



INTERNATIONAL FEDERATION
FOR SPINA BIFIDA AND HYDROCEPHALUS



Bayer HealthCare



Act against Europe's most common birth defects: one year on

Defining Neural Tube Defect
prevention strategies in Europe

EDITION
2011



This report is published in collaboration with our partners:



To download this report, please go to www.ifglobal.org/ntdreport

We hope you will enjoy reading this report, and that the evidence put forward will inspire you to join us now and act to reduce Neural Tube Defects in Europe. For more information about this report and to learn more about how you can make a difference in reducing NTDs please visit our website at www.ifglobal.org/ntdreport or send us an e-mail at reduceNTDs@ifglobal.org

*This report is sponsored by
Bayer HealthCare Pharmaceuticals and **MediClara**
as a contribution to public policy debate.*

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Foreword

Ms RIA OOMEN-RUIJTEN,
Member of the European Parliament



One year following the publication of the first report on Neural Tube Defects, it was without a moment's hesitation that I accepted to say a few words for the second edition '*Act against Europe's most common birth defects: one year on - Defining Neural Tube Defect prevention strategies in Europe*'.

It is appalling to witness in the 2011 update that progress in reducing NTD incidence remains disappointing; despite the long-standing recognition of the link between folate levels in women of childbearing age and the avoidance of up to 70% of NTD affected pregnancies. The result is that today we face a situation in Europe where we still have an unnecessarily high incidence of these birth defects due to inadequate periconceptional maternal folate levels!

With four additional partners joining this campaign since last year, and having widened the research on the situation of NTDs in Europe from 7 to 25 countries, it is clear that the European health community is united to deliver to us, policy makers, a strong and consistent message: **that the right advice is not reaching the right women at the right time.**

In addition, they also invite us to look further into some straightforward policy suggestions

that will contribute to the effective reduction of NTD affected pregnancies through concerted action in different policy areas. For example increasing awareness among the public health community and women of childbearing age, food fortification and supplementation strategies, improved use of existing health policies e.g. National Action Plans for Rare Diseases and the use of educational policies related to maternal and reproductive health.

As policy makers we should pause, think and promote the implementation of such suggestions to ensure that pregnancy is not viewed only as a nine month process, but that it requires recognition of the importance of maternal health and in particular preconception care.

I strongly welcome the work undertaken by all the partners involved in this report and invite you to join us to help ensure that we reduce Neural Tube Defects in Europe.

A handwritten signature in blue ink that reads "Ria Oomen-Ruijten". The signature is written in a cursive style and is positioned above a horizontal line.

Ria Oomen-Ruijten

Act against Europe's most common birth defects: one year on

Defining Neural Tube Defect prevention strategies in Europe

The second report on Neural Tube Defects: a few introductory remarks

Following the successful launch of their first joint report on Neural Tube Defects (NTDs) *'Act against Europe's most common birth defects - The right advice at the right time can reduce Neural Tube Defects now'*¹ in January 2010 and as an effort to contribute to an evidence-based health policy discussion, the International Federation for Spina Bifida and Hydrocephalus (IF) and Bayer HealthCare Pharmaceuticals agreed to work on a second report on NTD prevention.

This second report is not designed as a scientific report, but rather as a tool supporting policy-makers' public health decisions and ensuring these are based on the latest evidence. As such, the second report was put together to provide a horizontal overview of the policies that could contribute to increased NTD prevention in the EU and Norway (e.g. rare disease policy, preconception care, education, etc). We were unfortunately unable to collect data in Malta, Luxembourg and Cyprus, therefore the report excludes information from these countries. We hope that this policy focus gives an accurate depiction of the NTD situation at a

pan-European level and identifies legislative gaps to be addressed by national and EU policy makers.

It is striking to see that more than one year after the publication of the first report and after widening our analysis to more European countries in this second report, the conclusion remains alarmingly the same:

Little has happened in the last 20 years to ensure effective NTD prevention!

The second report is sponsored by MediClara and Bayer HealthCare Pharmaceuticals and endorsed by the International Federation for Spina Bifida and Hydrocephalus (IF), the European Foundation for the Care of Newborn Infants (EFCNI) and the European

Association of Service Providers for Persons with Disabilities (EASPD). Two of the factsheets of this report have also been endorsed by Rare Diseases Europe (EURORDIS). All partners have reviewed, commented and approved the content of the report they are endorsing. The publication of this report was also made possible thanks to the contribution of EUROCAT, which provided most of the data used in this report and to the support of Burson-Marsteller Brussels, consultants to Bayer HealthCare Pharmaceuticals.

We hope you will enjoy reading this report and that the evidence put forward will inspire you to join us now and support our campaign. To learn more about how you can make a difference in reducing NTDs after reading this report please send us an e-mail at reduceNTDs@ifglobal.org



Pierre Mertens

International Federation for Spina Bifida and Hydrocephalus, President



Lars Joensson

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MediClara, Director projects and research



Yann Le Cam

EURORDIS, Chief Executive Officer



Silke Mader

European Foundation for the Care of Newborn Infants, Chairwoman of the Executive Board



Luk Zelderloo

European Association of Service Providers for Persons with Disabilities, Secretary General

Executive Summary

- It is estimated that 70% of NTDs can be avoided by adequate folate levels in women of childbearing age before conception³. Despite the existing knowledge about preventive measures for the reduction of NTD affected pregnancies, prevalence still remains too high, with a high termination rate often being misperceived as a preventive measure in some European countries.
- Evidence suggests younger women and women from more disadvantaged backgrounds are at a greater risk of a NTD affected pregnancy².
- NTD related policy, such as policy on rare diseases, continues to neglect the inclusion of preventive measures to raise women's folate levels prior to conception and in early pregnancy.
- Voluntary fortification with folic acid and a healthy diet are insufficient to raise women's folate levels, in particular women from disadvantaged backgrounds, prior to conception and in early pregnancy.
- Recommendations on daily intake of folic acid to prevent the occurrence of a NTD affected pregnancy in Europe generally fail to be fully aligned with the WHO standard, especially in terms of timing for folic acid intake.
- Recommendations on daily intake of folic acid to prevent the occurrence of a NTD affected pregnancy in Europe are scarcely implemented¹¹.
- The intake of folic acid to prevent the occurrence of a NTD affected pregnancy, as recommended by the WHO standard, is practiced by only a very small proportion of the women that become pregnant throughout Europe every year. This poor compliance can be explained by the high number of unplanned pregnancies, leading to women consulting healthcare professionals only when they are pregnant already and the lack of effective and ongoing educational campaigns that advise women to raise their level of folates prior to conception. This situation leads to a lack of timely and sufficient knowledge amongst women of childbearing age about the importance of adequate folate levels.
- Health education campaigns are too scarce and often limited in scope, duration and effectiveness. For example, information on NTD prevention is neglected in school education.

Call to Action

1. Ensure national recommendations on folic acid intake to prevent NTDs are updated, in line with the WHO's standard on NTD prevention, and that their implementation by healthcare professionals is monitored.
2. Raise awareness about NTDs and NTD prevention among women of childbearing age and the healthcare community through education campaigns, and by including NTD prevention in the curriculum for sexual and reproductive health education in schools throughout Europe.
3. Ensure that NTD prevention by raising women's folate levels is promoted in health-related policy, e.g. on rare diseases, maternal health, preconception care, etc.
4. Investigate further the costs and benefits of food fortification or other supplementation strategies.
5. Improve NTD surveillance systems and the collection of comparable data across the EU, including compliance with folic acid intake recommendations.
6. Explore new methods to raise women's folate levels prior to conception, regardless of whether their pregnancy is planned or not and in view of addressing health inequalities.

Women of childbearing age should start getting the right advice about NTD prevention at the right time, i.e. prior to conception

Act against Europe’s most common birth defects: one year on

Defining Neural Tube Defect prevention strategies in Europe

Facts & Figures on Prevention of Neural Tube Defects (NTDs)

Neural Tube Defects (NTDs) are severe malformations which are mostly preventable by increasing the levels of folate in women of childbearing age

- Neural Tube Defects (NTDs), such as Spina Bifida, are birth defects which occur when the neural tube fails to close within the first 28 days of pregnancy and which result in severe malformations. Surviving infants, in the majority of cases, will have severe lifelong disabilities. There are three types of NTDs: Encephalocele, Anencephaly and Spina Bifida.
- Worldwide, at least 300,000⁴ newborns are affected by a NTD every year. In Europe, data suggests that there are more than 4,500 affected pregnancies every year⁵. An estimated 72% of NTD

affected pregnancies are terminated every year following a prenatal diagnosis⁶. This means that the number of surviving infants with a NTD has decreased, leading to a misperception that NTD affected pregnancies are being prevented.

- The role of women’s folate levels in reducing the risk of a NTD affected pregnancy is well recognised by the international community, including the WHO⁷ and the European Commission⁸.
- Evidence suggests that younger women and women from disadvantaged backgrounds² are at particular risk of a NTD affected pregnancy due to low periconceptional folic acid supplement use, i.e. before and in early pregnancy.



Newborn with Spina Bifida

NTD TYPE	SEVERITY	NTDs IN EUROPE ⁶
Encephalocele	Lethal anomaly	<ul style="list-style-type: none"> • More than 4,500 pregnancies are affected by a NTD every year
Anencephaly	Lethal anomaly	<ul style="list-style-type: none"> • Total NTD prevalence rate: 0.96 per 1,000 births
Spina Bifida	Very serious group of anomalies of the spinal cord	<ul style="list-style-type: none"> • Total live birth NTD prevalence rate: 0.24 per 1,000 births

Three numbers you need to remember about Neural Tube Defects

4,500⁵

Is the number of **pregnancies affected by a NTD each year** in Europe of which an estimated 72% are terminated following prenatal diagnosis⁹

70%

Is the percentage of NTDs that can be avoided **through adequate folate levels** in women of childbearing age before conception³

2

Is the minimum number of months for women to start taking **0.4 mg of folic acid daily before conception** to reduce the risk of a NTD affected pregnancy⁷

How can NTDs be prevented?

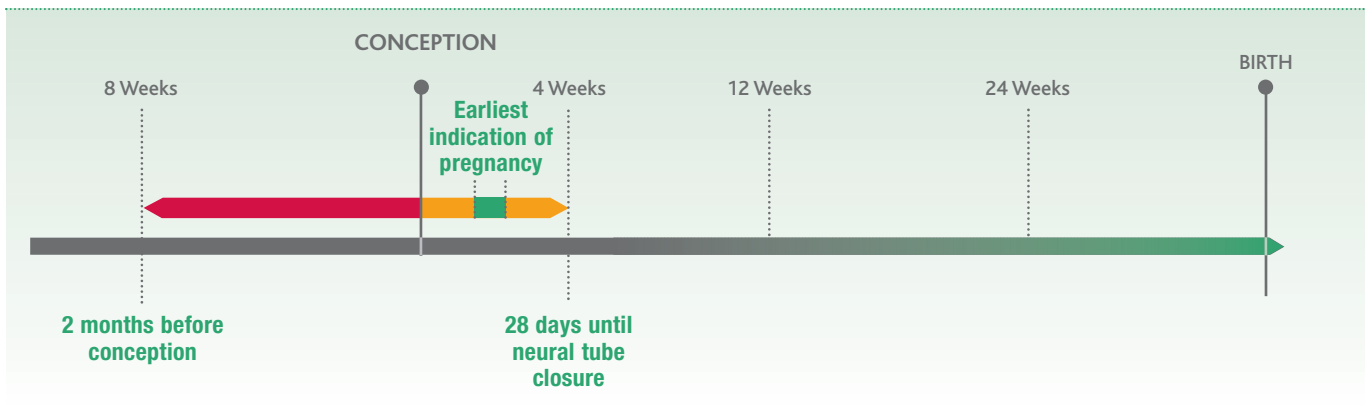
- Research indicates that up to 70% of cases can be avoided by ensuring adequate folate levels before conception and during early pregnancy in women of childbearing age³.
- To date, folate levels in women of childbearing age can be raised via three methods: natural folate intake through a

healthy diet, folic acid supplements to increase folate levels and food fortification with folic acid.

