

REPORT ON PERICONCEPTIONAL FOLIC ACID SUPPLEMENTATION FOR ITALY

Prof E Calzolari, Dr G Cocchi, Dr A J Neville

Folic Acid Supplementation Policy

There is not a guideline or official recommendation for folic acid supplementation in Italy. When considering the factors to be assessed in a decision to introduce a preventative health policy, the size of the problem must be weighed against safety and efficacy. The lack of policy in Italy is a reflection of the low neural tube defect (NTD) prevalence in the country, the wide use of prenatal diagnosis, and the political and economic problems related to aging taking priority on the public health agenda. It appears there is no balance between cost/effectiveness in the implementation of a folic acid policy. See details in report of BIOMED II (Goujard 2001).

Folic acid supplements are on sale in Italian pharmacies. 0.4mg alone is the dose for some preparations, but higher doses (5 to 15mg tablets) are available on prescription. The 0.4mg dose is also available as part of a multivitamin pill (Litrison-Roche), whilst lower doses are included in other multivitamin pills available over the counter. Combinations of 0.4mg or 0.8mg of folic acid combined with ferritin and B12 are also available (Ferrolin, Ferrotre)

Food Fortification Policy

There is not an official food fortification policy. There are food products on sale which are enriched with folate or folic acid derivatives, eg Kellogg Cornflakes and other breakfast cereals, cereal bars (eg Cerealix, Barilla) but there are no recommendations. In Italy there is nothing comparable to the USA Food and Drug Administration (FDA) to manage or introduce a policy. Food additives are regulated at a national level by a Ministerial Decree (27.02.96 no. 209) which recognises the CE directives.

Health Education Initiatives

There is not, and has not been, an official health education initiative in Italy. Some scientific societies such as the Society of Gynecologists and Obstetricians have published advice and recommendations in their bulletins but not in an official manner. Prescribing habits for folic acid vary widely within the country.

Knowledge and Uptake about Folic Acid

To our knowledge no national epidemiological studies have been conducted.

At a regional level the following studies have been reported:

1. A study was conducted at the Obstetric Clinic of Bologna (Cocchi et al 2000) on the percentage of women who had correctly consumed folic acid in the periconceptional period. In the early part of the study 3.5% of women took folic acid correctly; a year later 5% did so.
2. Details of the study entitled “Primary prevention of neural tube defects: lack of information about folic acid supplementation in Italy: Emilia-Romagna region” (Cocchi 2000) looked at knowledge and uptake of folic acid. *Objective:* To detect the level of knowledge of women of childbearing age about the ability of folic acid (FA) supplementation to reduce the risk of having a pregnancy affected by neural tube defects (NTD). To administer an ad hoc questionnaire prepared in relation to the goals of the BIOMED Project and conduct a survey in Bologna (one of the centres of the IMER Registry, Italy) on the policy of consuming FA before conception (at least 2 months) and in the first quarter after conception. *Design:* An educational campaign about the health benefits of periconceptional consumption of FA and reduction of the risk of NTD. *Participants:* A sample of women in hospital for delivery during November and December 1999. The questionnaire, in Italian, was given to 302 women with healthy babies who were randomly selected. The collected information included data about maternal age, parity, education, smoking use, knowledge of the effect of FA and of food intake, changes in diet during pregnancy, and consumption of FA or a FA-containing multivitamin, specifically related to the period of consumption. *Main outcome measures:* Number of women who were aware of the FA recommendations, number who were aware of what FA is, who advised them about the benefits of FA, and when FA should be taken. *Results:* The same doctor interviewed 302 women in the 2-month period. Only 9 women (2.9%) took FA correctly, in the perinatal period. These 9 women tended to be informed by their gynecologist about FA preventive effect for NTD, tended to have a higher education level (university) ($\chi^2=8.920$; 2 gdl; $p=0.0012$) and tended to be older (> 30 years) ($\chi^2=9.364$; 2 gdl; $p=0.009$). *Conclusions:* These results demonstrate the lack of

medical information in Italy about the preventive effect of FA and the necessity of carrying out information campaigns addressed to gynecologists, general practitioners and to all women in childbearing age

3. In Sicily a study (Ginecol 1999) was carried out on periconceptional folic acid intake by Sicilian couples at increased risk of NTD. The authors conclude that pregnant Sicilian women at risk for recurring NTD interviewed by the authors were not aware of the possible prevention of NTD using folic acid supplements during the periconceptional phase. In the study period, January 1997 until December 1998, 18 couples were identified as being at risk for recurring NTD. A further 15 couples showed a positive family history for NTD. Of 11 planned pregnancies, none of the pregnant women took folic acid during the periconceptional phase. A similar level of ignorance was found in a study conducted by the Emilia Romagna region (2). Details of this study: "Periconceptional folic acid intake by Sicilian couples at a risk of recurrence of NTD" BACKGROUND AND AIM: The authors aimed to evaluate the frequency with which pregnant Sicilian women with a high risk of recurring neural tube defects (NTD) attending the Ultrasonography and Prenatal Diagnosis Clinic in the Department of Diagnosis and Treatment at Ospedale S. Bambino in Catania were aware of the preventive effect of folic acid supplements during the periconceptional period and whether they therefore took folic acid supplements before the next pregnancy. *METHODS*: All pregnant women undergoing ultrasonography between January 1997 and December 1998 were interviewed. It was noted whether any earlier offspring had suffered from NTD or whether relatives (sisters, brothers, parents) had suffered from a NTD. They were also asked whether they knew about the preventive effect of periconceptional folic acid supplements on the development of NTD, whether their pregnancy was planned and whether they had taken periconceptional folic acid supplements and, if so, at what dose. *RESULTS*: Eighteen couples were identified as being at risk for recurring NTD: 3 cases had an earlier pregnancy resulting in NTD (2 cases of spina bifida and 1 case of anencephalus) with a negative family history for NTD; a further 15 couples showed a positive family history for NTD. None of the women were aware of the preventive effect of folic acid supplements during the periconceptional period on the development of NTD. Out of 11 planned pregnancies, none of the pregnant women took folic acid during the periconceptional phase. *CONCLUSIONS*: Pregnant Sicilian women at risk for

recurring NTD interviewed by the authors were not aware of the possible prevention of NTD using folic acid supplements during the periconceptional phase.

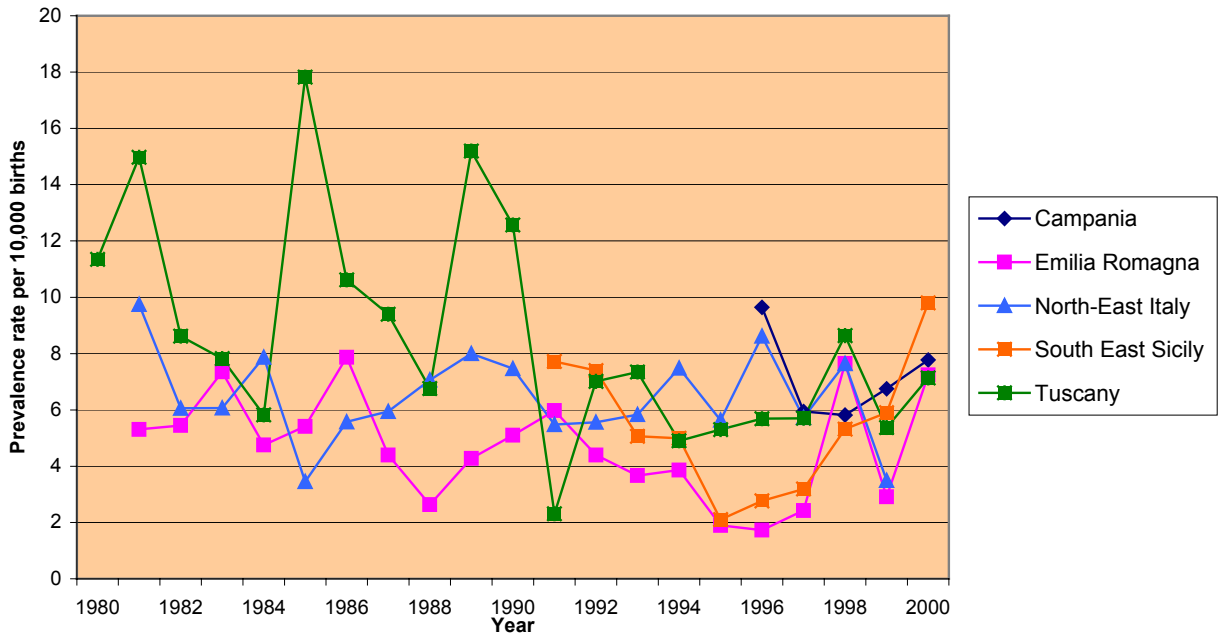
Laws Regarding Termination of Pregnancy

Voluntary termination of pregnancy became legal in Italy in 1984. Termination because of a congenital anomaly can be done until gestational age of 23-24 weeks. A psychiatric report is required. Termination of pregnancy is allowed only in NHS hospitals, not in private clinics.

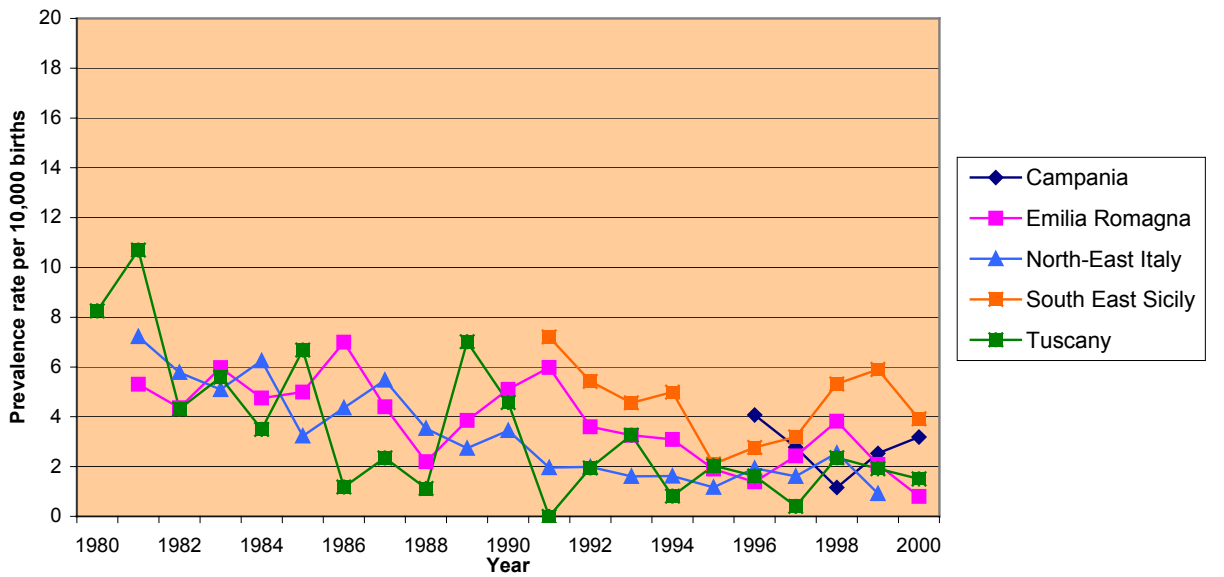
References:

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2. Guido Cocchi, S. Gualdi, P.M.A. Mammoliti, L. Piccolo, C. (2000) Primary prevention of neural tube defects: lack of information about folic acid supplementation in Italy: Emilia-Romagna region; La Rosa Istituto Clinico di Pediatria Preventiva e Neonatologia, Università degli studi di Bologna, Italy, Supported by Grants of EC: NTD & Primary prevention strategies: European Medical Research Concerted Action. Biomed 2. 1st International Symposium on Prevention and Epidemiology of Congenital Malformations. Cardiff, September 15-16. Frontiers in Fetal Health Vol 2, pp 9-11
3. Minerva Ginecol (1999) [Periconceptional folic acid intake by Sicilian couples at a risk of recurrence of NTD][Article in Italian] Pepe F, Pepe P, Grillo S, Insolia G. I Divisione di Diagnosi e Cura Ambulatorio di Ecografia e Diagnosi Prenatale, Ospedale di Maternita S. Bambino, Catania. Vol 51, No 10, pp 399-401

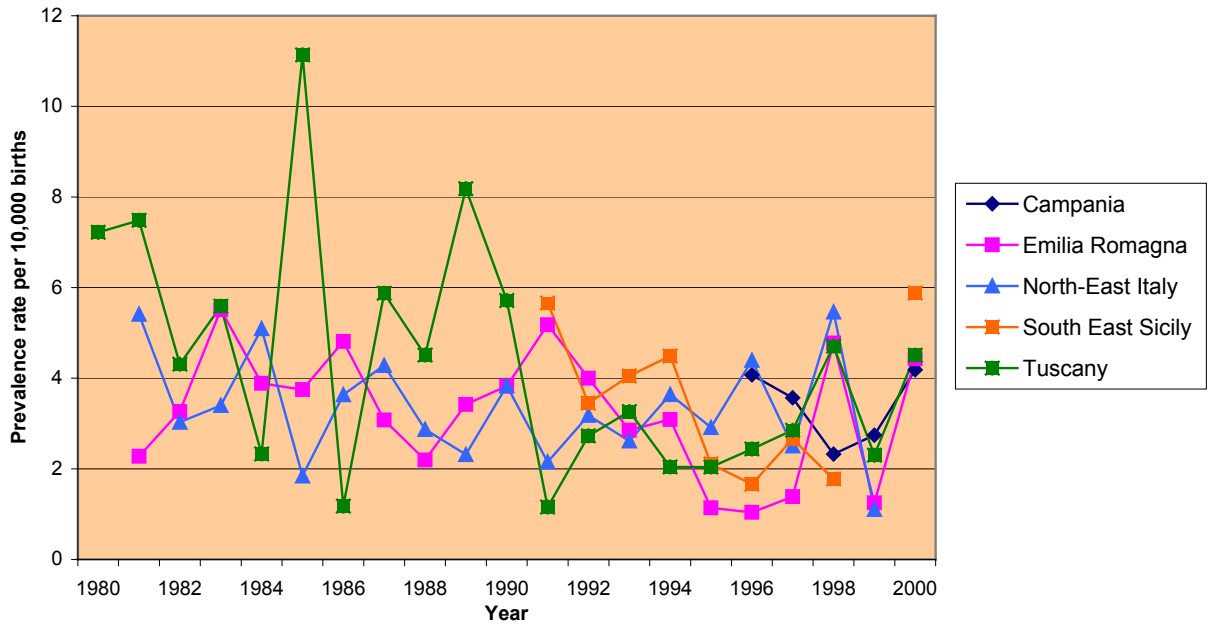
Italy (Campania, Emilia Romagna, North East Italy, South East Sicily and Tuscany): Total Prevalence Rate for Neural Tube Defects



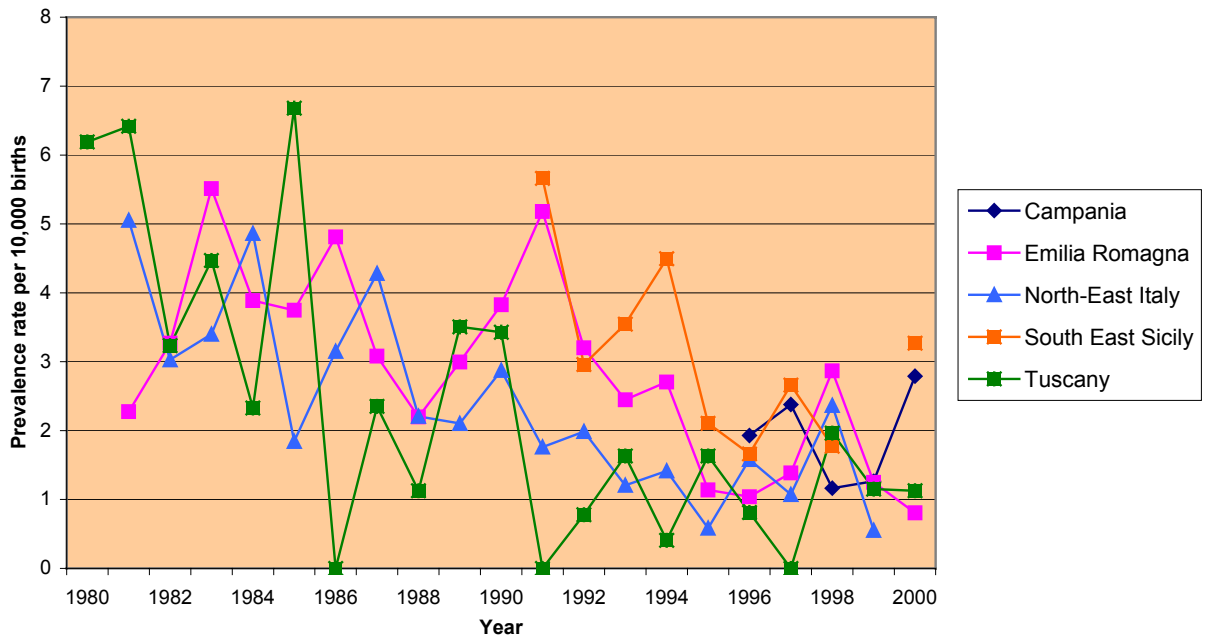
Italy (Campania, Emilia Romagna, North East Italy, South East Sicily and Tuscany): Livebirth Prevalence Rate for Neural Tube Defects



