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Strategies in the Prevention of Preterm Births During and Before Pregnancy

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1. Introduction

Preterm birth – defined as a childbirth before 259 days of gestation (<37 weeks) – is the major challenge in obstetrics and gynaecology worldwide. Preterm birth is associated with high perinatal mortality and surviving children often suffer higher morbidity throughout their lives. The incidence of preterm birth is very high in developing countries but also in some developed countries. According to a worldwide WHO report, Africa and North America, with rates of 11.9% and 10.6% in 2005, are the regions with the highest rates of incidence (Beck et al., 2010). Preterm birth not only causes much harm but also is associated with high costs. Despite considerable technical and medical improvements in obstetrics over recent decades, in developed countries preterm birth rates are not decreasing. On the contrary, the incidence continues to increase. In relation to possible preventive and epidemiologically well-founded measures, although onset and aetiology are not completely understood, our epidemiological knowledge concerning risk and protective factors of preterm birth is in no way poor. As regards preventive approaches, a distinction has to be made between primary and secondary preventive interventions, with this chapter focusing on the former.

After presenting some epidemiological and economic data on preterm birth, we will summarise the scope and results of certain programmes aiming to prevent preterm births. Subsequently, we will introduce the framework and methods of our prevention programme BabyCare. Special attention will be given to the evaluative methods and results achieved by our programme in terms of effectiveness and efficiency. While we can register a considerable and stable reduction in the incidence of preterm birth by at least 25% when comparing participants in the programme with a control data set, epidemiological analysis of our data indicates further that certain persistent risk factors of preterm birth observed in relation to programme participants require additional preventive measures which, ideally, should be implemented at the pre-conceptual stage. Consequently, after releasing the BabyCare Program in 2000, the PlanBaby Program was launched in 2007. In conclusion, interventional as well as evaluative problems and limitations of our programmes will be discussed.

2. Epidemiology and costs of preterm births

2.1 Incidence of preterm births

When dealing with the incidence of preterm births, a precise definition of the rates involved is often lacking. Both the numerator and denominator used in compiling rates can be differently defined. We have to distinguish rates referring to birth events from rates referring to infants born (either live births or all births). Logically, the rates referring to infants will be higher than those which refer to events.

		Absolute number		
A	Pregnant w omen / Birth events	89419		
B	Live births	90704		
C	Live births and still births	90986		
D	Preterm births	7123		
E	Preterm infants born alive	7860		
F	Preterm infants born alive and dead	8046		
		Definition		Incidence
	Birth event rate	D/A	7123/89419	8,0%
	Live birth rate	E/B	7860/90704	8,7%
	Live and still birth rate	F/C	8046/90986	8,8%

Table 1. Definitions of preterm birth rates (Perinatal Data from Medical association of Baden-Wuerttemberg, 2006).

In the United States of America, the incidence of preterm birth increased between 1990 and 2006 by 16%, rising from 10.6% to 12.8%, while since 2007 a slight reduction can be observed (Hamilton, 2010).

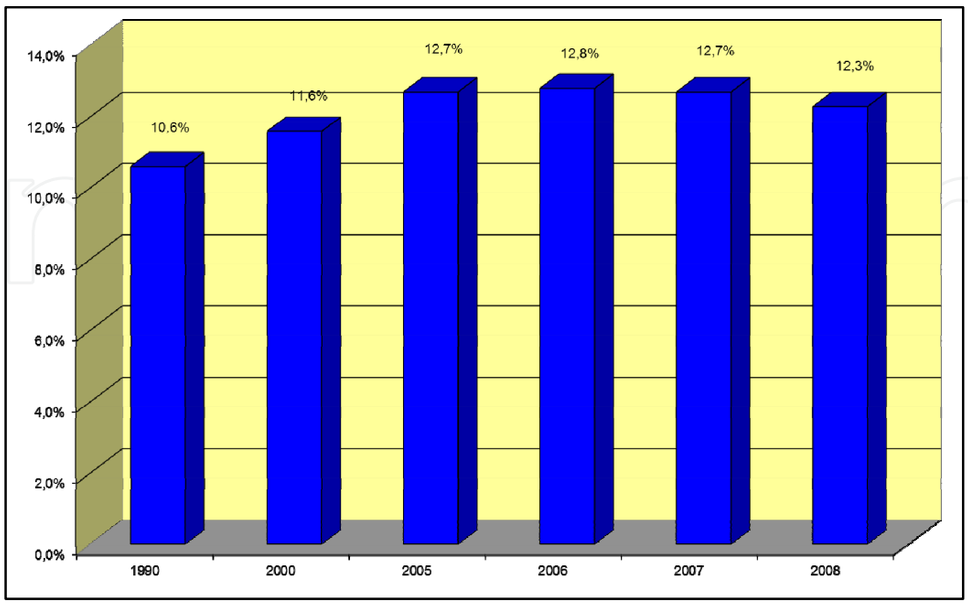

Fig. 1. Incidence of preterm birth in the USA 1990-2008 (Live births).

In the German region of Lower Saxony, we can observe an increase from 7.0% in 1987 to 8.5% in 2009. Again, here, a slight reduction can be seen since 2002. The increased rate can be attributed to the increased age of primiparous women, increased prevalence of risk factors (e.g. smoking, abnormal body weight), iatrogenic effects resulting from saving very preterm infants and fertilisation methods which contribute to preterm birth through a higher incidence of multiple pregnancies. In Germany, at least, the decline in rates may be traced back to the restriction imposed in 2004 on the reimbursement of fertilisation costs which led to a strong reduction of fertility treatments (DIR- Deutsches IVF-Register, Jahresbericht 2009, Annual Report English Version 2009).

