice of positioning.

Indicators:

The number of maternity wards including these recommendations in the protocol of assistance at childbirth.

3.1.7. Episiotomy

Available evidence (see details in Annex I):

Two systematic reviews of the Cochrane Database, the Agency for Healthcare Research and Quality (AHRQ) and the recommendations of

the World Health Organisation (WHO) were evaluated. They studied the effects of restricted use of episiotomy and established comparisons with its routine application during vaginal delivery and its influence on the mother in postpartum recovery. Its routine use or systematic application has been called into question.

Recommendations:

- Encourage selective episiotomy rather than systematic application.
- Do not suture smaller tears or minor cuts.
- When necessary, it is recommended that the episiotomy performed be mediolateral with a suture made of absorbable material.
- Improve training on the protection of the perineum.

Indicators:

Number of episiotomies carried out in first-time mothers and multiple births (source: minimum basic data set of hospitals).

3.1.8. Delivery

Available evidence (see details in Annex I):

Four systematic reviews were included of the Cochrane Database, randomized clinical trials, comments from the WHO Reproductive Health Library and recommendations of the WHO which compared the effects of active and passive forms of conduct in relation to the loss of blood and haemorrhaging along with other complications for the mother during the birth. The interventions studied included different techniques and different combinations of these forms of active participation, varying doses and ways of administering uterotonic agents, differences in the timing of clamping the umbilical cord and non-standardised use of cord traction.

Recommendations:

- Do not clamp the cord with a pulse as routine practice.
- As there is no uniformity regarding expectant or active birth as a practice in the National Health System, it is recommended that research be carried out into the risk of bleeding in the third phase of birth. Studies of physiological births without intervention and those with active manipulation would provide useful information for the elaboration of appropriate guidelines.

Indicators:

Starting the research.

The following sections are concerned with clinical practices in instrumental births and caesarean sections without entering into the procedures in detail, because they are applied in situations where the birth has complications which are not part of the remit of this strategy document. They are included in this section due to the existing interrelationship which, according to current knowledge, indicates that the development and advancement of the recommendations included in this strategy document would render instrumental births and caesarean sections less frequent.

3.1.9. Instrumental births

Available evidence (see details in Annex I):

A systematic review of the Cochrane Database was evaluated along with comments from the RHL and randomized clinical trials which analysed the effects of extraction by vacuum as compared with forceps in assisted vaginal birth. The Cochrane review included ten randomized clinical trials with sound methodological quality.

Recommendations:

- Avoid instrumental births except when pathology is indicated, and respect the duration of the expulsive phase.
- In light of the fact that the probability of maternal morbidity is reduced by the use of suction cup instead of forceps, and considering the availability of personnel trained in the use of vacuum technique, this method is recommended as first option when an assisted birth is indicated. Training programmes in the use of the suction cup for extraction should be set up in those areas lacking in experienced personnel. The adoption of the suction cup as the method of choice in assisted births should be encouraged only after a minimum standard of training has been provided for personnel present at birth.

Indicators:

- The number of maternity wards including these recommendations in the protocol of assistance at childbirth.
- Percentage of births with forceps.
- Percentage of births with suction cup.
- Percentage of births with spatula.

3.1.10. Caesarean sections

The WHO includes the number of caesarean sections among its indicators of the quality of assistance offered to mothers at birth. The recommendations published in 1985 regarded the rate of caesarean sections at 15% of all births to be an indicator of quality, based on the number of women who are predicted to undergo potentially mortal complications in childbirth.

Such high rates of caesarean section can be attributed to potential complications for mother and child, and lead to significantly higher costs and overmedication for a normal procedure, such as giving birth. The rate of caesarean sections in Spain and other European countries is above this level and has gradually been rising. There are a number of new factors which may be related to this increase, such as the rise in the average age of the mothers, the increase of multiple births, the requests made by mothers and the legal actions started for suspicions of negligence.

It is a fact that the causes of this phenomenon are not sufficiently understood to enable us to establish a standard rate of caesarean sections. However, it is known that the variation in the number of caesarean sections by maternity wards is wide, even when the severity of the cases attended to are considered.

Available evidence (see details in Annex I):

The databases available were evaluated, and systematic reviews of the Cochrane Database, meta-analysis and articles published in Medline, AHRQ, BVS (Virtual Health Library) were extracted that revealed differing quality and methodological design, with mixed results.

Recommendations:

- Investigate the causes of the increase and variations in the rate of caesarean sections.
- Facilitate access whenever possible of the person accompanying the mother.
- Provide an ambience of silence and intimacy so that the first visual, tactile, olfactory and microbiological contact for the newborn child is with its mother.
- Implement programmes to rationalise the rate of caesarean sections and the to reduce their unjustified variability.
- Facilitate, save in exceptional cases, the possibility of vaginal birth after a caesarean section.

Indicators:

- Rate of caesarean sections (source: minimum basic data set of hospitals).

- Rate of caesarean sections adjusted by risk (source: minimum basic data set of hospitals).
- Rate of vaginal births after a previous caesarean section (source: minimum basic data set of hospitals).
- Set up and start research into the causes of the increase and variations in the rate of caesarean sections.
- Number of maternity units that have initiated a programme to rationalise the rate of caesarean sections and their unjustified variability.

3.1.11. Early contact between mother and newborn child

Available evidence (see details in Annex I):

During the first two hours after birth, the newborn child is in a state of tranquil alert for an extended period, a stage called a sensitive period which is provoked by a discharge of noradrenalin during birth. This enables early olfactory recognition of the mother, which is very important for establishing a bond and adapting to the postpartum environment.

If the child is laid in skin contact with the mother, it will slowly move towards the breasts by instinctive flexing and extension of its legs until it reaches the nipple, at which point the reflex actions of locating it and sucking are set in motion correctly. This process cannot be forced, it must be spontaneous. It takes approximately 70 minutes in 90 % of cases. The separation of the mother and child alters this process and reduces the frequency of successful breast-feeding.

The skin contact entails other benefits for the newborn child (a quicker recovery from stress, the child's glycaemia, acid-base equilibrium and temperature are regulated earlier) and for the mother (reduction of the uterus via secretion of oxytocin). The bond between mother and child increases the duration of maternal breast-feeding and prevents negative emotional reactions.

Recommendations:

- The healthy newborn child and its mother should remain together and not be separated at any time as long as the condition of the mother allows it.
- Immediately after birth, the newborn child should be placed on the mother's abdomen, where it should be dried and a dry towel be placed over it. In this way it will cling spontaneously to the breast in most cases, remaining for at least 70 minutes in close skin contact with its mother.

- The only procedures to be taken with the newborn child during this period of skin contact with the mother are its identification and the assignation of punctuation on according to the Apgar test.
- Inform mothers of the advantage of skin contact.
- Postpone the practice of ocular prophylaxis, weighing, vitamin K etc. until the end of the contact period, carrying out the procedures in presence of the parents and with their full consent.
- There should be no routine suction of secretions or application of gastric lavage, nor should there be routine application of an orogastric probe, nor should the nasal cavities be probed nor a rectal probe used. They are not necessary and are not free of risk.
- The same recommendation holds for caesarean sections. Whenever possible, the area should be prepared for mother – child skin contact.
- Should the mother's condition not allow her to make skin contact with the child, the possibility should be offered to the father.
- Establish a care methodology centred on development, stimulating the mother-kangaroo method, with skin contact between mothers and fathers and the full cooperation of these in the caring procedures, especially in cases where the newborn child is more vulnerable.
- Encourage the elimination of hospital nurseries.
- Work with support groups in favour of better practice.

Indicators:

The number of maternity wards including these recommendations in the protocol of assistance at childbirth.

3.1.12. Immediate postpartum care. Breast-feeding

Available evidence (see details in Annex I):

Existing studies and reviews indicate the beneficial effects for the newborn child, which are associated with the reduction of otitis media, gastroenteritis, respiratory infections, dermatitis, asthma, obesity, diabetes, leukaemia, enterocolitis and cot death syndrome. There are also beneficial effects for the mother. Besides the affective, psychological effects and the strengthening of the bond between mother and child, women who breastfeed have a reduced risk of diabetes and breast or womb cancer.

The immediate postpartum period is a sensitive period of extreme importance for the establishment of breast-feeding and has a vital role in the development of the mother-child bond. The bond between the mother / father / newborn child is regarded as a complex and far-reaching human experience which calls for physical contact and interaction at the earliest stages of life.

This postpartum period has been invaded by a number of medical and nursing procedures which cannot always be justified and which frequently involve the separation of the mother and the newborn child.

Modern society may create barriers preventing mothers from developing the instinct for breastfeeding their children, especially where the birth has not been physiological. There are also obstacles in the absence of sufficient experience and knowledge which would enable women to feel secure when starting to breastfeed.

Newborn children are repositories of instincts, and require prolonged intimate contact with the mother in order for these instincts to flourish correctly, preferably during the first two hours after birth, giving them the opportunity to attach themselves to the breast and take their first feed spontaneously. This postpartum sensitive period is not indefinite, and to postpone contact means that the newborn child cannot develop its instincts with the same effectiveness as it would immediately after birth.

Recommendations for postpartum practices:

- Abandon unjustified procedures (suction, testing of permeability of the choanae, oesophagus and anus).
- Delay the procedures which may be necessary but which involve separating the child from its mother.
- When the newborn child required hospitalisation, ensure that their environment is comfortable and pleasant, as close as possible to a home for them and their families, and encourage a policy of Neonatal Units which are open to the parents 24 hours a day.
- Solicit the consent of the parents for any procedure which may interfere with maternal breastfeeding (administration of serum, bottle feeding etc.).
- Divulge and ensure compliance of the applicable guidelines for the rights of hospitalised children (Declaration of the Rights of Hospitalised Children passed by the European Union in 1986).

Recommendations on breast-feeding:

- Encourage efficient practices in support of breastfeeding.
- Offer the possibility of breast-feeding to every mother in every hospital, including extraction, conservation and maintenance for the administration of its mother's milk to every newborn child.
- Encourage the donation of breast milk and start up a Milk Bank.
- Work with support groups in favour of better practice in breastfeeding.
- Respect the choice of fully-informed mothers who prefer bottle-feeding.

- Provide adequate information and develop bottle-feeding skills for those mothers who choose this option.

Indicators:

- The number of maternity wards including these recommendations in the protocol of *assistance at childbirth*.
- The number of maternity wards including these recommendations in the protocol of *assistance for the newborn child*.

3.2. Participation of women patients in decision making

Giving birth has been transformed from a social event which was shared by the community, in which women could rely on the support and experience of other women in their family group, professionals and friends, to one in which the medical professions have control. The loss of protagonism and control suffered by women during this process has coincided with the transfer from the home to the medical centre, leading to progressively greater levels of intervention and the reduction of the woman's role.

Today, the active participation of women so that they can exercise the power of choice regarding their health implies that they and their families should be fully aware of the reproductive period in which they find themselves, be involved in the care they receive and participate actively at the moment of birth. This can be encouraged with the provision of sufficient, adequate and timely information concerning the best practices available from order to achieve optimal results.

This knowledge will enable them to reach agreement with the medical professionals about the behaviour and care to be used, selecting them in accordance with their preferences, beliefs and cultural expectations. However, it is not enough merely to inform. Adequate institutional mechanisms must be created to ensure the effective participation of women's groups, which would require a radical change in the current models of assistance.

The empowering of women means that they will be capable of experiencing their pregnancy and birthing as protagonists of the process. In order that women be capable of participating and taking decisions in such an important process in their lives, they must be well-informed.

The right to have access to information is supported by the existing legal framework (Act of Parliament 41/2002 of patient autonomy) This information must be: a) complete as regards the reason, benefits, risks and

results, b) relevant to the needs of women, c) presented in language that can be understood and at a suitable time, and d) available from a suitable format.