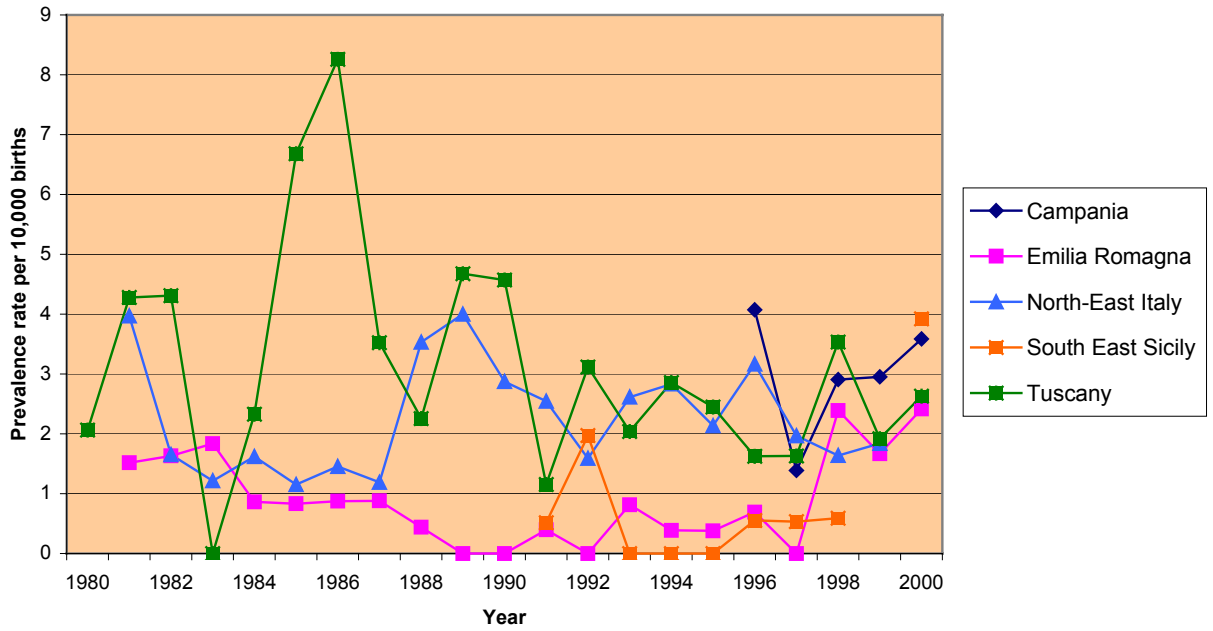
Italy (Campania, Emilia Romagna, North East Italy, South East Sicily and Tuscany): Total Prevalence Rate for Spina Bifida



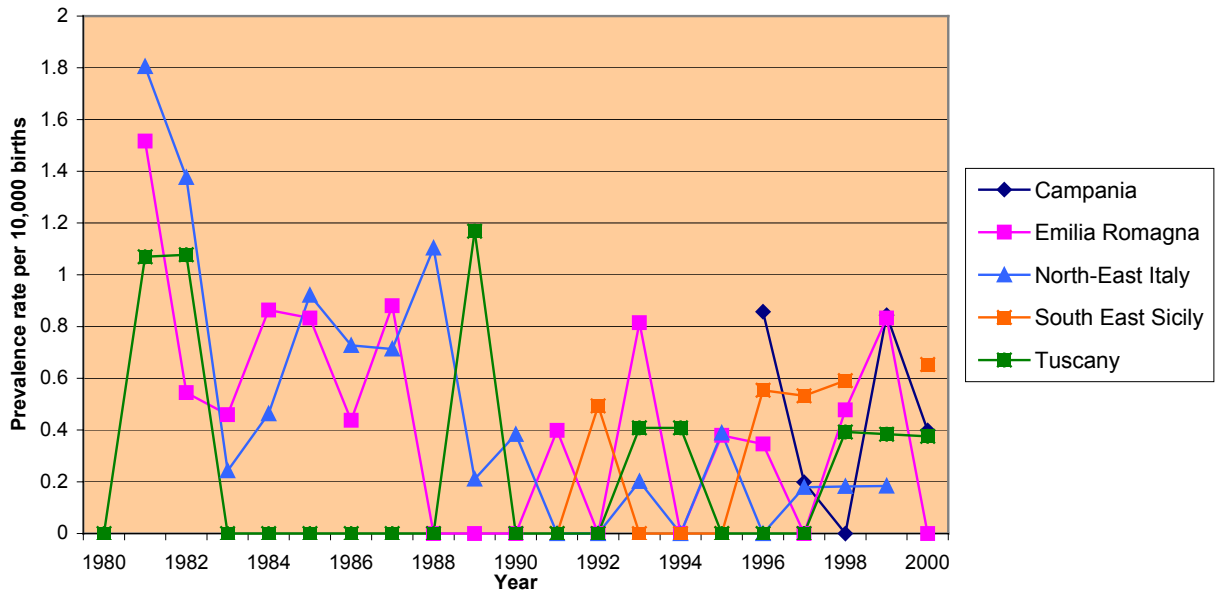
Italy (Campania, Emilia Romagna, North East Italy, South East Sicily and Tuscany): Livebirth Prevalence Rate for Spina Bifida



Italy (Campania, Emilia Romagna, North East Italy, South East Sicily and Tuscany): Total Prevalence Rate for Anencephalus



Italy (Campania, Emilia Romagna, North East Italy, South East Sicily and Tuscany): Livebirth Prevalence Rate for Anencephalus



REPORT ON PERICONCEPTIONAL FOLIC ACID SUPPLEMENTATION FOR MALTA

Dr Miriam Gatt

Folic Acid Supplementation Policy

In Malta an official policy regarding increasing folate in the diet was introduced in 1994. The policy advises that pregnant women and women intending to become pregnant should increase their intake of foods rich in folate. This is a Department of Health Circular No. 36/94

Food Fortification Policy

There is no official food fortification policy and none is being planned. However, a wide variety of imported fortified cereals and malted drinks are available. Cereals are relatively expensive locally and may not be accessible to people of all income brackets. Fortified breads are not readily available.

Health Education Initiatives

No official Department of Health Promotion campaigns have been undertaken, but GPs, gynecologists, midwives and organised antenatal courses inform women of the benefits of folic acid. The official dietary policy mentioned above was aimed to inform and educate health professionals. A health promotion officer is currently (2002) presenting his postgraduate research investigating the needs of a national health promotion campaign to raise awareness of the benefits of periconceptional folic acid supplementation among sexually active Maltese women of childbearing age. This research utilises the data collected during a folic acid survey conducted in 1999-2000 as part of the needs assessment¹. It is envisaged that following the results of this research, a health promotion campaign regarding periconceptional folic acid will be launched officially in Malta.

Folic Acid Awareness and Uptake

A study regarding folic acid awareness in Maltese mothers was undertaken between October 1999 and February 2000 (Gatt 1999). The results were published as a report from the Malta Congenital Anomalies Register. Of the mothers interviewed in the study, 72% had known that folic acid was important in pregnancy. 15% of mothers took folic acid supplementation prior to pregnancy; another 59% of mothers started folic acid after conception but before 12

weeks of gestation. 35% said that they had changed their diet during pregnancy, increasing their folate intake.

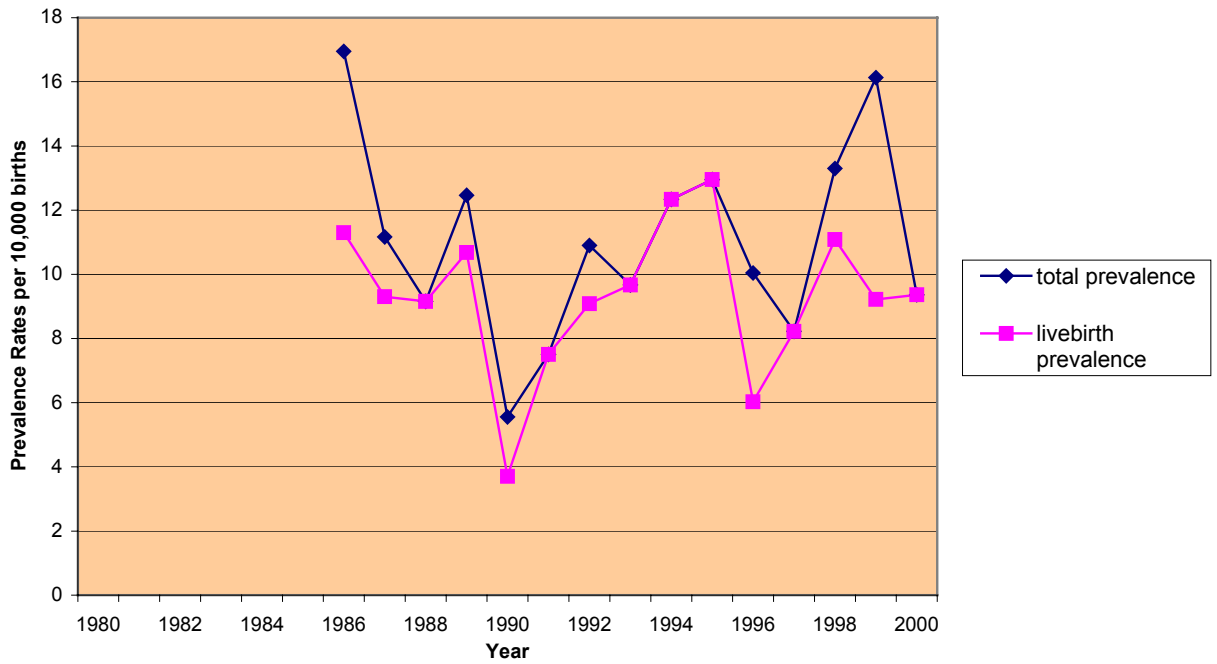
Laws Regarding Termination of Pregnancy

In Malta, termination of pregnancy is not legal.

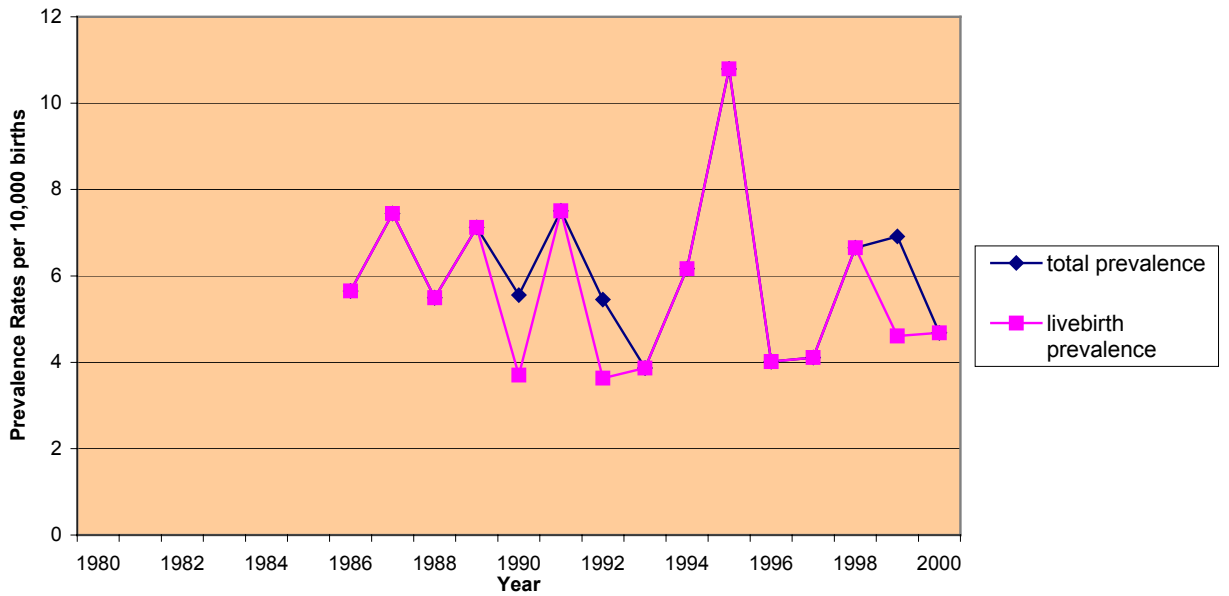
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Malta: Total and Livebirth Prevalence Rates for Neural Tube Defects

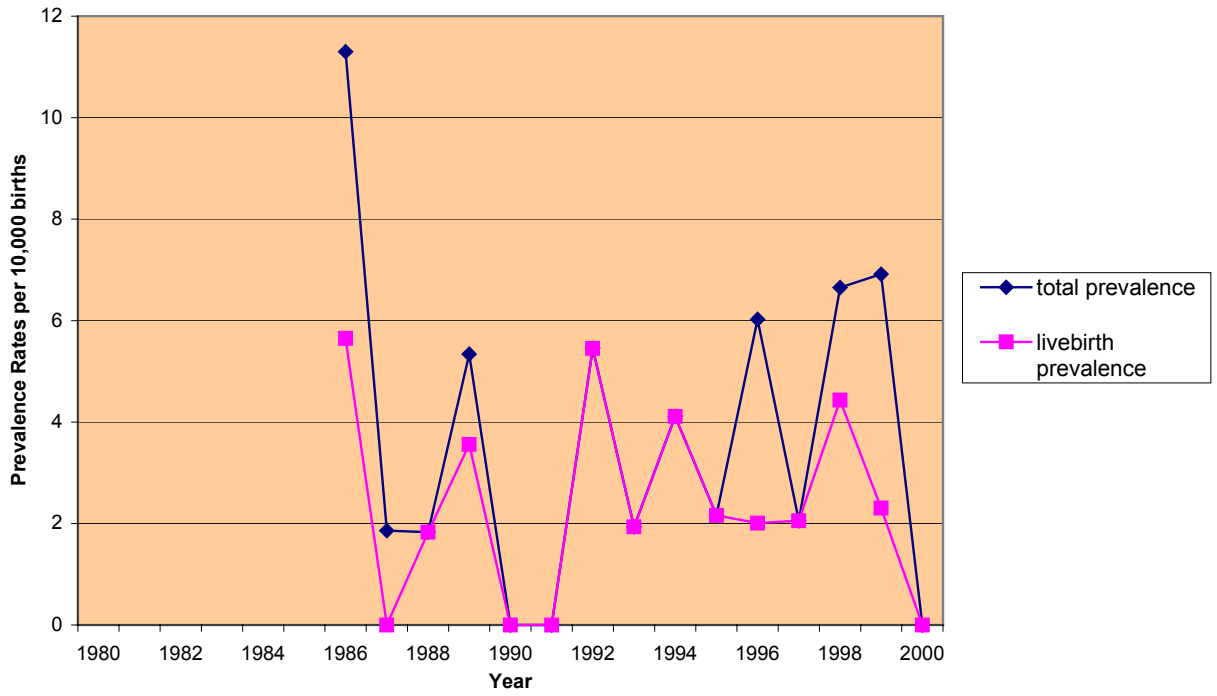


Malta: Total and Livebirth Prevalence Rates for Spina Bifida



† Where only one line appears, the total prevalence and the live birth prevalence are the same.