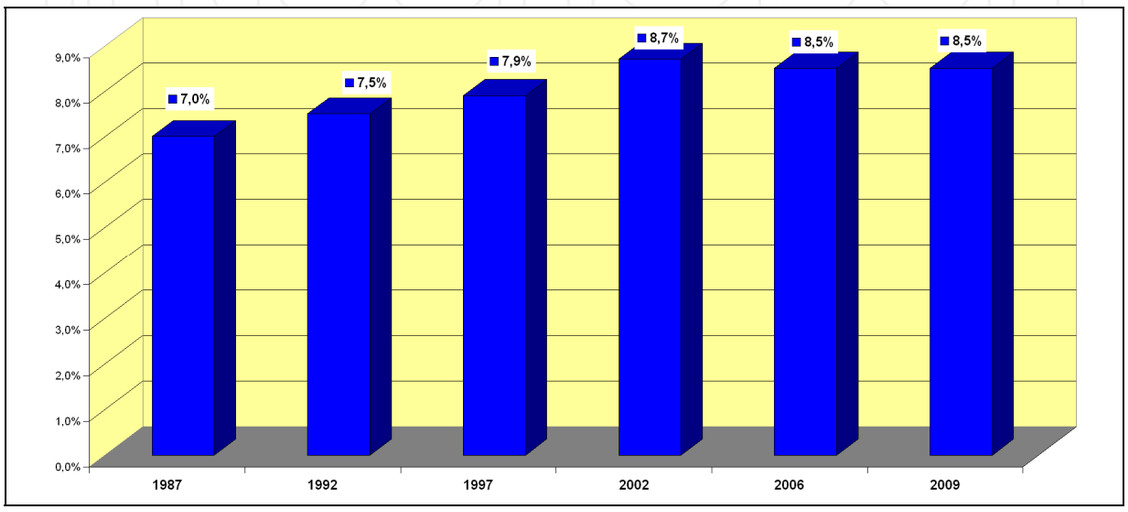

Fig. 2. Incidence of preterm birth in Germany (Lower Saxony) 1987-2009 (Birth events) (Perinatal Data from Medical association of Lower Saxony)

A comparison of preterm birth rates between Europe and North America reveals considerable differences in the incidence of preterm birth. The highest rates are found in the USA, Austria, Germany and Hungary while Ireland and Finland have very low rates (EURO-PERISTAT project, 2008). These differences are probably associated with different risk constellations in the populations (see below), but also differences in the frequency of sonographic determination of gestational age cannot be ruled out completely. "This indicator is defined as the number of live births and fetal deaths at each completed week of gestation (starting from 22 weeks), expressed as a proportion of all live and stillbirths. In most countries, data on gestational age is based on the "best obstetrical estimate", which combines clinical and ultrasound data, but some countries favour use of last menstrual period and others use only ultrasound estimates. There are also differences within countries. The method of determining gestational age can influence the gestational age distribution; use of ultrasound estimates tends to shift the distribution to the left and increase the preterm birth rate, although not all studies have found that this is the case". (European Perinatal Health Report, p. 129)

In addition to the variation in the preterm birth rate between countries, we must also note significant differences within an individual country. For example, in the German region of North Rhine-Westphalia, we can observe variations between municipalities with rates ranging from 9% to 14%, linked to socio-economic differences in the population, and with the highest rates to be found in economically underprivileged regions.

USA	**12,5%**	DNK	7,2%
AUT	**11,6%**	FRA	7,2%
GER	**9,1%**	ITA	7,2%
HUN	**8,9%**	POL	7,1%
CAN	8,2%	PRT	7,0%
BEL / Flanders	8,2%	GBR / NI	7,0%
ESP	8,2%	SWE	6,4%
GBR / Scotland	8,1%	GRC	6,3%
NLD	7,8%	LVA	6,2%
BEL / Brussels	7,4%	LUX	6,2%
MLT	7,4%	EST	6,1%
SVN	7,4%	**IRL**	**5,8%**
CZE	7,3%	**FIN**	**5,8%**
NOR	7,3%	**LTU**	**5,6%**

Table 2. Preterm birth rates in selected countries in Europe and North America, 2004 (Live births).

Looking more closely at the descriptive epidemiology of preterm birth in Germany, using the example of the perinatal database of Lower Saxony,[1] we find that the incidence of preterm birth is greater in primiparous women (9.5%) than in multiparous women (7.5%). In relation to age, we see a typical j-shaped distribution with high rates in very young and older pregnant women. In primiparous women aged 35 years and over the rate of preterm birth is almost 12%.

2.2 Analytical epidemiology of preterm births

Both in relation to the high incidence of preterm birth and the harm and costs involved (see below) the question to be answered is whether preterm birth can be prevented by primary or secondary interventions. In that regard, it must be conceded that the complex process of preterm birth is not completely understood. Nonetheless, epidemiology of preterm birth has identified a stable set of risk and protective factors associated with preterm birth. The epidemiological evidence is comparable, thus, to that which exists in relation to cardiovascular diseases, leading to numerous primary prevention programmes worldwide.

When looking at the medical conditions of an imminent preterm birth, we must first distinguish spontaneous preterm birth (SPB) from elective preterm birth (EPB) by caesarean section. In Lower Saxony, 29% of all deliveries in 2007 were carried out by caesarean section. However, in preterms that proportion rose to 55%. In addition, 16% of all caesarean sections were performed on pregnant women before 37 weeks of gestation.

