# CONSUMPTION OF MEDICATIONS, ALCOHOL AND SMOKING IN PREGNANCY AND ASSESSMENT OF TERATOGENIC RISKS

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## ABSTRACT

Medications, alcohol and smoking can cause fetal damage. A cross-sectional study was conducted with 326 mothers of the Fortaleza General Hospital to evaluate the use of drugs, alcohol and smoking during pregnancy and its relation to teratogenic potential in different population characteristics, between 2006 and 2007. Postpartum women who had their babies in the research site were included and those whose babies were not admitted as hospital inpatients were excluded. Chi-square tests and t-tests were used in the analysis, with a p value <0.05 considered significant. 96.6% of the mothers took medications (2.8 drugs/pregnancy) and self-medication occurred in 11.3% of the cases. Single women took more drugs with high teratogenic potential (p=0.037). 11 cases of fetal malformation were observed, five of them were exposed to high teratogenic risks. Smoking occurred in 11.3% and alcohol use in 16%. Being single was found to be a risk factor for exposure to high teratogenic potential. Quality of prenatal care and other sociodemographic variables weren't related to exposure to teratogenic risks.

**Descriptors:** Teratology. Abnormalities, drug-induced. Pregnancy.

## *RESUMO*

*Medicações, álcool e fumo podem gerar danos fetais. Este estudo transversal foi realizado entre 2006 e 2007, com 326 puérperas do Hospital Geral de Fortaleza, para avaliar o uso de medicamentos, álcool e fumo na gestação e potencial teratogênico relacionado a diferentes características populacionais. Incluíram-se as puérperas com partos no local da pesquisa e excluíram-se as que não tinham seus filhos internados. Na análise, utilizaram-se os testes Qui-quadrado e t de Student, adotando p < 0,05. O consumo de medicamentos ocorreu em 96,6% (2,8 medicamentos/gestante), e 11,3% automedicaram-se. Solteiras utilizaram mais medicações com alto risco teratogênico (p = 0,037). Foram observados 11 casos de malformação fetal, sendo cinco expostos a elevado risco teratogênico, na gestação. O tabagismo ocorreu em 11,3%, e o etilismo em 16%. Observou-se como fator de risco para exposição a maior risco teratogênico o estado civil solteira. Outras variáveis sociodemográficas e a qualidade do pré-natal não se mostraram relacionadas ao risco teratogênico das exposições.*

***Descritores:*** *Teratologia. Anormalidades induzidas por medicamentos. Gravidez.*
***Título:*** *Consumo de medicamentos, álcool e fumo na gestação e avaliação dos riscos teratogênicos.*

## *RESUMEN*

*Medicamentos, alcohol y tabaco pueden causar daño fetal. Estudio transversal, realizado entre 2006 y 2007, con 326 madres del Hospital Geral de Fortaleza, para evaluar uso de drogas, alcohol y tabaco durante el embarazo y potencial teratogénico en relación con distintas características de la población. Madres con partos en sitio de investigación fueron incluidos y las que no tienen niños hospitalizados excluidas. En análisis, se utilizaron los test chi-cuadrado y t de Student, considerando p<0,05. Consumo de medicamentos se produjo en un 96,6% (2,8 drogas/embarazo) y automedicación en un 11,3%. Solteras utilizan más medicamentos de alto riesgo teratogénico (p=0,037). Se observaron 11 casos de malformación fetal, con cinco expuestos a riesgo teratogénico elevado. Fumar se produjo en un 11,3% y un 16% bebía alcohol. Se señaló como factor de riesgo de exposición a alto potencial teratogénico en el estado civil soltero. Otras variables sociodemográficas y calidad de la atención prenatal no se relacionaron con el riesgo teratogénico de exposición.*

***Descriptores:*** *Teratología. Anomalías inducidas por medicamentos. Embarazo.*
***Título:*** *Consumo de fármacos alcohol y tabaco el embarazo y la evaluación del riesgos teratogénicos.*

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## INTRODUCTION

Infant mortality is an important indicator of health care in a country because it reflects the quality and access to health services, the socioeconomic conditions, public health practices, as well as women's health. Analysis of the causes of infant mortality indicates that in recent years there has been a decrease in the overall rate of infectious-related diseases and, in turn, an increase in the rate of deaths due to congenital malformations [1]. Among the possible causes of these malformations, besides environmental factors, there are some medications and other drugs such as alcohol and tobacco.

It is important to stress that maternal exposure to drugs is extended to the fetus and the effects of these drugs will depend on the drug, the patient, and the time of exposure during pregnancy and the total dose, which may result in miscarriage, death or malformation. Therefore, the use of medications during pregnancy should be avoided in the first place [2]. However, studies have shown that this is an increasingly frequent event. Studies have also demonstrated the effects of alcohol and smoking during pregnancy, discouraging this practice, since there is no known safe level of use of these substances during pregnancy [3].

Developing countries, including Brazil, have characteristics that potentialize teratogenic risks. Among these features, it is worth mentioning the difficulty of access to health care services, unrestricted sale of medicines in drugstores, lack of an effective pharmacovigilance system and belief of the population in the effects of drugs[4].

In Brazil, there are few studies that assess the potential teratogenic risks for our population. The present study was aimed to assess the use of alcohol, smoking and other drugs during pregnancy and the teratogenic potential related to the different population characteristics.

## METHOD

The investigational model applied was a cross-sectional, descriptive and analytical, quantitative approach. The total sample of this study consisted of 326 postpartum women who had their babies in Hospital Geral, of Fortaleza (HGF), and were randomly selected in the November 2006-June 2007 period. The inclusion criterion was delivery in the research site. Postpartum women whose babies were not admitted as inpatients in the hospital at the time of the research were excluded, because this would make it impossible to assess the presence of congenital malformation.