Malta: Total and Livebirth Prevalence Rates for Anencephalus



REPORT ON PERICONCEPTIONAL FOLIC ACID SUPPLEMENTATION FOR THE NETHERLANDS

Dr HEK de Walle

Folic Acid Supplementation Policy

In 1993 the official Dutch advice was that all women wishing to become pregnant should take a folic acid supplement of 0.5 mg per day. The official status for that policy was the Ministry of Health Welfare and Sports (Gezondheidsraad/Voedingsraad 1993).

Food Fortification Policy

Since 1996 different types of food have been fortified with vitamins and minerals in the Netherlands. For example, extra calcium is added to milk and vitamins are added to (expensive brands of) marmalade. Folic acid was not on the list of vitamins because of the risk of masking a vitamin B₁₂ deficiency; only restoration was possible.

The likelihood of appropriate fortification of food with folic acid in the Netherlands is further decreased after the publication of a recent report of the Dutch Health Council.(2000) They did not advise fortification of staple foods such as flour, but only products that can be specifically aimed at the target-population: women who want to become pregnant. No suggestions were made as to what these products could be or what the recommended amount of folic acid to be added to these products would be.

Health Education Initiatives

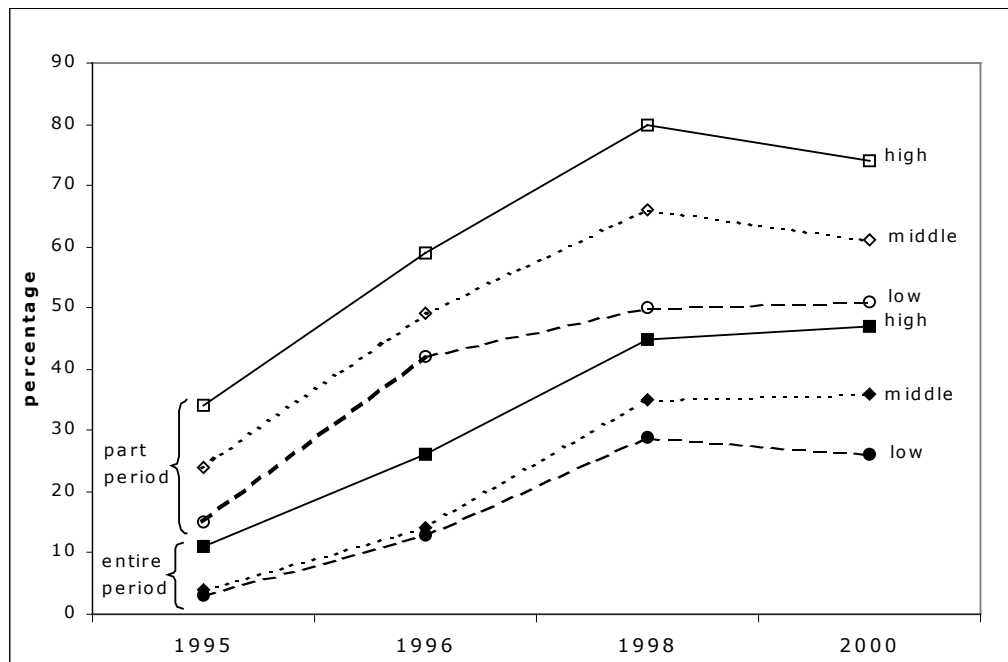
A campaign was aimed at all women of childbearing age but with a special emphasis on reaching women with a low socioeconomic status. General targets of the campaign were that 70% of women planning a pregnancy should know the recommended period to use folic acid and that 65% of women who knew of the advice before pregnancy should use folic acid during the entire recommended period(Voorlichtingsbureau voor de voeding 1994). This campaign was carried out in 1995.

Folic Acid Awareness and Uptake

The level of knowledge increased satisfactorily in the five years after the campaign. However, the percentage that used it in the advised period did not follow the same trend. Figure 1 shows how socioeconomic status is related to use of folic acid during the last five years in which we did the four surveys (de Jong-van den Berg et al 1998, de Walle et al 1999,

de Walle et al 1998, De Walle et al 1999). It is clear that the target that 65% of the women who were aware of the folic acid advice before their pregnancy should use folic acid during the entire recommended period is not reached in any of the surveys (36% of women surveyed in 1999 used folic acid during the entire recommended time. Socioeconomic differences with respect to knowledge and use of folic acid remained statistically significant in all the surveys. This means that another goal of the public campaign, the reduction of socioeconomic differences with respect to the use of folic acid, was not reached. It is disappointing to conclude this was also true in the regions where an extra intervention was made to reach women with a low education. Striking examples are the billboards with the folic acid message, which were placed in public areas and in buses. The more highly educated women remembered this information much better than the group for whom it was intended.

Figure 1 The use of folic acid in the three educational groups (low, middle, high) either in part of the period (3 lines at the top) or during the entire advised period (3 lines at the bottom).



Proportion of Pregnancies which are Planned

The Netherlands has a high percentage of planned pregnancies (Vennix 1990). In our surveys the percentage of planned pregnancies was high (around 85%) and it was not related to the

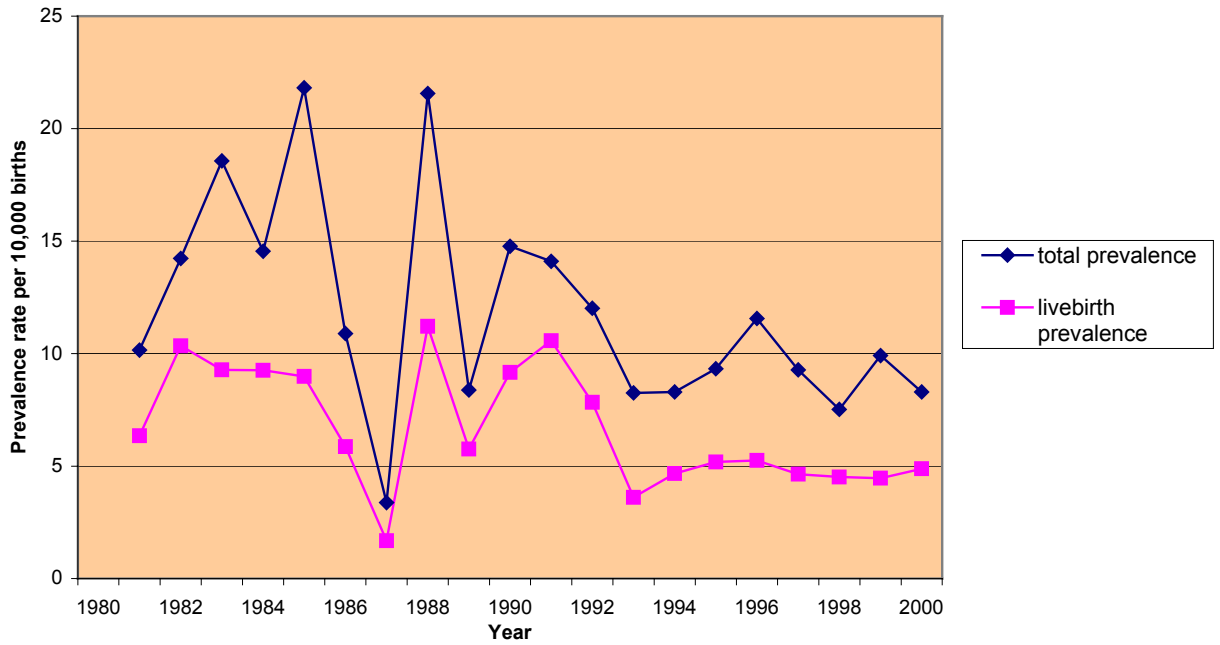
socioeconomic status of the respondents. However, the concept of “planned” in the way the respondents are using it might be different from the way it is interpreted by researchers.

Our study shows that in the Northern Netherlands, in 2000, women were aware of the importance and the correct time frame of using folic acid. However, not all of them took folic acid in the periconceptional period. This was not because of a negative attitude towards taking folic acid but, according to the most often mentioned reason, because although the pregnancy was planned they conceived sooner than expected.

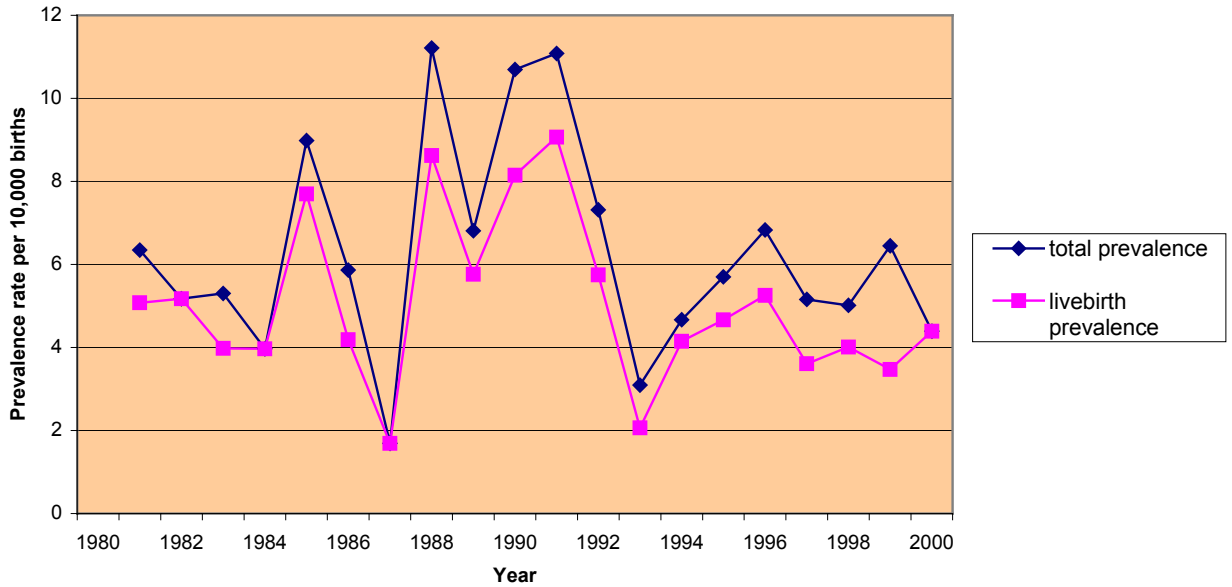
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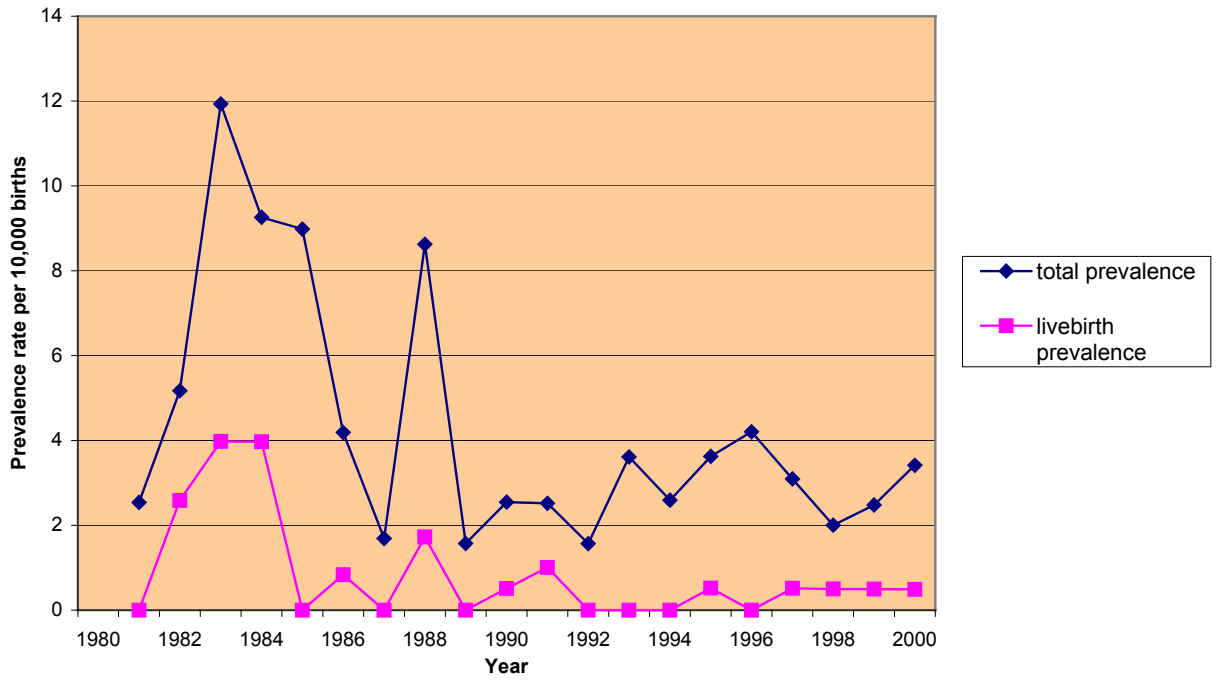
The Netherlands (Northern): Total and Livebirth Prevalence Rates for Neural Tube Defects



The Netherlands (Northern): Total and Livebirth Prevalence Rates for Spina Bifida



The Netherlands (Northern): Total and Livebirth Prevalence Rates for Anencephalus



REPORT ON PERICONCEPTIONAL FOLIC ACID SUPPLEMENTATION IN NORWAY

Anne Kjersti Daltveit dr.ph

Folic Acid Supplementation Policy

The official folic acid supplementation policy in Norway is that women who are planning a pregnancy or who may become pregnant are recommended to have a total intake of at least 400 µg of folic acid per day. Since an intake of 400 µg through the diet is unlikely to be achieved by many women, and since there are reasons to believe that supplementation is more efficient than diet in reducing the risk, the practical recommendation is to take a folic acid supplement of 400 µg per day. The supplementation should begin prior to the first month before conception and continue until 2-3 months of gestation.

Women with an increased need for folic acid due to disease or medication (eg anti-epileptic medication), and women with neural tube defects in their own or their partner's family, are recommended to confer with their doctor about a supplement of more than 400 µg per day. The supplementation should begin prior to the first month before conception and continue until 2-3 months of gestation.

Women who have previously had a fetus with a neural tube defect as well as women who themselves or their partner have a neural tube defect are recommended to take 4 mg of folic acid supplement per day. The supplementation should begin prior to the first month before conception and continue until 2-3 months of gestation.

After the first 2-3 months of pregnancy, pregnant and breastfeeding women are recommended to have a total intake of folic acid of 400 µg per day. It is suggested that a common level of dietary intake of folic acid among Norwegian women in the child-bearing age is about 200 µg per day. It is therefore recommended that women continue with a folic acid supplement of 200 µg per day during the last 6 months of pregnancy and during the breastfeeding period.

Women of child-bearing age are recommended to have a dietary intake of folic acid of 300 µg per day. With the exception of recommendations regarding pregnancy and breastfeeding, child-bearing women are not recommended to take folic acid supplementation.

The above recommendations were issued in the Spring of 1998 by the National Council on Nutrition and Physical Activity (1998). Before 1998, the official recommendations were those issued by the Board of Health in February 1993. These first recommendations did not recommend the use of supplements for any women other than those at risk of recurrence, but stated that women of child-bearing age should consume 400 µg through their diet.

Food Fortification Policy

There is no policy in Norway to fortify food with folic acid. A working group was established in 1997 by the National Council on Nutrition and Physical Activity to suggest recommendations and means of increasing the intake of folic acid among women of child bearing age. The working group's recommendation was not to implement food fortification with folic acid: it maintained that women should be recommended to have a supplementary intake of folic acid in connection with pregnancy (Rapport nr. 1/1998). Further decisions on food fortification policy will depend on current knowledge and uptake of advice regarding folic acid supplementation in the childbearing population. If a beneficial effect of folic acid supplementation on the general population (i.e. related to heart disease) is documented, this will also be an inducement to implement food fortification.

Health Education Initiatives

An official Health Education Initiative began in Norway in Autumn 1998 to inform women about the role of folic acid in reducing the risk for neural tube defects. The Norwegian Agency for Health and Social Welfare (formerly National Council on Nutrition and Physical Activity) has a public web site (1998). At the web site there is information on the occurrence of neural tube defects in Norway, recommended daily intake of folic acid, contents of folic acid in different foods, when to take supplementation of folic acid in connection with pregnancy, potential side effects related to high intake of vitamin A through multivitamin supplementation, and needs for special groups such as epileptic women.

