The Relevance of Maternal Socioeconomic Characteristics for Low Birth Weight – a Case-Control Study

Die Bedeutung mütterlicher sozioökonomischer Merkmale für das Auftreten eines zu geringen Geburtsgewichts – eine Fallkontrollstudie

T. Altenhöner1, M. Köhler1,2, M. Philippi3

1 Fachbereich Sozialwesen, Fachhochschule Bielefeld, Bielefeld
2 Steinbeis-Transferzentrum Interventions- und Evaluationsforschung, Rheda-Wiedenbrück
3 Fakultät für Sozialwissenschaften, htw saar, Saarbrücken

Abstract

Introduction: The number of children born underweight (low birth weight, LBW) is increasing despite extensive prevention and screening programmes. The cost is high for the health system, and affected children are burdened with health predictors that can affect them negatively throughout their lives. This study investigates to what extent socioeconomic factors, in addition to known medical causes and the health behaviour of pregnant women, influence LBW.

Materials and Methods: In this case-control study 131 mothers of singletons with a birth weight ≤ 2500 g (cases) and 323 mothers of normal birth weight babies (controls) were interviewed with respect to socioeconomic status, health behaviour and stress in the workplace. Medical data were collected by specialist staff using a questionnaire.

Results: Independent of medical diagnosis and health behaviour, women with lower level education (OR [95% CI] = 2.24 [1.12; 4.51]) and those who were not working (OR [95% CI] = 1.82 [1.10; 3.00]) were more likely to have an LBW baby. No effect was shown for immigrant background (OR [95% CI] = 1.14 [0.59; 2.21]) or stress in the workplace (OR [95% CI] = 1.17 [0.90; 1.51]).

Discussion and Conclusion: These results show that the association between social and health inequalities starts from before birth. In order to reduce the rising number of babies born underweight, socioeconomic determinants in the care and supervision of pregnant women should systematically receive more attention to enable appropriate early preventive strategies to be implemented.

Zusammenfassung


Material und Methodik: In einer Fallkontrollstudie wurden 131 Mütter von Einlingen (Geburtsgewicht ≤ 2500 g) (Fälle) sowie 323 Mütter mit normalgewichtigen Kindern (Kontrollen) zu sozioökonomischen Aspekten, ihrem Gesundheitsverhalten und ihren Belastungen am Arbeitsplatz befragt. Mit einem vom Fachpersonal ausgefüllten Fragebogen wurden medizinische Informationen erfasst.

Ergebnisse: Frauen mit niedriger Schulbildung (OR [95%-KI] = 2,24 [1,12; 4,51]) sowie Nichterwerbstätige (OR [95%-KI] = 1,82 [1,10; 3,00]) hatten unabhängig von medizinischen Diagnosen und dem Gesundheitsverhalten eine höhere Chance auf ein untergewichtiges Neugeborenes. Keine Effekte zeigten sich für den Migrationshintergrund (OR [95%-KI] = 1,14 [0,59; 2,21]) sowie die beruflichen Belastungen (OR [95%-KI] = 1,17 [0,90; 1,51]).

Diskussion und Fazit: Die Befunde zeigen, dass der Zusammenhang zwischen sozialer und gesundheitlicher Ungleichheit bereits vor der Geburt beginnt. Um den steigenden Anteil unterge wichtiger Neugeborener reduzieren zu können, sollte sozioökonomischen Determinanten in der Versorgung und Begleitung Schwangerer systematisch noch mehr Aufmerksamkeit gewidmet werden und bei Bedarf frühzeitig angemessene Präventionsmaßnahmen eingeleitet werden.
Introduction

The percentage of children born before 37 completed weeks of gestation and with low birth weight (LBW, WHO definition < 2500 g) has increased worldwide in recent years [1]. Even in Germany, despite comprehensive screening and preventive measures, 7 of every 100 newborns are born either premature or small for gestational age (SGA) [2]. These children are at increased risk of perinatal death and severe disability [3,4]. Moreover, LBW is a risk factor for lifestyle diseases later in life, e.g. type II diabetes mellitus and cardiovascular disease [5], and can have negative effects on mental potential and psychosocial development at school-going age [6]. In general, health problems and mortality in the perinatal period become more likely the shorter the pregnancy. Low birth weight due to placental insufficiency (IUGR) can also result in severe complications, however it is generally regarded as a risk factor for lifestyle diseases [3]. In view of diverse health consequences and the high treatment costs of acute complications and resultant chronic diseases the causes of prematurity and LBW have been the focus of study and preventive measures for a long time [7].