- According to the WHO, women should ensure a daily intake of 0.4mg of folic acid at least 2 months prior to conception and 12 weeks into their pregnancy in order to reduce the risk of a NTD affected pregnancy⁷.

- High folate levels in women are also thought to contribute to reducing the occurrence of premature delivery and of congenital defects such as orofacial, limb, heart and urinary tract defects. In view of an effective reduction of NTD affected pregnancies, women's folate levels remain too low prior to conception.

Graph 1 – The importance of timing in the prevention of NTDs



Why is NTD prevalence so high in Europe? Why does progress on prevention remain disappointing even after 20 years of knowledge?

- Up to 50% of pregnancies are estimated to be unplanned⁹ and women are therefore not seeking prenatal advice. Once a woman becomes aware of her pregnancy it is too late to ensure that she has adequate folate levels to reduce the risk of a NTD. This is why women of childbearing age would be better protected if they would raise their folate levels in advance of conception, regardless of whether they are planning a pregnancy or not.
- There is a lack of systematic and consistent preconception care provided by healthcare professionals to women of childbearing age in a timely manner¹⁰.
- There is little awareness in women of childbearing age, and in particular in

younger women and women of disadvantaged backgrounds², about the issue or about the preventive measures needed before conception and in early pregnancy to reduce the risk of a NTD affected pregnancy.

- There is a lack of compliance by women with the existing recommendations on daily folic acid intake to prevent NTDs¹¹.

What can we do to ensure the reduction of NTD affected pregnancies in the future?

- Ensure national recommendations on folic acid intake to prevent NTDs are updated, in line with the WHO's standard on NTD prevention, and that their implementation by healthcare professionals is monitored.
- Raise awareness about NTDs and NTD prevention among women of childbearing age and the healthcare

community by including NTD prevention in health-related policy, e.g. on rare diseases, maternal health, preconception care, etc., through education campaigns and by including NTD prevention in the curriculum for sexual and reproductive health education in schools throughout Europe.

- Improve NTD surveillance systems and the collection of comparable data across the EU.
- Investigate further the costs and benefits of food fortification or other supplementation strategies.
- Explore new methods to raise women's folate levels prior to conception, regardless of whether their pregnancy is planned or not and in view of addressing health inequalities.

Act against Europe's most common birth defects: one year on

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Methodology

The information contained in this report is based on:

- The results of an online questionnaire completed between mid July-September 2010 by representatives of IF's national member or partner organisations and/or national Bayer HealthCare Pharmaceuticals representatives¹⁰.
- EUROCAT's¹² Special Report on Prevention of NTDs⁵.
- EUROCAT's¹² latest comparable data on NTDs received in February 2011⁶.
- The European Commission's website on Rare Disease Action Plans¹³.
- Qualitative input from the partners endorsing the report and other stakeholders active in the debate.

Phase I – Research & initial collection of information (Mid July-end September 2010)

To ensure the report would include information from a large number of countries, IF and Bayer HealthCare Pharmaceuticals' European networks were involved in the collection of information in their country through an online questionnaire. The questionnaire was elaborated by IF Global and Bayer HealthCare

Pharmaceuticals on the basis of a joint workshop held in Dublin on 9-10 June 2010 and at a brainstorm session held in Brussels on 28 June 2010. The questionnaire was sent to representatives of IF's national members or partner organisations and national Bayer HealthCare Pharmaceuticals representatives, who were encouraged to coordinate their responses and to possibly submit joint responses. The questionnaire included questions requesting specific feedback and qualitative input from the respondents. Respondents were asked to reference all the information provided at the risk of not seeing their answers reflected in the report if failing to do so. To answer the questionnaire, respondents conducted desk research and sometimes telephone interviews with national stakeholders.

Phase II – Analysis of the information collected, clarifications and drafting (September 2010-May 2011)

A lot of time was invested in cross-checking the information provided by all 33 respondents. Clarifications of the responses were conducted through individual follow-up calls, teleconferences and e-mail exchanges. As a result of those clarifications and upon respondents' approval, some changes were made to the answers initially collected.

Apart from the respondents' opinion on the current legislation in place, all answers collected were "weighted out" to avoid duplication.

Where it was not possible to verify, or provide a reference for, the information collected in the questionnaire, it was agreed with the respondents to omit this information from the report. For some questions there were no verifiable or conclusive answers and therefore these are not addressed in this report. However all questions asked are available online at www.ifglobal.org/ntdreport.

Phase III – Revision by all parties involved (May 2011)

The report was reviewed by all partners endorsing it. The revision by all parties involved led to further corrections in some factsheets with the aim to bring them more up to date (e.g. update of the rare diseases factsheet grid).

Limitations of the methodology

The report's methodology has certain limitations:

- **Timing:** new initiatives may have occurred after the research period closed in which case they are not reflected in the report.
- **Interpretation:** available information may be subject to different interpretations. Also, some of the information collected is based on the opinions of the respondents to the questionnaire and authors of the studies referenced.
- **Language:** the online questionnaire was only available in English which may have hindered non-native speakers to understand the questions thoroughly and therefore identify important developments.

If you wish to send us your feedback, comments or any question you may have regarding the methodology and this report, please do not hesitate to contact us at reduceNTDs@ifglobal.org

COLLECTION OF INFORMATION

Number of online questionnaires sent out 28 IF affiliates and partner organisations 25 Bayer HealthCare Pharmaceuticals national representatives	53
Number of joint IF-Bayer HealthCare Pharmaceuticals responses (Belgium, Denmark, Ireland and Sweden)	4
Number of responses received from IF representatives (France, Italy, The Netherlands, Poland, Portugal, Romania, Spain, UK - England and Wales, Scotland)	9
Number of responses received from Bayer HealthCare Pharmaceuticals representatives (Austria, Bulgaria, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Latvia, Lithuania, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and UK- England and Wales)	20
TOTAL number of responses collected to the online questionnaire	33
TOTAL number of countries covered by the online questionnaire (Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, The Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, UK)	25

About the partners



The International Federation for Spina Bifida and Hydrocephalus (IF) is the world-wide umbrella organisation (INGO) for Spina Bifida and Hydrocephalus organisations. Created in 1979, IF's membership consists today of 41 regional and national umbrella organisations for Spina Bifida and Hydrocephalus. IF has intensive contact with regional and national organisations in over 50 countries, spread over five continents. The mission of IF is to improve the quality of life of people with Spina Bifida and Hydrocephalus throughout the world and to decrease the prevalence of Spina Bifida and Hydrocephalus by primary prevention.

This report has been drafted, reviewed and endorsed by IF.

For more information about IF, visit www.ifglobal.org



Bayer HealthCare Pharmaceuticals is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine and Women's Healthcare. Using new ideas, Bayer HealthCare aims to make a contribution to medical progress and strives to improve the quality of life.

This report has been sponsored, drafted, reviewed and endorsed by Bayer HealthCare Pharmaceuticals.

For more information about Bayer HealthCare Pharmaceuticals, visit www.bayerpharma.com



The European Association of Service Providers for Persons with Disabilities (EASPD) is a non-profit NGO in the disability sector promoting the equalisation of opportunities for people with disabilities through effective and high quality service systems. The correct and full implementation of the UN Convention on the Rights of Persons with Disabilities is key to the work of EASPD.

Aiming at high quality of services facilitating full participation and inclusion in society for persons with a disability, EASPD is committed to promote user participation in the development and delivery of services, the implementation of governance principles, active lifelong learning opportunities for staff and focuses on accessibility, availability, affordability and adaptability of services.

At the European level EASPD plays a key role as the representative of disability service providers by working on socio-economic policies in close cooperation with other European and international networks.

This report has been reviewed and endorsed by EASPD.

For more information about EASPD, visit www.easpd.eu



The European Foundation for the Care of Newborn Infants (EFCNI) is the first pan-European organisation to represent the interests of preterm and newborn infants and their families. It gathers together parents and medical professionals from different disciplines with the common goal of improving long-term health of newborn and preterm children by ensuring the best possible prevention, treatment, care and support.

This report has been reviewed and endorsed by EFCNI.

For more information about EFCNI, visit www.efcni.org



The European Organisation for Rare Diseases (EURORDIS) is a non-governmental patient organisation active in the field of rare diseases, founded in 1997 and dedicated to improve the quality of life of all people living with rare diseases in Europe. EURORDIS' mission is to build a strong pan-European community of patient organisations and people living with rare diseases, to be their voice at the European level, and to fight against the impact of rare diseases on their lives.

EURORDIS has 469 members in 45 countries. EURORDIS is represented by four patient representatives and their alternates in the European Union Committee of Experts on Rare Diseases (EUCERD), and is involved in the development of national action plans on Rare Diseases, with its 25 National Alliances on Rare Diseases.

This report has been partly reviewed and partly endorsed by EURORDIS.

For more information about EURORDIS, visit www.eurordis.org



MediClara is an independent company, based in The Netherlands, which contributes to the improvement of healthcare by accompanying healthcare professionals on specific tasks.

MediClara developed and implemented a Folic Acid education programme for community pharmacies in The Netherlands to prevent NTDs. MediClara has recently taken the lead in the organisation and fundraising of a large Folic Acid-trial (5000 women to be included in the preconception period) in The Netherlands, that started in 2011. MediClara's clients include individual care givers, academic research centres, vocational training centres for GP's, pharmaceutical companies, the Dutch Ministry of Health, and national organisations of healthcare providers.

This report has been sponsored, drafted, reviewed and endorsed by MediClara.

For more information about MediClara, visit www.mediclara.nl

Endnotes

1. Report available on the European Commission website: http://ec.europa.eu/health/rare_diseases/policy/index_en.htm
2. Ray: BJOG: An international Journal of Obstetrics and Gynaecology May 2004, Vol 111 pp 399-408
3. Prevention of Neural Tube Defects: Results of the Medical Research Council Vitamin Study. MRC Vitamin Study Research Group. Lancet 1991; 338(8760):131-7
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5. "Prevention of Neural Tube Defects by Periconceptional Folic Acid Supplementation in Europe" EUROCAT (Updated 2009) <http://www.eurocat-network.eu/PREVENTIONAndRISKFACTORS/FolicAcid/FolicAcidSpecialReports>
6. Figures provided by EUROCAT in February 2011
7. Preventing neural tube defects, a WHO Standard in Maternal and Neonatal Care, 2002 http://www.who.int/making_pregnancy_safer/publications/Standards1.5N.pdf
8. European Commission Communication on Rare Diseases: Europe's Challenges (COM(2008) 679), November 2008: http://ec.europa.eu/health/ph_threats/non_com/docs/rare_com_en.pdf
9. Busby A, Armstrong B, Dolk H et al, Preventing Neural Tube Defects in Europe: A Missed Opportunity, Reproductive Toxicology, Vol 20, No 3, pp 393-402, (2005)
10. 2010 online questionnaire on NTDs. For more information about the methodology of the questionnaire please check online at: www.ifglobal.org/ntdreport
11. Inskip, H, Crozier, et al (2009), Women's compliance with nutrition and lifestyle recommendations before pregnancy: general population cohort study, BMJ 2009; 338:b481
12. EUROCAT is the European network of population-based registries for the epidemiologic surveillance of congenital anomalies: www.eurocat-network.eu
13. European Commission website, Rare Diseases, 2011: http://ec.europa.eu/health/rare_diseases/national_plans/detailed/index_en.htm





We are not all born equal in Europe: Why do health inequalities start before birth?