[1]In Germany, perinatal statistics are compiled on a regional basis. A national database has only existed since 2003. For the first evaluation of the BabyCare Program in 2002 (see below), the perinatal database of Lower Saxony was used. Both then and now, in relation to preterm birth rates, the figures for Lower Saxony reflect the average across the whole of Germany.

	Total	Preterm	Term	% Preterm
Vaginal birth	41871	2236	39635	5,3%
Caesarean section	17196	2688	14508	**15,6%**
Total	59067	4924	54143	**8,3%**
% Section	29,1%	**54,6%**	26,8%	

Table 3. Caesarean section and preterm birth (Perinatal Data from Medical association of Lower Saxony, 2008).

The medical conditions at the onset of SPB and EPB are well known and will be illustrated with data from a cohort study of BabyCare participants. Medical conditions associated with preterm birth are placental complications, premature rupture of membranes (PROM), uterine complications, preterm labour and vaginal bleeding. When calculating odds ratios with respect to pregnancy complications in relation to the mode of preterm and term birth, we find PROM to be the strongest risk factor overall and especially for spontaneous preterm birth, whereas preeclampsia and placental complications are strongly associated with elective preterm birth.

	Preterm	**Not Preterm**	**OR**	**CONF 95%***	
n=	67	814			
Placental complications	20.9%	3.6%	7.2	3.9	13.1
Preeclampsia	28.4%	3.1%	12.5	7.3	21.5
Premature rupture of membranes	41.8%	0.5%	145.4	82.9	255.0
Preterm labour	41.8%	13.3%	4.7	2.9	7.6
Vaginal bleeding	25.4%	11.9%	2.5	1.4	4.5
Uterine complications	25.4%	4.5%	7.1	4.1	12.5
**** calculated by Miettinen***					

Table 4. Odds ratios for pregnancy complications (BabyCare Cohort Study).

Prevention of preterm birth is limited, thus, to the prevention of spontaneous preterm birth, as elective preterm birth is actively induced to avoid even greater health risks to the mother or the foetus. This does not imply, however, that preventive interventions are likely to be efficient only in the prevention of SPB because they may also reduce risks of emerging complications leading to EPB. We have to emphasise that at the onset of these medical conditions there is need, at most, for secondary prevention but, normally, urgent therapeutic interventions are required. However, primary prevention of SPB needs to address all medical and in particular non-medical risk factors established by international epidemiological research, ideally, in the earliest stage of pregnancy and, better still, prior to conception. In the context of this chapter, a differentiated analysis or even meta-analysis of analytical epidemiological studies is unnecessary. Quite simply, we wish to emphasise that of the known risk factors over half can either be addressed by preventive interventions or timely diagnosis, supervision of risk patients at close intervals and specific treatment (*italicised* below).

- Age of primiparous >=35 years / < 18 years
- Male sex of infant
- Low educational level
- Prior history of preterm birth

- Prior history of abortion
- *Smoking*
- *Illicit drug use*
- *Overweight / underweight*
- *Vaginal infections, e.g. bacterial vaginosis*
- *Folic acid deficiency*
- *Iron deficiency*
- *Stress in pregnancy*
- *Periodontitis*
- *Diabetes*
- *Hypertension*
- *Thrombosis / clotting disorder*
- *Eating disorders*
- Multifetal pregnancy
- Fertilisation