One reason for the increasing numbers of underweight births is thought to be the rising number of multiple births as a result of more widely used fertility treatments. Known medical causes of shortened pregnancy and fetal growth retardation include (chronic) maternal illness, uterine or placental anomalies, infections or other pregnancy complications such as preeclampsia and bleeding [8]. The influence of maternal health behaviour on fetal development and duration of pregnancy is controversial. For example, the risk of delivering an underweight baby is increased both among underweight women and those whose body mass index (BMI) is too high [8]. The effects of alcohol and particularly nicotine consumption on fetal growth and duration of pregnancy are proven [9,10]. The damaging effects of environmental factors such as pollution levels (atmospheric particulate matter) are also in discussion [11].

Behavioural and environmental factors offer an explanation for the social disparities in prematurity and SGA incidence, as reported in international studies [12,13]; a clear trend is apparent to the disadvantage of women with poorer education and worse employment/income status, particularly with respect to living situation and smoking in pregnancy [14–16]. This is exacerbated by the fact that this group of women appears to make less use of the antenatal care on offer [17]. Emerging data endorse the idea that, in Germany too, an association between social and health inequalities, manifest as LBW, is already present at birth [18,19]. The role of an immigrant background in this context remains unclear [19,20].

This epidemiological case-control study investigates the extent to which socioeconomic characteristics such as education and income, and indicators of social status such as immigrant background and maternal employment, constitute predictors of LBW. In order to extend current knowledge specific attention is given to whether the possible effects of socioeconomic factors remain after statistically controlling for other important influences. Concurrently various components of socioeconomic status are analysed in detail.

Materials and Methods

Sample selection and data collection

Sample calculation was carried out before the study started with the help of the programme “G*Power Version 3.1.2” [21] based on a significance level of $\alpha = 0.05$ and a power ($1-\beta$) of 0.90. To compensate for moderate differences between the case and control groups a sample of at least 338 women was necessary. We therefore planned for a study population of at least n = 400.

Mothers whose babies had a birth weight of a maximum of 2500 g formed the case group. The control group comprised mothers of normal birth weight babies (birth weight > 2500 g).

Study participants were recruited between July 2011 and December 2013 at the perinatal centre of the Klinikum Saarbrücken during admission for inpatient hospital delivery. Among the controls 323 of the 541 distributed questionnaires were completed, a response rate of 60%. The response rate for cases (57%) was comparable (131 of 229 questionnaires).

Standardised questionnaires were used for data collection; women were asked to provide information on their sociodemographic and socioeconomic characteristics, including aspects relevant to health, and on their health behaviour. A second questionnaire covering medical data of participants and their children was completed by medical staff at the study centre with participants’ consent. Questionnaires were distributed on the 2nd – 3rd day after delivery with the following exclusion criteria:

- Age < 18 years
- Multiple birth
- Mothers whose child died shortly after birth
- Confirmed psychiatric illness
- Insufficient German language proficiency

Tools

The participant questionnaire comprised mostly single items. Questions from the health surveys of the Robert Koch Institute [22] and the socioeconomic panel (SOEP) [23] were used. Socio-demographics collected included age, marital status, nationality and mother’s country of birth. Immigrant background was assumed when participants were born in countries other than Germany or France. Because of the study centre’s situation near the national border, many pregnant women from a neighbouring country used it as their delivery hospital without immigration being a factor. In addition, schooling/education, income and employment status were assessed.

For the assessment of stress in the work place we used 5 items from a tool recommended by the Union of German Annuity Assurance Institutions (VDR) in 1999 [24]. This tool assesses stress factors characterising particular jobs. The following are some example items: “... stressful physical work (e.g. one-sided posture, carrying heavy objects)?”, or “... noise, dust, gases, fumes, ‘bad air’?”, or “... stress in the work place (e.g. time pressure, pressure to perform, intense concentration, bad working environment)?”