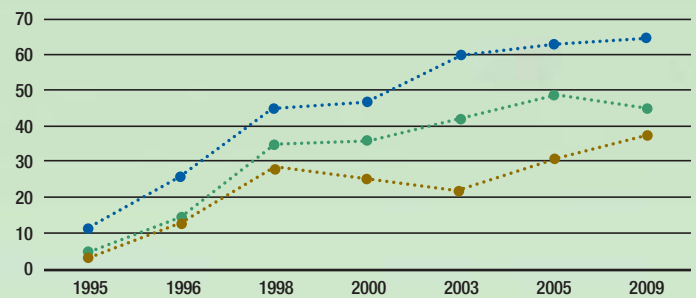
“There is evidence that women of higher social status are more likely to know the benefits of taking supplemental folic acid and to be aware of the correct timing, potentially leading to a widening of socio-economic inequalities prevalence”

EUROCAT special report: Prevention of Neural Tube Defects by Periconceptional Folic Acid Supplementation in Europe, December 2009¹

- Research indicates that up to 70% of pregnancies affected by NTDs can be avoided by adequate folate levels².
- In many countries, fewer than 50% of women take periconceptional folic acid supplements³.
- Evidence suggests that NTD affected pregnancies occur in particular in younger women and women from disadvantaged backgrounds³.

Graph 01

Folic acid use in advised period in The Netherlands, according to education



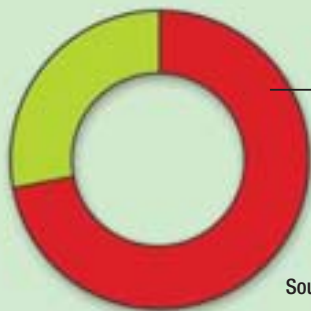
Source: de Walle HE, de Jong-van den Berg LT. Ten years after the Dutch public health campaign on folic acid: the continuing challenge. Eur J Clin Pharmacol 2008; 64(5):539-543. Ref ID: 1804 (updated with data of the 2009 survey)

..... high educated (%) middle educated (%) low educated (%)

Graph 02

8 out of 11 countries responded that in the last 20 years there was an increase of women from disadvantaged backgrounds conceiving children with Spina Bifida

Compared to 20 years ago, has the demographic of women conceiving children with Spina Bifida changed?



73%
of respondents said the number of women from disadvantaged backgrounds conceiving children with Spina Bifida has increased in the last 20 years

Source: 2010 online questionnaire on NTDs⁴

- This idea is reinforced by the findings of the 2010 online questionnaire on NTDs⁴ where 73% of the respondents to the question on the socio-economic background of women conceiving children with Spina Bifida, indicated that **more of these women came from disadvantaged backgrounds.**

Women of childbearing age, and in particular younger women and women of disadvantaged backgrounds, are not getting the right advice about NTD prevention at the right time, i.e. prior to conception

- Neural Tube Defects (NTDs), such as Spina Bifida, are birth defects which occur when the neural tube fails to close within 28 days into pregnancy and which result in severe malformations.
- The occurrence of NTDs is linked to women's folate levels before conception and in early pregnancy.
- Research indicates that up to 70% of pregnancies affected by NTDs can be avoided by adequate folate levels². To date, folate levels in women of childbearing age can be raised via three methods: natural folate intake through a healthy diet, folic acid supplements to increase folate levels and food fortification with folic acid.
- According to the WHO women should ensure a daily intake of 0.4mg of folic acid at least 2 months prior to conception and 12 weeks

into their pregnancy in order to reduce the risk of NTD affected pregnancies⁵.

- Evidence suggests that NTD affected pregnancies occur more often in younger women and women from disadvantaged backgrounds³, who are less likely to have adequate folate levels.
- According to EUROCAT, NTD prevalence in Europe has not decreased significantly in the UK and in Continental Europe (except in Southern Europe and Northern Netherlands) between 1992-2007¹.
- In Europe, there are still geographical health inequalities in terms of prevalence and care of NTDs⁴.
 - In some countries, like Romania, governments do not reimburse elements of the operations needed for the lifesaving treatment of children with Spina Bifida⁴.

We need political willingness to ensure that Europeans are born equal in terms of access to information on prevention, access to treatment and care of NTDs and a commitment to monitor NTD prevalence in Europe

Health inequalities before birth leading to a NTD affected pregnancy can be partly explained by:

- In many countries, up to 50% of pregnancies are estimated to be unplanned⁶ and women are therefore not able to ensure they have the necessary folate levels in advance of conception.
- Limited access to proper and systematic preconception care.
- Lack of compliance by women with the recommendations on periconceptional folic acid to prevent NTDs⁷.
- Little awareness by women of childbearing age, in particular among younger women and women of disadvantaged backgrounds, about preventive measures of NTDs before conception and in early pregnancy.

Snapshot Interview

Ms Edite Estrela
Member of the European Parliament



In 2010, the European Union proposed to tackle health inequalities. The Member of the European Parliament responsible for the dossier, Ms Edite Estrela, speaks about her report on health inequalities and how it relates to NTD prevention.

Do you think health inequalities start before birth in the EU?

E.E. — Yes, looking at the data I agree that health inequalities start before birth in the EU. This is clear when looking specifically at congenital defects such as NTDs, where the mother's health and her levels of folate before conception are a crucial factor for preventing a NTD affected pregnancy. Evidence suggests that women from disadvantaged backgrounds are more susceptible to having lower levels of folate and are hence more likely to have a NTD affected pregnancy.

What is the EU's added value in terms of addressing health inequalities?

E.E. — As mentioned in my report, health inequalities will not be overcome without a common and overall strategy. In this sense the EU has a key role to play to ensure that the 'health in all policies' principle is implemented to reduce health inequalities.

More specifically, what can the EU do to reduce the incidence of NTDs?

E.E. — The EU can support NTD prevention in 4 concrete ways:

1. Ensure that national recommendations on folic acid intake to prevent NTDs are developed and implemented according to the WHO standard;
2. Improve NTD surveillance systems and the collection of comparable data across the region;
3. Ensure that NTD prevention by raising women's folate levels is promoted across health-related policies;
4. Ensure that national governments raise awareness on NTD prevention among women of childbearing age.

Endnotes

1. EUROCAT, Prevention of Neural Tube Defects by Periconceptional Folic Acid Supplementation in Europe, Updated December 2009: <http://www.eurocat-network.eu/content/Special-Report-NTD-3rdEd-Part-I.pdf>
2. Prevention of Neural Tube Defects: Results of the Medical Research Council Vitamin Study. MRC Vitamin Study Research Group. *Lancet* 1991; 338(8760):131-7
3. Ray: *BJOG: an International Journal of Obstetrics and Gynaecology* May 2004, Vol. 111, pp. 399-408
4. 2010 online questionnaire on NTDs. For more information about the methodology of the questionnaire please check online at : www.ifglobal.org/ntdreport
5. Preventing neural tube defects, a WHO Standard in Maternal and Neonatal Care, 2002 http://www.who.int/making_pregnancy_safer/publications/Standards1.5N.pdf
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7. Inskip, H, Crozier, et al (2009) ,Women's compliance with nutrition and lifestyle recommendations before pregnancy: general population cohort study, *BMJ* 2009; 338:b481

For more information about the methodology, sponsors and partners of the report 'Act against Europe's most common birth defects: one year on. Defining Neural Tube Defect prevention strategies in Europe', please visit our website at : www.ifglobal.org/ntdreport



Prevalence of Neural Tube Defects in Europe

The European Surveillance of Congenital Anomalies (EUROCAT) is a network of population-based registries of congenital anomaly covering 1.7 million births per year, including 31% of births in the European Union. EUROCAT is funded as a Joint Action of the EU and Member States through the DG Sanco Public Health Programme.

EUROCAT has registered the following figures regarding Neural Tube Defects (NTDs):

- The total prevalence of NTDs in Europe, between 2004 and 2008, was 0.96 per 1,000 births.
- The live birth prevalence in Europe, between 2004 and 2008, was 0.24 per 1,000 births.
- The discrepancy between live birth prevalence and total NTD prevalence is mainly explained by terminations of NTD affected pregnancies following prenatal diagnosis.
- Over 4,500 pregnancies are affected by a NTD every year in Europe. Between 2004 and 2008 recorded data¹ shows that an estimated 72% of these pregnancies were terminated following prenatal diagnosis.
- Within all NTDs the total prevalence for Spina Bifida in Europe, looking at data from 2004 to 2008, was 0.5 per 1,000 births. The live birth prevalence for Spina Bifida in the same period was 0.19 per 1,000 births.

Table 01

Prevalence of Neural Tube Defects² (per 1,000 births) in European countries³ 2004-2008: EUROCAT data

Anomaly registry	Year range	Live birth prevalence* per 1,000 births	Total prevalence** per 1,000 births
Austria (1 region)	2004 - 2008	0.41	0.97
Belgium (2 regions)	2004 - 2008	0.24	0.92
Czech Republic (entire country)	2004 - 2007	0.18	0.85
Denmark (1 region)	2004 - 2008	0.11	1.01
Finland (entire country)	2004 - 2006	0.23	0.85
France (3 regions)	2004 - 2008	0.20	1.46
Germany (2 regions)	2004 - 2008	0.40	1.01
Ireland (3 regions)	2004 - 2008	0.58	0.76
Italy (4 regions)	2004 - 2008	0.09	0.59
Malta (entire country)	2004 - 2008	0.96	1.11
The Netherlands (1 region)	2004 - 2008	0.29	0.73
Norway (entire country)	2004 - 2006	0.32	1.04
Poland (1 region)	2004 - 2008	0.86	0.93
Portugal (1 region)	2004 - 2008	0.14	0.20
Spain (3 regions)	2004 - 2008	0.08	1.00
Sweden (entire country)	2007 - 2008	0.24	0.97
Switzerland (1 region)	2004 - 2008	0.16	1.30
United Kingdom (7 regions)	2004 - 2008	0.19	1.19
Total (all member registries)	2004 - 2008	0.24	0.96

Data accessed at <http://www.eurocat-network.eu/ACCESSPREVALENCEDATA/PrevalenceTables> (05-01-2011)

* Live birth prevalence = live born cases only

** Total prevalence = all cases affected by NTD (live births, still births and foetal deaths from 20 weeks gestation, and terminations of pregnancy (any gestational age) following prenatal diagnosis)

What does EUROCAT monitor about NTDs and why?

- Birth defects registries are vital to monitor the impact of strategies to raise folic acid status of women periconceptionally in order to prevent NTDs.
- Every few years, EUROCAT updates the EUROCAT Special Report on Prevention of Neural Tube Defects by folic acid. The latest edition (2009) includes a policy survey of European countries, and detailed presentation of prevalence data for each country (see <http://www.eurocat-network.eu/PREVENTIONAndRISKFACTORS/FolicAcid/FolicAcidSpecialReports>).
- Total prevalence of NTDs includes live births with a NTD, stillbirths and foetal deaths from 20 weeks gestation with a NTD, and Termination of Pregnancy for Foetal Anomaly (TOPFA) following prenatal diagnosis. The total prevalence measure is used to track progress in primary prevention.
- The live birth prevalence measure includes only live births. The live birth measure is used to inform EU Member States regarding the need to provide high quality health and other services for children living with a NTD and their families.

What does the EUROCAT data on NTDs tell us?