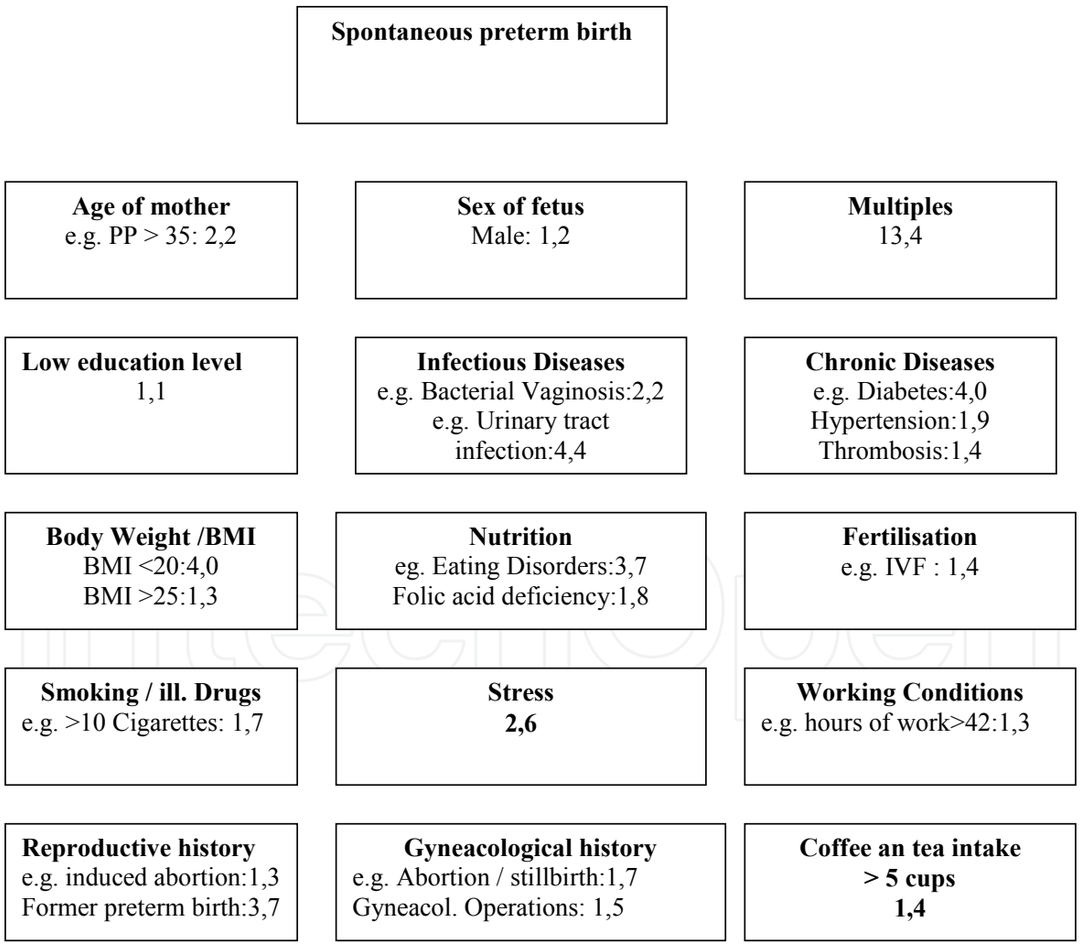

Table 5. Risk factors for SPB with odds ratios and relative risk estimates from different publications (Danielian & Hall, 2005; Holzgreve et al., 2006; BabyCare data).

Thus, having regard to the relationship between risk factors and preterm birth measured by odds ratios or relative risks (an overview is given in Table 5), the interventive potential is anything other than small especially when, in addition, the prevalence of risk factors in the population is taken into account (not shown).

2.3 Costs of preterm births

Preterm birth not only causes harm and in many cases increases morbidity across an individual's life, preterm birth is also expensive. A conservative cost estimate for Germany based on DRG data and calculated by the authors reveals a cost premium in excess of EUR 10 000. In fact, the real costs are much higher as our estimate only includes the first two days in perinatal care. According to our calculations, the costs of preterm birth are EUR 12 800 compared to EUR 2 300 for vaginal deliveries (Kirschner et al., 2009). In the United States of America, the annual cost estimate for preterm birth based on 2005 figures is USD 26.2 billion (Beck et al., 2010). According to a press release of March of Dimes, a non-profit organisation working to reduce the incidence of preterm birth, the average medical cost for healthy full-term babies from birth through to their first birthday was USD 4 551, whereas for infants born preterm the average cost was nearly USD 50 000 (March of Dimes, 2009).
To summarise, preterm birth causes much harm to families and children and is extremely costly to society but there are reasonable possibilities for preventive interventions.

3. Principal strategies in preterm birth prevention and findings of prevention programmes

3.1 Principal strategies

Strategies for preterm birth prevention may differ according to time of intervention, instruments and methods, the target population and the setting chosen. With respect to the time of intervention, we can distinguish:

- preconceptional interventions
- prenatal interventions beginning at best in earliest pregnancy
- antenatal interventions at the onset of labor

Clearly antenatal interventions will not comprise real primary preventive measures and are limited to secondary prevention and the often difficult task of managing imminent preterm birth.
With respect to the instruments, we have to distinguish unifactorial and multifactorial interventions. Multifactorial interventions address a set of risk factors, using specific combinations of health counselling and health promotion measures as well as the application of diagnostic tools (e.g. pH test, oral glucose tolerance test (oGTT)). However, in addition to screening and diagnostics, the main aim of primary interventions is to change risk behaviour.
With respect to the target population, the main differences consist in the choice of risk groups versus interventions which address the whole female population of childbearing age or pregnant women.
The setting of the programmes needs to be organised such that the target population can be easily reached in a timely manner and as comprehensively as possible. Generally, prenatal interventions are likely to be integrated in the existing system of obstetric care provided in a particular country.

3.2 Findings of prevention programmes

In the context of this chapter, it is impossible to paint a concise picture of all the prevention programmes to reduce preterm births or of the evaluative outcomes in that regard. However, preterm birth prevention has a long history reaching back to the 1930s (Papiernik, n.d.). Without a doubt, the national prevention programme operated in France between 1972 and 1988 appears to be the most important intervention in an European country, with a reported reduction in preterm births from 8.2% in 1972 to 4.9% in 1988 (Papiernik, n.d.). Nevertheless, some shortcomings in the evaluation need to be addressed, although the standards of evaluation at the time were slightly different from those in force today.

On the basis of existing assessments of the programmes concerned, we have to conclude that results conflict with respect to effectiveness and efficiency (Alexander et al., 1991; Canadian Task Force on the Periodic Health Examination, 1994; Collaborative group on preterm births prevention, 1993; Dyson et al., 1998; Hueston, 1992; Papiernik, n.d.). However, this result is not surprising as strategies, settings, organisation of obstetric care and the target populations are often very different. In addition, there are shortcomings in evaluation methods, that is, if programmes are indeed documented and rigorously evaluated.

In addition to social policy interventions aiming to reduce preterm birth, there are studies aiming to find biological markers (e.g. cytokines) with high specificity and sensitivity in the prediction of preterm birth risks. However, the predictive values of those markers identified hitherto with respect to the onset of preterm birth are regarded as inadequate (David et al., 2002). As a tool of secondary prevention, they will be excluded from the following discussion.