The co-existence of many cultures leads us to consider the culture and circumstances from which the pregnant women come, and the barriers to communication that may exist in order to offer them the appropriate information. Similarly, handicapped women require information that is adapted to their physical, intellectual and sensorial capacities.

The information provided will give women the opportunity to discuss the options available with health workers. When they are adequately informed, patients can acquire autonomy to decide on the treatment and procedures that they consider best for themselves.

Those pregnant women that do not have information do not have the capacity to give opinions, discuss or make decisions with the health professionals that are to assist them. This capacity of the patients contributes to the creation of a relationship based on equality in which the debate takes place on the basis of the knowledge and expectations of both parties (professionals and patients), but taking into consideration the needs and wishes of the users. In this way, the decisions on the practices to be used will be taken together, with agreement, consensus and shared responsibility.

It is fundamental that the teams of health workers share information with the women and their families regarding the limited effectiveness of some practices. This knowledge of the effectiveness of the services will make it possible for an adequate orientation of the patients' expectations and probably reduce the number of complaints for adverse or unexpected results.

There is an enormous amount of information available from both the printed media (magazines and newspapers) and in Internet. It is customary to attribute a greater degree of rigour and truthfulness to texts that have been published. Unfortunately, this is not always true. Many articles are published in pursuit of commercial interests, and do not present the best evidence available. One should always question the information that is available and examine it with a critical eye. The medical and nursing professionals who are in contact with the parturient are key informants.

The participation of women in the decision making process constitutes the first step in the principle of autonomy that is implicit in the process in which the user and the health professional pool their information, participate in the decisions and agree on a specified plan of action. The aim is to abandon the classical paternalist model of the doctor / patient relationship and establish a new model of an alliance, a consensus and shared responsibility. It implies that passive obedience and dependence should be transformed into an active cooperation and participation in health matters.

In the classical model, the health personnel decide what is best for the patient, assuming his / her ignorance of the case and dispensing with his / her intervention. The new model incorporates other elements involved in the process of decision-making, such as:

- **Information:** There is a false belief that by simply providing the user with information, one is enabling the users to participate in the decisions, but this is not enough. The information which is provided for the patient to use as a tool to help them decide must be based on the documented evidence concerning the effectiveness, benefits and risks of the options available. A number of the complaints and court cases presented have been prompted by deficient or inadequate information, rather than actual errors or negligence. The information should be appropriate for each case, given that the patient has the right to know the truth about the treatment she is to receive.
- **Incorporation of the patients' preferences:** It has been affirmed that those patients that have participated in the taking of decisions with health professionals feel more satisfied with the assistance received and the results obtained. This is more probable if the chosen method is more closely adapted to their needs and personal values, including their beliefs, fears, experiences and habits. In many cases, including the preferences of the users implies that they have to face their own insecurity regarding the options. Similarly, one must consider that patients also have the right to not be informed, and this right must be respected.
- **Consensus and shared decision making:** The process of shared decision making requires clear information on the options for professionals and patients to be able to participate actively in the choice and agree on a preferred course of assistance. It is assumed that the users have examined their own values concerning the benefits and potential hazards of receiving or not a specific medical treatment.
- **Shared responsibility and drawing up a plan of action:** The joint taking of decisions implies that the user assumes responsibility not only for the choices made, but also for the results of those choices. There have been experiences in the shared drawing up of plans for the birth during pregnancy.

The incorporation into medical practice of informed consent constituted an important advance, but it is not enough by itself to involve the patient in the decisions. The consent which is given freely, voluntarily and in full possession of the adequate information is habitually used as an instrument of jurisprudence and does not guarantee the active participation of the users in the taking of decisions.

The process of shared decision making implies the active participation of the patients in taking decisions, where unbiased information is shared and analysed, and the values of the user are evaluated as regards the benefits and potential hazards, and a health care plan is agreed upon and the responsibility for the results are shared.

Available evidence

Systematic reviews were included and studies which were both experimental and non-experimental, extracted from the Cochrane Database, AHRQ, Medline and the Database of Abstracts of Reviews and Effects (DARE).

Results

The literature available includes both systematic reviews and other primary studies with differing methodological quality, which evaluated different strategies and methods used in encouraging and promoting active participation of women in the taking of decisions during the reproductive process.

Four Cochrane systematic reviews were evaluated which studied the effectiveness of the information offered to women as part of a strategy to stimulate the taking of informed decisions and their active participation when faced with alternatives concerning their state of health.

An analysis was carried out of the different channels used as sources of information for the users, including: leaflets, audiovisual material, computer programmes, internet sites such as forums, counselling, online consultancies and personalised risk assessment, whether separately or used in combination.

On the whole, the strategy of providing women with information was seen to have a beneficial effect inasmuch as it improved their awareness and led them to have more realistic expectations about their health, and it lowered the level of indecisiveness when it came to choosing between different options. If the results are considered from the perspective of the active participation of the patients, there was little significant difference, however, the results were not homogeneous, and definitive conclusions cannot be drawn.

There was no beneficial effect noted when the measurements of different practices that it was intended to modify by means of informed decisions were evaluated, such as the rate of caesarean sections, the rate of vaginal births and the adherence to treatments and methods of screening.

Several qualitative investigations evaluated women's perception of their level of awareness and the adequacy of their knowledge at the moment of making decisions affecting their state of health, and found that it was often claimed to be unsatisfactory.

Other studies provided information about the perceptions of pregnant women who had participated actively with health professionals in drawing up their birth programme as part of a strategy for encouraging active

participation of the mothers in taking informed decisions. The results were mixed, impeding the drawing of conclusions about their effectiveness in terms of patient satisfaction.

In general, the quality of these reviews was poor, and the random studies did not provide conclusive results. The primary studies were mostly descriptive and were drawn from a reduced sample, while the results obtained were inconsistent and heterogeneous, and therefore we can draw no conclusions about the effectiveness of any of the interventions analysed.

Situation in Spain

The Spanish law regulating patient autonomy and rights and obligations concerning clinical documents and information (LBRAP) has been in force since 2002, and it sets out the principles of patient autonomy and establishes the framework in which informed consent can be applied.

Recommendations:

- Ensure and guarantee access and comprehension of the information available for women concerning the physiological process of giving birth, and current research into the different clinical practices exercised in assisting at childbirth.
- This information must be: complete as regards the reason, benefits, risks and results; relevant to the needs of women; presented in language that can be understood and at a suitable time, and available from a suitable format.
- Offer women information founded on scientific evidence to enable them to take informed decisions in accordance with their needs and expectations.
- Respect the decisions that women make about the actions to be carried out in the birth (for example in the birth programme drawn up during pregnancy) within a framework of safety and quality in assistance.
- Guarantee the recognition of the rights of the mother, father or legal guardian in any decision taken over the newborn child.
- Enable and guarantee that women and women's associations can participate in the evaluation of the services of assistance in childbirth, bearing in mind the scientific evidence.
- Introduce corrective mechanisms to counter physical, psychological, linguistic and cultural barriers which can prevent women from participating in the decision making process.
- Make it possible for pregnant women and their partners to become familiar with the maternity ward and its personnel prior to the birth, and inform them of the existence of mothering support groups in the hospital.

- Develop programmes that encourage women to participate actively in the taking of decisions regarding their pregnancy, birth and postpartum care.
- Investigate strategies for effective distribution to ensure that women have access to sufficient, relevant and consistent information which is consistent with their values and beliefs.
- Establish mechanisms to guarantee that all patients can make use of their right to take informed decisions with full awareness of the risks and benefits of their medical condition.
- Provide information about positive experiences of non-medicalized births (videos, testimony of other women etc.).
- Set up health care training programmes which encourage the active participation of the community in health care issues. Promote and stimulate patients associations as an important contribution towards achieving their fuller participation.
- Make explicit mention of patient's preferences during the process of making decisions.
- Ensure that patients with difficulties in communication are provided with adequate mechanisms that will enable them to receive appropriate information and exercise their right to active participation in accordance with their possibilities.
- Obtain the commitment of the health professionals and ensure the capacity of the patients to create a setting that favours effective participation and the shared taking of decisions about medical treatments.
- Draw up a model of medical decision-making, and design instruments that permit the measurement of participation on the part of the patients.

Indicators:

The number of maternity wards including these recommendations in the protocol of assistance at childbirth.

3.3. Training of medical professions and nursing (specialisation and continuous training)

The training of medical specialisation (MIR) in obstetrics and gynaecology, and that of obstetric-gynaecological nursing for midwives (EIR) in Spain is conducted through regulated courses with programmes involving practice assisting at births in hospitals. There are National Commissions which evaluate and regulate each of these specialisations, and recognised centres for training.

Continuous training is carried out in each Autonomous Community and hospital in accordance with the criteria established depending on demand.

Priority must be given to the training of health professionals and the proposed courses should be aimed at specific actions and which can be carried out in any of the Autonomous Communities or hospitals at short notice. It has been noted that there is a need for training in assistance at normal births to be given not only in MIR and EIR courses, but also in the continuous training programmes which are aimed at all personnel involved in childbirth.

It is regarded as fundamental that training courses for trainers should be set up in all Autonomous Communities, so that training can be offered to even the most qualified professionals.

Recommendations:

- Develop training courses for improving the skills and knowledge of medical and nursing professionals on both theoretical and practical aspects of the contents of this strategy document for assistance at normal childbirth, during the period when they are trained in their speciality (EIR and MIR) and when they are taking part in ongoing continuous professional training courses.
- Prepare the health care personnel who are in attendance at normal births so that they can improve their communication with patients and make the taking and sharing of decisions and responsibilities easier.
- Facilitate the training of training personnel and the design of common training models so that the personnel assisting at normal childbirths are aware of the latest information, especially concerning the psychological and social aspects of childbirth, communication and participation.
- Include the issue of equity as cross curricular material in the training programmes, with special emphasis on gender perspectives, laying greater emphasis on the empowering of women, multi-cultural aspects and the diversity of capacities.

Indicators:

- Inclusion of these recommendations in the training programme designed for MIR and EIR specialists in gynaecology and obstetrics.
- The number of ongoing vocational training courses including this material.
- Percentage of specialists in obstetric medicine working in the NHS (National Health System) that have taken part in courses to bring them up to date in assistance at normal births.
- Percentage of specialists in obstetric nursing working in the NHS that have taken part in courses to bring them up to date in assistance at normal births.

3.4. Investigation and innovation. Spread of good practices in assistance at ordinary childbirths

Research into all aspects related to assistance at childbirth is considered necessary. This is especially true of those areas where there is not enough evidence, or where more information is required, such as the handling of active / expectant birth practices, the causes behind the increase in caesarean sections and the variation in the statistics, the alternative techniques of pain management during childbirth and the mother's positioning during the expulsive phase, among others.

The more qualitative aspects of the research into improvements of the assistance at childbirth become particularly relevant when the different requirements of women according to their physical, intellectual and sensorial capacities are taken into account. Differences of culture, customs and emotional response should also be considered as well as the gender perspective.

As a model of institutional learning, it is important to be aware of the experiences of health centres which work on developing innovations and improving their practices in assistance at childbirth. The spread of this information will permit the transfer of knowledge and the replication of improvements in other centres, as well as their inclusion in future teaching plans.

There are annual calls from the Carlos III Health Institute and Autonomous Communities to present research projects and to evaluate medical technologies and health services in order to improve the scientific understanding available concerning assistance at normal childbirth in public hospitals.

The Spanish Ministry of Health and Consumers' Affairs also concedes annual grants for non-profit organizations for the creation of programmes specifically aimed at the development of Health Strategies.