Leaflets published by the Norwegian Agency for Health and Social Welfare (formerly National Council on Nutrition and Physical Activity) are distributed to women by general practitioners, specialists in gynecology and obstetrics, midwives, health care centres for

mother and child, drugstores, and pharmacies. Also posters and post cards are distributed, and there have been advertisements in women's magazines and other relevant magazines.

Health personnel are requested to inform women about folic acid and pregnancy at the time of giving guidance on contraceptive devices, doing pregnancy tests, removing an intrauterine device, selling of pregnancy tests, and selling of contraceptive devices. The Norwegian Agency for Health and Social Welfare has distributed a guide for health personnel with these items.

Folic Acid Awareness and Uptake

One paper was published in Norway concerning the awareness in the child bearing population of recommendations regarding folic acid supplementation and the uptake of advice regarding folic acid supplementation (Vollset & Lande 2000). After the recommendations were issued in the Spring of 1998, a random sample of 1500 Norwegian women of reproductive age was selected for study during the autumn 1998. Among the 1500 women, telephone interviews were carried out with 1146 women (Vollset & Lande 2000). A repeat study was done in 2000, in which telephone interviews were carried out with 1218 women. Results from this repeat study are not yet published, but some results are referred to here.

The folic acid recommendation issued by the National Council on Nutrition and Physical Activity in March 1998 was known by 22% of women in 1998 increasing to 32% in 2000. Supplementation with folic acid before conception or early in pregnancy, when that pregnancy was less than one year ago, was reported by 10% of women in 1998 increasing to 46% in 2000. Intention to follow the recommendations on folic acid supplementation in a future pregnancy was reported by 56% of women in 1998 increasing to 68% in 2000. Intention to follow recommendations on folate rich food in a future pregnancy was reported by 75% of women in 1998 and again in 2000. The women were also asked about other vitamin supplementation. Supplementation of other vitamins or minerals before or early in pregnancy among women in whom the last pregnancy was less than one year ago, was reported by (numbers for 2000 in parenthesis) 57% (79%) for any vitamin or mineral supplementation, 29% (30%) for multivitamins, 5% (11%) for vitamin B, 28%(20%) for iron, and 21% (32%) for cod liver oil.

Proportion of Pregnancies which are Planned

There is little knowledge in Norway about the proportion of pregnancies that are planned. In the Norwegian Cohort Study (www.fhi.no), preliminary unpublished data show that 76% of the pregnancies were planned. The response rate in this study was about 50%, and we believe that the proportion of planned pregnancies is lower in the total population than that reported in the Norwegian Cohort Study.

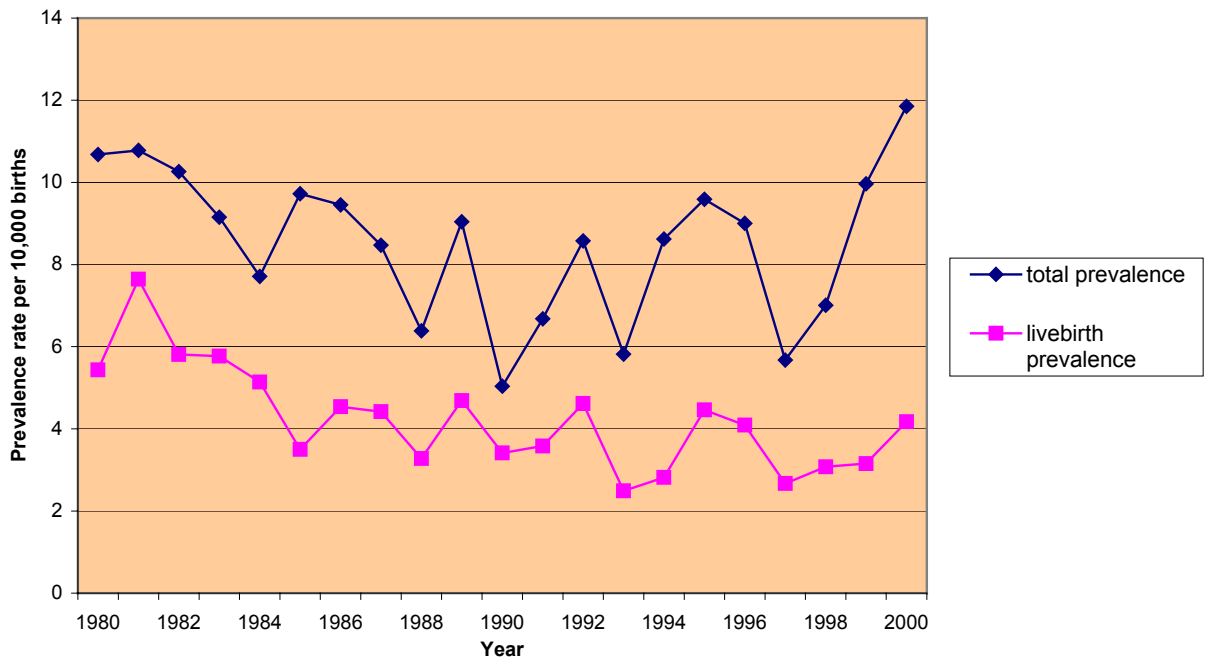
Laws Regarding Termination of Pregnancy

Induced abortion is legal at a woman's request up to 12 completed weeks of gestation. Induced abortion is legal on specified medical and social indications above 12 completed weeks and up to 18 completed weeks, and the decision is made by an abortion board. After 18 completed weeks, induced abortion is legal if the pregnancy represents a serious risk to the mother, or if the fetus suffers from a condition incompatible with life. In those cases there is no gestational age limit.

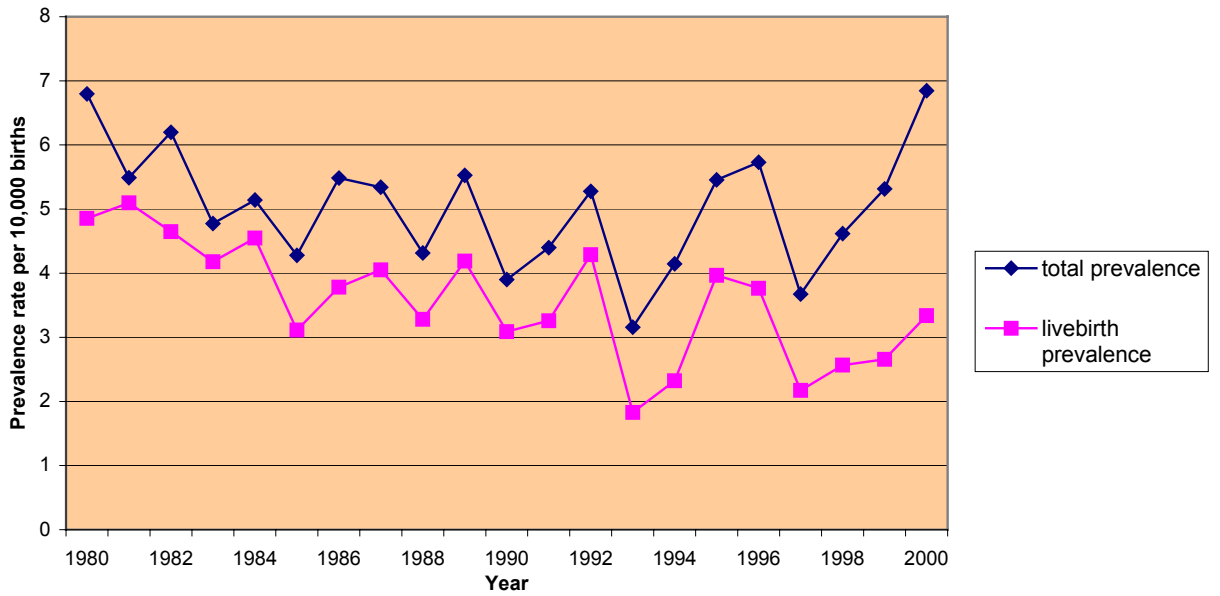
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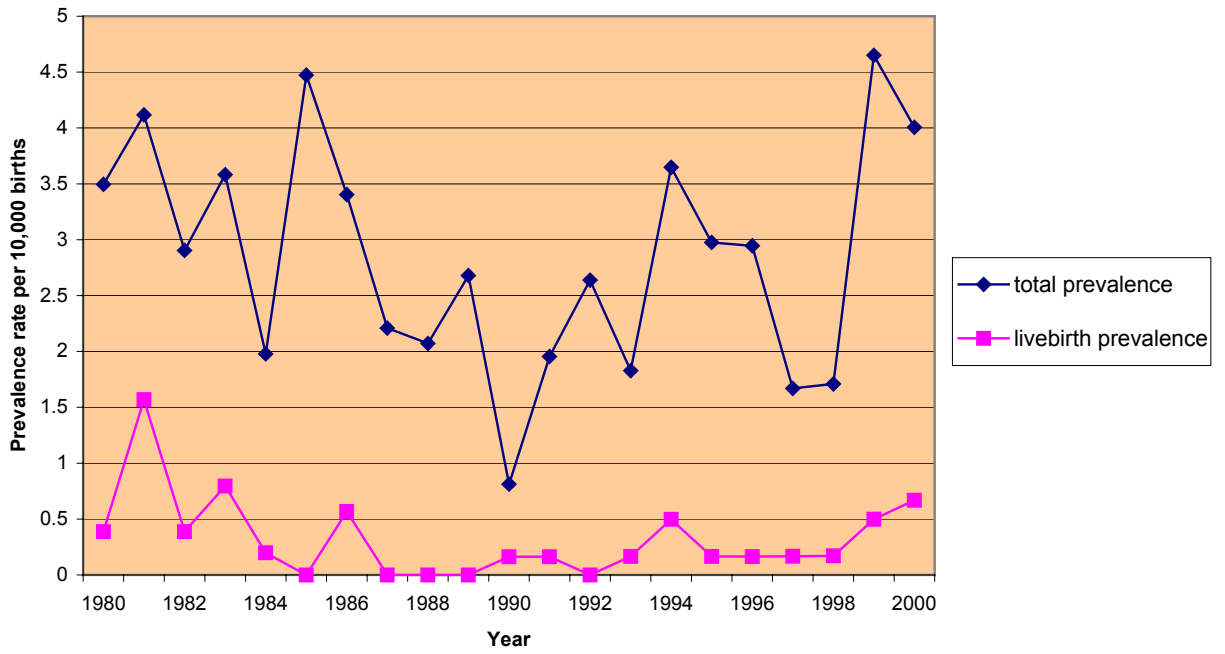
Norway: Total and Livebirth Prevalence Rates for Neural Tube Defects



Norway: Total and Livebirth Prevalence Rates for Spina Bifida



Norway: Total and Livebirth Prevalence Rates for Anencephalus



REPORT ON PERICONCEPTIONAL FOLIC ACID SUPPLEMENTATION FOR POLAND

Dr Anna Latos-Bielenska

Folic Acid Supplementation Policy

Since 1997 there has been a nation wide government program regarding periconceptional folic acid supplementation. The program “Primary Prophylaxis of Neural Tube Defects”, is headed by Professor Zbigniew Brzezinski, from the Department of Epidemiology, Institute of Mother and Child, Warsaw.

Food Fortification Policy

Food fortification is planned for the Lublin Province in which there are approximately 30,000 births per year.

Health Education Initiatives

An educational program is aimed at women, health care professionals and children over fifteen years of age.

Knowledge and Uptake of Folic Acid

In 1999, folic acid supplementation was taken by 15% of women aged 18-45; by 11% of non-pregnant women between those ages; and by 9% of women under 20 years of age.

In 2001, folic acid supplementation was taken by 19% of women aged 18-45; by 13% of non-pregnant women between those ages, and by 16% of women under 20 years of age. Thus, folic acid supplementation rates had gone up for all three categories within the space of two years. (Report on realization of program of primary prophylaxis of neural tube defects in 1997-2001, Institute of Mother and Child, Warsaw 2000).

57% of women took other vitamin supplements.

Proportion of Pregnancies which are Planned

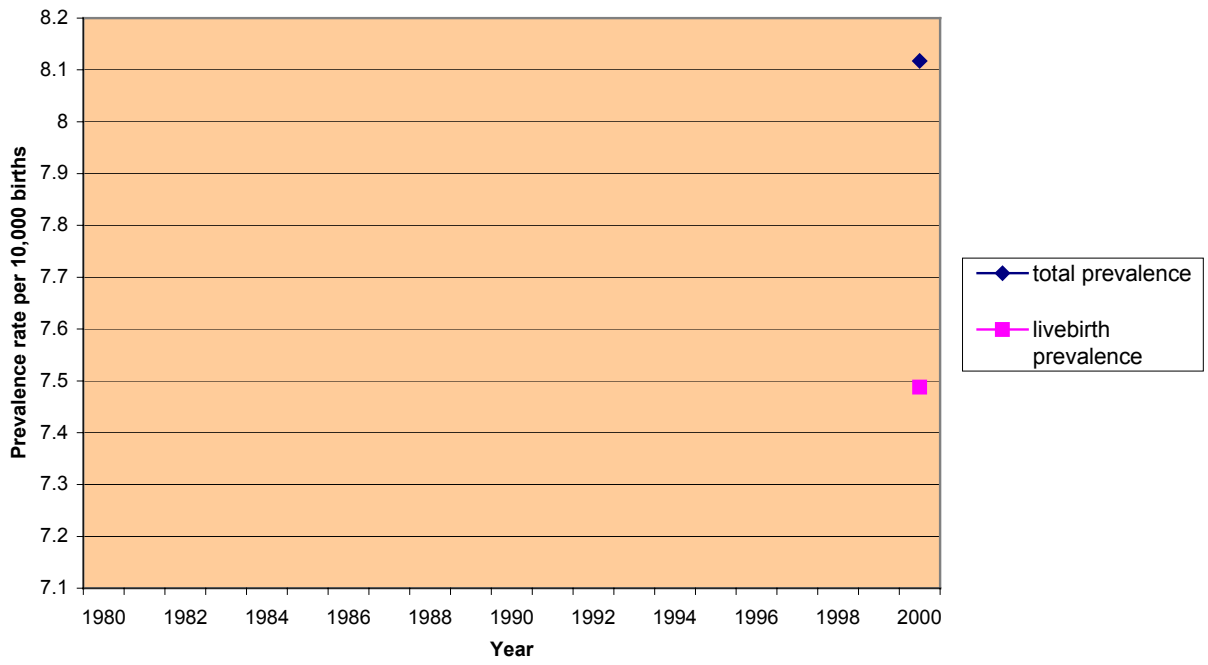
The proportion of pregnancies which are planned in Poland is low.

References

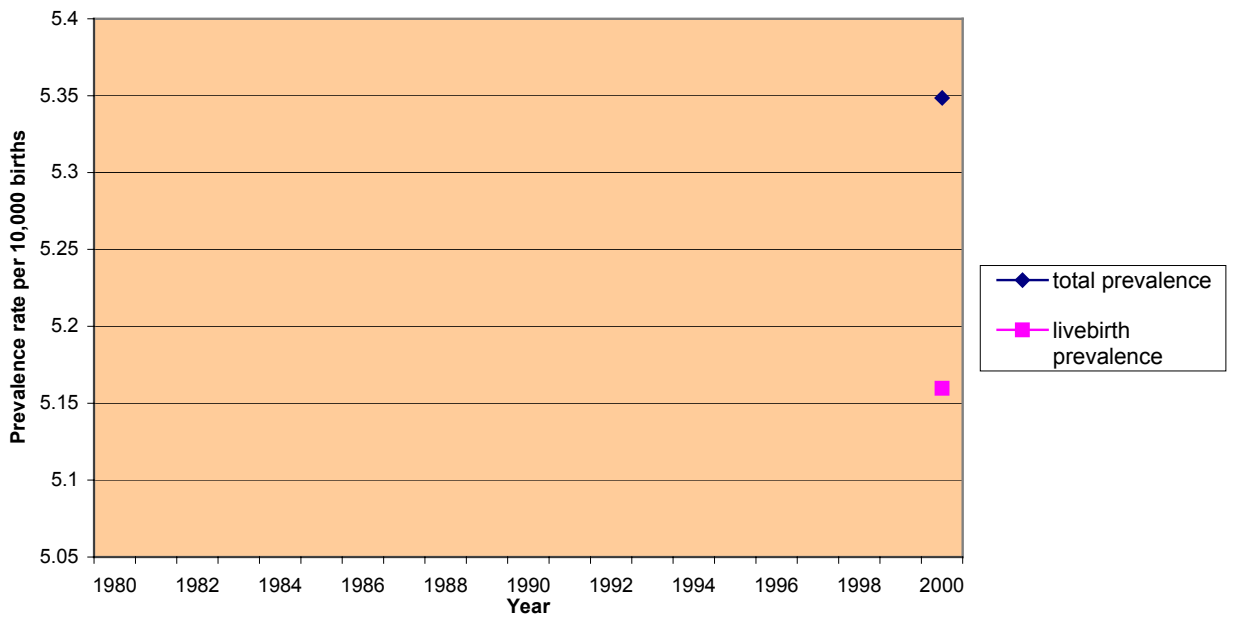
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Program of primary prophylaxis of neural tube defects, Institute of Mother and Child, Warsaw, **2002**.