To reduce complexity in the analysis, we will concentrate firstly on current strategies in Germany and Austria which are unifactorial and address vaginal infections. In this context, in Germany, vaginal pH measurement plays an important role and was recommended for inclusion in obstetric care in the 1990s by Saling, the founder of the Journal of Perinatal Medicine. In several studies, Saling and other researchers reported on the effectiveness and efficiency of pH self-measurement (Hoyme & Saling, 2004). However, the evaluation of these interventions had some shortcomings, the most important of which was the lack of a rigorous case control study. In the wake of the BabyCare Program, as a result of which an increased interest in the prevention of preterm birth especially among health insurance providers could be registered (see below), Saling et al. were successful in establishing programmes based on pH measurement. A pilot project was carried out between 2004 and 2006 by four health insurance providers, which was subject to external evaluation. In addition to this project, the programme "Hallo Baby" was established in 2004 and has since been offered by a number of health insurance providers to their members who are pregnant. This programme also primarily uses the pH measurement supplemented by additional counselling by gynaecologists. However, the latter programme has not been evaluated. In 2010, the evaluation of the pilot project was published. The evaluation did not demonstrate the efficacy of self-testing of vaginal pH for the prevention of preterm delivery. On the contrary, the rate of preterm birth was slightly higher among participants compared to those in control groups (Bitzer et al., 2011).

At this point, it is impossible to identify whether the evaluative conclusion in terms of the 2 x 2 table constitutes a true negative or false negative.[2] As far as we can see, the evaluative methods

[2]For this discussion we refer to Saling (2011).

chosen were not appropriate to reach a final judgement on the efficiency of the instrument. The main shortcomings of the evaluation are an extremely self-selected population of participants and the abandonment of a comprehensive survey concerning the cases and controls, controlling for differences in both samples. Thus, positive interventive effects could not be detected, the reasons for this remain unclear however (Friese et al., 2011).

Another approach to the prevention of preterm birth through screening of vaginal infections was a study of vaginal screening in early pregnancy in Vienna (Kiss et al, 2004). They conclude:

"In the intervention group, the number of preterm births was significantly lower than in the control group (3.0% v 5.3%, 95% confidence interval 1.2 to 3.6; P = 0.0001). Preterm births were also significantly reduced in lower weight categories at less than 37 weeks and ≤ 2500 g. Eight late miscarriages occurred in the intervention group and 15 in the control group. Conclusion: Integrating a simple infection screening programme into routine antenatal care leads to a significant reduction in preterm births and reduces the rate of late miscarriage in a general population of pregnant women."(p. 371).

Though the reduction is remarkable, it must be observed that the intervention was a clinical study and the effects have to be confirmed in a non-clinical setting. Additionally, the overall rate of preterm births in the study appears very low which may result from selection. In addition the outcomes of international intervention studies screening vaginal infections with respect to the reduction of preterm birth by antibiotic treatment in asymptomatic pregnant women are conflicting and effects could only be seen in women with prior histories of preterm birth (Riggs, M.A, Klebanoff, M.A., 2004).

4.The BabyCare Program

The BabyCare Program was developed from 1998 to 2000. Following an evaluation of existing national and international prevention projects, we decided to create a multifactorial programme comprising health information and education and health promotion including an important role for nutrition especially in relation to folic acid, iodine and iron.

4.1 Frame and methods

The programme comprises:

- a book covering all the issues arising in pregnancy.
- a self-administered questionnaire addressing all possible risk and protective factors. Part of the questionnaire incorporates the dietary history protocol established by the German Society of Nutrition.
- individual health and nutritional recommendations based on the questionnaire responses given by letter or e-mail.
- optimised recipes especially for women not willing to accept the supplementation of micronutrients.
- individual advice on medication during pregnancy.
- relaxation CD with specially composed music for stress reduction.
- pH test kit – supplied when the number of vaginal infections disclosed in the questionnaire is above average or prior histories of preterm birth or miscarriage are documented.

Fig. 3. The BabyCare Program.

For a better understanding of how the programme works, we will first provide some background information on the German health care system. In Germany, medical care outside of hospitals is organised through private practices of general practitioners and medical specialists. In contrast to countries such as the Netherlands, where obstetric care is organised by general practitioners, in Germany, gynaecologists are responsible for obstetric care. There are approximately 7 000 gynaecological practices caring for nearly 750 000 pregnant women annually,[3] and, as a result, on average, each practice sees about 100 pregnant women. Additional care through midwives remains reserved to a few weeks before and after childbirth. Consequently, midwives cannot play an important part in programme implementation, as pregnant women need to be included in the programme as early as possible. In Germany, 90% of the population is a member of a statutory health insurance scheme and, in 2010, there were approximately 150 different insurance providers. In 2010, some 100 or so insurance providers and 1 000 gynaecologists cooperated with BabyCare. The health insurance providers reimburse the programme costs which vary from EUR 30 to EUR 45 depending on the options chosen.

4.2 Evaluative strategies

The programme is evaluated annually with respect to preterm birth rates. For these purposes, the co-operating gynaecologist documents the birth outcomes of a random sample of their participants. This data is compared with the perinatal data of Lower Saxony which reflects the average preterm birth rate for Germany as a whole. An alternative evaluation design involving a prospective case control study with BabyCare participants as cases included in the evaluation and non-participants as controls was rejected both on grounds of excessive costs and anticipated selection effects and biases in the control group. In order to compare cases with controls, the members of the control group would also have to fill in the questionnaire. However, this would lead to uncorrectable intervention effects in the control group. In addition, the comprehensive questionnaire including some 60 questions would probably lead to a sample strongly selected by education, social class and health awareness.

[3]In 2008, there were 658 000 births in Germany. As there are 15% to 20% miscarriages, the number of women diagnosed as pregnant can be estimated as 750 000.