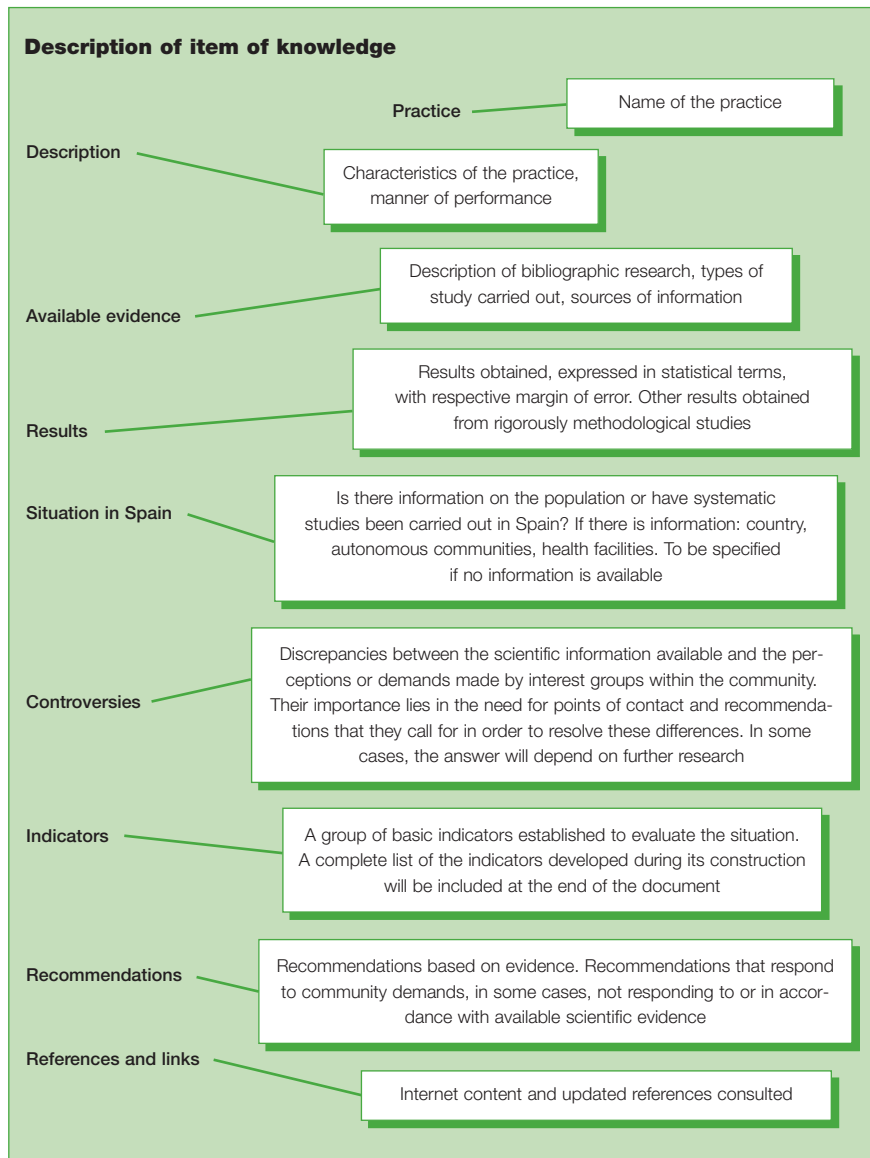
Recommendations:

- Promote research which extends our knowledge about the physiological processes of normal childbirth and the psychological and social aspects.
- Reinforce the research into comparisons of the potential risks and benefits of different forms of intervention available, and that of removing some of these interventions.
- Encourage studies that evaluate the most recent practices in pain relief.
- Promote studies into the impact that different practices have on the physical and psychological-affective health of mothers, babies and fathers.
- Draw up a guide to clinical practice which will be common to the whole NHS.
- Identify good practices in assistance at normal childbirth, analyse the processes of innovation applied and broadcast them for their possible replication in other centres.

Indicators:

- Inclusion of aspects of this strategy document in the annual research calls.
- Guide to clinical practice drawn up and debated within the NHS.
- The setting up of a system for gathering, analysing and broadcasting good practices.

Annex I. Review of currently available knowledge of different clinical practices during the birth process



Levels of evidence and the strength of recommendations

The recommendations are the product of the synthesis applied to the evidence under analysis for the childbirth practices selected. They should be combined with the values and importance of the results, the costs and particular circumstances of each location. The recommendations suggest what to do in different circumstances, in an attempt to respond to questions which are linked, as in our case, to the use of certain practices during delivery.

This synthesis of the evidence is carried out with attention focused on the intervention. The recommendations are also focused, in our case, on the patients, according to the risk or pathology involved, the seriousness of the illness or condition of the person.

The recommendations are graded as strong or weak in response to several factors:

- A.** Quality of the evidence on which the recommendation is based.
- B.** Methodological design
- C.** Consistency or homogeneity of the results
- D.** Magnitude of the estimated effect in absolute or relative terms (RR or OR).
- E.** Precision of the effect: CI, P-value.

A. The methodological quality of a study determines the degree of confidence that can be held concerning its results and their validity. In those cases where it is decided that the article lacks the methodological rigour that is expected, it is unlikely that the results are a reflection of the truth. There are guidebooks for the evaluation and selection of articles which are more likely to yield valid results.

B. The selection of appropriate methodological design allows us to reach solid and scientifically trustworthy conclusions. An inappropriate design will not give us a reliable answer to the question being asked.

The appropriate design for responding to queries about the effect of treatments is that of *Randomized Clinical Trial*, an experimental study which makes use of comparable groups to which patients are randomly assigned, and which are only differentiated by whether they receive one or more treatments. *Systematic Review* is the search for studies with the same design that respond to the same question, and their evaluation. *Meta-analysis* is a quantitative synthesis. Both techniques are governed by strict methodological guidelines and a systematic search strategy which enables them to incorporate all the major studies.

C. Homogeneous or consistency of the results and/or magnitude of the effect of the different studies under consideration. In contrast, the heterogeneousness of the results might be due to differences in the sample population, the treatments administered, the method of measuring the results or different study methodology.

D. The magnitude of the effect of an intervention or treatment is calculated by means of risk calculations.

Risk: Probability of the occurrence of a given event. It is calculated from the quotient obtained by expressing the number of patients who reported the result being measured from the total number of patients in the group. RR is defined as the ratio of the risk of an event occurring in the experimental group and the risk of the event occurring in the control group. In other words the RR shows us the magnitude of the association between exposure and result and indicates the probability of the event developing in the exposed group in relation to the unexposed group.

E. Precision of the effect: The true reduction of risk can never be known. The best approximation of the real effect of the treatment is that observed in the RCTs. This estimate is known as “point estimation.” Although it is unlikely that this is precise “true value,” this must surely be found in close proximity to it. The confidence interval (CI) signals the limits or range within which the true magnitude of the effect on the reference group can be found, with a certain degree of confidence (usually 95 %). Another way of estimating the precision of the effect is through the value of p or statistical significance.

Different workgroups have drawn up guidelines for classification according to the degree of recommendation. The following is one of the guides most widely used in medical literature, making use of others (1, 2, 3, 4) based on formulae with similar criteria.

Recommendation	Level of evidence		Studies on which it is based
A	1	1a	Systematic review of high quality homogeneous RCTs
		1b	Systematic review of individual RCT with narrow CI
		1c	Experimental studies without controls (dramatic results)
B	2	2a	Systematic review of cohort studies
		2b	Individual cohort study and low quality RCTs
		2c	Cohort studies without controls / Ecological studie
	3	3a	Systematic review of cases and controls
		3b	Individual case control
C	4	Series of cases and cohort studies or low quality case control	
D	5	Expert opinion without critical appreciation or based on psychopathological principles	

Source: Phillips B, Ball C, Sackett D, et al. Oxford Centre for Evidence-based Medicine

Bibliographic search in electronic databases

AHRQ: Agency for Healthcare Research and Quality: www.ahrq.gov/

Biblioteca Virtual de Salud Materna y Perinatal (Virtual Library of Maternal and Perinatal Health):

perinatal.bvsalud.org/html/es/home.html;

www.ingentaconnect.com/; www.tripdatabase.com/

Centre for Reviews and Dissemination databases-CRD DARE – (Database of Abstracts of Reviews of Effects): www.crd.york.ac.uk/crdweb/

Cochrane Database of Systematic Reviews (CDSR):

www.update-software.com

Medline (PubMed): www.ncbi.nlm.nih.gov/sites/entrez

The WHO Reproductive Health Library (RHL Library) number 10. Year 2007: www.rhlibrary.com

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1. Shaving of the perineum

Description

The shaving of the perineum as a routine procedure during childbirth in order to reduce the risk of maternal infection in case of episiotomy or tearing and enable easier suturing of the perineum if required. Its purpose has been questioned as it can cause infection in the skin due to microabrasion in the shaved area. The patient suffers discomfort and irritation when the hair grows back. It is performed without taking women's preferences into consideration.

Available evidence

A systematic review of the Cochrane Database and the recommendations of the WHO were analysed. Two clinical trials that evaluated the effect of the routine procedure of shaving the perineum on maternal infection were included.

Results

There was no difference found between the incidence of maternal infection in the shaved group as compared with the unshaved group (OR: 1.26; CI 95 %: 0.75-2.12). Neither the preferences of the health professionals nor the patients were evaluated.

Conclusion

There is insufficient evidence to recommend the shaving of the perineum for women in delivery in order to prevent perineal infection. It is an unjustified practice due to the inconvenience caused.

Situation in Spain

There is no data because this information is not recorded systematically in the health reports system. Individual studies seem to indicate that it is performed in a third of all childbirths.

Recommendations of the available evidence

Avoid the shaving of the perineum as a routine procedure for women in childbirth.

If it is necessary to apply a suture, a part of the pubic hair may be shaved, in accordance with the wishes of the patient.

References and links

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2. Enema

Description

The administration of an enema to the parturient during the initial phase of childbirth with the purpose of reducing infection during and after the delivery. It would prevent any maternal faecal matter from coming into contact with possible wounds the newborn child may have. It is a procedure that is both uncomfortable for the mother and adds unnecessary costs to the health budget. It is administered in accordance with the preferences of the health professional who assists at the birth without consideration for the distress of the mother or the costs that it adds to the procedure.

Available evidence

A randomized clinical trial was included, with a systematic review of the Cochrane Database and the recommendations of the WHO. They evaluated the effects of routine administration of an enema in the first phase of childbirth and its relevance to rates of maternal and neonatal infection, duration of birth and dehiscence of episiorrhaphy.

Results

No significant differences were found in the rates of puerperal infection (OR: 0.61; CI 95 %: 0.36-1.04) and neonatal infection (RR: 1.12; CI 95 %:

0.76-1.66) There were no differences found in the duration of labour (515 min in the enema group / 585 min in the control group; $P = 0.24$) nor in the dehiscence of episiorhaphy (21/182 [12 %] with enema / 32/190 [17 %] without enema; $P = 0.30$). The preferences of the health professionals and the patients were not registered. There is not enough evidence to support the routine use of enemas during the preparation for childbirth as a means of improving maternal and neonatal outcomes.

Situation in Spain

The information relative to the application of this procedure is not collected as a matter of routine, but its use appears to be widespread.

Recommendations of the available evidence

Discourage the routine administration of an enema to the parturient.

It can be applied optionally, if the woman has been informed and her opinion sought, and it can be applied only as a hygienic measure.

References and links

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3. Accompaniment during the process

Description

The presence of a companion chosen by the parturient (partner, relative, friend) or by the medical personnel (midwife, doula, nurse) to accompany her continuously and provide personalised support during childbirth.