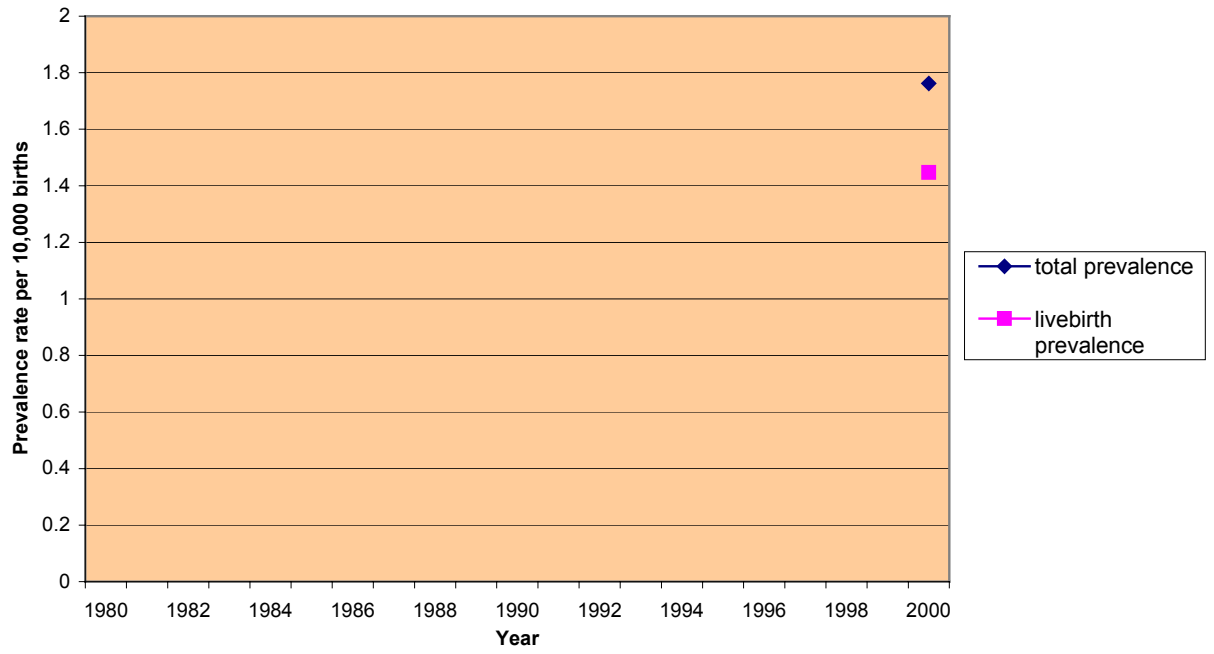
Poland: Total and Livebirth Prevalence Rates for Neural Tube Defects



Poland: Total and Livebirth Prevalence Rates for Spina Bifida



Poland: Total and Livebirth Prevalence Rates for Anencephalus



REPORT ON PERICONCEPTIONAL FOLIC ACID SUPPLEMENTATION FOR PORTUGAL

Dr Paula Braz

Folic Acid Supplementation Policy

There is a recommendation from the Directory of Health “Directory of Health guideline number 2/DSMIA” to all health care professionals, to inform the childbearing population about the importance of folic acid. There is no information about dosage. This policy was introduced in March 1998

Food Fortification Policy

There is no food fortification policy, but one of the most important commercial firms in Portugal for milk products (Mimosa) decided three years ago to fortify milk with 50µg/100ml of folic acid.

Health Education Initiatives

There is no official health education initiative, but the recommendation from the Directory of Health in March 1998, suggested that general practitioners should inform their female patients about the importance of folic acid supplementation.

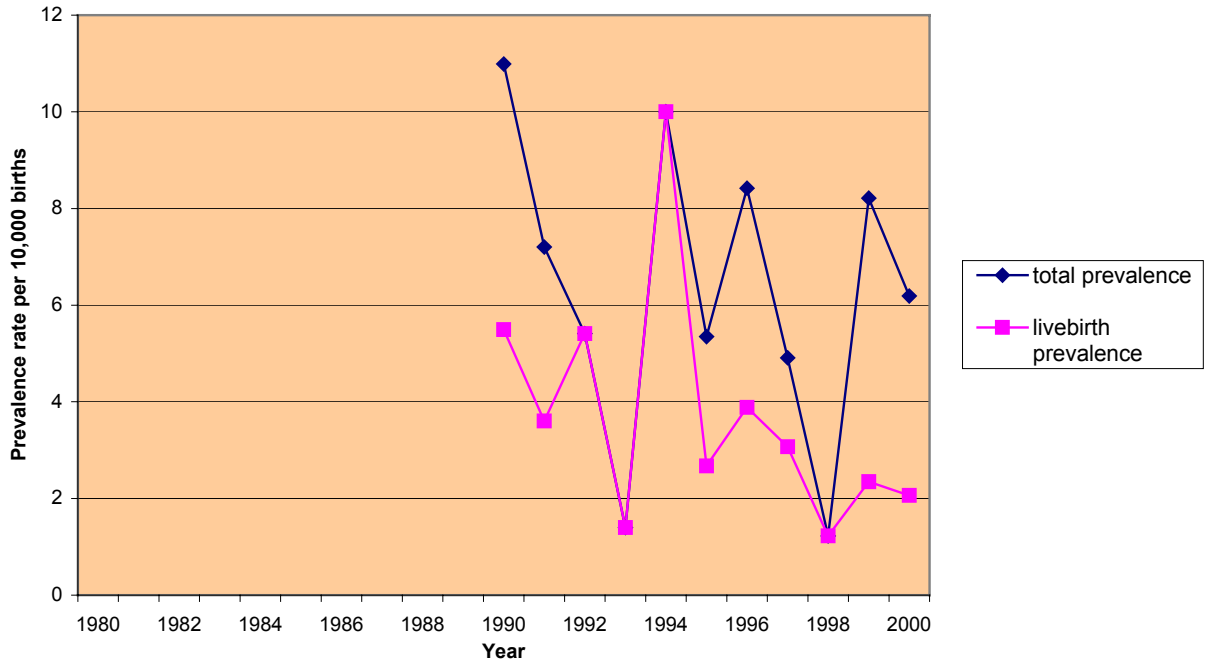
Knowledge and Uptake of Folic Acid

To our knowledge there are no studies in the Portuguese population.

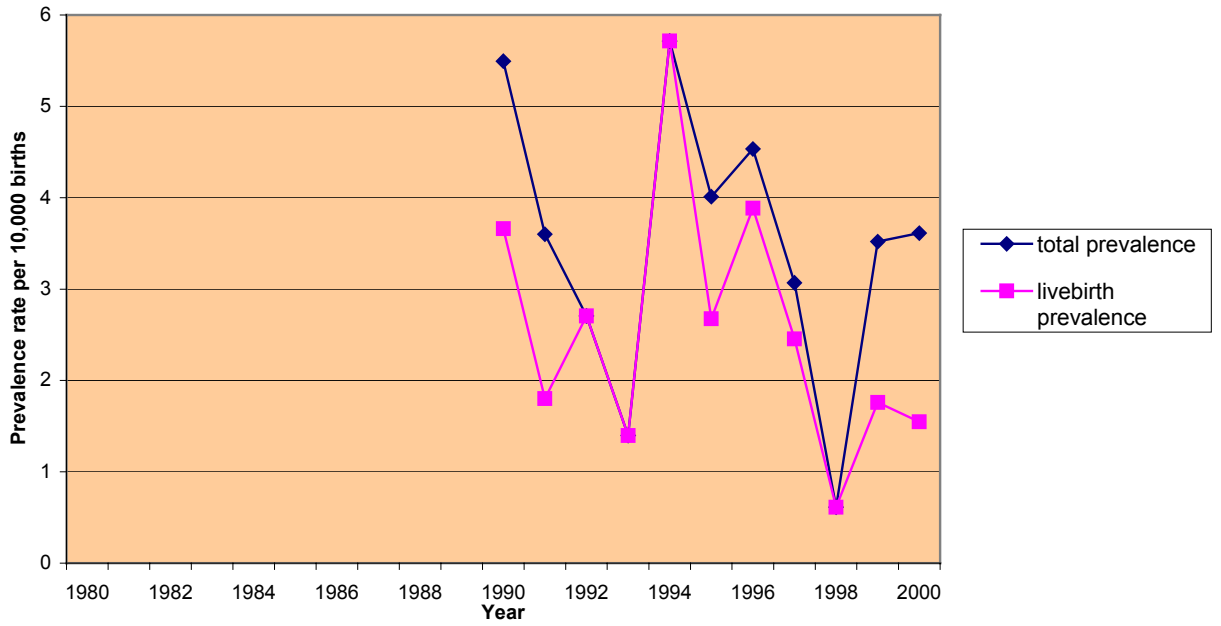
Laws Regarding Termination of Pregnancy

Termination of pregnancy is legal in Portugal until 24 weeks gestation for major congenital anomalies, rape, and risk to the mother’s health. It is legal up to term if an anomaly is incompatible with life. There is a technical committee in each obstetric unit in which terminations are performed which decides in each case if the procedure is legal.

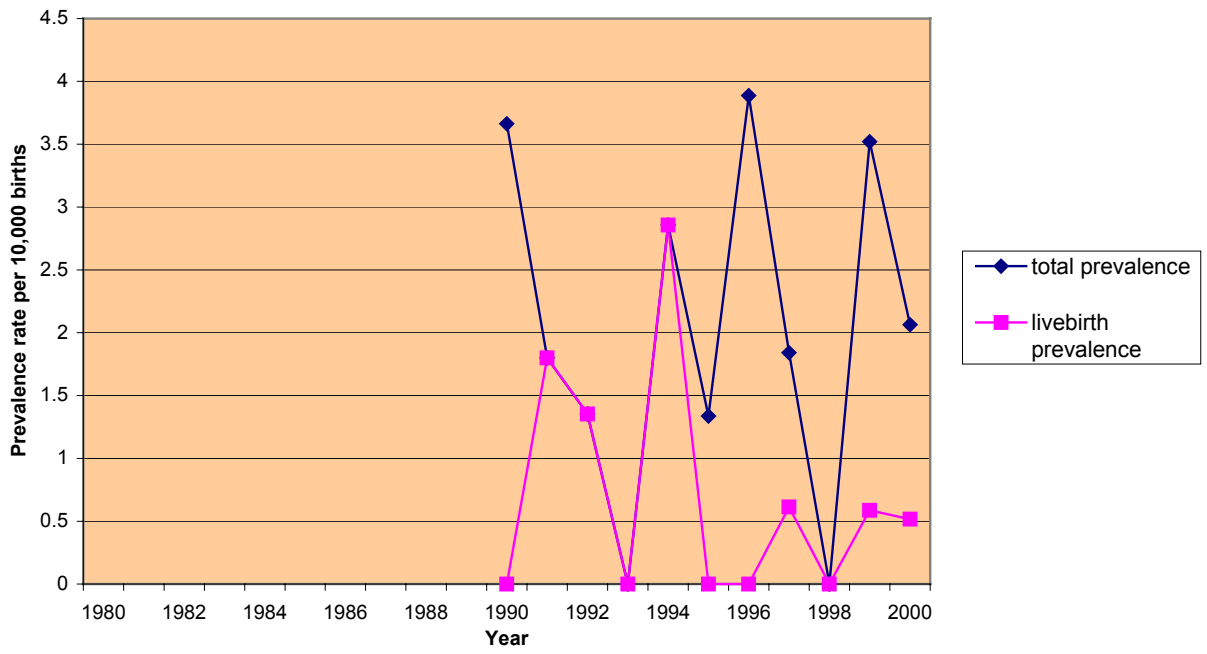
Portugal (Southern): Total and Livebirth Prevalence Rates for Neural Tube Defects



Portugal (Southern): Total and Livebirth Prevalence Rates for Spina Bifida



Portugal (Southern): Total and Livebirth Prevalence Rates for Anencephalus



REPORT ON PERICONCEPTIONAL FOLIC ACID SUPPLEMENTATION IN SPAIN

Dr Blanca Gener

Folic Acid Supplementation Policy

The most recent official recommendations from the Ministry of Health regarding folic acid supplementation in order to reduce the risk of having a child affected with an NTD was published in 2001 (*Dirección General de Salud Pública. M° de Sanidad y Consumo. Int Ter Sist Nac Salud 2001, Vol 25, pp 66-67*). These recommendations stated that all women who are considering a pregnancy and have no family history of NTD should take 0.4 mg per day of folic acid at least one month before conception and during the first three months of pregnancy. Those women who have already had a child affected with NTD should take a dose of 4 mg per day of folic acid at least one month before conception and during the first three months of pregnancy. In addition, the Ministry of Health recommends that any pregnant woman should consume food rich in folic acid. The daily requirements of folic acid in a pregnant woman's diet are estimated to be 400 µg, twice that of a non pregnant woman (200 µg). A table with the content of folic acid in certain foods is also available.

The 2001 recommendations replaced those published in 1998, which had targeted only those women who had previously had a child affected with an NTD.

In addition to government recommendations, the Spanish Society of Gynecology and Obstetrics (SEGO) is very interested in promoting the preconceptional care of women. Special stress is laid on supplementation with folic acid. It should start at least one month before conception, and continue until 10-12 weeks of gestation. The specific recommendations are detailed below.

- All women with a low risk of having a fetus affected with NTD should take 0.8 mg per day of folic acid, besides ensuring they have a balanced diet.
- All women with high risk of having a fetus affected with NTD, should take at least 4mg per day of folic acid, besides ensuring they have a balanced diet.

- It is advisable to avoid the use of multivitamin tablets in order to achieve the expected doses of folic acid, because an excess of other vitamins (e.g. vitamins A and D) could be dangerous both for the fetus and the mother.

Food Fortification Policy

For the moment there is no specific official food fortification policy. However, there is voluntary food fortification with folic acid. In Spain most breakfast cereals are fortified by food companies.

Knowledge and Uptake of Folic Acid

In Spain, the average daily intake of folic acid in the adult female population is estimated at: 252 (103) μg (Aranceta et al 1994). The average daily intake of folic acid in pregnant women is estimated at: 258 (89) μg (Aranceta et al 1994). 10% of women in Spain are at risk of having a diet without enough folic acid.

In the Basque country the daily intake of folic acid in the adult female population is estimated to be 212 (108) μg (Aranceta et al 1994). 14% of adult females have suboptimal levels of serum folate. 25.7% of adult females have suboptimal levels of red cell folate. The percentage of women of reproductive age with inadequate intake of folic acid is 25%.

¹indicates the standard deviation of the mean folic acid intake.

“Folates and vitamin B12 in pregnant women”. Ballesteros G, Muñoz P, Lopez M.E., De Miguel J.R. Prog Obstet Ginecol 1999, Vol 42, pp 543-557.

Study design: A prospective observational serial prevalence study to determine levels of red cell folate and serum levels of folate and vitamin B12 in a sample group of 406 pregnant women in Cantabria (Spain), distributed by areas and health care centres related to their number of births in 1993. All the women underwent an analytical determination upon beginning prenatal care. Some 94,5% had a second and 84,2% a third such determination. For each of the vitamins the values obtained were analysed for their distribution and correlation with respect to gestational age, considering the incidence of supplementation and the moment in which it took place. Results: Folate

and vitamin B12 levels in the sample group were comparable throughout the gestation period with figures published in other studies, and generally higher. However, in the first trimester, only 12% had optimum folate levels to prevent NTD, whereas levels in 68,2% of the women involved risks of NTD greater than those in other population groups.