Questions required yes or no answers allowing the total stress score to be included in the statistical analysis. Net equivalent income groups were formed based on the median for Germany in 2012 [25]. Rating of sociodemographics and socioeconomic characteristics was based on recommendations of the German Epidemiology Working Group [26] and the Robert Koch Institute [22].

Women also gave information on their weight and height before pregnancy, smoking before and during pregnancy, and utilisation of screening examinations and antenatal classes. Data collected
on pregnancy and birth included baby’s birth weight and sex, gestational age at birth and type of delivery. From the medical questionnaire gestational hypertension and/or uterine anomalies were included in the analysis. Diagnoses were pulled from the patient clinical records by medical staff and operationalised to single items.

Data analysis
Data analysis was performed using the statistics software SPSS (version 22). T-tests for independent variables or $\chi^2$-tests were used for the bivariate analyses of differences between the case and control groups. Three logistic regression models were calculated for each predictor in order to answer the main study questions. The first model used a bivariate analysis for testing the influence of individual predictors. The second model tested the effects of these predictors while controlling for important biolgical factors such as age, gestational hypertension and/or uterine anomalies. The third model additionally controlled for smoking, BMI before pregnancy and participation in antenatal screening in order to determine whether the predictors had an effect independent of health behaviour. In each model the group with the lowest presumed risk (e.g. better education) formed the reference group. Odds ratios (OR) and 95% confidence intervals were then calculated for each derived group.

Results
Sample
The study population comprised a total of 454 mothers and their newborns. There were 131 women in the case group and 323 controls producing a ratio of cases (28.9%) to controls (71.1%) approaching 1 to 3. The average age of participants in both groups was slightly over 30 years. Approximately 3 out of every 4 mothers were married or lived in a partnership, a status slightly more common among women with normal birth weight infants (Table 1).

Just over half of newborns were male (Table 2). Almost 90% of newborns in the case group were premature, i.e. less than 37 completed weeks gestation, compared to only 7.4% of children in the control group. As expected almost twice as many underweight newborns were delivered by cesarean section than normal birth weight infants. Around 1% of controls did not regularly attend antenatal care. In comparison the proportion of cases for which the same was true was almost triple this (approx. 3%), though this was also regarded as a small percentage. There was a significant difference in number of previous pregnancies. Women in the case group had been pregnant more often before the study than controls, though number of previous live births did not differ between groups (not shown). There were also differences associated with body mass and smoking: Children of mothers who were overweight or underweight before pregnancy more often had LBW than those of normal weight newborns (Table 1).

Immigrant background
Mothers with an immigrant background had underweight babies slightly more commonly (17.8%) than those without an immigrant background (15.2%). The difference was not significant after logistic regression models were applied. In the completely controlled model III the OR (95% CI) for mothers with immigrant background was 1.14 (0.59; 2.21).

Education and income
In contrast, clear differences in schooling history were apparent. Mothers with not more than a lower secondary school certificate had the 2.6-fold chance of having a child with LBW than those

Table 1  Distribution of sociodemographic characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Cases¹</th>
<th>Controls²</th>
<th>Test value</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample, % (n)</td>
<td>28.9 (131)</td>
<td>71.1 (323)</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Age in years, M (SD)</td>
<td>30.7 (5.6)</td>
<td>30.5 (5.6)</td>
<td>t = 0.3</td>
<td>0.744</td>
</tr>
<tr>
<td>Marital status, % (n)</td>
<td></td>
<td></td>
<td>$\chi^2 = 0.21$</td>
<td>0.571</td>
</tr>
<tr>
<td>married/living together with partner</td>
<td>71.5 (93)</td>
<td>74.1 (238)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>single/living alone</td>
<td>28.5 (37)</td>
<td>25.9 (83)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ Mothers with newborns (≤ 2500 g); ² Mothers with newborns (> 2500 g)