- Countries vary in total prevalence (see Table 01).
- As EUROCAT's Special Reports show, there has been **no real progress in preventing NTDs in Europe** for the fifteen years since an MRC randomised trial of periconceptional folic acid supplementation showed this to be an effective preventive measure. Instead, **NTD prevalence has remained relatively stable**.
- Only very recently do we see a decline in prevalence in some countries. This needs to be monitored further to see if the decline will be sustained. It is part of EUROCAT's mission to bring these problems within health policy and its implementation to the attention of the Member States.
- The majority of NTD affected pregnancies in Europe are terminated following prenatal diagnosis, except in some countries¹.
- Low total prevalence rates of NTD may indicate
 1. Better folic acid/vitamin status through supplementation and/or voluntary food fortification and diet;
 2. A lesser genetic predisposition for NTD;
 3. Incomplete data⁴.

“Member States should ensure that their registries are adequately resourced and supported to produce high quality data.”

About EUROCAT

- **A European network of population-based registries** for the epidemiologic surveillance of congenital anomalies. Started in 1979.
- **More than 1.7 million births surveyed per year in Europe**. 41 registries in 21 countries. 31% of EU birth population covered.
- **High quality multiple source registries**, ascertaining terminations of pregnancy as well as births.
- **Member registries send anonymised individual case data** (full members) or summary data (associate members) to the EUROCAT Central Registry database.
- **WHO Collaborating Centre** for the Epidemiological Surveillance of Congenital Anomalies
- **All EUROCAT publications on NTDs are available at** [http://www.eurocat-network.eu/ABOUTUS/Publications/Collaborative\(BySubject\)/NeuralTubeDefects](http://www.eurocat-network.eu/ABOUTUS/Publications/Collaborative(BySubject)/NeuralTubeDefects)

Endnotes

1. In Ireland and Malta, termination of pregnancy for foetal anomaly is illegal, and in Poland it is not practiced.
2. Including Anencephaly, Spina Bifida and Encephalocele. Prevalence data for all Neural Tube Defects (or Anencephaly, Spina Bifida or Encephalocele separately) can be found on the EUROCAT website, updated each year (<http://www.eurocat-network.eu/ACCESSPREVALENCE/PrevalenceTables>). This table is an extract; the data was accessed on 5 January 2011.
3. Regions included in the table are full member registries and associate member registries in countries where there are no full member registries. For regions covered in each EUROCAT country see: <http://www.eurocat-network.eu/ABOUTUS/MemberRegistries/CoverageofEuropeanPopulation/PopulationTable>
4. Data quality indicators are available at <http://www.eurocat-network.eu/ABOUTUS/DataCollection/DataQuality/DataQualityIndicators>

This factsheet was independently developed by EUROCAT as an insert to the report 'Act against Europe's most common birth defects: one year on. Defining Neural Tube Defect prevention strategies in Europe'. You can find the entire report at www.ifglobal.org/ntdreport



Lack of systematic preconception care is a barrier to the prevention of Neural Tube Defects in the EU

“All women, from the moment they begin trying to conceive until 12 weeks of gestation, should take a folic acid supplement. Women who have had a fetus diagnosed as affected by a neural tube defect (NTD) or have given birth to a baby with NTD should receive information on the risk of recurrence, be advised on the protective effect of periconceptional¹ folate supplementation and be offered high-dose supplementation.”

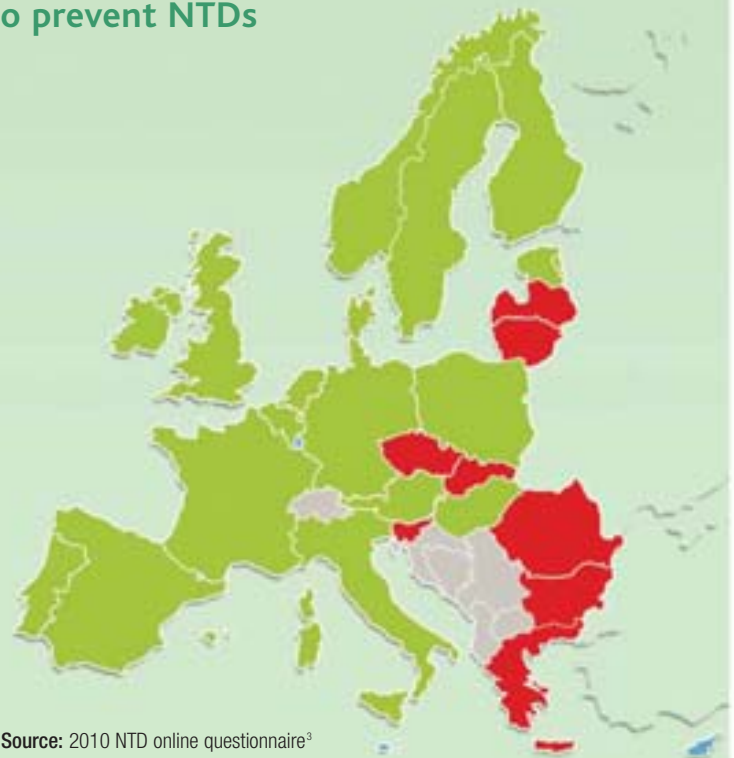
WHO, 2002²

- At least 8 countries³ in the EU have no formal recommendation or guidance on periconceptional folate intake to reduce the risk of Neural Tube Defects.
- No EU country has national or local guidance that is completely consistent with the WHO Standard on NTD prevention.
- 16 out of 17 countries give advice that clearly reflects the need for folate before conception. To ensure a protective level is reached in time, the WHO Standard recommends starting supplementation 2 months before the planned pregnancy.

- Yes
- No
- Non Applicable
- Non EU

Graph 01

Only 17 of the 25 European countries surveyed currently have recommendations on periconceptional folic acid supplementation to prevent NTDs



Source: 2010 NTD online questionnaire³

Table 01

Implementation of preconception care advice is a barrier to reducing NTDs in Europe

Is there systematic preconceptional care in your country that includes recommendations on folate intake?

Austria	•	Estonia	•	Ireland	•	The Netherlands	•	Slovenia	•
Belgium	•	Finland	•	Italy	•	Norway	•	Spain	•
Bulgaria	•	France	•	Latvia	•	Poland	•	Sweden	•
Cyprus	•	Germany	•	Lithuania	•	Portugal	•	United Kingdom	•
Czech Republic	•	Greece	•	Luxembourg	•	Romania	•		
Denmark	•	Hungary	•	Malta	•	Slovakia	•		

Source: 2010 NTD online questionnaire³

- The majority of women surveyed for the 2009 EUROCAT report on periconceptional folic acid supplementation are still not taking folic acid supplements at the right time. Only in The Netherlands and Denmark is the periconceptional use of folic acid above 30%, other countries are not reaching 10%⁴.
- For Europe, in many countries up to 50% of pregnancies are unplanned⁴ and even for women planning their pregnancy

the timing of supplementation advice is crucial. All countries in Europe need to implement systematic preconception care to prevent NTDs: ensuring that all women get the right advice about supplementing their folate levels before they think about pregnancy.

Women of childbearing age are not getting the right advice about NTD prevention at the right time, i.e. prior to conception

- Neural Tube Defects (NTDs), such as Spina Bifida, are birth defects which occur when the neural tube fails to close within 28 days into pregnancy and which result in severe malformations.
- Research indicates that up to 70% of NTDs can be avoided by adequate folate levels⁵. To date, folate levels in women of childbearing age can be raised via three methods: natural folate intake through a healthy diet, folic acid supplements to increase folate levels and food fortification with folic acid.
- The WHO Standard on Prevention of Neural Tube Defects² states that all women should be advised to take a dose of 0.4mg folic acid daily, starting 2 months before the pregnancy and for the first 12 weeks following conception. The dose should be 4mg daily for women at high risk of a NTD affected pregnancy.
- Prevalence of NTDs remains high in Europe with more than 4,500⁴ pregnancies affected each year and in particular in younger women and women from disadvantaged backgrounds⁶. Four interlinked reasons may explain why prevalence remains so high in Europe:
 1. In many countries, up to 50% of pregnancies are estimated to be unplanned⁴ and women are therefore not able to ensure they have the necessary folate levels in advance of conception.
 2. Little awareness among women of childbearing age, about preventive measures of NTDs before conception and in early pregnancy.
 3. Lack of compliance by women with the recommendations on folic acid to prevent NTDs .
 4. Limited access to proper and systematic preconception care⁷.

Governments across Europe should implement the WHO standard on prevention of NTDs and systematically ensure that all women, whether they are planning a pregnancy or not, receive preconception care

In order to improve systematic implementation of the right advice at the right time, European governments should take the following steps in line with the WHO standard:

- Adopt or update national and local recommendations on periconceptional folic acid supplementation and preconception care guidance for the prevention of NTDs.
- Improve the knowledge regarding compliance with recommendations on periconceptional folic acid supplementation (e.g. record the treatment given on the maternity card).
- Raise awareness among all women of childbearing age as to the importance of adequate folate levels prior to conception. This should be done through healthcare professionals, but also in the wider media to reach the general public as well as in school education.
- Promote and monitor compliance with these recommendations, as part of a systematic preconception care system for all women of childbearing age.

Snapshot Interview

Zoe Burnay

Creative Partner, Grace Blue, Executive search company, mother of three children: not having planned the pregnancy her youngest daughter Hattie was born with Spina Bifida



You have three children. Were you aware of the existence of Spina Bifida before conceiving?

Z.B. — I was aware of a condition called Spina Bifida but didn't know what it was. Although I did not seek advice from healthcare professionals, I was aware that folic acid reduced chances of conceiving a baby with

Spina Bifida from the books I read when planning pregnancy. But my third pregnancy was unplanned and Hattie was born with Spina Bifida.

As many pregnancies in Europe are unplanned what is your advice to reduce the risk of a NTD affected unplanned pregnancy?

Z.B. — As my third pregnancy was unplanned I was not taking folic acid supplementation. I have many friends with children whose pregnancies were unplanned too, so I would recommend that governments promote folic acid use to all women of childbearing age, whether they are planning a family or not!

Endnotes

1. WHO definition of periconceptional: "Before pregnancy and in the first three months of pregnancy."
2. Preventing neural tube defects, a WHO Standard in Maternal and Neonatal Care, 2002 http://www.who.int/making_pregnancy_safer/publications/Standards1.5N.pdf
3. 2010 online questionnaire on NTDs. For more information about the methodology of the questionnaire please check online at: www.ifglobal.org/ntdreport
4. Busby A, Armstrong B, Dolk H et al, Preventing Neural Tube Defects in Europe: A Missed Opportunity, Reproductive Toxicology, Vol 20, No 3, pp 393-402, (2005)
5. Prevention of Neural Tube Defects: Results of the Medical Research Council Vitamin Study. MRC Vitamin Study Research Group. Lancet 1991; 338(8760):131-7
6. Ray: BJOG: an International Journal of Obstetrics and Gynaecology May 2004, Vol. 111, pp. 399-408
7. Inskip, H, Crozier, et al (2009), Women's compliance with nutrition and lifestyle recommendations before pregnancy: general population cohort study, BMJ 2009; 338:b481

For more information about the methodology, sponsors and partners of the report 'Act against Europe's most common birth defects: one year on. Defining Neural Tube Defect prevention strategies in Europe', please visit our website at: www.ifglobal.org/ntdreport





Terminating pregnancies is not prevention of Neural Tube Defects

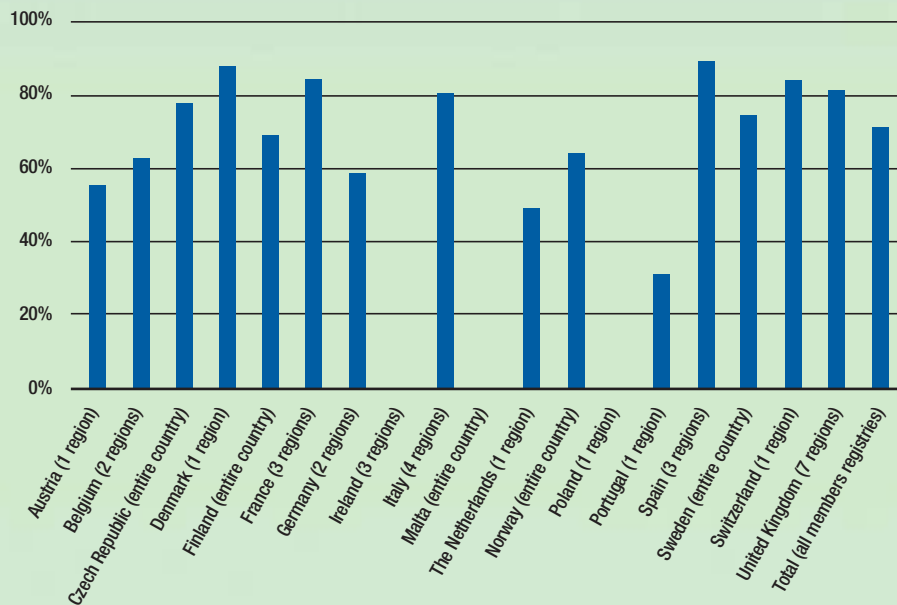
With adequate maternal folate levels the same child may be born without a disability

“The potential for preventing NTDs by periconceptional folic acid supplementation is still far from being fulfilled in Europe. In order to achieve a reduction in NTD prevalence, new efforts are needed in all countries to implement a combined strategy to increase folate status by dietary means, increase uptake of folic acid supplements periconceptionally, and to increase availability and identification of fortified foods.”