“Primary prevention of neural tube defects in the population served by a reference hospital”.

Gilbert M.J., Juncosa N, Martín I. Prog Obstet Ginecol 2000, Vol 43, pp 13-20.

Study design: Retrospective descriptive study of 651 mothers attended in the Hospital Son Dureta in Palma de Mallorca (Balear Isles) during the second trimester in 1998.

Results: Folic acid supplementation was used by 381 pregnant women (58,5%). Only 4,5% of the prescribed preventions were sufficient and they were more frequent in private medicine (12%) than in public medicine (3,4%) (p= 0.036). 85,2 % of midwives and 45,7% of gynecologists recommended prophylaxis when the mother first attended the antenatal clinic or before (p<0.001).

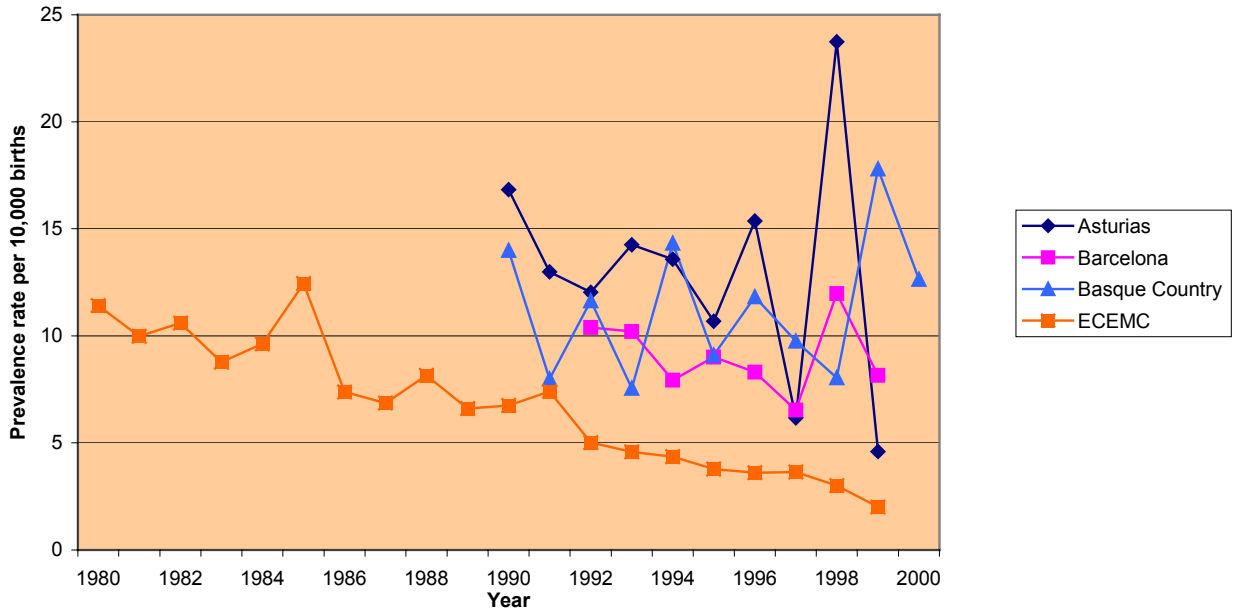
Laws Regarding Termination of Pregnancy

Termination of pregnancy in Spain is allowed up to 22 weeks of gestation if the fetus is expected to be born with severe physical or intellectual defects (unspecified). Two doctors must sign that any of those indications is present.

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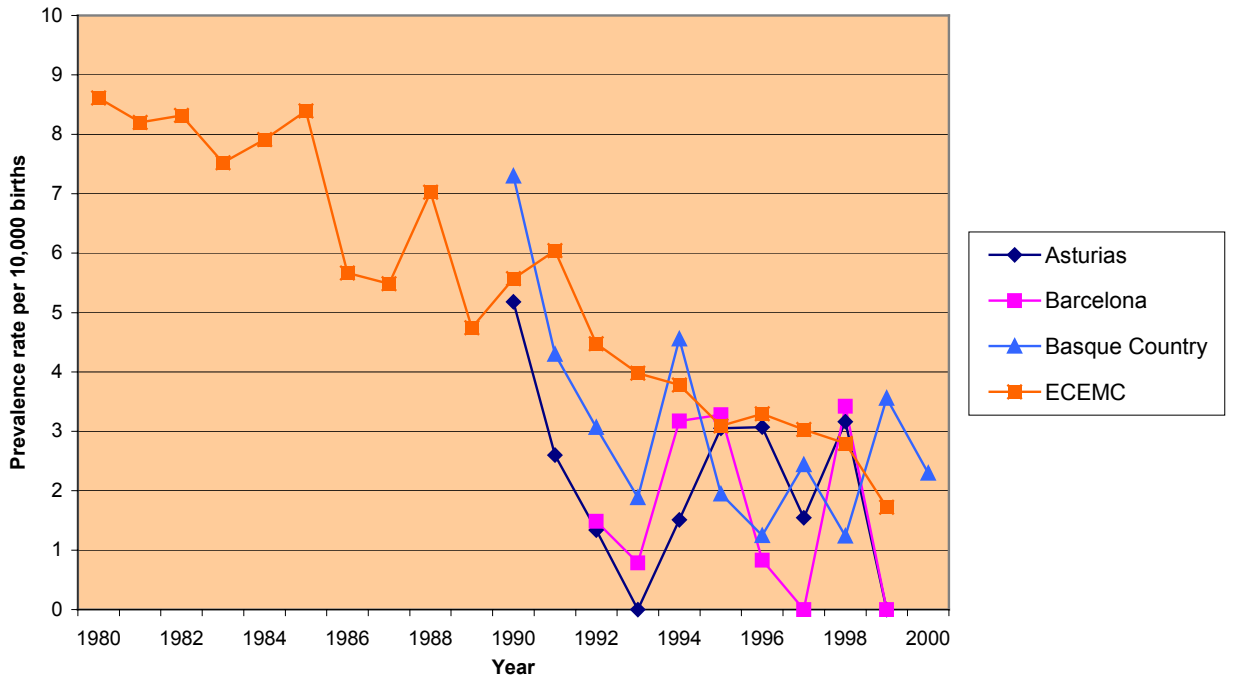
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Spain (Asturias, Barcelona, Basque Country and ECEMC): Total Prevalence Rate* for Neural Tube Defects

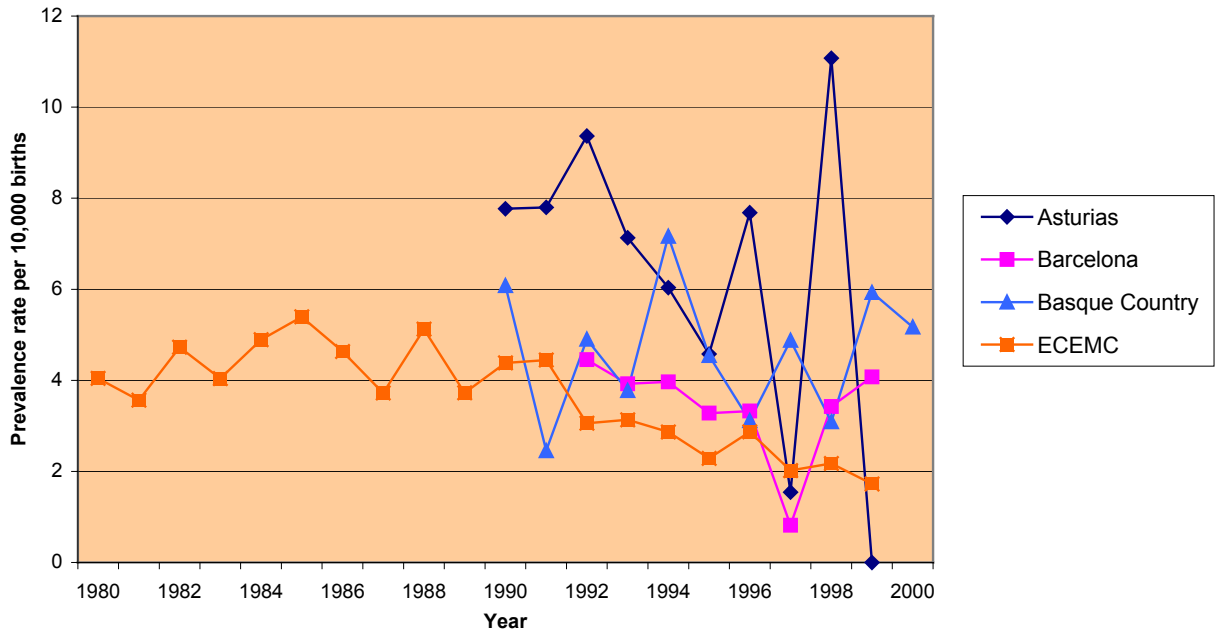


*Data for the ECEMC registry do not include pregnancies that were terminated.

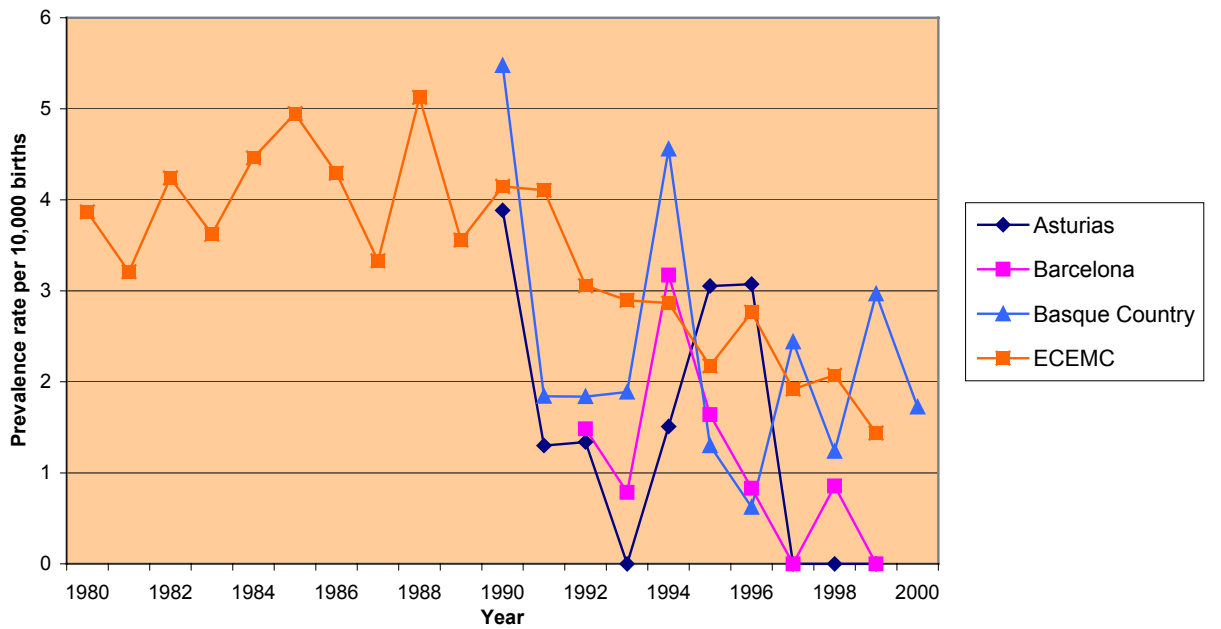
Spain (Asturias, Barcelona, Basque Country and ECEMC): Livebirth Prevalence Rate for Neural Tube Defects



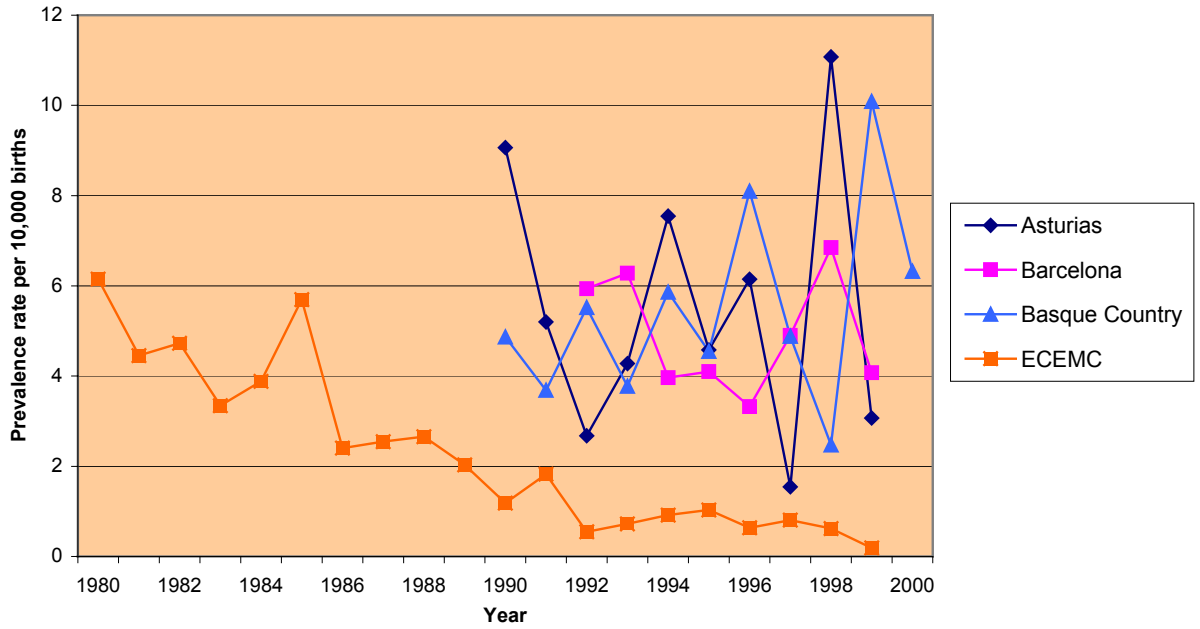
Spain (Asturias, Barcelona, Basque Country and ECEMC): Total Prevalence Rate for Spina Bifida



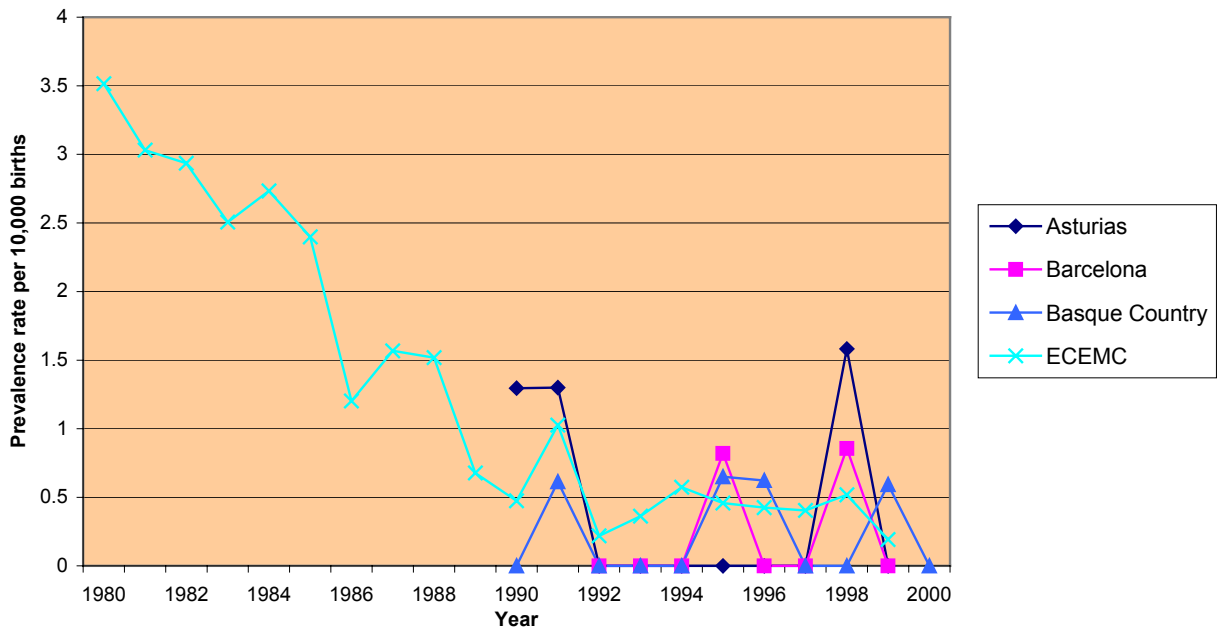
Spain (Asturias, Barcelona, Basque Country and ECEMC): Livebirth Prevalence Rate for Spina Bifida



Spain (Asturias, Barcelona, Basque Country and ECEMC): Total Prevalence Rate for Anencephalus



Spain (Asturias, Barcelona, Basque Country and ECEMC): Livebirth Prevalence Rate for Anencephalus



REPORT ON PERICONCEPTIONAL FOLIC ACID SUPPLEMENTATION FOR SWITZERLAND

Dr Marie-Claude Addor

Switzerland is a federal country comprising 26 cantons. Most responsibilities in the health field are vested in the Cantonal Public Health Services. On the federal level, there is a Federal Office of Public Health whose guidelines now have a large audience and are used as the legal basis.