Table 2  Distribution of health and pregnancy related characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Cases¹</th>
<th>Controls²</th>
<th>Test value</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery before 37 completed weeks, % (n)</td>
<td>87.8 (115)</td>
<td>7.4 (24)</td>
<td>$\chi^2 = 283.3$</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Caesarean section, % (n)</td>
<td>73.8 (96)</td>
<td>35.8 (115)</td>
<td>$\chi^2 = 53.7$</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Newborn sex female, % (n)</td>
<td>48.1 (63)</td>
<td>47.1 (152)</td>
<td>$\chi^2 = 0.0$</td>
<td>0.842</td>
</tr>
<tr>
<td>Regular antenatal examinations, % (n)</td>
<td>96.9 (125)</td>
<td>99.1 (319)</td>
<td>$\chi^2 = 2.8$</td>
<td>0.092</td>
</tr>
<tr>
<td>Number of previous pregnancies, M (SD)</td>
<td>1.2 (1.6)</td>
<td>0.9 (1.1)</td>
<td>t = 2.3</td>
<td>0.020</td>
</tr>
<tr>
<td>BMI (kg/m²) at beginning of pregnancy, % (n)</td>
<td>90.9 (56)</td>
<td>90.9 (56)</td>
<td>$\chi^2 = 8.2$</td>
<td>0.017</td>
</tr>
<tr>
<td>&lt; 18.5 (underweight)</td>
<td>9.9  (13)</td>
<td>6.1 (24)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 18.5 to 30 (normal/mildly overweight)</td>
<td>68.7 (90)</td>
<td>80.8 (257)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 30 (obese)</td>
<td>21.4 (28)</td>
<td>14.2 (45)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking during pregnancy, % (n)</td>
<td>30.5 (40)</td>
<td>30.5 (40)</td>
<td>$\chi^2 = 18.4$</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

¹ Mothers with newborns (≤ 2500 g); ² Mothers with newborns (> 2500 g)
with university/technological college entrance certificate (OR [95% CI] = 2.65 [1.61; 4.36]). After controlling for age and diagnosed pregnancy/uterine diseases chances further increased to 3.8 times (OR [95% CI] = 3.77 [2.10; 6.78]). The effect of lower education level remained after applying the third model – adjusted for the behavioural factors smoking, BMI before pregnancy and regular antenatal care attendance – though it was somewhat less marked (OR [95% CI] = 2.24 [1.12; 4.51]).

No significant risk increase was shown in any of the analysis models for mothers with an intermediate school-leaving certificate, (“Fach-”/”Abitur”) (Ref.)

The influence of stress in the workplace was also tested among women who were employed. The odds ratios for the number of workplace stressors represent the risk increase for having an LBW baby due to an additional workplace stressor. The only significant result was in the bivariate analysis (model I). The effect was not detectable in the adjusted models so that overall this study showed that stress in the workplace had no effect on the incidence of LBW (OR for the overall model: OR [95% CI] = 1.17 [0.90; 1.51]).

### Discussion

The findings of this case-control study, conducted in one perinatal centre, support the results of national and international studies [12, 13] showing that socioeconomic factors influence the incidence of LBW [19, 28]. Education level is highly significant: A lower level schooling-leaving certificate was found to be a predictor of LBW, independently of other factors such as maternal illness and health behaviour. Monthly net equivalent income was also shown to have an effect: Risk of having an LBW baby was increased when monthly income fell below 60% of the median income for Germany in 2012.

Employment status is closely linked to income. Other studies on the causes of prematurity and LBW have shown that the risk of having an LBW baby decreases with increasing maternal employment status [19, 28]. Our results provide further evidence that general participation in gainful employment during pregnancy is protective against LBW. A Danish study produced similar results finding that maternal employment in the first trimester of pregnancy reduced the risk of premature birth. In contrast, however, no association was found between maternal employment and SGA [29]. This result underlines the call for better support of employed women during their family-building phase, as expressed in the German government’s Poverty and Wealth Report [27]. Perceived high physical and mental demands in the workplace however, more common in the lower employment status