4.3 Evaluative results

4.3.1 Reduction of preterm births

Compared with many other countries, the quantity and quality of epidemiological data in Germany is, in general, not particularly satisfying. This applies also to representative current data on relevant behavioural issues concerning women before and during pregnancy. As already mentioned, perinatal data exists and is collected at a regional level through obstetrics clinics. Therefore, the quality of medical data is good but the quantity and quality of behavioural data only poor. Thus, for example, the prevalence of smoking is likely to be highly underestimated. However, the biggest problem is the fact that the perinatal data does not include socio-demographic variables such as educational level or social class.

Logically, from a statistical point of view, BabyCare participants certainly do not constitute a representative sample of the overall population of pregnant women. They are:

- older
- more often primiparous than multiparous, which is attributable to the fact that amongst women who have already given birth to children without complications acceptance of the programme is likely to be low. In turn, however, this means that multiparous participants will have generally experienced more complications in preceding pregnancies leading them to seek greater advice.
- better educated, something which is a quite normal finding in prevention programmes.
- more often women with multiple pregnancies, a factor which results from a high participation of fertility centres in the programme.

With a view to comparing preterm birth rates of participants with preterm birth rates of Lower Saxony, the structure of our participant group has to be weighted to reflect the structure of the perinatal database which is possible for all variables except the missing educational variable. To correct for education, we have chosen a different approach. As we have representative data on the educational levels of women of childbearing age in Lower Saxony, that distribution is used on the assumption that the distribution of educational levels among pregnant women will not differ significantly – or more importantly, relevantly – from the former group. Although this assumption may be questionable, the weighting procedure gives reasonable estimates and, ultimately, there is no alternative to adopting this approach.

The analysis is based on 12 555 birth documentations produced by cooperating gynaecologists since the year 2000 compiled on the basis of random sampling. The perinatal data used for comparison is the cumulative data for 2005 to 2009 which indicates an overall preterm birth rate of 8.4%, in primiparous women: 9.5% and in multiparous women: 7.5%.

The results of the weighting procedure are shown in Table 6. When weighting for age, a slight variation in the rates can be seen. In primiparous women, there is a reduction due to the fact that older participants with high preterm birth rates are down weighted. Weighting for education increases the rates as preterm birth rates are higher in participants with a basic level of education. After weighting for multiple pregnancy, we have the total weighted rates of 6.9% in primiparous women and 5.1% in multiparous women with an overall reduction of 29%, with a 95% confidence interval between 34% and 24%. Thus, on a conservative estimate, the programme achieves a reduction of about 25%. An analysis by weeks of gestation demonstrates, in addition, that the reduction also takes place in very preterms (<31 weeks). The fact that the preventive effect in multiparous women is even greater than in

primiparous women appears particularly striking given their higher risks of prior pregnancy complications. It is possible that this is attributable to the inclusion of the pH testing component for participants with above average rates of vaginal infections and histories of preterm birth and miscarriage. However, this is very difficult to evaluate not least because of the relatively small sample size of multiparous women. There is also no possibility to compare our interventive results with respect to parity with other respective studies as published data does not give informations separated for primi- and multiparous.

	BabyCare data				Perinatal data			
	Unweighted	Weighted for age	Weighted for education	Weighted for multiple pregnancy	cumulative data for 2005-2009	Difference	%	Reduction
n	12555	12555	12555	12438	298158			
PP	**7,4%**	**7,2%**	**7,4%**	**6,9%**	**9,5%**	2,6%	73%	**27,1%**
MP	**5,1%**	**5,3%**	**5,4%**	**5,1%**	**7,5%**	2,4%	68%	**31,6%**
Total	**6,2%**	**6,2%**	**6,3%**	**6,0%**	**8,4%**	2,5%	71%	**29,2%**

95% Confidence interval		
Lower limit		Upper limit
5,6%	**6,0%**	**6,4%**
66,4%	70,8%	75,9%
33,6%	**29,2%**	**24,1%**

Table 6. Reduction in preterm birth rates (Perinatal data from Lower Saxony)

In addition to the factors for which weighting has already been carried out, BabyCare participants may also differ from the overall population of pregnant women in relation to health awareness and health behaviour and in the prevalence of other risks of preterm birth which may possibly be lower in BabyCare participants. However, a recent study suggests that low educational level is only a very low independent risk factor when other risks are controlled. "The lowest-educated pregnant women had a statistically significant higher risk of preterm birth (odds ratio (OR)=1.89 (95% CI 1.28 to 2.80)) than the highest educated women. This increased OR was reduced by up to 22% after separate adjustment for age, height, preeclampsia, intrauterine growth restriction, financial concerns, long-lasting difficulties, psychopathology, smoking habits, alcohol consumption, and body mass index (BMI) of the pregnant women. Joint adjustment for these variables resulted in a reduction of 89% of the increased risk of preterm birth among low-educated pregnant women (fully adjusted OR=1.10)."(Jansen et al., 2009)

Nevertheless, to rule out or to control for this possible selection representative data of a pregnant population would be needed, something which in Germany is currently unavailable. Moreover, even if such data existed, it would have to be treated with caution.