Folic Acid Supplementation Policy

In the early 1990s, the Public Health Officer for the canton of Vaud, at the request of the University Department of Gynecology and Obstetrics, asked the Federal Office of Public Health to support the idea of a national recommendation concerning folic acid and the prevention of neural tube defects (NTD).

The current recommendations (2002) for primary prevention are as follows:

- 0.4 mg folic acid supplementation (with or without other vitamins) should be taken daily from four weeks before conception until twelve weeks after.
- All women of child bearing age without safe contraception should consume a folate rich diet (fresh fruits and vegetables, whole grain products and fortified food eg cereals and breakfast beverages).
- Women who have had a previous pregnancy affected by a neural tube defect are advised to take the following supplements periconceptionally:
 - 4-5 mg folic acid daily, monopreparation (Folvite, Ac. Folicum, Foli-Rivo)
 - polyvitamins = 0.4-1 mg folic acid (vit A \leq 8000 UI)

Food Fortification Policy

In 1997, Wiederkehr et al submitted to the Swiss representative assembly a proposal for the mandatory fortification of flour with folic acid for the prevention of neural tube defects.

Since 2000, the Federal Office of Public Health has been studying the folate situation in Switzerland (3) and a working group of the Swiss Nutrition Council has submitted a report for the Federal Government with scientific recommendations, published in 2002(4).

The current recommendation regarding fortification is that flour should be fortified on a mandatory basis by 3 mg folic acid and 10 micrograms of vitamin B12 per kg of flour in order to obtain a supplementary daily intake of folic acid of 275 micrograms and about 1 microgram of B12 per day. This is the most efficacious, sure and economic way to prevent NTD.

It should be noted that this recommendation is supported by the Swiss Nutrition Council but not yet by the Federal Office of Public Health. The fortification with folic acid of other foods is under re-evaluation. The potential benefits of folic acid in the Swiss population have now been evaluated and this knowledge will influence the official federal policy for folic acid fortification in Switzerland. At the moment the Federal Office of Public Health is considering the next steps to be taken.

Health Education Initiatives

A working group of the Federal Office of Public Health is preparing a booklet and a leaflet for women in childbearing age. Some booklets, edited by pharmacists “vitamin info” are available in waiting rooms of gynaecologists.

Uptake and Knowledge of Folic Acid.

The percentage of pregnancies that are planned in Switzerland is very low and there are very few “preconceptional consultations”. Awareness in the child bearing population of the recommendations regarding folic acid supplementation is still poor.

In Switzerland, the daily dietary intake of folate has been estimated to be 275 µg or even less.

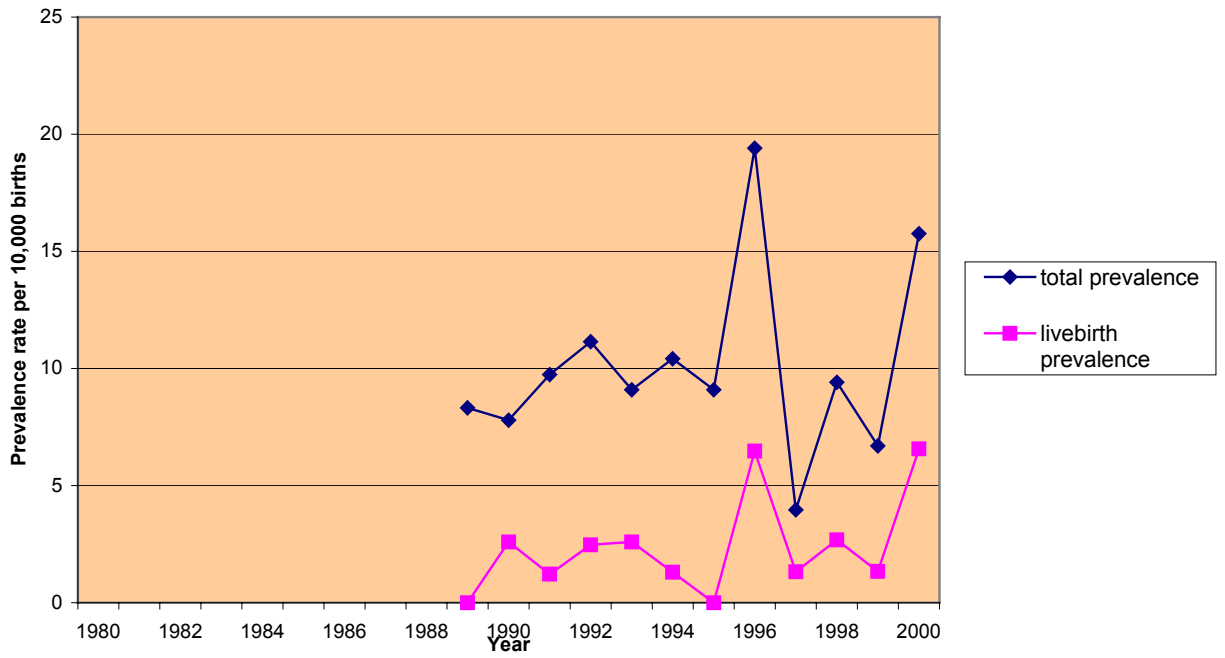
Laws Regarding Termination of Pregnancy

Termination of pregnancy is legal up to 24 weeks gestation. Thereafter, it is not legal for any indication.

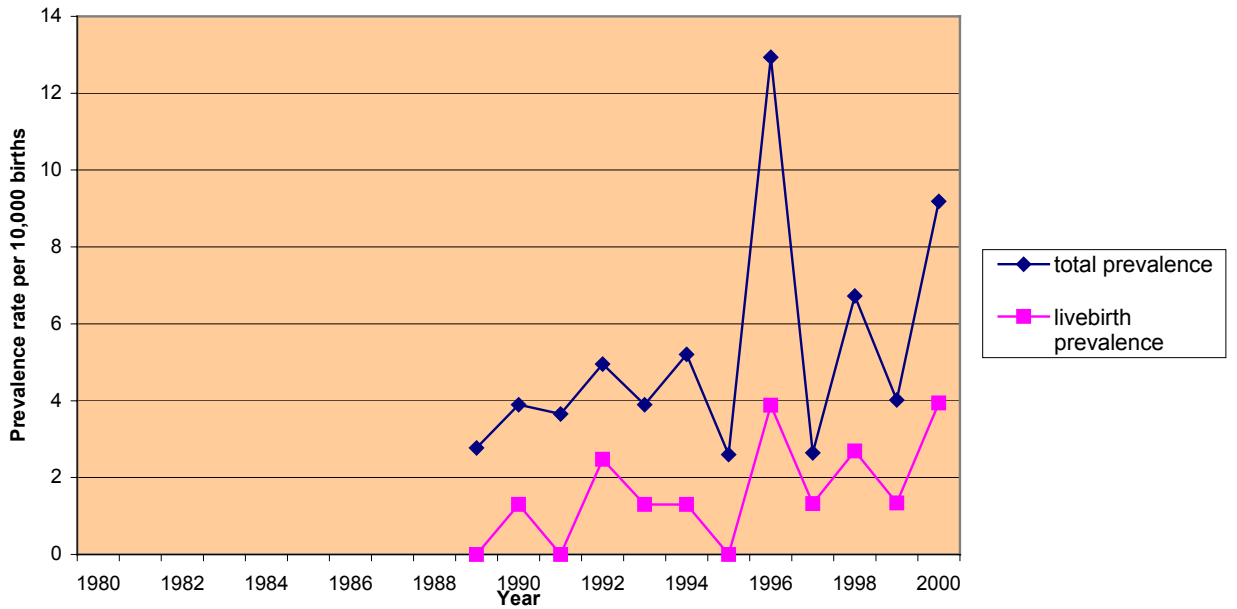
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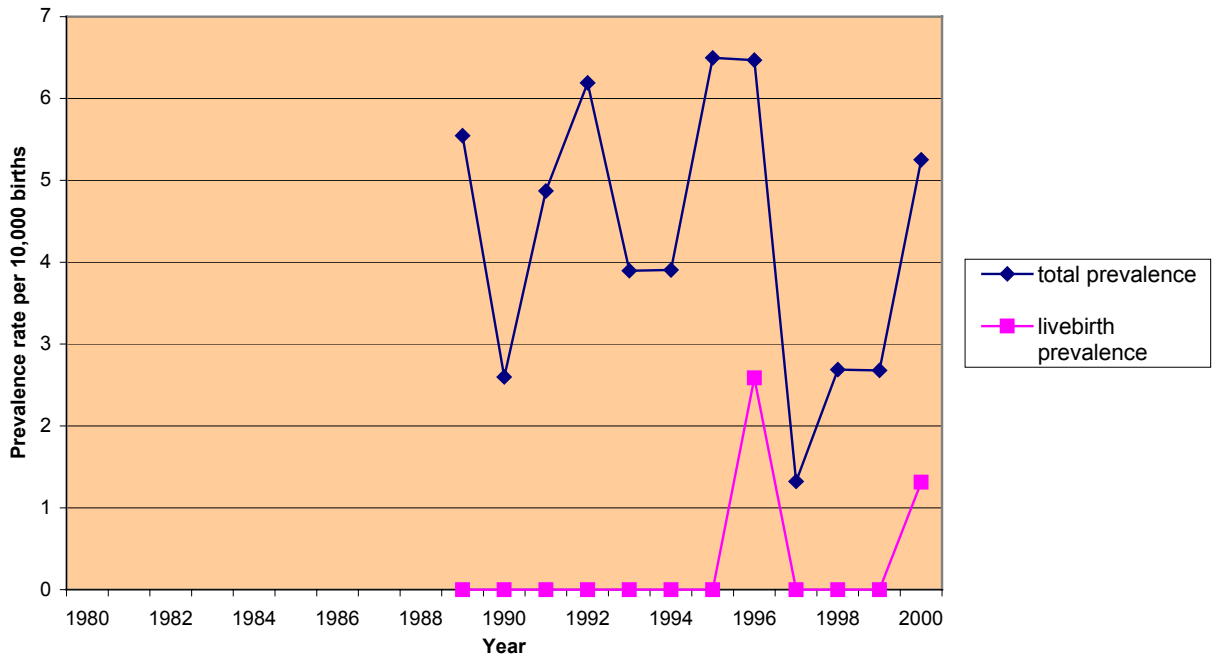
Switzerland (Vaud): Total Prevalence Rate for Neural Tube Defects



Switzerland (Vaud): Total Prevalence Rate for Spina Bifida



Switzerland (Vaud): Total Prevalence Rate for Anencephalus



REPORT ON PERICONCEPTIONAL FOLIC ACID SUPPLEMENTATION FOR THE UNITED KINGDOM

Dr Grace Edwards

Folic Acid Supplementation Policy

The link between folate deficiency in pregnancy and neural tube defects was first reported in the United Kingdom by Hibbard and Smithells in 1968. A randomised control trial funded by The Medical Research Council, UK, confirmed that improving folic acid status periconceptionally in women who had had a previous child with a neural tube defect reduced the recurrence risk in that pregnancy (MRC Vitamin Study research Group 1991). As a result, in 1992 the Department of Health in conjunction with the Scottish Office, the Welsh Office and the Northern Ireland office produced a report recommending that folic acid supplementation should be taken by all women contemplating pregnancy (Department of Health 1992). The report recommended that all women take 400 µg of folic acid per day when planning a pregnancy. Women who have had a baby with a previous neural tube defect are advised to take 5 mg per day before conception and until 12 weeks of pregnancy.

Food Fortification Policy

There is no mandatory fortification of food in the United Kingdom. However, most breakfast cereals have been fortified voluntarily with vitamins and minerals such as B vitamins, including folic acid, and iron for many years, although there is no standardised amount and there are varying levels of fortification with folic acid.

Since the original work of Hibbard and Smithells there has been increasing debate on the fortification of flour with folic acid. A recent report on the role of folic acid in preventing neural tube defects was published by the Committee of Medical Aspects of Food and Nutrition (COMA 2000). This report concluded that by fortifying flour with folic acid, a significant proportion of neural tube defect affected births could be prevented. The report looked at both the benefits and possible risks of folic acid intake and concluded that:

- Universal fortification of flour with folic acid at 240 µg per 100 grams in food products as consumed would reduce the risk of a neural tube defect in unborn babies and children by 41% without resulting in unacceptably high intakes in any group of the population

- Women who could become pregnant should continue to be advised to take a diet rich in folate and take folic acid supplementation.

However, there is no consensus on the introduction of a food fortification programme without a controlled field trial. The main concern is that fortification may mask megaloblastic anaemia in people with vitamin B12 deficiency (Wharton & Booth 2001). A recent review for the Cochrane collaboration looked at four trials of supplementation involving 6425 women. The review concluded that periconceptional folate supplementation has a strong protective effect against neural tube defects. Consensus regarding the relative benefits and risks of fortifying basic foodstuffs such as flour remain unresolved (Lumley et al 2000), in spite of recognition of the success of food fortification in the US which has reduced the rate of neural tube defects from 37.8 per 100,000 livebirths before fortification to 30.5 per 100,000 livebirths following fortification, representing a 19% decline (Wise 2001, Honein et al 2001). A public consultation was undertaken in the United Kingdom. In May 2002, the Food Standards Agency recommended that mandatory fortification should not be implemented.

Health Education Initiatives

In 1995 a UK campaign led by the Health Education Authority (HEA) was launched to improve folate status awareness in women of child bearing age. This campaign highlighted ways of improving folate status before conception and up to 12 weeks of pregnancy by increasing folic acid intake from foods and supplements. This was a large and expensive campaign with advertisements on television, in newspaper, magazines and professional journals. Although the campaign raised awareness in women from 9% in 1995 to 68% in 1998, only 38% of women surveyed in 1998 took folic acid around the time of conception (Health Education Authority 1998).

It should be noted that Northern Ireland was not covered by the television advertising campaign launched by the HEA in 1995. However, a Northern Ireland television advertising campaign was broadcast as part of a public information initiative developed by the Health Promotion Agency for Northern Ireland and launched in 1998.

Knowledge and Uptake of Folic Acid

Studies undertaken in the UK found that approximately half of women sampled were unaware of when they should take folic acid and of what effect it had. Work by Sens *et al* 2001 studied the knowledge, attitude and practice of pregnant women regarding periconceptional folic acid intake. A total of 300 women were sampled. Knowledge of the correct timing of folic acid intake was present in only 76% and was more likely in those women with a higher educational status. Less than half of the women (44.6%) had taken folic acid in the preconceptional period (Sens et al 2001). Other research by Mathews *et al* 1998 studied 969 randomly selected primigravida at 16 weeks gestation, found similar results and noted that women who are young, are of low educational status and are smokers were least likely to take folic acid (Mathews et al 1998). Although periconceptional supplementation with folic acid has been shown to be effective, the rate of decline in the true incidence of neural tube defects has slowed. Supplementation may not be taken at the appropriate time, or may not be taken by women who are at greatest risk (Mathews et al 1998).

Some work has been undertaken in the United Kingdom to measure the changes in folate consumption. Murphy et al found that dietary folate consumption had increased by 1.6% per annum in Scotland and 1.4% in England from 1980 to 1996. This increase was thought to have been linked with the introduction of folate fortification of cereals (Murphy et al 2000).

In Northern Ireland anecdotal evidence from antenatal clinics indicates an increase in uptake of folic acid supplements.

Proportion of Pregnancies which are Planned

A study by While (1990) found that up to one out of every three livebirths are unplanned (While 1990). These findings were supported by research in Merseyside, England (2000) where forty percent of women reported that their pregnancies were unplanned (Edwards 2001), and by research in other parts of Britain (McGovern et al 1997).