### Table 3

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Cases</th>
<th>Controls</th>
<th>Model I</th>
<th>Model II</th>
<th>Model III</th>
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<tr>
<td></td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
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<tr>
<td>Immigrant background, % (n) (Ref.)</td>
<td>17.8 (23)</td>
<td>15.2 (49)</td>
<td>1.21 (0.70; 2.08)</td>
<td>1.16 (0.65; 2.07)</td>
<td>1.14 (0.59; 2.21)</td>
</tr>
<tr>
<td>Immigrant background, % (n)</td>
<td>82.2 (106)</td>
<td>84.8 (273)</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Schooling/education, % (n)</td>
<td></td>
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<tr>
<td>lower secondary school (“Hauptschule”), or less</td>
<td>37.1 (46)</td>
<td>18.5 (58)</td>
<td>2.65 (1.61; 4.36)</td>
<td>3.77 (2.10; 6.78)</td>
<td>2.24 (1.12; 4.51)</td>
</tr>
<tr>
<td>intermediate secondary school, (“Realschule”)</td>
<td>22.6 (28)</td>
<td>28.3 (89)</td>
<td>1.05 (0.62; 1.78)</td>
<td>1.09 (0.61; 1.95)</td>
<td>0.86 (0.46; 1.63)</td>
</tr>
<tr>
<td>university/technological college entrance certificate, (“Fach-”/”Abitur”) (Ref.)</td>
<td>40.3 (50)</td>
<td>53.2 (167)</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Income, % (n)</td>
<td></td>
<td></td>
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<tr>
<td>≤ 60%</td>
<td>47.4 (55)</td>
<td>30.1 (91)</td>
<td>2.19 (1.31; 3.67)</td>
<td>2.43 (1.36; 4.35)</td>
<td>1.53 (0.79; 2.96)</td>
</tr>
<tr>
<td>60 to 99%</td>
<td>25.0 (29)</td>
<td>31.5 (95)</td>
<td>1.11 (0.63; 1.96)</td>
<td>1.13 (0.62; 2.06)</td>
<td>0.94 (0.49; 1.80)</td>
</tr>
<tr>
<td>100% and above (Ref.)</td>
<td>21.6 (32)</td>
<td>38.4 (116)</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Employment, % (n)</td>
<td></td>
<td></td>
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<tr>
<td>unemployed</td>
<td>45.8 (60)</td>
<td>33.0 (105)</td>
<td>1.71 (1.13; 2.60)</td>
<td>2.17 (1.38; 3.43)</td>
<td>1.82 (1.10; 3.00)</td>
</tr>
<tr>
<td>employed (Ref.)</td>
<td>54.2 (71)</td>
<td>67.0 (213)</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Number of workplace stressors, M (SD) (Σ of 0 to 5)</td>
<td>1.8 (0.5)</td>
<td>1.4 (0.5)</td>
<td>1.27 (1.03; 1.56)</td>
<td>1.23 (0.98; 1.55)</td>
<td>1.17 (0.90; 1.51)</td>
</tr>
</tbody>
</table>

1 Mothers with newborns ≤ 2500 g; 2 Mothers with newborns > 2500 g; 3 Mothers not born in Germany or France; 4 Net equivalent income (< 60% [≤ 979.8 €]; 60 to 100% [979.8–1633 €]; 100% and above [≥ 1633 €])

* bivariate; 1 controlled for age, gestational hypertension and/or uterine anomalies; 2 controlled for age, gestational hypertension and/or uterine anomalies, regular antenatal checks, smoking, BMI before pregnancy; 4 significant findings in bold type

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groups [30], have the opposite effect, influencing birth weight negatively.

The effects of the variables education, income and employment were in some instances considerably reduced in model III, which controlled for health behaviour. The main contributor appears to be maternal smoking during pregnancy, in this context representing a classical confounder: The chemical compounds in tobacco are toxic to the embryo and its development; the children of mothers who smoke thus tend to be smaller. As has been shown in other studies [15, 31], participants from the lowest social strata (χ² = 93.7; p < 0.001) and those with the lowest education levels (χ² = 100.8; p < 0.001) smoked more commonly despite being pregnant (not shown), thus putting their children's health at risk [32]. In contrast, women with immigrant background did not have underweight babies more often than those without immigrant background, a result that is in agreement with existing evidence [19, 28].