It is well known in social research that many behavioural questions in surveys result in a bias towards "socially desired" answers. This means, for example, both the underreporting of risk behaviour and the overreporting of protective factors. Consequently, alcohol consumption and cigarette smoking are generally underreported in surveys while physical activity and "positive health behaviour" in general (for example, participation in cancer screening programmes for women) is overreported. We assume that in surveys with pregnant women these biases are even stronger, although the effects are difficultly to assess methodologically. It appears logical to assume that by the time of diagnosis of pregnancy women, in general, are more aware of health issues than women of childbearing age. While

many will reduce health risks, some will only report doing so. Consequently, the results of behavioural surveys relating to women in the general population of childbearing age cannot be regarded as valid in relation to pregnant women.
Second, the results of surveys, where these exist, carried out with pregnant women pose difficulties for interpretation. To control for a possible bias for positive health awareness among BabyCare participants compared with surveys carried out among the overall population of childbearing age, the following variables had to be excluded:

- alcohol consumption
- cigarette use
- use of illegal drugs

Of the spectrum of indicative variables found in existing female population surveys finally only two remained:

- the body mass index (BMI) and
- the nutritional types

While the first variable does not risk producing a bias as simply weight and height are measured and a ratio obtained, the second item appears even more important in the context of a programme which places particular emphasis on nutrition. Although BabyCare participants more often are underweight to a degree which is statistically significant, because of the high sample size involved in BabyCare the distributions are, however, quite comparable. Moreover, the slightly higher rate of underweight participants in the programme would not constitute a positive selection but a negative selection towards the higher risks of preterm birth.

	BabyCare	German Health Survey 1998
	Women aged 20-29 years	
n=	14765	2015
BMI		
<18.5	6,2%	2,5%
18.5<25	69,2%	71,1%
25<30	16,4%	17,5%
>=30	8,2%	8,9%
	100,0%	100,0%

Table 7. Body mass index of BabyCare participants aged 20-29 years compared to the general female population in Germany 1998 (RKI, 2010).

	BabyCare	Gruner + Jahr Study
n=	8593	10035
completely agree	**13%**	**13%**
agree somew hat	**25%**	**23%**
disagree somew hat	36%	36%
disagree completely	26%	28%
Total	100%	100%

Table 8. Acceptance of nutritional supplements ("For health reasons I take vitamins and/or minerals")

Data analysis shows that in respect of both variables there is no relevant difference in the distribution. As a result, we can conclude that a serious and fundamental bias towards health awareness among BabyCare participants does not exist. The distribution of nutritional types in BabyCare participants is consistent with the distribution in the general population.

In conclusion, significant evidence exists to suggest that the BabyCare questionnaire data reflects the behavioural patterns of pregnant women in Germany, although a final judgement cannot be given in the absence of comparable data.

Reasons for the data displaying this "representativeness" – or, more accurately, only marginal selection effects – may be found in the following facts:

- first, the programme is reimbursed by health insurance providers, hence, women's participation is not influenced by financial factors
- second, health insurance providers with members drawn from weak socio-economic backgrounds are involved in the programme

In summary, the annual evaluation of the programme shows a stable reduction in the rate of PTB of about 25% where, on the basis of the data currently available in Germany, effects of underlying selection and bias can be ruled out.

4.3.2 Remaining risk factors

Although the incidence of preterm birth can be relevantly reduced as a result of the BabyCare programme, even in our population further risk factors of preterm birth are prevalent. An existing epidemiological study suggests that through prevention a target of 5% incidence appears, at best, to be realisable. "Our multi-dimensional analyses revealed rates of prematurity (≤36 weeks) between 5.1% and 27.5% depending on the combination of parameters. We found the highest rate of prematurity of 27.5% in women with the following combination of parameters: ≥1 stillbirth, ≥2 terminations of pregnancy and ≥2 miscarriages. A rather high risk of premature delivery (>11%) was also found for elderly (≥40 years) grand multiparous women as well as small (≤155 cm) and slim women (≤45 kg)" (Voigt et al., 2009, p. 138).

Generally speaking, with a few exceptions, the data on associations presented below do not contain new results but stress the need for and possibilities of additional preventive measures and, in particular, raise issues concerning timing. Some results of the analysis with respect to nutrition require further research, for example, concerning the use of iodine and magnesium. While the latter is plausible in the treatment of preterm labour, the first is not. Also interesting is the betacarotene finding, according to which a high intake constitutes a protective factor. When looking at the other associations we observe, first of all, that certain chronic diseases such as hypertension and thrombosis rarely require closer supervision of risk patients and specific treatment, which, in any event, should start, ideally, even prior to conception. This applies also where women are overweight and smokers. While weight reduction is contraindicated in pregnancy, both risk factors can be reduced more easily and more efficiently before pregnancy. Also improvements to nutritional behaviour and the intake of micronutrients often required, such as, folic acid, iodine and iron, should ideally be implemented before conception in order to be more effective. The same applies to vaccination and the timely diagnosis and treatment of sexually transmitted diseases and the early identification of possible fertility problems.

	Total	PT	NPT	OR	CONF 95%	
	6228	491	5737			
Multiple pregnancy	2,4%	15,3%	1,3%	**13,43**	**17,49**	**10,31**
Diabetes	0,6%	2,0%	0,5%	**3,95**	**7,72**	**2,03**
Eating disorders	1,1%	3,3%	0,9%	**3,68**	**6,26**	**2,17**
Score of pregnancy risks above average	10,6%	21,8%	9,6%	**2,62**	**3,28**	**2,10**
Hypertension	3,7%	6,5%	3,5%	**1,92**	**2,80**	**1,31**
Hospital admission in the last 12 months	15,4%	23,2%	14,7%	**1,75**	**2,18**	**1,41**
History of miscarriage	10,8%	16,1%	10,4%	**1,65**	**2,13**	**1,28**
History of gynaecological operations	20,9%	27,5%	20,3%	**1,49**	**1,83**	**1,21**
Varices and thrombosis	4,0%	5,5%	3,9%	**1,44**	**2,16**	**0,96**
Fertilisation treatment	15,4%	20,2%	15,0%	**1,43**	**1,81**	**1,14**
Daily intake of magnesium in pregnancy	28,1%	34,2%	27,6%	**1,36**	**1,66**	**1,12**
Overweight (BMI >25)	20,8%	25,3%	20,4%	**1,32**	**1,63**	**1,07**
Daily intake of iodine in pregnancy	62,8%	68,4%	62,3%	**1,31**	**1,59**	**1,07**
Folic acid preventive potential known	55,7%	61,3%	55,2%	**1,28**	**1,55**	**1,06**
Smoker on diagnosis of pregnancy	19,9%	23,2%	19,6%	**1,24**	**1,54**	**1,00**
Physically demanding work	18,2%	21,1%	17,9%	**1,23**	**1,56**	**0,96**
Age >=32 years	38,0%	41,5%	37,7%	**1,20**	**1,42**	**0,98**
Betacarotene intake >110% (Sample size reduced n=3025**)	29,3%	23,4%	29,8%	**0,72**	**0,53**	**0,98**
**calculated by Miettinen*						
***Diet history questionnaire filled in*						