Available evidence

A systematic review of the Cochrane database was included, with the recommendations of the WHO and a review of publications that evaluated the effects of continuous and personalised support during pregnancy and birth on mothers and infants compared with standard assistance.

Results

Women who received continuous support were less likely to:

- Receive local analgesia/anesthesia (RR: 0.90; CI 95 %: 0.81-0.99)
- Receive any form of analgesia/anesthesia (RR: 0.87; CI 95 %: 0.79-0.96)
- Have instrumental vaginal births (RR: 0.89; CI 95 %: 0.83-0.96)
- Have caesarean sections (RR: 0.90; CI 95 %: 0.82-0.99)
- Express dissatisfaction with their experience during childbirth (RR: 0.73; CI 95 %: 0.65-0.83)

Women who received continuous support during childbirth were **more** likely to:

- Have spontaneous vaginal births (RR 1.08; CI 95 %: 1.04-1.13)

Continuous accompaniment is not associated with a lower probability of

- Artificial oxytocin during labour (RR 0.94; CI 95 %: 0.83-1.06)
- Low Apgar score at 5 minutes (RR: 0.81; CI 95 %: 0.56-1.16)
- Admission of the newborn infant into intensive care unit.(RR: 0.94; CI 95 %: 0.82-1.09)

It has not been associated with a significant reduction in the period of labour (weighted mean difference -0.28; CI 95 %: -0.64-0.08). It has not been associated with a significant reduction in the probability of post-natal depression (RR 0.89; CI 95 %: 0.75-1.05).

In an analysis of sub-groups, continuous support during childbirth is associated with greater benefits if the companion does not form part of the hospital staff and is associated with the mother at an early stage. No adverse effects have been noted.

Situation in Spain

There is no systematic information available on the subject of accompaniment during childbirth.

Controversy

The spread of medicine and its institutions were determining factors in the initial separation of the family at the moment of childbirth. The physical structure of these institutions and hospital routine were established to meet the requirements of the medical profession rather than those of women in labour or their families. There is a clear contradiction between what our evidence indicates and the way in which medical assistance is organised. Accompaniment during childbirth forms an essential part of the strategy of humanizing assistance.

Recommendations of the available evidence

Permit and encourage all women, if they so desire, to seek support from companions during the process without interruption, enabling any companion to participate from the earliest possible moment.

Promote a policy within the institution that allows the mother-to-be to choose her companion freely from the people she knows and have their company during the whole birthing process.

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4. Period of dilation

Evidence

Systematic review of the Cochrane database, the WHO Reproductive Health Library, RCTs and recommendations of the WHO were included.

Results

1. **Specific prenatal education to reduce the number of consultations for false alarms of onsets of labour.** Number of consultations from women who received specific prenatal classes compared with those from women who received ordinary prenatal preparation. Average difference: 0.29; (CI 95 %: 0.47-0.11).
2. **Continuous support throughout process.** Women with support were less likely to require any kind of analgesic / anaesthetic (RR: 0.87; CI 95 %: 0.79-0.96). Have instrumental vaginal births (RR: 0.89; CI 95 %: 0.83-0.96). Have caesarean sections (RR: 0.90; CI 95 %: 0.82-0.99). They displayed a greater tendency to have spontaneous vaginal births (RR: 1.08; CI 95 %: 1.04-1.13).
3. **Freedom of movement and positioning.** During labour, women who chose to walk freely did not display any difference as regards the duration of labour (p: 0.83), need for oxytocics (p: 0.25), need for analgesics (p: 0.59), forceps (p: 0.25) or caesarean sections (p: 0.35), compared with those who remained prone.

Women who were in vertical or lateral positioning during the expulsive phase registered a reduction in the duration of this phase (average 4.29 minutes; CI 95 %: 2.95-5.64 minutes); reduction in assisted childbirth (RR: 0.84; CI 95 %: 0.73-0.98) and lower incidence of episiotomies (RR: 0.84; CI 95 %: 0.79-0.91), compared with those who were lying down or in the lithotomic position.
4. **Intake of liquids and food.** Despite the lack of controlled studies, there is no indication in the available literature which supports the restriction of liquids and food during labour in order to prevent gastric aspiration. Only one study evaluated the probability of maternal death to be 7 out of 10 million births. The strict withholding of liquids and food from the mother for a prolonged period of time can lead to dehydration and ketosis, which could be prevented with a moderate intake.
5. **Usefulness of the partograph¹ to predict the conditions of birth and the duration of labour.** Spontaneous vaginal birth OR: 1.68 for primigravidas; OR 1.59 for multigravidas. Probability of instrumental vaginal birth OR: 0.67 for primigravidas; OR: 0.64 for multigravidas.

¹ Use of the partograph. World Health Organization Handling of complications during pregnancy and childbirth. Guide for midwives* and medical specialists. Department of reproductive health and associated research. Geneva: World Health Organization, 2002.

*Midwives: includes men and women who exercise this profession (Federation of Spanish Midwives Associations FAME)

6. **Amniotomy.**

Premature amniotomy vs. Spontaneous breaking of the sac
Duration of labour: reduction 60-120 min. Caesarean section: OR: 1.26 (CI 95 %: 0.96-1.66). Cord pH and admission of newborn child in intensive care: no differences were observed. Use of oxytocin: OR: 0.79 (CI 95 %: 0.67-0.92).

7. **Information and availability of different methods of analgesia.**

Epidural analgesia was associated with a greater reduction in pain (weighted mean difference [WMD] -2.60; CI 95 %: -3.82-1.38) and a greater risk of instrumental vaginal birth (RR: 1.38; CI 95 %: 1.24-1.53) than in patients without epidural analgesia. There is no difference in the risk of caesarean section (RR: 1.07; CI 95 %: 0.93-1.23), long term pain in the lower back (RR: 1; CI 95 %: 0.89-1.12) and neonatal depression (RR: 0.70; CI 95 %: 0.44-1.10)

8. **Monitoring.**

Efficiency and safety provided by routine electronic monitoring of the foetus during labour compared with intermittent auscultation of foetal heartbeat in low-risk pregnancies.

One systematic review which included thirteen randomized clinical trials compared the efficiency of routine monitoring during labour with intermittent auscultation in low-risk pregnancies. It was noted that the only benefit of the use of routine monitoring was the reduction of neonatal convulsions, in cases where this was accompanied by the determination of the pH in scalp blood (RR: 0.51; CI 95 %: 0.32-0.82).

Monitoring during labour without the determination of the pH has no effect on perinatal morbidity, and no differences were found in: Apgar after one minute, admission to intensive care units, perinatal mortality or cerebral paralysis. The routine use of monitoring led to an increase in the rate of caesarean sections (RR: 1.41; CI 95 %: 1.23-1.61) and operative vaginal births (RR: 1.20; CI 95 %: 1.11-1.30).

In view of the increase in the rate of caesarean sections and operative vaginal births, and the lack of any impact on perinatal morbidity or mortality, the use of routine monitoring without determination of the pH in scalp blood is not justified for use as standard procedure compared with intermittent auscultation of foetal heartbeat.

Recommendations of the available evidence

Instruct the mother-to-be so that she can recognise the onset of true labour, thereby avoiding a number of consultations for false alarms.

Offer the patient support, in the physical, emotional and psychological aspects during the whole process, allowing the continuous presence of a companion chosen by the parturient.

Make it easier for the mother to move freely in accordance with her requirements and preferences, and enable her to adopt the posture she finds most comfortable.

Allow the moderate intake of sweetened liquids and light snacks. Do not apply intravenous hydration for all women in normal labour, as it limits their movements and comfort. Reserve parenteral hydration only for those mothers who are dehydrated, experience vomiting, require anaesthesia or other procedures that require intravenous application.

Monitor the progress of labour by using the partograph as an objective element for the management of the second phase.

Do not carry out early amniotomy as routine practice. This should be reserved for parturients with abnormal progress of labour according to the partograph.

Carry out monitoring of the foetal heartbeat during labour with intermittent auscultation of the heartbeats and only use continuous electronic cardiac monitoring in high-risk pregnancies or where there is abnormal progress of labour.

Reduce the number of vaginal examinations to the minimum required, recommending no more than one every three hours unless they are necessary.

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5. Pain management during birth

Description

Pharmacological and non pharmacological methods of pain relief during childbirth have been described.

The most widespread and most studied method of pain relief is epidural analgesia. This consists of the blockage of the central nervous system by means of a local anaesthetic near the pain transmitting nerves of the lumbar region, for relief of pain during childbirth. Some countries use the administration of inhaled 50 % nitrous oxide as an alternative to this blockage. Other non-pharmacological methods have been studied, such as: company and support, immersion in water, acupuncture, massage and rubber balls.

Available evidence

RCTs and systematic reviews of the Cochrane database which analysed the effects of different methods of analgesia during childbirth for mothers and children were evaluated.

Results

One systematic review evaluated all the different varieties of epidural analgesia (including the combination of spinal-epidural) for the mother and the child, in comparison with any other form of pain relief which did not involve regional blockage, or with no relief during labour and childbirth. Epidural analgesia was associated with a greater reduction in pain (weighted mean difference [WMD] -2.60; CI 95 %: -3.82-1.38) than in the other groups. Epidural analgesia was also associated with a greater risk of instrumental vaginal birth (RR: 1.38; CI 95 %: 1.24-1.53).

There is no difference in the risk of caesarean section (RR: 1.07; CI 95 %: 0.93-1.23), long term pain in the lower back (RR: 1; CI 95 %: 0.89-1.12) and neonatal depression (RR: 0.70; CI 95 %: 0.44-1.10). One RCT evaluated the effectiveness of combined epidural and spinal analgesia against the inhalation of nitrous oxide. The analgesic effect was far greater in the epidural group than the nitrous oxide group ($P < 0.01$). The rate of instrumental birth was greater in the epidural group than the control group ($P < 0.01$). The rate of caesarean sections was greater in the nitrous oxide group than the epidural group.

Epidural analgesia appears to be the most effective method of pain relief during childbirth. However, women who use this method have a higher risk of undergoing instrumental birth. Nitrous oxide is not a powerful analgesic during childbirth, but it appears to be safe for both parturient and newborn child. Women who receive treatment with nitrous oxide should be

provided with a pulse oxymeter and the additional application of local anaesthetic in case it be necessary to perform an episiotomy.

The benefit of having a companion near during childbirth has been proven with the need for any kind of analgesia/anaesthesia (RR: 0.87; CI 95 %: 0.79-0.96).

There is little evidence founded among clinical studies to study the effectiveness of non-pharmacological methods. Few of these complementary treatments have been subjected to adequate scientific study. There appears to be evidence to indicate that immersion in water during dilation reduces the need for analgesia (OR: 0.84; CI 95 %: CI 0.71-0.99) and the registration of maternal pain (OR: 0.23; CI 95 %: 0.08-0.63), without adverse effects on the duration of labour, surgical labour or neonatal results. The effects of immersion in water during pregnancy or childbirth are unclear. One essay analyses childbirth in water, but it is too small to determine the results for the women or the newborn children.

Acupuncture and hypnosis can contribute to pain relief during labour, but further research is required into these complementary treatments. There is not enough evidence of the benefits of music, massage, relaxation, uniform sound, acupressure or aromatherapy, nor any evidence of the effectiveness of massage or other complementary treatments (for example, the use of rubber balls).

Situation in Spain

There is no information in the Health Information System. Epidural anaesthesia has been encouraged, and the desired objective is for its use in 100 % of births. At present, it is the most widely-used analgesic.

Recommendations of the available evidence

Ensure that women are informed beforehand of the different methods of pain relief, their benefits and potential risks. Do not apply analgesia as standard, offer women the choice of method, if they desire it.