It is possible that the results pertaining to immigrant background are biased. The questionnaire was only available in German and only women who were proficient enough to complete it were included in the study. It can be assumed that these women had been living in Germany for longer, and were better integrated than those not able to speak German. We also did not test whether the country of origin was significant.

The response rate (returned questionnaires) of approximately 60% in both case and control groups was equally high, making selection bias unlikely. Similarly it can be assumed that there was no selection bias by which fewer women of lower education level participated. In fact the percentage of participants with a lower education level (χ² = 93.7; p < 0.001) and those with the lowest education levels (χ² = 100.8; p < 0.001) smoked more commonly despite being pregnant (not shown), thus putting their children's health at risk [32]. In contrast, women with immigrant background did not have underweight babies more often than those without immigrant background, a result that is in agreement with existing evidence [19,28].

The evidence suggests that pregnant women with lower socioeconomic status are doubly disadvantaged: Firstly, they face numerous stressors including e.g. unemployment or stressful employment, financial insecurity or poor living conditions, and secondly, in view of their low education levels they often lack the necessary ability to deal with this stress. A further complicating factor is that both perceived stressors and poor coping strategies are themselves associated with worse health behaviour, such as smoking or poor nutrition [36].

Our study is one of very few in Germany [39] investigating the socioeconomic status of young mothers in detail according to income, education, employment and workplace stress. Despite potentially limited generalisability, our findings confirm the existence of a vicious cycle, where deficient education is associated with worse employment and income status as well as deleterious health behaviour. In pregnant women this association not only affects their own health negatively, but has negative effects on the health of their children too. Children are more often born premature or small for gestational age, both of which are important risk factors for perinatal mortality and various diseases in childhood and adulthood [3,4]. Thus the foundations of health inequality are laid already at birth.

The findings highlight the need for public health initiatives, aimed at socially disadvantaged women, to be developed and implemented. Although further prospective trials should be conducted to precisely explain the association between socioeconomic status and birth weight, associations between inequality and health are thought to be highly complex. In its statement “Health in all policies” [40], the WHO calls for a comprehensive package of interventions to reduce health inequality. Important elements include political measures such as improving education and reducing poverty among young families, as well as preventive and health promoting interventions. Among pregnant women and women wanting to fall pregnant, these measures could initially be aimed at reducing perceived stress and improving coping strategies. A potential access point within antenatal care in Germany could be through intensifying the use of, and expanding existing structures e.g. the nationwide “Early Help” program (Frühe Hilfen, www.fruehehilfen.de). This program has been shown to be effective [41], however currently it only focuses on few women before or soon after falling pregnant, the emphasis being rather on families following the birth of a child. More support programs should be developed and tested. Gynaecologists and midwives could fulfill an important role in providing access to these programs.

The importance of interventions to reduce premature births and LBW in the lower social strata becomes even more apparent when one considers that children from socially weaker families have worse chances of optimal development than children born prematurely to mothers with better social status [18]. Apart from reducing the association between social and health inequality, the adequate implementation of appropriate preventive programs also has the potential to counteract the growing number of underweight births, which would simultaneously and sustain-
ably reduce the high costs to the health system of initial and subsequent treatment of these at risk newborns.

**Conclusion**

- Independent of medically relevant gestational diseases or malformations, women at risk of poverty had increased chances of having an LBW baby.
- Women with lower secondary school education (“Hauptschule”) or less were more likely to give birth to a child with a birth weight of 2500 g or less, and this was independent of relevant illnesses, malformations or damaging health behaviours.
- Maternal immigrant background and workplace stress did not have a direct negative effect on birth weight.
- In the setting of antenatal care and among women wanting to fall pregnant, potential social disadvantage should be detected earlier; existing preventive, health promoting interventions should be implemented early and new programs developed and tested.

**Ethical Considerations**

This study was approved by the ethics commission of the Saarland medical council (identification number: 96/11).

**Acknowledgement**

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**Conflict of Interest**

None.

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