Laws Regarding Termination of Pregnancy

Under the 1967 Abortion Act (amended in 1990) abortion is legal in England, Scotland and Wales at gestational age up to 24 weeks provided that two doctors certify that a woman's mental or physical health (or that of her children) is at greater risk if she continues with the pregnancy than if she has a termination. There is now no gestational age limit for termination of pregnancy because of serious fetal abnormality or because there is a risk of permanent injury to a woman's health or life. The 1967 Abortion act does not apply in Northern Ireland.

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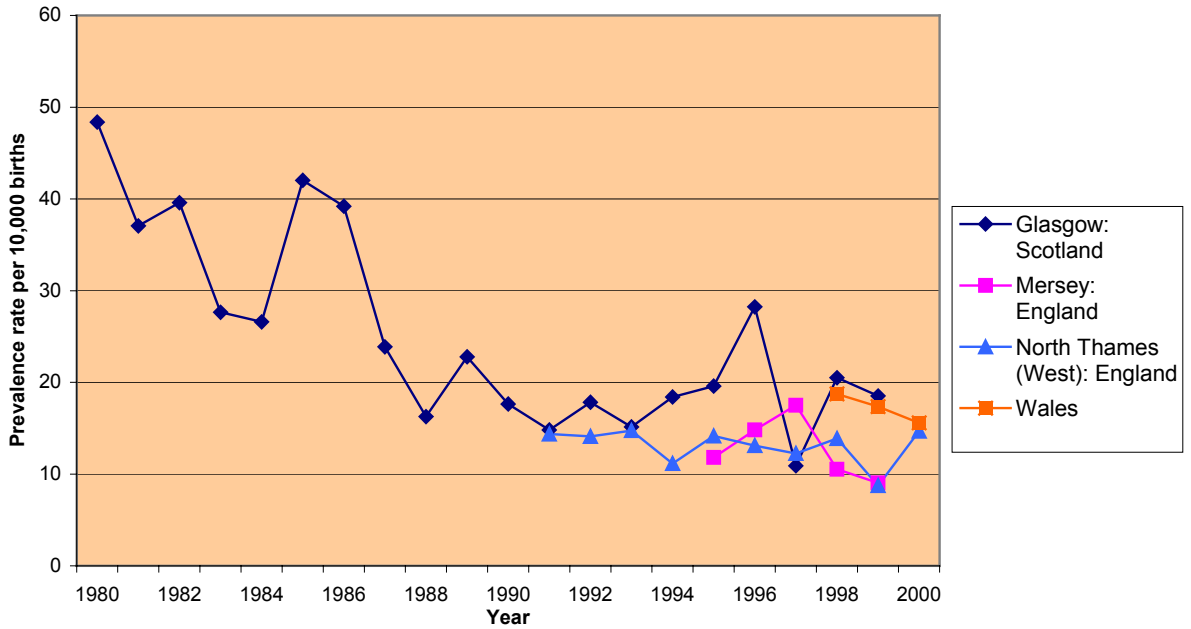
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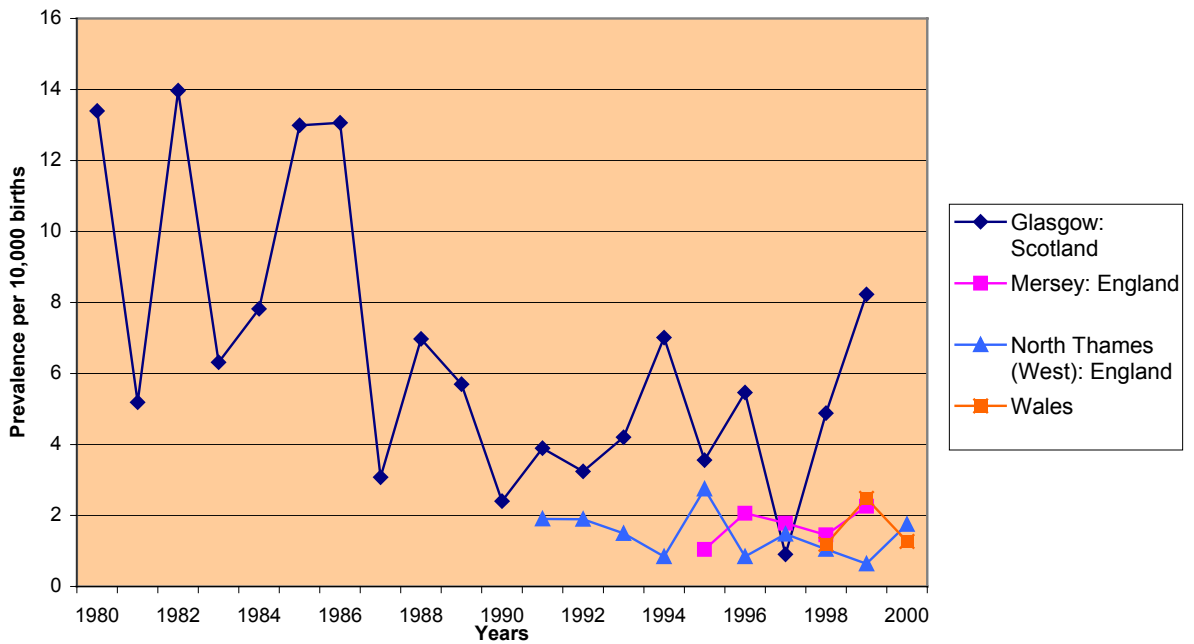
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Thanks to Margaret Slane of the Health Promotion Agency in Northern Ireland and Margaret Boyle, Senior Medical Officer, Department of Health, Social Services and Personal Safety Northern Ireland for their input about the situation in Northern Ireland.

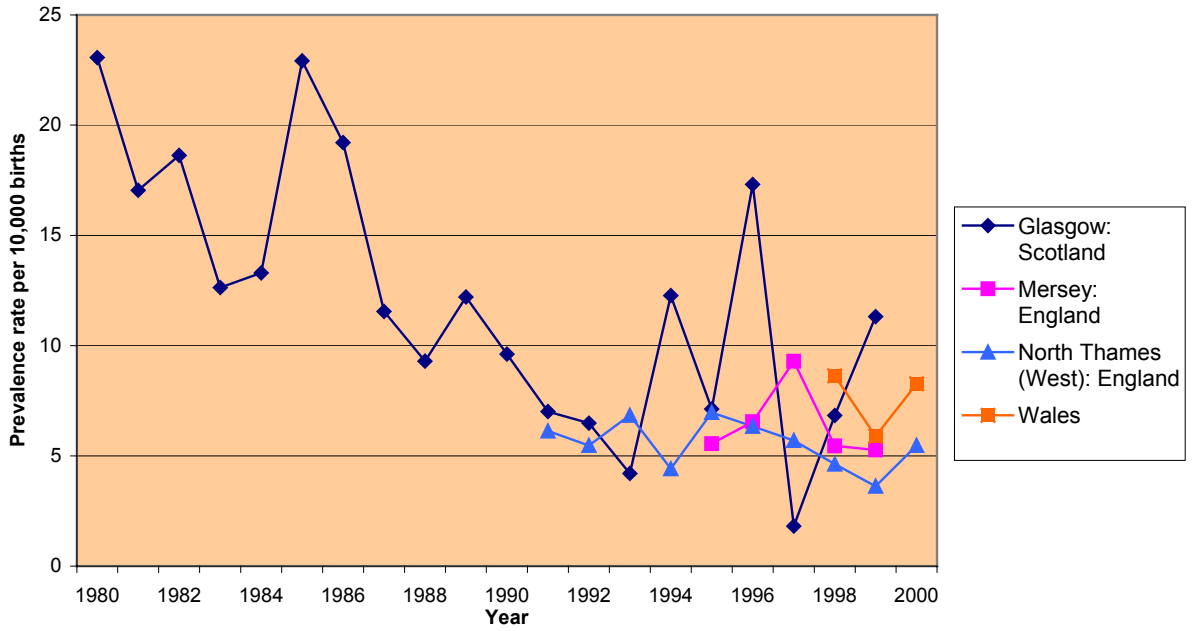
United Kingdom (Glasgow, Mersey, North Thames (West) and Wales): Total Prevalence Rate for Neural Tube Defects



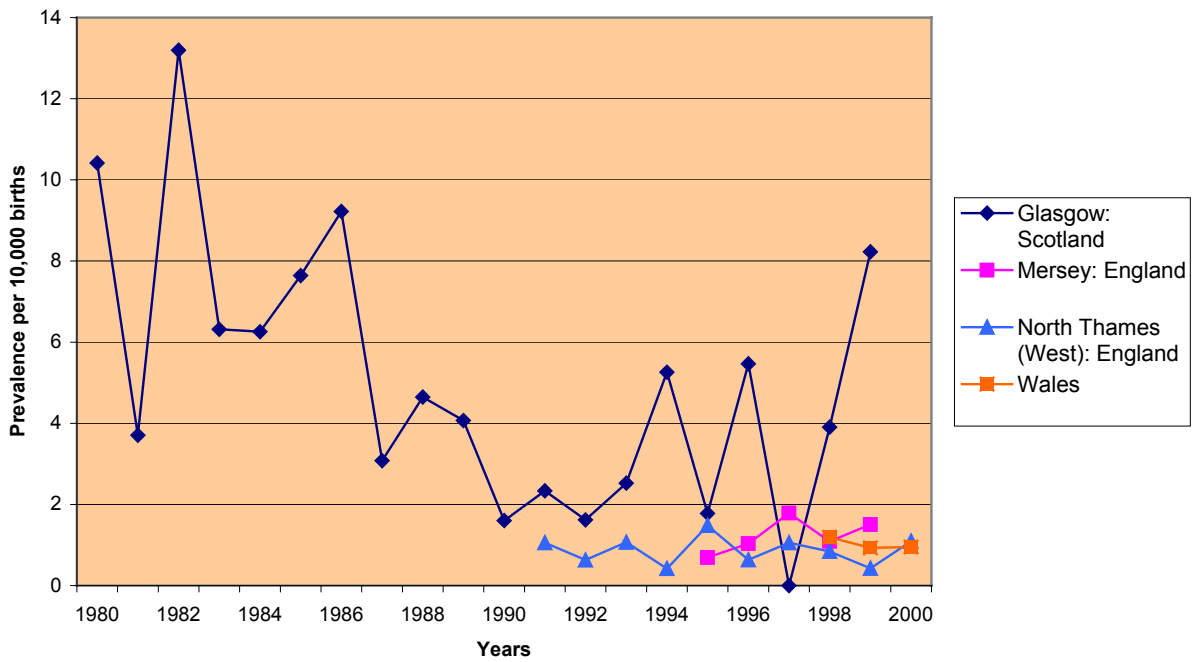
United Kingdom (Glasgow, Mersey, North Thames (West) and Wales): Livebirth Prevalence Rate for Neural Tube Defects



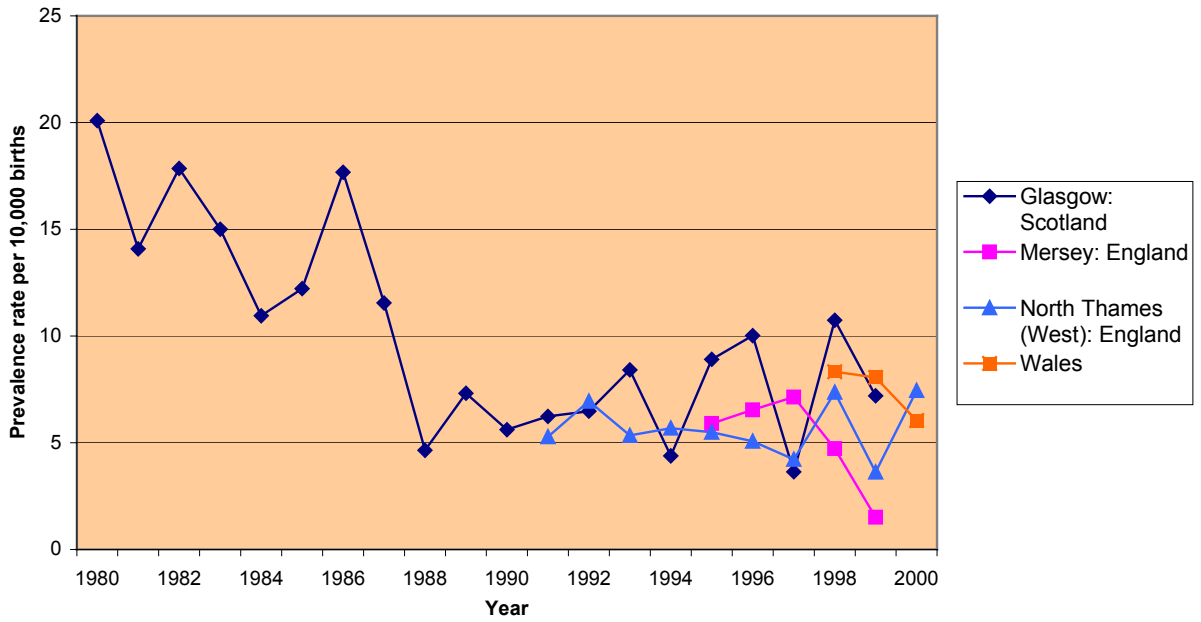
United Kingdom (Glasgow, Mersey, North Thames (West) and Wales): Total Prevalence Rate for Spina Bifida



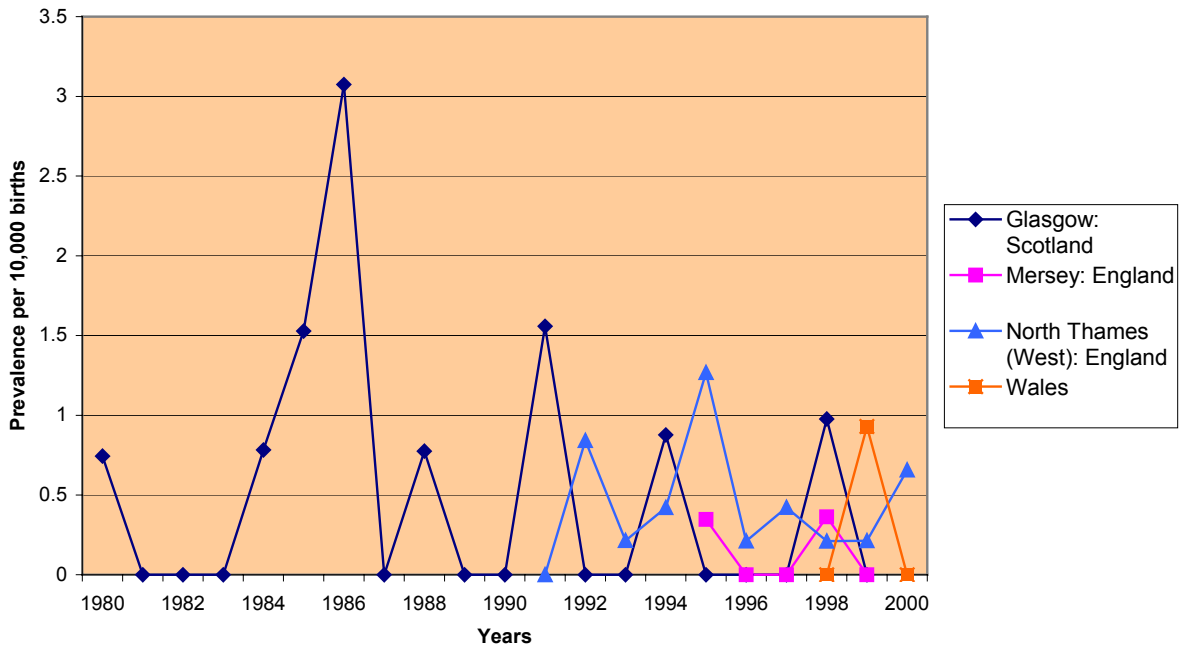
United Kingdom (Glasgow, Mersey, North Thames (West) and Wales): Livebirth Prevalence Rate for Spina Bifida



United Kingdom (Glasgow, Mersey, North Thames (West) and Wales): Total Prevalence Rate for Anencephalus



United Kingdom (Glasgow, Mersey, North Thames (West) and Wales): Livebirth Prevalence Rate for Anencephalus



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