Table 9. Risk factors of preterm birth in primiparous BabyCare participants.

4.3.3 Improvements through an additional preconceptional programme

In the light of our analysis, we decided to develop a preconceptional prevention programme and the PlanBaby programme was launched in 2007. The target groups of the programme are couples planning a baby, couples suspecting fertility problems, and couples undergoing fertilisation treatment. The interventional instruments are the same as in BabyCare but are aimed at both women and men. Although there is growing interest in this programme, it takes time to introduce. As yet, the available data does not permit any firm evaluation.

5. Discussion and conclusion

As we have shown, the number of preterm deliveries can be reduced successfully by at least 25%. After weighting for age, parity, education and multiple pregnancy, the BabyCare participants represent the average population of pregnant women in Germany. With regard to an additional selection bias of participants e.g. towards health awareness or health behaviour, available data on pregnant women and/or representative data of women of childbearing age in Germany are sparse. However, using two lead variables, nutritional types and BMI, does not indicate relevant differences between the data compared. In addition, a specific study dealing with the higher risks of poorly educated women for preterm birth suggests that only a very modest effect comes from education level directly, while the majority of variance is explained by risk behaviour related to educational level, e.g. smoking or physical inactivity. This implies, in turn, that weighting for education, as we have done, does not leave much room for an additional and relevant selection in relation to health awareness or behaviour.

When discussing possible biases in the reduction of the rate of preterm birth, we also have to consider the participating gynaecologists. It is reasonable to assume that they may be more open to prevention issues and, possibly, that the quality of prenatal care may, in any event, be better. On the other hand, there are many reasons to participate in the programme, for example, image of the practice, fees or reduced time needed for consultations. However, we have to concede that there is no possibility whatsoever to evaluate this.

The final indicator that the effect measured is real comes from an independent evaluation produced by a participating health insurance provider. In 2005, the health insurer compared the numbers of preterm birth with those of previous years before the programme was introduced. They registered a reduction from 6.1% to 4.9%, that is, a reduction of 20%. In general, we are interested in external customer evaluations but analyses are often complicated and time-consuming.

Further reductions in the rate of preterm birth are likely to be achieved with a health promotion strategy for the pre-conceptual stage. To meet that need we created the programme PlanBaby, which has been available since 2007. However, as yet, no evaluative results exist and it is much more difficult to develop the appropriate evaluative scheme.

Currently, we are developing a further module for the programme on the choice of maternity clinic. This is intended to address the common situation where women with an increased risk of preterm delivery find themselves giving birth in the delivery unit of a local maternity hospital and not in a clinic offering specialised prenatal, natal and neonatal care.

Finally, we have to mention the most significant obstacle to intervention: programme coverage. In Germany, about 12 000 babies are born every week. Regrettably, however, a pregnancy does not have to be reported to the relevant health insurer at diagnosis, but only six weeks before delivery.

Unlike a disease management programme for a group such as diabetics where the incidence is relatively low and, accordingly, the target population is quite stable, pregnancy is a completely different case. To increase programme coverage would require regular weekly advertising for the target population. However, not even the health insurance providers which currently cooperate with the programme have the necessary financial or, in some cases, technical resources to make this possible.

In recent years we had 30 000 to 50 000 participants annually which means that we reach about 12% to 15% of primiparous pregnant women. To improve programme coverage significantly the legal basis of the programme needs to be modified. At present, the programme is offered by health insurers on a voluntary basis. However, initial discussions are underway to integrate the programme in existing contracts of integrated cooperation between gynaecologists, hospitals and the institutional purchasers/regulators (*kassenärztliche Vereinigungen*). This would increase the participation of gynaecologists and subsequently the number of pregnant women significantly. To summarise for an international audience: the programme can be seen as a positive example in efforts to reduce preterm births.

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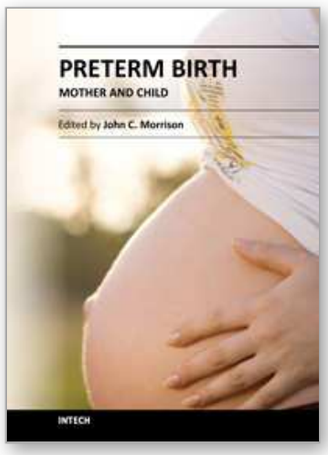

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While there are many studies and books regarding preterm birth, both the obstetric and in the neonatal/pediatric literature, what is missing is the integration of data from obstetrics through neonatal course and into pediatrics as the neonate transverses childhood. A continued dialogue between specialties is essential in the battle against preterm birth in an attempt to relieve the effects or after-effects of preterm birth. For all of our medical advances to date, preterm birth is still all too common, and its ramifications are significant for hospitals, families and society in general.

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