EUROCAT, 2009¹

Graph 01

Proportion² of Neural Tube Defect³ cases resulting in termination of pregnancy in European countries⁴ (2004-2008: EUROCAT data)



- **72% of Neural Tube Defect (NTD) affected pregnancies are terminated in Europe following prenatal diagnosis of a NTD in the regions covered by EUROCAT.** With more than 4,500 pregnancies affected by a NTD each year in Europe¹, this percentage represents at least **3,240 terminations a year**. Note, in some countries covered by EUROCAT terminations are not legal.
- All too often prenatal diagnosis is wrongly mentioned as a preventative measure of NTDs in government policies. **Diagnosis and termination of pregnancy is NOT prevention.**
- The reduced incidence of newborns with Spina Bifida in Europe is

caused by termination of NTD affected pregnancies and not by primary prevention, such as measures to raise the folate levels of women of childbearing age.

- **Primary prevention is the only way to reduce the occurrence of NTDs, lower the burden on families and society, and decrease infant and child mortality. Up to 70% of NTDs can be prevented by increasing folate levels in women of childbearing age before conception and in early pregnancy².**

Women of childbearing age are not getting the right advice about NTD prevention at the right time, i.e. prior to conception

- Neural Tube Defects (NTDs), such as Spina Bifida, are birth defects which occur when the neural tube fails to close within 28 days into pregnancy and which result in severe malformations.
- Primary prevention is possible. Research indicates that up to 70% of NTDs can be avoided by adequate folate levels⁵. To date, folate levels in women of childbearing age can be raised via three methods: natural folate intake through a healthy diet, folic acid supplements to increase folate levels and food fortification with folic acid.
- According to the WHO women should ensure a daily intake of 0.4mg of folic acid at least 2 months prior to conception and 12 weeks into their pregnancy in order to reduce the risk of NTD affected pregnancies⁶.
- Prevalence of NTDs remains high in Europe with more than 4,500¹ pregnancies affected each year and in particular in younger women and women from disadvantaged backgrounds⁷.

Four interlinked reasons may explain why prevalence remains so high in Europe:

1. In many countries, up to 50% of pregnancies are estimated to be unplanned⁸ and women are therefore not able to ensure they have the necessary folate levels in advance of conception.
2. Little awareness among women of childbearing age, in particular among younger women and women of disadvantaged backgrounds⁷ about preventive measures of NTDs before conception and in early pregnancy.
3. Lack of compliance with the recommendations on periconceptional folic acid to prevent NTDs⁹.
4. Limited access to proper and systematic preconception care¹⁰.

Governments need to recognise that termination of a NTD affected pregnancy following prenatal diagnosis is not prevention and instead ensure the implementation of primary prevention measures such as the recommendations on folate levels of women of childbearing age

- Like Down syndrome or a cleft palate, Spina Bifida can be detected in-utero through ultrasound prenatal diagnosis. This is now available and increasingly routine in most EU countries.
- Most of the time, expecting parents will agree to an ultrasound examination without realising that the results could put them in a difficult situation of unexpected decision-making. Upon diagnosis of a NTD, parents must choose between continuing the pregnancy, termination of the pregnancy, or performance of prenatal foetal surgery, where this is possible. The psychological burden of such a decision is huge.
- Although the life prospects for a newborn with Spina Bifida have never been as good as they are today, the prenatal advice given to parents is too often still based on outdated medical information and negative stereotypes regarding disability. This results in up to 90% of parents opting to terminate the NTD affected pregnancy in consultation with their doctor.



Alexandra Ekerow at 8 years of age
After timely and correct surgery and with the appropriate care, she now walks and cycles.

“One of the major findings of this study is that life satisfaction of young adults born with Spina Bifida (SB) is more or less similar to that of their typically developing peers, and that severity of SB has only a minor impact on life satisfaction.”

Barf HA et al “Life satisfaction of young adults with Spina Bifida”
Developmental Medicine & Child Neurology 2007 Jun;49(6):458-63

Endnotes

1. EUROCAT, *Prevention of Neural Tube Defects by Periconceptional Folic Acid Supplementation in Europe*, Updated December 2009: <http://www.eurocat-network.eu/content/Special-Report-NTD-3rdEd-Part-1.pdf>
2. Proportion means the number of cases of termination of NTD affected pregnancies as a percentage of all NTD cases (live born or stillborn/fetal death from 20 weeks gestation or Termination of Pregnancy for Fetal Anomaly following prenatal diagnosis -TOPFA).
3. All NTD cases, the data includes Anencephaly, Spina Bifida and Encephalocele. For more information see ‘Facts and Figures on Preventing NTDs’. Note that the proportion of cases prenatally diagnosed for anencephaly and Spina Bifida (regardless of pregnancy outcome) can be found at: <http://www.eurocat-network.eu/PRENATALSCREENINGAndDIAGNOSIS/PrenatalDetectionRates>
4. All NTD cases, the data includes Anencephaly, Spina Bifida and Encephalocele. For more information see ‘Facts and Figures on Preventing NTDs’. Note that the proportion of cases prenatally diagnosed for anencephaly and Spina Bifida (regardless of pregnancy outcome) can be found at: <http://www.eurocat-network.eu/PRENATALSCREENINGAndDIAGNOSIS/PrenatalDetectionRates>
5. *Prevention of Neural Tube Defects: Results of the Medical Research Council Vitamin Study*. MRC Vitamin Study Research Group. *Lancet* 1991; 338(8760):131-7
6. *Preventing neural tube defects, a WHO Standard in Maternal and Neonatal Care*, 2002 http://www.who.int/making_pregnancy_safer/publications/Standards1.5N.pdf
7. Ray: *BJOG: An International Journal of Obstetrics and Gynaecology* May 2004, Vol 111 pp 399-408
8. Busby A, Armstrong B, Dolk H et al, *Preventing Neural Tube Defects in Europe: A Missed Opportunity*, *Reproductive Toxicology*, Vol 20, No 3, pp 393-402, (2005)
9. Inskip, H, Crozier, et al (2009) ‘Women’s compliance with nutrition and lifestyle recommendations before pregnancy: general population cohort study’, *BMJ* 2009; 338:b481
10. 2010 online questionnaire on NTDs. For more information about the methodology of the questionnaire please check online at: www.ifglobal.org/intdreport

For more information about the methodology, sponsors and partners of the report ‘Act against Europe’s most common birth defects: one year on. Defining Neural Tube Defect prevention strategies in Europe’, please visit our website at: www.ifglobal.org/intdreport





Primary prevention of Neural Tube Defects requires higher priority in the EU health debate and national Action Plans for Rare Diseases!

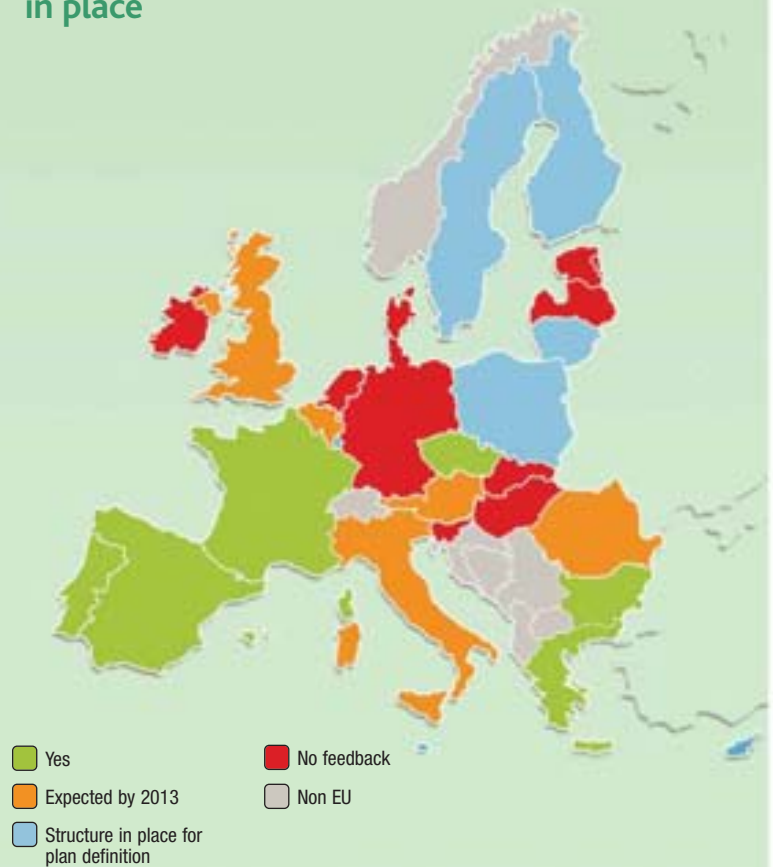
“There are very few rare diseases for which a primary prevention is possible. Still, primary preventive measures for rare diseases will be taken when possible (e.g. prevention of neural tube defects by Folic Acid supplementation). Action in this field should be the topic for a debate at EU level led by the Commission aiming to determine for which rare diseases primary preventive measures may be successful.”

European Commission, 2008¹

- As of end 2010, only **6 countries have a National Action Plan for Rare Diseases** in place: Bulgaria, Czech Republic, France, Greece, Portugal and Spain².
- According to the EU Recommendation on an Action in the field of Rare Diseases adopted in June 2009³, all EU Member States are expected to have adopted a national plan for rare diseases by the end of 2013. This Recommendation is articulated with the Commission Communication on Rare Diseases: Europe’s Challenges¹ which recommends action in the field of prevention of rare diseases.
- As of 2011, progress is ongoing in most Member States with the supportive actions of the EU Committee of Experts on Rare Diseases (EUCERD) and the EuroPlan Project.