Allow women to be accompanied during labour and childbirth.

Those women who do not wish to use pharmaceuticals during labour should be informed about the available evidence regarding non-pharmacological methods.

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6. Maternal positioning during the expulsive phase

Description

The posture adopted by the parturients during the expulsive phase is strongly influenced by the cultural standards which have been adapted to the needs of the health professionals and the restrictions imposed by medical procedures, which limit the postural options available to women. The positioning of parturients on their backs or inclined backwards is widely used, and it is argued that this posture allows the doctor rapid access to the maternal abdomen and makes the procedures easier. There is controversy concerning the advantages and disadvantages of the vertical position (sitting, crouching, kneeling or squatting) compared with the supine or with lithotomy during the expulsive phase.

Available evidence

One systematic review of the Cochrane Database and recommendations from the WHO were included which evaluated the benefits and risks of different maternal positioning during labour. Clinical investigations comparing different positioning adopted by the parturients and comparing them with the prone position were evaluated. In general, the quality of the methodology employed in the 19 clinical trials included in the review was deficient, and as a result, the conclusions cannot be said to be definitive.

Results

The women who were assigned to the group allowed to adopt any vertical or lateral position as opposed to lying on their backs or the lithotomic position reported the following benefits:

- Shortening of the expulsive phase (average 4.29 minutes; CI 95 %: 2.95-5.64 minutes)
- Slight reduction in assisted births (RR: 0.84; CI 95 %: 0.73-0.98)
- Fewer episiotomies (RR: 0.84; CI 95 %: 0.79-0.91)

The same comparison revealed the following disadvantages:

- Increase in second-degree perineal lacerations (RR: 1.2; CI 95 %: 1.09-1.39).
- Greater risk of blood loss of over 500 ml based on estimate (RR: 1.68; CI 95 %: 1.32-2.15).
- Only one clinical study indicated that fewer women reported intense pain during childbirth (RR: 0.73; CI 95 %: 0.60-0.90), and there were fewer abnormal patterns registered in the foetal cardiac rhythm (RR: 0.28; CI 95 %: 0.08-0.98)
- No significant differences were demonstrated for:

- Use of analgesia or anaesthesia during the expulsive phase (RR: 0.97; CI 95%: 0.93-1.02)
- Caesarean sections (RR: 0.87; CI 95 %: 0.52-1.45)
- Third or fourth degree perineal lacerations (RR: 0.91; CI 95 %: 0.31-2.68)
- Need for blood transfusions (RR: 1.66; CI 95 %: 0.70-3.94)
- Manual delivery (RR: 1.71; CI 95 %: 0.86-3.39)

Despite being evaluated in few of the studies, there were no differences noted for: unpleasant experience during birth, lack of satisfaction with the expulsive phase of labour, admission to neonatal intensive care units and perinatal mortality.

Situation in Spain

In Spain the habitual position is that of the mother lying supine on her back or in lithotomic position, due to the preferences of the medical staff.

Recommendations of the available evidence

Given that the published results available cannot be relied upon, and until more reliable data is provided by more rigorous clinical studies, the recommendations should be regarded as tentative:

Bearing in mind the potential benefits, it is recommended that:

- Women should be encouraged to take informed decisions about the posture that they consider most comfortable.
- They should decide freely which position they adopt during the expulsive phase.
- Train the medical personnel present at the birth to assist in the different positions.
- Investigate women's perceptions.
- Investigate the factors which influence in choosing the posture.

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7. Episiotomy

Description

Incision of the perineum performed in the moment of birth in order to prevent more severe perineal laceration. Its use as a routine or systematic practice has been called into question.

Available evidence

Two systematic reviews of the Cochrane Database, the Agency for Healthcare Research and Quality (AHRQ) and the recommendations of the World Health Organisation (WHO) were evaluated. They studied the effects of restricted use of episiotomy and established comparisons with its routine application during vaginal delivery and its influence on the mother in postpartum recovery.

Results

The group with selective episiotomy was associated with a reduced risk of posterior perineal traumatism (RR: 0.88; CI 95 %: 0.84-0.92); reduced need for suture (RR: 0.74; CI 95 %: 0.71-0.77) and fewer complications in healing (RR: 0.69; CI 95 %: 0.56-0.85).

Restrictive use of episiotomy was associated with a greater risk of anterior perineal trauma (RR: 1.79; CI 95 %: 1.55-2.07). There were no differences noted in the risk of serious vaginal or perineal trauma (RR: 1.11; CI 95 %: 0.83-1.50); dyspareunia (RR: 1.02; CI 95 %: 0.90-1.16); urinary incontinence (RR: 0.98; CI 95 %: 0.79-1.20), or measures related with severe pain.

The results were similar when the restrictive practice of medio-lateral episiotomy were compared with those of midline episiotomy. Medium quality evidence suggests that it is more beneficial to leave first-degree lacerations or minor cuts in the skin of the perineum unsutured.

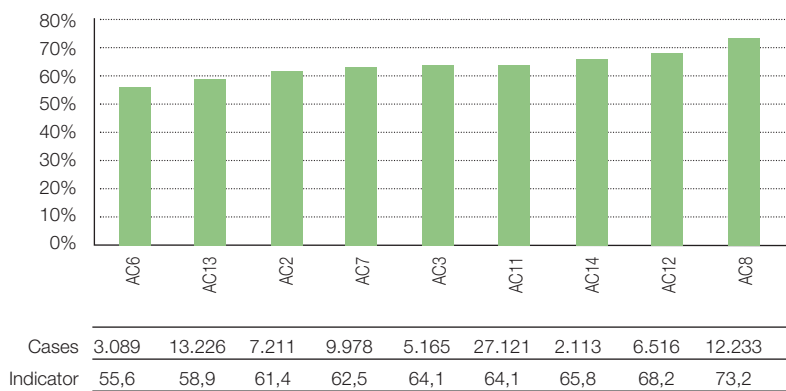
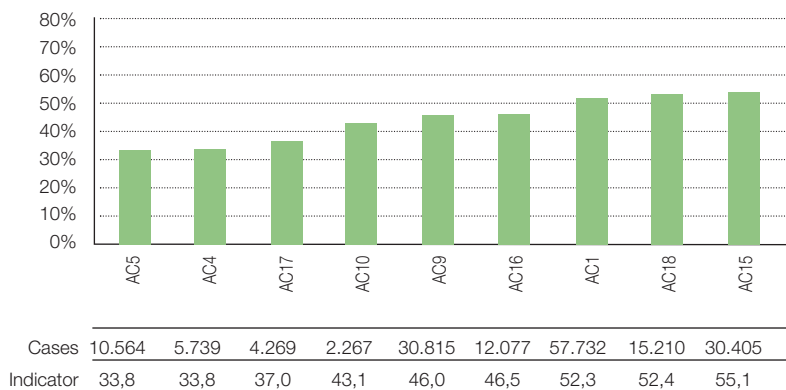
If an episiotomy was performed, or if repairs are required, there is evidence to indicate that a continuous suture with absorbable synthetic material is associated with less pain than a suture consisting of separate stitches and non-synthetic material (OR: 0.62; CI 95 %: 0.54-0.71) and a reduced need for analgesia (OR: 0.63; CI 95 %: 0.52-0.77) in the short term. There is no difference in long-term dyspareunia.

The quality of the evidence relative to long-term after effects is deficient as regards faecal and urinary incontinence, pelvic floor function and sexual function. It is consistent, however, in demonstrating the absence of any benefit in the short term from its use.

Situation in Spain

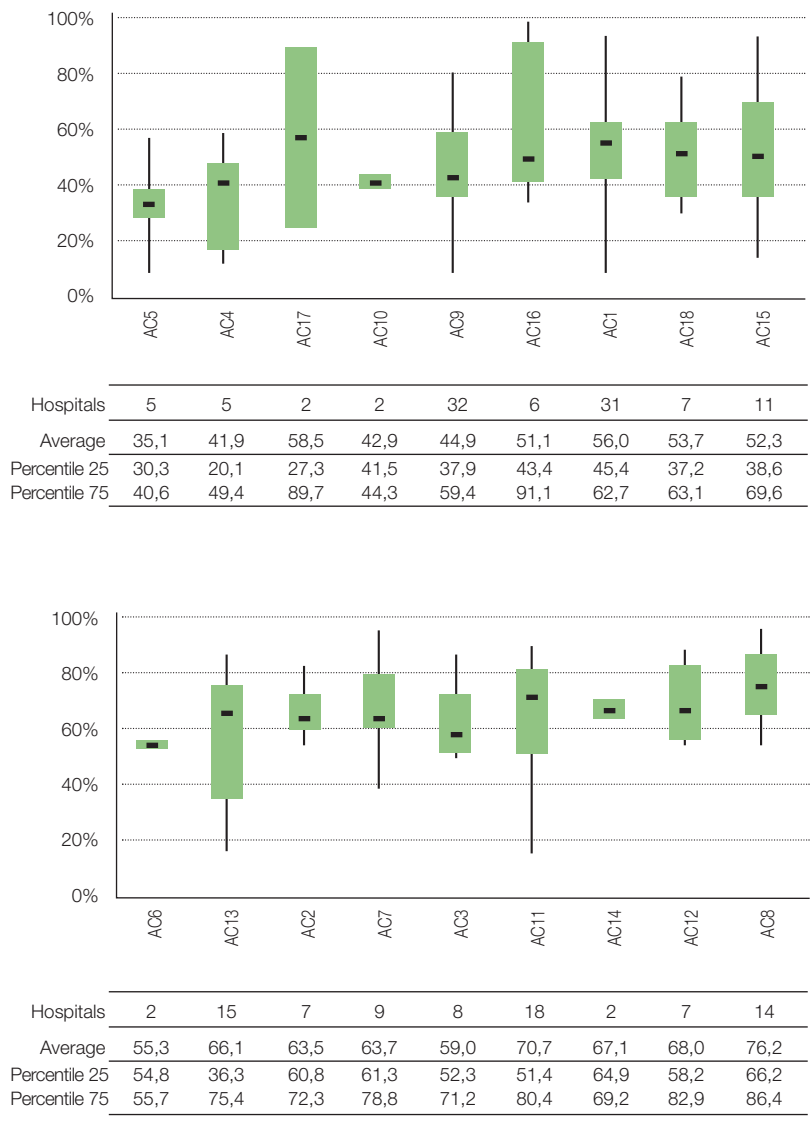
The analysis by Autonomous Community shows a range that extends from 33 % to 73 % (fig. 16). The variability analysis reveals a wide interquartile

Figure 16. Percentage of vaginal births with episiotomy by community, 2005



Distribution of the indicator by Autonomous Community (AC)

Figure 17. Variability analysis of vaginal births with episiotomy by community, 2005



Analysis of the variability (Box-plot)

range among the autonomous communities (maximum of 48 % and minimum of 11%) (fig. 17). The differences noted can be explained in part by the variation in the policies used in registers for this practice in different centres.

Controversy

Despite the abundant evidence available that reports the benefits of a restrictive episiotomy policy, the procedure is still being used in a significant proportion of births, and there is no shared criteria, as the wide variations demonstrate. Better quality information is necessary in order to monitor this practice.

Recommendations of the available evidence

- Promote a policy of selective episiotomy.
- Do not suture smaller tears or minor cuts.
- When necessary, perform continuous sutures with absorbable synthetic material.

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8. Delivery

Description

The active management of delivery, or the third phase of birth consists of a group of interventions which prevent postpartum haemorrhaging. These interventions include: Prophylactic administration of uterotonic agents at birth or immediately after birth, the clamping and cutting of the umbilical cord, and the controlled traction of the same for the expulsion of the placenta.