Graph 01

Only 6 countries of the EU-27 have a national Action Plan for Rare Diseases in place



Source: European Commission website² and 2010 NTD online questionnaire¹⁵

Table 01

National Action Plans for Rare Diseases generally do not include measures on primary prevention of NTDs

Bulgaria	●	Portugal	●
Czech Republic	●	Spain	●
France	●		
Greece	●		
		● Yes	
		● No	

Source: European Commission² website and 2010 NTD online questionnaire¹⁵

- Of the 6 countries that have a national Action Plan in place, **5 do not include provisions on primary prevention of Neural Tube Defects (NTDs)**. Spain⁴ is the exception and although Bulgaria⁵ refers to NTDs in its national plan, it focuses on prenatal screening and medical trainings only.
- Similarly France⁶ and Poland⁷ highlighted that to some extent provisions on NTD prevention are included in other national health plans. As for Hungary, the increase of folate intake to prevent NTDs is mentioned in the 2010 work plan of the Hungarian Centre for Rare Diseases⁸.

Women of childbearing age are not getting the right advice about NTD prevention at the right time, i.e. prior to conception

- Neural Tube Defects (NTDs), such as Spina Bifida, are birth defects which occur when the neural tube fails to close within 28 days into pregnancy and which result in severe malformations.
- Research indicates that up to 70% of cases can be avoided by adequate folate levels⁹. To date, folate levels in women of childbearing age can be raised via three methods: natural folate intake through a healthy diet, folic acid supplements to increase folate levels and food fortification with folic acid.
- According to the WHO women should ensure a daily intake of 0.4mg of folic acid at least 2 months prior to conception and 12 weeks into their pregnancy in order to reduce the risk of NTD affected pregnancies¹⁰.
- Prevalence of NTDs remains high in Europe with more than 4,500¹¹ pregnancies affected each year and in particular in younger women

and women from disadvantaged backgrounds¹². Four interlinked reasons may explain this:

1. In many countries, up to 50% of pregnancies are estimated to be unplanned¹³ and women are therefore not able to ensure they have the necessary folate levels in advance of conception.
2. Little awareness by women of childbearing age, in particular by women of disadvantaged backgrounds¹² about preventive measures of NTDs before conception and in early pregnancy.
3. Lack of compliance by women with the recommendations on folic acid to prevent NTDs¹⁴.
4. Limited access to proper and systematic preconception care that includes recommendations on adequate folate levels to prevent NTDs¹⁵.

As one of the few preventable rare diseases, National Governments and EU policy makers should ensure that provisions on primary prevention of NTDs are included in Rare Diseases policies

As requested by the EU, the development of national Action Plans for Rare Diseases provides a unique opportunity for governments to make a difference or contribute to reducing their national NTD prevalence if they include measures to:

- Adopt national recommendations on folate supplementation for the prevention of NTDs or update existing preconception medical care

guidance and recommendations when necessary to reflect the importance of reaching adequate folate levels before conception.

- Raise awareness with women of childbearing age on folate supplementation recommendations.
- Promote compliance with the recommendations on folate intake before pregnancy.

Snapshot Interview

Yann Le Cam
Chief Executive Officer of Rare Diseases Europe (EURORDIS[®]), the European non-governmental patient-driven alliance of patient organisations and individuals active in the field of rare diseases



Why is prevention of NTDs important for EURORDIS?

Y.L.C. — Today, there is a lack of awareness of all stakeholders and policy makers that some rare diseases may be prevented by adequate public health primary prevention measures. These measures are simple to implement and affordable. It is unethical

not to take adequate measures when they are known and possible.

Would EURORDIS support the inclusion of provisions on primary prevention of NTDs in national Action Plans for Rare Diseases and how could this be achieved?

Y.L.C. — EURORDIS is already doing so. We are promoting this debate, supporting public

policy action (e.g. EuroPlan guiding documents) and disseminating information. We will continue to do so in the EU Committee of Experts on Rare Diseases (EUCERD) future recommendations and in 2012 and 2013. To this end, EURORDIS now includes prevention in its patient advocates capacity building sessions and in its European Conferences on Rare Diseases and Orphan Products.

Endnotes

1. European Commission Communication on Rare Diseases: Europe's Challenges (COM(2008) 679), November 2008
2. European Commission website, Rare Diseases, 2011: http://ec.europa.eu/health/rare_diseases/national_plans/detailed/index_en.htm
3. Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02)
4. Spanish Ministry of Health, Spanish national Action Plan for Rare Diseases, 2009
5. Bulgarian national Action Plan for Rare Diseases, 2009
6. French Ministry of Health, Second national health nutrition programme: actions and measures 2006-2010, 2006
7. Programme for complex diagnostics and intrauterine therapy in the prevention of the consequences and complications of developmental defects and fetal diseases – as an element of improving fetal and newborn health for 2009-2013 – parts A and B., 2008
8. Dr. Brunner Péter et al, Hungarian Rare Diseases Centre 2010 work plan, 2009
9. Prevention of Neural Tube Defects: Results of the Medical Research Council Vitamin Study. MRC Vitamin Study Research Group. *Lancet* 1991; 338(8760):131-7
10. Preventing neural tube defects, a WHO Standard in Maternal and Neonatal Care, 2002 http://www.who.int/making_pregnancy_safer/publications/Standards_1.5N.pdf
11. Prevention of Neural Tube Defects by Periconceptional Folic Acid Supplementation in Europe[®] EUROCAT (Updated 2009) <http://www.eurocat-network.eu/PREVENTIONAndRISKFACTORS/FolicAcid/FolicAcidSpecialReports>
12. Ray: BJOG: an International Journal of Obstetrics and Gynaecology May 2004, Vol. 111, pp. 399–408
13. Busby A, Armstrong B, Dolk H et al, Preventing Neural Tube Defects in Europe: A Missed Opportunity, *Reproductive Toxicology*, Vol 20, No 3, pp 393-402, (2005)
14. Inskip, H, Crozier, et al (2009), Women's compliance with nutrition and lifestyle recommendations before pregnancy: general population cohort study, *BMJ* 2009; 338:b481
15. 2010 online questionnaire on NTDs. For more information about the methodology of the questionnaire please check online at: www.ifglobal.org/ntdreport
16. EURORDIS, section on Rare Diseases policy: <http://www.eurordis.org/eu-rare-disease-policy>

For more information about the methodology, sponsors and partners of the report 'Act against Europe's most common birth defects: one year on. Defining Neural Tube Defect prevention strategies in Europe', please visit our website at: www.ifglobal.org/ntdreport





Given the right circumstances, people with Spina Bifida and Hydrocephalus can live fulfilling, independent lives equal to others. They wish people would look beyond their medical condition

“The more opportunities people with Spina Bifida are given, the more self-confidence they develop, so that they are able to overcome most of their problems and lead a meaningful life. The treatment and care of children and adults with Spina Bifida has made tremendous progress. Consequently, the quality of life of people with Spina Bifida and Hydrocephalus also has improved considerably.”

Pierre Mertens, President International Federation for Spina Bifida and Hydrocephalus (IF)



“Parents and adults state that the impairment is not the burden. The burden is the constant struggle against inaccessible environments and inadequate systems, which should be their allies and should be supportive of them.”

IF Resolution on Prenatal Diagnosis and the Right to be Different, September 2000¹⁰

- Spina Bifida cannot be cured, but thanks to timely medical interventions many people with Spina Bifida live into old age and have a good quality of life. However, long-term care is often necessary and lifelong follow-up is required.
- Timely and correct multidisciplinary treatment and an inclusive society are crucial for the quality of life of people living with Spina Bifida and Hydrocephalus.
- Providing and sharing the right knowledge is the first step towards limiting the effects of Spina Bifida. It ensures that people with these impairments are full partners in decision making and that carers, healthcare professionals and people living with Spina Bifida have access to the latest information.
- Information sharing and awareness also helps to prevent negative stereotypes about disabilities being applied to people with Spina Bifida and Hydrocephalus, creating a more accessible environment.
- Although people living with Spina Bifida face medical and social challenges, their opportunities are endless: when treated correctly, children with Spina Bifida and Hydrocephalus can go to school, get an education, perform a job, live independently and as adults contribute to society in the same way as any other person.



Heidi Rahm,
41 years old, graduated in Philosophy and Journalism, married and mother of two children, living with Spina Bifida

“I do my very best in my daily life and I try to give myself credit for that. I have to pick my battles sometimes, I cannot manage everything alone and it is ok to get some assistance. I like to have an active life together with my husband and children.”

What are Neural Tube Defects (NTDs)?

- Neural Tube Defects (NTDs) are birth defects which occur when the neural tube fails to close within 28 days into pregnancy and which result in severe malformations.
- Failure of the neural tube to close over the lower spine leads to Spina Bifida. Failure to close in the region of the developing brain causes Anencephaly or Encephalocele. Anencephaly and Encephalocele are fatal conditions. Spina Bifida cannot be cured, but often requires long-term care and follow-up.
- In addition to an obvious gap in the skin covering the spine, the vertebrae and the nervous system are damaged, leading to some degree of paralysis. Spina Bifida might cause physical disabilities

- that range from mild to severe. Most children and adults with Spina Bifida have problems with bowel and bladder control.
- More than 85% of children with Spina Bifida also have or will develop Hydrocephalus, which is the accumulation of cerebrospinal fluid (CSF) in the brain and is caused by blockages in the narrow channels (ventricles) that are meant to drain it².
- Hydrocephalus needs to be followed closely and treated properly to prevent brain injury. Timely diagnosis and treatment of Hydrocephalus is essential in the survival and outcome of a child.

Why are so many babies still born with Spina Bifida in Europe?

Research indicates that up to 70% of NTDs can be avoided by adequate folate levels³. To date, folate levels in women of childbearing age can be raised via three methods: natural folate intake through a healthy diet, folic acid supplements and food fortification with folic acid.

- According to the WHO women should ensure a daily intake of 0.4mg of folic acid at least 2 months prior to conception and 12 weeks into their pregnancy in order to reduce the risk of NTD affected pregnancies⁴.
- Prevalence of NTDs remains high in Europe with more than 4,500⁵ pregnancies affected each year and in particular in younger women and women from disadvantaged backgrounds⁶.

Four interlinked reasons may explain why prevalence remains so high in Europe:

1. In many countries, up to 50% of pregnancies are estimated to be unplanned⁷ and women are therefore not able to ensure they have the necessary folate levels in advance of conception.
2. Little awareness among women of childbearing age, in particular among younger women and women of disadvantaged backgrounds about preventive measures of NTDs before conception and in early pregnancy.
3. Lack of compliance by women with the recommendations on periconceptional folic acid to prevent NTDs⁸.
4. Limited access to proper and systematic preconception care⁹.

Despite the medical and social challenges, people living with Spina Bifida can enjoy fulfilling lives if they receive proper healthcare and are welcomed in society



Guro Fjellanger,
former Minister of Environmental Affairs in
Norway, was born in 1964 with Spina Bifida

“Travelling to different conferences and negotiations as a Norwegian Minister on crutches because of Spina Bifida, I was very often faced with the question: “Did you have a ski-accident?” They were always smiling, but when I replied “No, I was born like this” the smile would usually disappear and they would say: “I’m sorry.””

Endnotes

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Europe is failing to educate women of childbearing age on the importance of folate levels prior to conception and in early pregnancy to prevent a Neural Tube Defect affected pregnancy

“In the UK only 5.5% of women who had taken folic acid were shown to have taken it at the right time and dose to give them the full preventative effect against their unborn child developing a NTD. Although many women may be partially aware of the benefits of folic acid, many mistakenly believe that it is something to take once pregnancy is established rather than before conception.”

Jackie Bland, Chief Executive, Association for Spina Bifida and Hydrocephalus in England and Wales

Table 01

The importance of folate levels in women of childbearing age to reduce the risk of a NTD affected pregnancy is not mentioned in school curricula in Europe

Is the importance of high levels of folate in women of childbearing age mentioned in the main school curriculum in your country?