On the other hand, the expectant approach implies a policy of “non-intervention”, in which the signs of spontaneous separation and expulsion of the placenta are waited for, and in which the clamping of the umbilical cord is done later. The components of the active approach are not employed as routine.

The following have been studied as uterotonic agents: oxytocin, rye ergot derivatives (ergometrina), sintometrina (oxytocin + ergometrina) and prostaglandins (misoprostol). Early clamping of the umbilical cord is that which is carried out within three minutes of birth, or before it ceases pulsing.

Available evidence

Four systematic reviews were included of the Cochrane Database, randomized clinical trials, comments from the WHO Reproductive Health Library and recommendations of the WHO which compared the effects of active and passive forms of conduct in relation to the loss of blood and haemorrhaging along with other complications for the mother during the birth. The interventions studied included different techniques and different combinations of these forms of active participation, varying doses and ways of administering uterotonic agents, differences in the timing of clamping the umbilical cord and non-standardised use of cord traction.

Results

Active management (any medication) vs. expectant management

The active approach is associated with a notable reduction in clinically significant results, such as severe puerperal haemorrhaging (equal to or greater than 1 litre): (RR: 0.33; CI 95 %: 0.21-0.51), need for a transfusion during the postpartum period (RR: 0.32; CI 95 %: 0.22-0.53) and additional use of oxytocic pharmaceuticals.

As regards adverse effects, the use of ergometrina as the uterotonic agent during an active procedure was observed to cause an increase in nausea (RR: 1.83; CI 95 %: 1.51-2.23); vomiting (RR: 2.19; CI 95 %: 1.68-2.86); headaches (RR: 1.97; CI 95 %: 1.01-3.82) and high blood pressure (RR: 3.46; CI 95 %: 1.68-7.09).

There was no significant difference observed in the need for manual delivery (RR: 1.21; CI 95 % 0.82-1.78). In summary, there are clear advantages in favour of the active approach (greater adverse effects with the use of ergometrina).

Comparison between medication

- Oxytocin vs. ergometrina; sintometrina vs. ergometrina; oxytocin vs. sintometrina. There were no differences observed as regards severe haemorrhaging and the need for transfusions. The oxytocin group reported less use of manual delivery (RR: 0.57; CI 95 %: 0.41-0.79). The group treated with sintometrina reported a higher rate of adverse effects: nausea (RR: 3.85; CI 95 %: 3.20-4.63); vomiting (RR: 5.72; CI 95 %: 4.44-7.38) and high arterial blood pressure (RR: 2.47; CI 95 %: 1.58-3.86). In conclusion, there are similar benefits but greater adverse effects with ergometrina.
- Oral prostaglandin (misoprostol 66 mcg) vs. oxytocin. The group treated with misoprostol reported a higher risk of severe postpartum haemorrhaging (over 1 litre) (RR: 1.34; CI 95 %: 1.16-1.55) and additional use of uterotonic agents (RR: 1.41; CI 95 %: 1.31-1.5) compared with the oxytocin group. No significant differences were noted in the need for transfusions. Among the adverse effects noted in the misoprostol group were noted a greater risk of trembling (RR: 3.29; CI 95 %: 3.03-3.56); diarrhoea (RR: 2.52; CI 95 %: 1.6-3.98) and temperatures above 38 °C (RR: 6.62; CI 95 %: 5.45-8.05). In summary, oxytocin offers greater advantages while misoprostol displays greater adverse effects and higher cost.
- Sublingual prostaglandin (misoprostol 600 mcg) vs. oxytocin. No significant difference in severe haemorrhaging and other results was found.

- Rectal prostaglandin (misoprostol 600 mcg) vs. oxytocin. No significant difference in severe haemorrhaging and the need for transfusion was found. Among the adverse effects noted in the misoprostol group were noted a greater risk of trembling (RR: 3.02; CI 95 %: 1.74-5.23) and temperatures above 38 °C (RR: 2.74; CI 95 %: 1.08-6.93) than with oxytocin. There are greater adverse effects with misoprostol and a higher cost, without any improvement in results.
- Injectable prostaglandins (carboprost 0.25 mg/sulprostone 0.5 mg) vs oxytocin. There is little evidence, because injectable prostaglandins have only been compared with other injectable uterotonic agents, but not specifically with oxytocin. There was no difference in blood loss and the need for transfusions, but more vomiting was noted (RR: 10.74; CI 95 %: 2.06-53.02); and diarrhoea (RR: 6.65; CI 95 %: 2.03-21.85) using prostaglandins. There are greater adverse effects with prostaglandins and a higher cost, without any improvement in results.
- Uterotonic agents without the active approach. Even when used in the absence of other components of the active approach, the use of uterotonic agents entail benefits for the expectant approach. The use of misoprostol is associated with a reduced risk of severe haemorrhaging (RR: 0.20; CI 95 %: 0.04-0.91) and transfusions (RR: 0.14; CI 95 %: 0.02-0.85). Oxytocin was associated with a reduced need for other uterotonic agents (RR: 0.66; CI 95 %: 0.48-0.9). Ergometrina reduced the risk of postpartum haemorrhaging of over 500 ml (RR: 0.38; CI 95 %: 0.21-0.69). Both misoprostol and ergometrina were associated with a greater risk of adverse effects.

Situation in Spain

There is no systematic information on the use of the active approach in delivery. It appears that the expectant approach is more common than the active.

Controversy

Timing of umbilical cord clamping.

There is neither consensus nor sufficient scientific evidence regarding the definition of what is early or late clamping of the cord. The definitions of early clamping range from 10 seconds after birth, to 3 minutes, or until the cord has stopped pulsing. Late clamping is associated with a lower incidence of anaemia in the newborn child between 24-48 hours after birth (hematocrit over 45 %) (RR: 0.2; CI 95 %: 0.06-0.6). There is not enough evidence to suggest that the moment of clamping can have an impact on postpartum haemorrhaging. There has been no evaluation of traction of the placenta outside the context of the active approach. There has been no evaluation of the possibility of applying the active approach in home births.

Recommendations of the available evidence

Offer active delivery procedures in vaginal births in order to prevent postpartum haemorrhaging.

Active management should be applied using oxytocin in preference to ergometrina / sintometrina, misoprostol (oral, sublingual, rectal), or injectable prostaglandins.

When active management is not employed, uterotonic agents should be used to prevent postpartum haemorrhaging.

In the light of the benefits for the child, the cord should not be clamped while pulsing, and no earlier than is necessary for the application of placenta traction, which is estimated to be some 3 to 5 minutes after birth.

According to the evidence and recommendations available, the components of the active procedure include:

- Administration of uterotonic agents, preferably oxytocin, immediately after birth.
- Late clamping of the umbilical cord.
- Controlled traction of the cord to extract the placenta.

The procedures must be carried out by staff trained in the practices and in a hospital environment. More investigation is required for its application in home births.

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9. Instrumental births

Description

A comparison of the benefits and adverse effects of using the suction cup or vacuum as opposed to the use of forceps when a birth is diagnosed as requiring assistance or instrumental means. Assistance during vaginal birth is a frequent occurrence in obstetric care. Different techniques of assistance at birth have proved to have beneficial effects that reduce the need for assisted births, such as having a companion during the process of giving birth, or adopting a vertical positioning during the expulsive period.

Available evidence

A systematic review of the Cochrane Database was evaluated along with comments from the RHL and randomized clinical trials which analysed the effects of extraction by vacuum as compared with forceps in assisted vaginal birth. The Cochrane review included ten randomized clinical trials with sound methodological quality.

Results

The use of a vacuum in assisted birth was associated with a significantly lower risk of maternal perineal trauma when compared with the extraction by forceps (OR: 0.41; CI 95 %: 0.33-0.50). It was also associated with a reduced use of general and local anaesthesia during birth. There were more births delivered using the suction cup than the forceps (OR: 1.69; CI 95 %: 1.31-2.19).

The rate of caesarean sections was lower in the vacuum group, probably because there was greater success with the forceps as a backup when the vacuum failed to work, than there was in using the vacuum as a backup when the forceps failed. However, the extraction by vacuum was associated with an increase in the risk of cephalohematoma and retinal haemorrhaging.

The occurrence of severe neonatal injuries was rare with both procedures, although more research is required on this point.

Situation in Spain

There is no collected information regarding the predominant technology used in instrumental births.

Recommendations of the available evidence

The existence of potential injuries and after-effects as a consequence of using forceps, suction cups or spatulas leads us to recommend avoiding the use of instruments in delivery except in those cases where a pathological condition calls for them. Their employment involves an increase in the size and frequency of episiotomies, and reduces the period of breast-feeding. This has been linked to difficulties in initiating lactation caused by the

longer period that mother and infant are separated, the stress which the newborn child suffers in a complicated delivery and the discomfort of the mother as a result of stitches, scars and pain.

In light of the fact that the probability of maternal morbidity is reduced by the use of suction cup instead of forceps, and considering the availability of personnel trained in the use of vacuum technique, this method is recommended as first option when an assisted birth is indicated. Training programmes in the use of the suction cup for extraction should be set up in those areas lacking in experienced personnel. The adoption of the suction cup as the method of choice in assisted births should be encouraged only after a minimum standard of training has been provided for personnel present at birth.

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10. Births by caesarean section

Description

This is a surgical-medical procedure which is carried out either by choice or as an emergency measure to prevent or in response to complications in childbirth for the mother or the baby. It is a major surgical operation which has a higher

rate of maternal or foetal morbidity and mortality than normal childbirth, and more after effects for the mother and newborn child.

A caesarean section on demand is that which is carried out at the pregnant woman's request, through her choice and preference, and which is not indicated for medical reasons.

The WHO includes the number of caesarean sections among its indicators of the quality of assistance offered to mothers at birth. The recommended rate of caesarean sections is 15%, based on the number of women who are predicted to have potentially mortal complications during labour and delivery.

As a result, the rate of caesarean sections can be used as an indicator of the level of access to obstetric surgery, or the excessive use of it. Such high rates of caesarean section can be attributed to potential complications for mother and child, and lead to significantly higher costs and overmedication for a normal procedure, such as giving birth.

In spite of this knowledge, the rate of caesarean section in Spain is above the recommended level. There is a general perception that the greater part of this increase is due on the one hand to the growing practice of performing caesarean section on demand at the patient's request, without any medical indication, and on the other hand to the increase in the number of court cases for malpractice.

Available evidence

The databases available were evaluated, and systematic reviews of the Cochrane Database, meta-analysis and articles published in Medline, AHRQ, BVS (Virtual Health Library) were extracted that revealed differing quality and methodological design, with mixed results.

Results

A Cochrane systematic review of 2006 evaluated the maternal and perinatal effects of caesarean section carried out by choice compared with vaginal childbirth among women who had not been recommended for a caesarean section. It concludes that there is no evidence of randomized clinical trials on which to base a recommendation as regards the practice of caesarean section on pregnant women who reach full term without medical indication to use it.

A review of the literature from the Research Triangle Institute /University of North Carolina-Chapel Hill (RTI/UNC-CH) in 2006 evaluated the available evidence on the tendency and number of on-demand caesarean sections performed in the USA and in Europe, comparing the maternal-perinatal results of the caesarean section when practiced by choice and without medical indication with those of planned vaginal birth.

It concludes that despite the apparent increase in the number of caesarean sections performed on demand, it is difficult to determine the true level or tendency with precision because the existing codes for diagnosis do not provide for its clear recognition as a clinical entity. The maternal-perinatal results of both groups were similar, but the evidence on this point is too weak to enable the drawing of definitive conclusions.

A Cochrane systematic review of 2004 found that the strategy of providing women with information about caesarean section and its possible adverse results was not effective as a means of reducing the number of caesarean sections carried out by choice. The data was insufficient to compare the adverse effects.