Austria	●	Estonia	●	Ireland	●	The Netherlands	●	Slovenia	●
Belgium	●	Finland	●	Italy	●	Norway	●	Spain	●
Bulgaria	●	France	●	Latvia	●	Poland	●	Sweden	●
Cyprus	●	Germany	●	Lithuania	●	Portugal	●	United Kingdom	●
Czech Republic	●	Greece	●	Luxembourg	●	Romania	●	● Yes	
Denmark	●	Hungary	●	Malta	●	Slovakia	●	● No	
								● Not Available	

Source: 2010 NTD online questionnaire¹

- No school curricula in Europe specifically mention the importance of folate levels in women of childbearing age to reduce the risk of having a NTD affected pregnancy¹.
- Up to 50% of pregnancies are estimated to be unplanned², meaning that women are also not getting timely preconceptional advice from healthcare professionals to plan their pregnancy¹.

Table 02

Only 14 out of 25 European countries developed in recent years an awareness raising campaign about the importance of women’s folate levels prior to conception

Are there any NTD awareness raising campaigns in your country?

Austria	●	Estonia	●	Ireland	●	The Netherlands	●	Slovenia	●
Belgium	●	Finland	●	Italy	●	Norway	●	Spain	●
Bulgaria	●	France	●	Latvia	●	Poland	●	Sweden	●
Cyprus	●	Germany	●	Lithuania	●	Portugal	●	United Kingdom	●
Czech Republic	●	Greece	●	Luxembourg	●	Romania	●	● Yes	
Denmark	●	Hungary	●	Malta	●	Slovakia	●	● No	
								● Not Available	

Source: 2010 NTD online questionnaire¹

- Only 14 out of 25 European countries surveyed developed in recent years an awareness raising campaign about the importance of women’s folate levels prior to conception and in early pregnancy to reduce the risk of a NTD affected pregnancy¹.
- Apart from The Netherlands, all awareness raising campaigns developed were led by patient organisations and/or by the pharmaceutical industry, not necessarily by healthcare authorities.
- The campaigns were generally limited in scope, duration and outreach¹.
- Since the survey was conducted, the Association for Spina Bifida and Hydrocephalus in England and Wales in association with the Scottish Spina Bifida Association launched, in March 2011, a comprehensive awareness raising campaign entitled ‘Go folic!’, which is available online at www.gofolic.co.uk

Women of childbearing age are not getting the right advice about NTD prevention at the right time, i.e. prior to conception

- Neural Tube Defects (NTDs), such as Spina Bifida, are birth defects which occur when the neural tube fails to close within 28 days into pregnancy and which result in severe malformations.
- Research indicates that up to 70% of NTDs can be avoided by adequate folate levels³. To date, folate levels in women of childbearing age can be raised via three methods: natural folate intake through a healthy diet, folic acid supplements to increase folate levels and food fortification with folic acid.
- According to the WHO women should ensure a daily intake of 0.4mg of folic acid at least 2 months prior to conception and 12 weeks into their pregnancy in order to reduce the risk of NTD affected pregnancies⁴.
- Prevalence of NTDs remains high in Europe with more than 4,500⁵ pregnancies affected each year and in particular in younger women and women from disadvantaged backgrounds⁶.
- Four interlinked reasons may explain why prevalence remains so high in Europe:
 1. In many countries, up to 50% of pregnancies are estimated to be unplanned², and women are therefore not able to ensure they have the necessary folate levels in advance of conception.
 2. Little awareness among women of childbearing age, in particular among younger women and women of disadvantaged backgrounds⁶, about preventive measures of NTDs before conception and in early pregnancy.
 3. Lack of compliance by women with the recommendations on periconceptional folic acid to prevent NTDs⁷.
 4. Limited access to proper and systematic preconception care¹.

National Governments should add folate advice to national school curricula and invest in awareness campaigns on measures to prevent NTD affected pregnancies!

- Some studies in Norway and in the UK reveal the limited effectiveness of health education campaigns for raising women's folate levels¹. In the UK in particular, a study concluded that awareness campaigns were not targeting women early enough, i.e. before conception.
- Health education campaigns on NTD prevention are also thought to be ineffective in reaching groups with an increased risk, i.e. younger women and women from disadvantaged backgrounds.

Snapshot Interview

Jackie Bland
Chief Executive, Association for Spina Bifida
and Hydrocephalus in England and Wales



Why did you feel the necessity to invest in the Go Folic! campaign?

J.B. — In the UK only 5.5% of women who had taken folic acid were shown to have taken it at the right time and dose to give them the full preventative effect against their unborn child developing a NTD. Many women mistakenly believe that it is something to take once pregnancy is established rather than before conception. At the same time, in some cases the problem is convincing Governments that this is a serious public

health issue in the first place (e.g. the last real UK government initiative to address this ended in 1996!). The 'Go Folic!' campaign therefore aims to be a popular mainstream campaign reaching out to women at home, in the workplace and within the health service.

What is the main focus of Go Folic! campaign?

J.B. — The main campaign message will be that if you are sexually active (i.e. you could become pregnant) then you should be taking

folic acid supplements on a daily basis. Analysing how women might be reached pre-conception and familiarising them with the concept of folic acid as a precautionary health measure (linked to sexual activity), rather than a pregnancy 'treatment' is in our view, a vital first step.

Endnotes

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A question of ethics: awareness, education and objective prenatal counselling on Neural Tube Defects are needed across Europe to overcome negative stereotypes about disability

“Unfortunately, many healthcare professionals are equally ignorant of the current prognosis of children with Spina Bifida who have ready access to comprehensive care in a modern multidisciplinary clinic. As a result, much of the information initially provided to couples with a newly diagnosed foetus is biased and misleading. [...] we have met and held intense conversations with more than 150 pregnant women and their partners. Many times, couples admitted, the initial counselling they received from their obstetrician was slanted - both against disability and toward termination of pregnancy. What they remembered was how the initial obstetric consultation portrayed as grim a picture as possible about their future child’s prognosis.”

‘Tell the truth about Spina Bifida’ J. P. Bruner and N. Tulipan, November 2004¹

- Many European countries offer a routine blood test and/or ultrasound screening to all pregnant women at 10-12 weeks and/or 18-20 weeks to detect congenital anomalies.
- Up to 70% of NTDs can be avoided by adequate folate levels⁴, which means that 30% of NTD affected pregnancies are the result of environmental or genetic factors. Parents and parents-to-be have the right to unbiased, up-to-date information about the health condition of their child.
- Prenatal counselling upon diagnosis of a NTD should not be biased towards termination of the pregnancy. Given access to treatment and appropriate care, children with Spina Bifida live full and active lives.



Liliana Sintra, psychologist and youngest author in Portugal, publishing her first book aged twelve, living with Spina Bifida
Ana Caridade, mother of Liliana

“Like every woman on that occasion, when I was born, my mum (a twenty year-old girl) asked if her baby was a boy or a girl. Doctors just answered ‘It doesn’t matter! Your baby will soon die!’”

The WHO and the UN acknowledge that people with disabilities, such as NTDs, should enjoy all human rights and fundamental freedoms. Access to available treatment is a human right!

- In the European Union, **one in six people, i.e. 80 million, have a disability** which often prevents them from access to society because of environmental and attitudinal barriers².
- All newborns, regardless of the severity of the birth defect, should have access to all available treatments that can improve their quality of life.
- Every year hundreds of children in Europe are discriminated against and their basic human rights are violated, because their parents received information based on a negative perception of disability. This denial of rights manifests in the institutionalisation of children living with Spina Bifida, lack of care, lack of education, and often, inhumane living conditions.
- Negative stereotypes about the lives of people with disabilities, and Spina Bifida in particular, drive recommendations such as the Dutch Groningen Protocol which justifies advice that hasten the death of newborns with severe impairments. These practices are perhaps the most serious instances of disability discrimination³.

“The Sixty-third World Health Assembly urges Member States to take all necessary measures to ensure the full enjoyment by children with disabilities of all human rights and fundamental freedoms on an equal basis with other children.”

World Health Organization, 63rd World Health Assembly Resolution on Birth Defects, May 2010¹¹

Women of childbearing age are not getting the right advice about NTD prevention at the right time, i.e. prior to conception

- Neural Tube Defects (NTDs), such as Spina Bifida, are birth defects which occur when the neural tube fails to close within 28 days into pregnancy and which result in severe malformations.
- Research indicates that up to 70% of NTDs can be avoided by adequate folate levels⁴. To date, folate levels in women of childbearing age can be raised via three methods: natural folate intake through a healthy diet, folic acid supplements to increase folate levels and food fortification with folic acid.
- According to the WHO women should ensure a daily intake of 0.4mg of folic acid at least 2 months prior to conception and 12 weeks into their pregnancy in order to reduce the risk of NTD affected pregnancies⁵.

- Prevalence of NTDs remains high in Europe with more than 4,500⁶ pregnancies affected each year and in particular in younger women and women from disadvantaged backgrounds⁷.

Four interlinked reasons may explain why prevalence remains so high in Europe:

1. In many countries, up to 50% of pregnancies are estimated to be unplanned⁸, and women are therefore not able to ensure they have the necessary folate levels in advance of conception.

2. Little awareness among women of childbearing age, in particular among younger women and women of disadvantaged backgrounds⁶, about preventive measures of NTDs before conception and in early pregnancy.

3. Lack of compliance by women with the recommendations on periconceptional folic acid to prevent NTDs⁹.

4. Limited access to proper and systematic preconception care¹⁰.

Governments need to implement the WHO Resolution on birth defects¹¹ and the WHO Standard on Prevention of Neural Tube Defects⁵ while ensuring access to treatment and improving education and awareness of NTDs to address preparedness of parents and societal perception of disability

- Upon diagnosis of a NTD affected pregnancy unbiased, up-to-date information about the health condition and expected life outcomes of their child should be standard across Europe.
- Termination of a NTD affected pregnancy is a decision with significant psychological burden and all parents-to-be should be aware of the potential need to decide, in advance.
- Severe birth defects such as Spina Bifida that are not treated properly will have a bad outcome for children with these conditions as it will

result in a negative perception of the predicted quality of life for these infants. This is even more the case in an environment where disability is seen as a curse or a burden on family and society where there is usually no referral for surgery.

- All newborns, regardless of the severity of the birth defect, should have access to all available treatments that can improve their quality of life. Prenatal foetal surgery is increasingly an option.

Snapshot Interview

Pierre Mertens
President of the International Federation
for Spina Bifida & Hydrocephalus



What advice do you think is given to parents upon diagnosis of a NTD affected pregnancy?

P.M. — Parents deserve full and balanced information on the condition of their baby informing them on the abilities and disabilities of the child, all possible treatments that can improve the quality of life of their child and they should be guided to other parents and

persons living with the condition before taking any decision.

Which barriers do parents and people with Spina Bifida face in access to treatment and to society?

P.M. — Negative stereotypes on the condition make that the society is not investing in correct treatment and in the inclusion of people

with disabilities. Access to correct information on the condition and the possibilities for treatment are the first barriers to overcome. Governments should work closely with the disability movement to ensure access to good care and to society and towards the implementation of the UN Convention on the Rights of Persons with Disabilities¹².

Endnotes

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Healthy diet policies alone are insufficient to reach the adequate folate levels needed in women to prevent Neural Tube Defects

“As it is difficult to achieve the extra folate needed through diet alone, all women of child-bearing age, especially those planning a pregnancy, are advised to take daily supplements (0.4mg/day) of folic acid. This is because the vitamin is important at a time when many women do not yet realise that they are pregnant.”