Other poor or medium quality studies indicate that there is only weak evidence to affirm that women are increasingly demanding to have a caesarean section by choice in the absence of precise medical indications. It is suggested that the doctor's influence is an important factor when taking this decision.

Observational studies have described different causes for the choice of caesarean section. There may be plans for only one child, fear of childbirth, a bad experience or a complication suffered in a previous birth, fear for the death or injury of the child in a vaginal birth.

Several studies evaluated the effectiveness of actions aimed at motivating and encouraging women to have vaginal births, but the evidence is inconclusive. There are inconsistencies in the results as regards the influence of the increasing number of cases of malpractice and the number of caesarean sections.

Strategies based on medical evidence for the reduction of the rate of caesarean sections were also evaluated. One RCT evaluated a 'second-option' strategy when a caesarean section was chosen, using guides based on medical evidence, which proved to be effective in reducing the number of caesarean sections (reduction RR: 7 %), without adverse effects for the mother or child, preventing 22 caesarean sections for every 1,000 women in labour.

A meta-analysis evaluated the effectiveness of different actions (based on clinical practice guidelines) for reducing the number of caesarean sections, and the impact of this reduction on the levels of maternal and perinatal morbidity and mortality, resulting in a significant reduction (RR: 0.81; CI 95 %: 0.75-0.87). Actions which included auditing and feedback proved to be effective (RR: 0.87; CI 95 %: 0.81-0.93); in improving the quality of the services (RR: 0.74; CI 95 %: 0.70-0.77) along with multi-faceted strategies (RR: 0.73; CI 95 %: 0.68-0.79).

Studies which included the identification of barriers to change were shown to be more effective than other actions in reducing the number of caesarean sections (RR: 0.74; CI 95 % 0.71-0.78 vs. RR: 0.88; CI 95 %: 0.82-0.94). There were no significant differences in maternal and perinatal

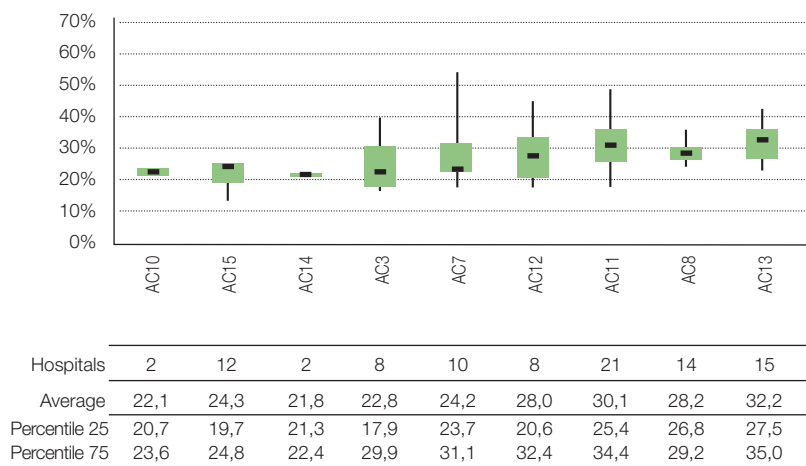
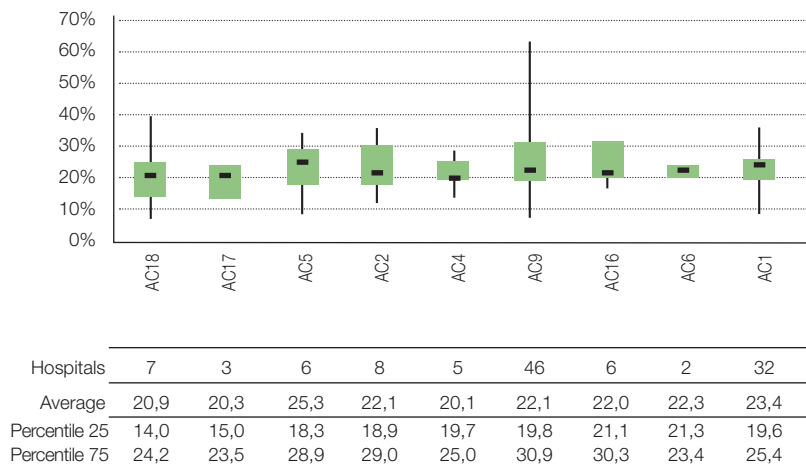
mortality and morbidity between the different ways of bringing the birth to its conclusion. There is sufficient evidence to conclude that the rate of caesarean section can be safely reduced by the use of multi-faceted actions that call for the involvement of health professionals in the analysis and modification of the indicators for this practice.

Situation in Spain

There is a rate of 16-25 % in public hospitals, and a rate of 33 % in private centres (OSM; June 2007).



Figure 19. Rate of caesarean sections adjusted by risk



Analysis of the variability (Box-plot)

Figures 18 and 19 show the variation in the prevalence of caesarean section between the different autonomous communities in Spain (13.1 to 28.7 %) and the variation within each community.

Recommendations of the available evidence

It is recommended that a programme be set up to reduce the number of caesarean sections which includes multi-faceted studies based on scientific evidence, with an estimate of the costs that its implementation would involve. Professionals from the health service should be enlisted to analyse the barriers to change and to evaluate the results.

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11. Early contact between mother and newborn child

Description

During the first two hours after birth, the newborn child is in a state of tranquil alert for an extended period, a stage called a sensitive period which is provoked by a discharge of noradrenalin during birth. This enables early olfactory recognition of the mother, which is very important for establishing a bond and adapting to the postpartum environment.

If the child is laid in skin contact with the mother, it will slowly move towards the breasts by instinctive flexing and extension of its legs until it reaches the nipple, at which point the reflex actions of locating it and sucking are set in motion correctly. This process cannot be forced, it must be spontaneous. It takes approximately 70 minutes in 90 % of cases. The separation of the mother and child alters this process and reduces the frequency of successful breast-feeding.

The skin contact entails other benefits for the newborn child (a quicker recovery from stress, the child's glycaemia, acid-base equilibrium and temperature are regulated earlier) and for the mother (reduction of the uterus via secretion of oxytocin). The bond between mother and child increases the duration of maternal breast-feeding and prevents negative emotional reactions.

Evidence

Commentaries and practical aspects from the RHL / WHO No. 10 and a Systematic Review of the Cochrane Database which analysed 30 randomized and semi-randomized studies of 1,925 mother-child couples were included. The effects of early contact between mother and child on lactation, behaviour and psychological adaptation to the relationship were evaluated.

Results

Early contact was associated with beneficial effects on breast-feeding from the 1st to the 4th month after birth (OR: 1.82; CI 95 %: 1.08-3.07) and the duration of breast-feeding (WMD: 42.55; CI 95 %: 1.69-86.79). Beneficial results were also noted in the bonding (mean difference: 0.52; CI 95 %: 0.31-0.72); shortening of the newborn child's crying (Weighted means difference: -8.01; CI 95 %: -8.98--7.04) and cardiorespiratory stability. No adverse effects were discovered either in the short or long term.

Situation in Spain

There is a lack of information about the population base as regards the implementation of early contact in the health services. There is information which indicates that some institutions have adopted a policy in which early contact is encouraged, while others have no such policy. It is suggested that studies be carried out to evaluate the performance of institutions regarding this practice.

Recommendations of the available evidence

The healthy newborn child and its mother should remain together and not be separated at any time as long as the condition of the mother allows it.

Immediately after birth, the newborn child should be placed on the mother's abdomen, where it should be dried and a dry towel be placed over it. In this way it will cling spontaneously to the breast in most cases, remaining for at least 70 minutes in close skin contact with its mother.

The only procedures to be taken with the newborn child during this period of skin contact with the mother are its identification and the assignation of punctuation on according to the Apgar test.

Inform mothers of the advantage of skin contact.

Postpone the practice of ocular prophylaxis, weighing, vitamin K etc. until the end of the contact period, carrying out the procedures in presence of the parents and with their full consent.

There should be no routine suction of secretions or application of gastric lavage, nor should there be routine application of an orogastric probe, nor should the nasal cavities be probed nor a rectal probe used. They are not necessary and are not free of risk.

The same recommendation holds for caesarean sections. Whenever possible, the area should be prepared for mother-child skin contact.

Should the mother's condition not allow her to make skin contact with the child, the possibility should be offered to the father.

Establish a care methodology centred on development, stimulating the mother-kangaroo method, with skin contact between mothers and fathers and the full cooperation of these in the caring procedures, especially in cases where the newborn child is more vulnerable.

Work with support groups in favour of better practice.

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12. Immediate postpartum care. Breast-feeding

Evidence

A review was carried out of the evidence regarding the short and medium term effects on health, and their relation with some outcomes in maternal health in developed countries. Medline®, CINAHL, and the Cochrane Library of November 2005 were the sources of the information as well as supplementary searches until May 2006². Certain bibliographies were incorporated at the suggestion of experts on the subject.

Among the evidence included were systematic reviews and meta-analysis, randomized and non-randomized studies, prospective cohorts, case-control studies and the effects of maternal lactation and relevant results published in English.

The studies included also had a comparative arm which consisted of the use of formula milk as an alternative or varying duration of natural lactation. Only studies carried out in developed countries were incorporated in the updates of previous systematic reviews. The studies were classified according to their quality.

² <http://www.ahrq.gov/downloads/pub/evidence/pdf/brfout/brfout.pdf> (2007)

Around 9,000 summaries were reviewed. Forty-three studies with primary results on children's health, another 43 studies based on the results regarding the health of the mother and 29 systematic reviews or meta-analysis which cover approximately 400 individual studies and which were finally entered in the present study for consideration.

It was discovered that a history of breast feeding was associated with a reduction of the risk of otitis media, non-specific gastro-enteritis, low or severe infection of the breathing apparatus, dermatitis, asthma (in young children), obesity, type 1 or 2 diabetes, childhood leukaemia, cot-death syndrome and necrotic enterocolitis. No relation was found to link breast-feeding with cognitive development. The relation between breast feeding and cardiovascular disease was not entirely clear. There was also a lack of definition in the relation between breast-feeding and child mortality in developed countries.

For the mother, breast-feeding resulted in a lowering of the risk of developing type 2 diabetes, breast cancer and ovarian cancer. Women who did not breast-feed their babies, or did so for a shortened period were associated with a greater risk of depression during infancy. No relation was found between lactation and the risk of osteoporosis. The effect of breast-feeding on mothers and their return to their pre-pregnancy weight was minor, while the effects of breast-feeding on weight loss after giving birth could not be clearly established.

Conclusions

Natural breast-feeding was associated with a reduced risk of suffering a number of illnesses for both children and mothers in developed countries. The fact that all the data collected in the review was derived from observational studies means that we are unable to attribute causes to the information available. There is a wide variation in the body of evidence when the resulting conditions of health are considered.

Future studies must establish clear criteria for selecting subjects as well as establishing a reliable criteria for defining what is "exclusively maternal lactation" and monitoring for the presence of factors which cause confusion, including those factors that specifically affect the children, and evaluating the process by which the results may become obscured.

The studies involving twins provide a method of checking for genetic and environmental factors which are of importance for certain results. As a complement, studies which analyse the actions taken in promoting maternal breast-feeding which use random and control clusters will provide us with an opportunity to investigate the variations in material used and their outcomes in terms of the health conditions that arise from them.

Existing studies and reviews indicate the beneficial effects for the newborn child, which are associated with the reduction of otitis media,

gastroenteritis, respiratory infections, dermatitis, asthma, obesity, diabetes, leukaemia, enterocolitis and cot death syndrome. There are also beneficial effects for the mother. Besides the affective, psychological effects and the strengthening of the bond between mother and child, women who breastfeed have a reduced risk of diabetes and breast or womb cancer.

The immediate postpartum period is a sensitive period of extreme importance for the establishment of breast-feeding and has a vital role in the development of the mother-child bond. The bond between the mother / father / newborn child is regarded as a complex and far-reaching human experience which calls for physical contact and interaction at the earliest stages of life. This postpartum period has been invaded by a number of medical and nursing procedures which cannot always be justified and which frequently involve the separation of the mother and the newborn child.

Modern society may create barriers preventing mothers from developing the instinct for breastfeeding their children, especially where the birth has not been physiological. There are also obstacles in the absence of sufficient experience and knowledge which would enable women to feel secure when starting to breastfeed. Newborn children are repositories of instincts, and require prolonged intimate contact with the mother in order for these instincts to flourish correctly, preferably during the first two hours after birth, giving them the opportunity to attach themselves to the breast and take their first feed spontaneously. This postpartum sensitive period is not indefinite, and to postpone contact means that the newborn child cannot develop its instincts with the same effectiveness as it would immediately after birth.

Recommendations for postpartum practices based on the available evidence

Abandon unjustified procedures and delay the performance of those that are necessary if they call for the separation of mother and baby. Request the mother's consent before applying any procedure.

Recommendations of the available evidence

Encourage efficient practices in support of maternal breast-feeding, making the extraction, preservation and maintenance of the mother's milk possible, so that the newborn child can be given the milk from its own mother.

Encourage the donation of breast milk and start up a Milk Bank.

Work with support groups in favour of better practice in breastfeeding.

Respect the choice of fully-informed mothers who prefer bottle-feeding.

Provide adequate information and develop bottle-feeding skills for those mothers who choose this option.

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Annex III. Some examples of good practice

1. Clinical practice

The Hospital of La Plana in Vila-Real (Castellón) has a protocol specifically for assistance at normal births, which is written and available on the hospital website, with a model birth plan.

The Inmaculada Hospital of Huércal-Overa (Almería) has been developing a specific protocol for some time for assistance at normal childbirth as well as promoting birth plans, early contact between mother and child, and breast-feeding.

The County Hospital of Salnés in Villagarcía de Arosa has been providing natural assistance to normal childbirth which respects the physiological process, women's autonomy and the taking of decisions, including those medical interventions which are necessary, when appropriate and opportune, based on the prevailing scientific findings.

The Doce de Octubre University Hospital in Madrid are developing a project "Family-Centred Perinatal Care" as a collaboration between the Neonatology, Obstetrics and Anaesthesia Services as a means of increasing the protagonism of women during childbirth, reduce the number of cases where mother and newborn child are separated, and involve the father actively in the process.

The Marqués de Valdecilla University Hospital of Santander has elaborated a Protocol of assistance at Normal Childbirth with minimal intervention (natural childbirth). It has been written and placed at the public's disposal on the hospital's website: www.humv.es.

2. Participation. Birth plans

The regional government of Cantabria has passed the decree 23/2007, of the 1st of March on the rights of the father, mother and newborn child as regards birth in a clinical environment (BOC, 16th March 2007). There is also a new Health Card for Pregnancy which includes the possibility of a Birth Plan.

The Health Department of the Regional Government of Catalonia has published the Protocol for natural assistance in normal childbirth and a Birth Plan in collaboration with Scientific Institutions and representatives of different Women's Associations. The objective is to include natural assistance for normal childbirth within the range of services available from hospitals that form part of the public health system.

The Gregorio Marañón Hospital in the Community of Madrid is running a programme aimed at encouraging men to participate in the process of pregnancy, birth and post-natal care, in order to promote responsible fatherhood.

The following hospitals are also developing initiatives for promoting participation and birth plans: Inmaculada Hospital of Huércal-Overa (Almeria). San Juan de la Cruz Hospital of Úbeda (Jaen), Baza Hospital (Baza-Granada), San Cecilio Hospital Clinic (Granada), Hospital Clinic (Barcelona), Santa Caterina Hospital (Gerona), Virgen del Camino Hospital (Pamplona), San Lázaro Hospital (Mallorca), Mataró Hospital, and Hospital of La Plana de Vila-Real (Castellón).

3. Breast feeding

The University Hospital of La Fe has signed an agreement with the AMAMANTA group to provide support for breast-feeding initiatives and as a support network, besides providing information on the health facilities and workshops led by midwives.

The University Hospital of Getafe (Madrid) is currently running a project to improve the quality of care and assistance as a form of promoting and supporting breast-feeding from the earliest moments.

4. Cross cultural issues and equity

The Punta Europa Hospital in Algeciras is developing a programme of assistance at childbirth with a multi-cultural component, called The Emigrant's Friend Hospital.

Fuenlabrada Hospital in the Community of Madrid is developing a project The Health of Women Immigrants in order to improve the quality of care provided for different collectives in accordance with their origins.

Zaragoza City Council has been running the Motherhood programme with the collaboration of the Vía Lactea Association since 1998 as a way of providing support for women who are in need or whose situation prevents them from an adequate experience of their pregnancy and childhood. They provide informed accompaniment in several languages at health centres and other resources in the city, with support and follow-up to encourage and consolidate the bond between mother and child.

5. Coordination hospital-primary care

An educational DVD is being prepared in the city of Ciudad Real which brings together all the relevant information for women from the moment when they are admitted to hospital, with the different possibilities and techniques for childbirth available from the hospital, and in which the different members of the team are introduced. The DVD is to be shown in classes for women.

The County Hospital of Salnés in Villagarcía de Arosa has been developing a coordination service between the Primary Care Services (Sexual and Reproductive Health) and those of the Hospital (Birth Plan).

6. Training of health care personnel

The Hospitals of San Cecilio and Baza, in Granada, have been running training courses for health care personnel for assistance at normal childbirth during two consecutive years.

Castile-La Mancha has developed a continuous training programme in which the hospital managements are included.

The Federation of Spanish Midwives (FAME) is running the programme The Normal Childbirth Initiative (IPN) which consists of elaborating a series of activities and documents with the aim of raising awareness and reinforcing midwives' responsibilities when assisting at normal childbirth, and leading opinion among mothers and society in general. The drawing up of the consensus document on assistance at normal childbirth and the campaign itself has been based on evidence and with the agreement of the different Midwives' Associations of the Autonomous Communities.

The Spanish Midwives' Association is carrying out a programme of acts to raise awareness of midwives' responsibilities when assisting at normal childbirths.

Annex IV. Description of indicators by subject

With the aim of establishing indicators which prove most helpful in evaluating the advances in the implementation of the recommendations contained in this strategy document over the short and medium-term, priority has been given to those which can be derived from sources that already exist. One of these is the MBDS, which is an information system that predates the National Health System, is stable and provides high quality data, although in some cases the data it provides is not readily comparable in areas which are necessary for the monitoring of this strategy (such as the analgesia applied or the practice of episiotomy).

The protocols, directives and guidelines for clinical practice and other documents produced by the Autonomous Communities and hospitals are a source for valuable information concerning the policies which are being followed in order to comply with the recommendations.

There are other sources dealing with training and research which are also useful for observing some of the lines proposed. However, other aspects will call for specific studies to be set up in order to obtain information on the process of implementing the recommendations and their results in the medium and long term.

It must be remembered that the evaluation of the implementation of the strategy is a process that is to be reviewed every two years, which will allow the recommendations to be modified and the indicators adapted to the new requirements.

RESULT INDICATORS	
Mortality	Perinatal mortality by cause Perinatal mortality by method of delivery Perinatal mortality by cause Perinatal mortality by method of delivery
Morbidity	Rate of postpartum haemorrhage (MBDS) Perinatal morbidity by delivery method Neonatal morbidity by delivery method
INDICATORS OF CLINICAL PRACTICES	
Shaving	The number of maternity wards including these strategy recommendations in the protocol of assistance at childbirth
Enema	The number of maternity wards including these strategy recommendations in the protocol of assistance at childbirth

Accompaniment during the process	The number of maternity wards including these strategy recommendations in the protocol of assistance at childbirth
Period of dilation	The number of maternity wards including these strategy recommendations in the protocol of assistance at childbirth
Pain management	Percentage of births with epidural anaesthesia (MBDS) The number of maternity wards including these strategy recommendations in the protocol of assistance at childbirth
Maternal positioning	The number of maternity wards including these strategy recommendations in the protocol of assistance at childbirth
Episiotomy	Number of episiotomies carried out in primigravidas and multigravidas (source MBDS)
Delivery	Establish a research project on risks of bleeding in the third stage of labour in physiological childbirths without medical intervention, which can provide useful information for recommending changes in active intervention
Instrumental births	Percentage of births with forceps Percentage of births with suction cup Percentage of births with spatula The number of maternity wards including these strategy recommendations in the protocol of assistance at childbirth
Births by caesarean section	Rate of caesarean sections (source MBDS) Rate of caesarean sections adjusted by risk (source MBDS) Rate of vaginal births after a previous caesarean section (source MBDS) Set up and start research into the causes of the increase and variations in the rate of caesarean sections Number of maternity wards that have initiated a programme to rationalise the rate of caesarean sections and their unjustified variability
Mother-newborn child skin contact	The number of maternity wards including these strategy recommendations in the protocol of assistance at childbirth
Maternal breast-feeding	The number of maternity wards including these strategy recommendations in the protocol of assistance at childbirth The number of maternity wards including these strategy recommendations in the protocol of neonatal childcare

INDICATORS OF WOMEN'S PARTICIPATION AND EMPOWERMENT

- The number of maternity wards including these strategy recommendations in the protocol of assistance at childbirth

INDICATORS OF TRAINING FOR MEDICAL AND NURSING PROFESSIONALS

- Inclusion of these recommendations in the training programme designed for MIR and EIR specialists in gynaecology and obstetrics
- The number of ongoing vocational training courses on these subjects
- Percentage of specialists in obstetric medicine working in the NHS that have taken part in courses to bring them up to date in assistance at normal births
- Percentage of specialists in obstetric nursing working in the NHS that have taken part in courses to bring them up to date in assistance at normal births

INDICATORS OF RESEARCH AND INNOVATION. SPREAD OF GOOD PRACTICES

- Inclusion of aspects of this strategy document in the annual research calls
- Guide to clinical practice drawn up and debated within the NHS
- The setting up of a system for gathering, analysing and broadcasting good practices

Annex V. List of abbreviations

AC	Autonomous Communities
AHRQ	Agency for Healthcare Research and Quality
CI	Confidence Interval
DARE	Database of Abstracts of Reviews of Effects
ESCRI	Statistics for Medical Institutions with Inpatient Facilities
EU	European Union
FAME	Federation of Spanish Midwives' Associations
HFA	Health for all database
LBRAP	Basic Regulatory Law on Patient Autonomy and Rights and Obligations concerning Information and Clinical Documentation
MBDS	minimum basic data set
MM	Maternal mortality
NHS	National Health System (Sistema Nacional de Salud)
OSM	Observatorio de Salud de la Mujer (Observatory on Women's Health)
OR	Odds ratio
RCT	Randomized Clinical Trial
RR	Relative Risk
RTI/UNC-CH	Research Triangle Institute/University North Carolina-Chapel Hill
WHO	World Health Organisation
WMD	Weighted mean difference

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This strategy document forms part of the Quality Plan for the National Health System and represents the combined efforts of the Spanish Ministry of Health and Consumers' Affairs, Professional Societies, Women's Associations and the Autonomous Communities and Cities, with the objective of improving the quality of health care in assistance at childbirth in all parts of the territory, and so contribute to the cohesion which our Health System requires in order to benefit all citizens equally.