Ms Brigid McKeivith, British Nutrition Foundation, 2004¹

Folate intake by women in Europe remains below the WHO recommended levels to prevent NTDs, i.e. 0.4mg/day

- Women can increase their folate levels through diet, as folates can be found in food such as green leafy vegetables, berries, beans, brewer’s yeast, endive, chick peas, lentils, oranges, peas, rice, soya beans, split peas, sprouts, wheat and wheat germ, spinach, broccoli, tomatoes, etc.
- Unfortunately, when ingested as food, folate absorption by the body is reduced to a small percentage². Increasing folate levels of women of childbearing age “through folate-rich foods alone would be very difficult if not impossible to achieve, as it would require a threefold increase of current dietary folate intakes”¹.
- Compared to the national recommendations, mean/median folate intakes of women were reported to be below the national recommendations in all countries except Belgium and UK².
- Furthermore, in all countries the mean/median folate intake of women was below that needed to prevent NTDs (0.4mg/day).
- No EU Member State has yet introduced mandatory food fortification with folic acid³.



Some examples of folate rich food

Table 01

No mandatory food fortification with folic acid has been introduced in any European country³

Austria	•	Estonia	•	Ireland	•	The Netherlands	•	Slovenia	•
Belgium	•	Finland	•	Italy	•	Norway	•	Spain	•
Bulgaria	•	France	•	Latvia	•	Poland	•	Sweden	•
Cyprus	•	Germany	•	Lithuania	•	Portugal	•	United Kingdom	•
Czech Republic	•	Greece	•	Luxembourg	•	Romania	•		
Denmark	•	Hungary	•	Malta	•	Slovakia	•		
								• No	

Source: EFSA 2009³

- 15 out of 21 countries covered by the EUROCAT registry have an official policy on folate supplementation. Malta is reported to only have dietary advice and there is no official government policy in place for Austria, Belgium, Germany and Croatia⁴.
- The majority of women in Europe surveyed for the 2009 EUROCAT report on periconceptional folic acid supplementation are still not taking folic acid supplements at the right time. Only in The Netherlands and Denmark is the periconceptional use of folic acid above 30%, other countries are not reaching 10%⁴.

Women of childbearing age are not getting the right advice about NTD prevention at the right time, i.e. prior to conception

- Neural Tube Defects (NTDs), such as Spina Bifida, are birth defects which occur when the neural tube fails to close within 28 days into pregnancy and which can result in severe malformations.
- Research indicates that up to 70% of NTDs can be avoided by adequate folate levels⁵. To date, folate levels in women of childbearing age can be raised via three methods: natural folate intake through a healthy diet, folic acids supplements to increase folate levels and food fortification with folic acid.
- According to the WHO, women should ensure a daily intake of 0.4mg of folic acid at least 2 months prior to conception and 12 weeks into their pregnancy in order to reduce the risk of NTD affected pregnancies⁶.
- Prevalence of NTDs remains high in Europe with more than 4,500⁴ pregnancies affected each year and in particular in younger women and women from disadvantaged backgrounds⁷.
- Four interlinked reasons may explain why prevalence remains so high in Europe:
 1. In many countries, up to 50% of pregnancies are estimated to be unplanned⁸ and women are therefore not able to ensure they have the necessary folate levels in advance of conception.
 2. Little awareness among women of childbearing age, in particular among women of disadvantaged backgrounds, about preventive measures of NTDs before conception and in early pregnancy.
 3. Lack of compliance by women with the recommendations on periconceptional folic acid to prevent NTDs⁹.
 4. Limited access to proper and systematic preconception care¹⁰.

National Governments need to ensure policy measures to prevent NTDs go beyond dietary recommendations and target women at the right time, i.e. before conception

- A healthy diet is extremely important for all women of childbearing age. However, dietary folate, even in a healthy and balanced diet, is insufficient to reach adequate folate levels to reduce the risk of a NTD affected pregnancy¹¹.
- Despite the (limited) awareness campaigns¹⁰ on the importance of a folate-rich diet in Europe, folate levels of women of childbearing age are still below the level needed to reduce the risk of a NTD affected pregnancy.
- With limited implementation of voluntary food fortification in Europe, health campaigns on the importance of a folate-rich diet become increasingly important. Health campaigns regarding diet also need to ensure that the right recommendations on NTD prevention reach women of childbearing age at the right time.
- With up to 50% of unplanned pregnancies in Europe⁸, with evidence suggesting that younger women and women of disadvantaged backgrounds are more at risk of a NTD affected pregnancy⁷, and with the failure of awareness campaigns to date, new methods should be explored across Europe to raise folate levels of women of childbearing age.

Endnotes

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Best Practice Case Study: MediClara's Pharmacy Project

Raising folate levels of women taking the pill in The Netherlands, to reduce the risk of a Neural Tube Defect (NTD) affected pregnancy

The situation

Women of childbearing age were not getting the right advice at the right time on the importance of raising their folate levels prior to conception to reduce the risk of a NTD affected pregnancy

- Neural Tube Defects (NTDs), such as Spina Bifida, are birth defects which occur when the neural tube fails to close within 28 days into pregnancy and which result in severe malformations.
- Research indicates that up to 70% of NTDs can be avoided by adequate folate levels¹ in women before conception and in early pregnancy.
- In the 90's, the Dutch Ministry of Health therefore adopted preconception recommendations targeted at healthcare professionals on folate intake and rolled out a one-off mass media campaign to reduce the risk of NTD affected pregnancies. To some extent, this campaign led to improved folate levels of women of childbearing age.

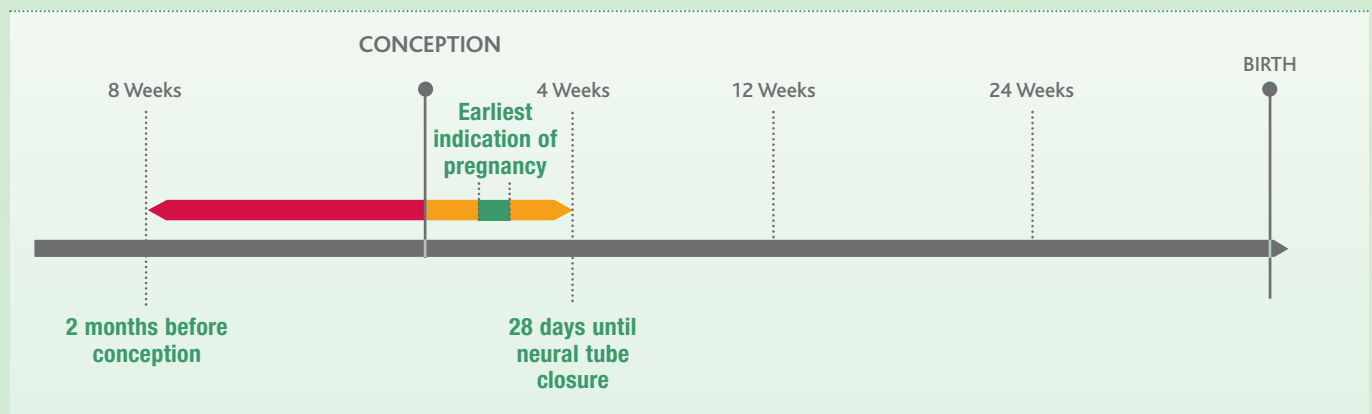
The issue

As in many other countries, the Dutch campaign failed to meet the need to further increase and maintain the timely delivery of the important message on folic acid use:

- The majority of women of childbearing age do not see a doctor before they become pregnant and will therefore not receive the message on folate recommendations in time, i.e. prior to conception, to reduce the risk of a NTD affected pregnancy.
- Up to 50% of pregnancies are estimated to be unplanned² and women are therefore not seeking prenatal advice. Once a woman becomes aware of her pregnancy it is too late to ensure that she has adequate folate levels to reduce the risk of a NTD affected pregnancy. **This is why women of childbearing age would be better protected if they would raise their folate levels in advance of conception, regardless of whether they are planning a pregnancy or not.**
- There is a lack of systematic and consistent preconception care provided by healthcare professionals to women of childbearing age³.
- There is little awareness in women of childbearing age, and in particular in younger women and women of disadvantaged backgrounds⁴, about the issue or about the preventive measures needed before conception and in early pregnancy to reduce the risk of a NTD affected pregnancy.
- There is a lack of compliance with the existing recommendations on daily folic acid intake to prevent NTDs³.

Graph 01

The importance of timing in the prevention of NTDs



The solution

The department of Pharmacoepidemiology of the University of Groningen and MediClara⁵ developed a campaign with Dutch pharmacies to raise folate levels of oral contraceptive users⁶

- Stickers with a message on folic acid were put on the packages of oral contraceptives that community pharmacies distributed to women.
- Dutch Pharmacists also provided information leaflets on adequate folate levels to the women buying oral contraceptives.
- Dutch Pharmacists and their teams were trained to implement this awareness raising project.
- Through an assignment from TEVA Nederland BV⁷ MediClara implemented the campaign in 700 pharmacies.
- Following the success of the project, the Dutch Ministry of Health was convinced of the relevance and feasibility of this practical method of promoting folic acid use and provided a grant to include another 300 pharmacies in the campaign.

- From 2004 to 2007, 60% of all community pharmacies in The Netherlands implemented this pro-active outreach to women of childbearing age on the importance of sufficient folate levels prior to conception.



Informative leaflet on the importance of folic acid distributed by pharmacists to women buying oral contraceptives

Sticker put on oral contraceptives' packages:

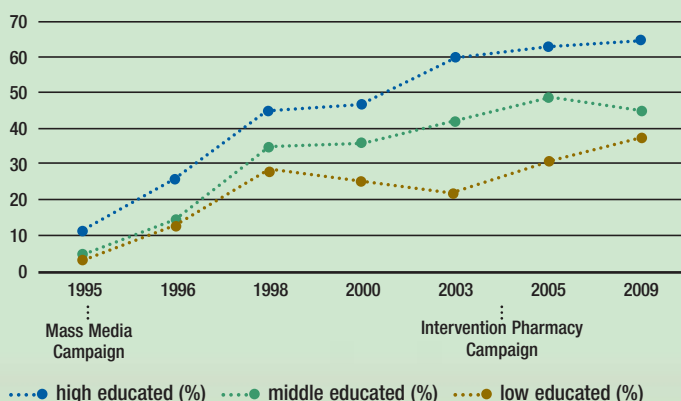
'Childwish? Ask your pharmacist about folic acid'

The results

The campaign reached its target audience and folate levels of oral contraceptive users increased

Graph 02

Preconception folate intake of women increased following the Pharmacy campaign



- The message on the importance of raising women's folate levels prior to conception reached the target audience and was welcomed.
- Within one year from the start of the project⁸, the awareness of childless women on the right timing to take folic acid prior to conception increased by 15%.
- As a consequence of the education of oral contraceptive users by pharmacies on adequate folate levels prior to conception, more use of periconceptional folic acid supplements was noted.

Other European countries can use the experience with the innovative MediClara strategy to set up and carry out successfully comparable and effective projects!

Source: de Walle HE, de Jong-van den Berg LT. Ten years after the Dutch public health campaign on folic acid: the continuing challenge. Eur J Clin Pharmacol 2008; 64(5):539-543. Ref ID: 1804 (updated with data of the 2009 survey)

About MediClara

MediClara is an independent company based in The Netherlands with a national and international network. Its mission is to contribute to the improvement of healthcare and healthcare outcomes by accompanying healthcare professionals on the implementation of specific tasks and services. More information on MediClara is available at: www.mediclara.nl

Endnotes

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For more information about the methodology, sponsors and partners of the report 'Act against Europe's most common birth defects: one year on. Defining Neural Tube Defect prevention strategies in Europe', please visit our website at: www.ifglobal.org/ntdreport



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- and relaying the views of the stakeholders and society at large.

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