Data were collected by undergraduate students in nursing from the State University of Ceará (UECE) who participated in the Teratogen Information System of Fortaleza (SIAT) and were trained to administer the questionnaire used under the supervision of the author. On random days, the field researchers randomly interviewed postpartum women who had delivered the day before and agreed to participate in the study by signing the Consent Form. Each week there was a minimum of 10 interviews.

The instrument consisted of a structured questionnaire adapted from SIAT. The interviews lasted from 40 to 45 minutes. Some data were obtained from medical records and prenatal care cards of the patients. The questionnaire included variables such as maternal sociodemographic data, current and previous pregnancies, use of drugs, smoking and alcohol during pregnancy. Newborns of each postpartum woman were also evaluated for the presence of possible fetal malformations and their association with the use of drugs, alcohol and smoking during pregnancy.

After analysis of the data collected (questionnaire), such data was entered daily into a database in the *Microsoft® Office Excel* do *Windows XP (Microsoft Corporation* 2003*)* software. Afterwards, this database was transferred to *Stata* version 8.0 (*StataCorp LP* 2002) software. Discrete variables were analyzed using Chi-square test for paired data and continuous variables with paired t-test. A $p < 0.05$ significance level was used.

For assessment of risk of teratogenicity, the classification of the *Food and Drug Administration* (FDA) was adopted. In this system, drugs are classified into five classes: class A, designating drugs safe in pregnancy; class B, including drugs that pose no fetal risks for animals, though not tested in humans; class C, including drugs with teratogenic effects in animals, though not tested in humans; class D, designating drugs with adverse effects in the fetus, but that allow risk-benefit analysis; and class X, whose drugs are contraindicated in pregnancy because they promote teratogenicity in humans[5]. For analysis purposes, we considered of

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low teratogenic risk the pregnancies exposed to A and B classes, according to the FDA, and of high risk those exposed to C, D and X classes.

Prenatal care was considered appropriate when 6 or more antepartum visits were made, according to the recommendations of the National Prenatal Care and Birth Humanization Program [6].

This project was approved by the Ethics and Research Committee of Hospital Geral, Fortaleza on September 14, 2006 (nº140906/2006).

## RESULTS

The consumption of at least one medication during pregnancy had a prevalence of 96.6% and an average of 2.8 drugs per pregnant woman. The types of drugs most commonly used were vitamins (57.7% of total exposures), followed by analgesics and antipyretics (14.1%), antibiotics (10%), anti-inflammatory agents (5.2%), antihypertensives (3%), antihistamines (2.6%), corticoids (1.4%), antacids (0.9%) and antirheumatic drugs (0.1%). Other types of drugs represented 4.1% of the sample, with 37 exposures. Self-medication was reported by 37 (11.3%) post-partum women.

Table 1 shows the quantitative consumption of drugs during pregnancy described in classes, according to medical indication or self-medication.

Given the use of medications and other drugs during pregnancy, 56.4% of the postpartum women were exposed to low teratogenic risk, with 26.4% of the total number of postpartum women subject to risk A and 30.1% to risk B. Among those women exposed to high teratogenic risk (35.6%), 8.6% were subject to risk C, 6.4% to risk D, 20.5% to risk X. 8% of them were subject to undetermined teratogenic risk.

Table 2 details the use of drugs only during the first trimester of pregnancy according to the type of medication, either by medical indication or self-medication. The highest prevalence of self-medication in the first trimester of pregnancy was observed in the use of anti-inflammatory agents, with 14 (38.9%) exposures out of the 36 that occurred.

The average age was 24.8 years, with a minimum age of 13 years old and maximum of 45. By establishing a relationship between age group with teratogenic risk during pregnancy, we found that there is no statistical significance between the groups, although half of the older mothers (35-45 years) presented high teratogenic risk (p = 0.295). Regarding marital status, single women were found to be exposed to drugs with higher risk of teratogenicity compared to two other groups (p = 0.037). Regarding schooling and occupation, there was no statistical significance (p = 0.281 and p = 0.377, respectively) in the intersection between variables and teratogenic risk.

Table 3 shows a characterization of the sample according to sociodemographic variables, related to teratogenic risk.

**Table 1** – Types of drugs used throughout pregnancy. Fortaleza, CE, 2007.

| Type of drug | Self-medication | | Medical Indication | | Total |
|---|---|---|---|---|---|
| | N* | % | N* | % | |
| Vitamins | 3 | 0.6 | 515 | 99.4 | 518 |
| Analgesic/ antipyretic | 13 | 10.2 | 114 | 89.8 | 127 |
| Antibiotic | 2 | 2.2 | 88 | 97.8 | 90 |
| Anti-inflammatory agent | 21 | 44.7 | 26 | 55.3 | 47 |
| Antihypertensive | 1 | 3.7 | 26 | 96.3 | 27 |
| Antihistamines | 1 | 4.3 | 22 | 95.7 | 23 |
| Corticoid | 0 | 0 | 13 | 100 | 13 |
| Antacid | 4 | 50 | 4 | 50 | 8 |
| Anticonvulsant | 0 | 0 | 7 | 100 | 7 |
| Antirheumatic | 0 | 0 | 1 | 100 | 1 |
| Others | 8 | 21.6 | 29 | 78.4 | 37 |

*Number of times the type of drug was used.

**Table 2** – Types of drugs used during the first trimester of pregnancy. Fortaleza, CE, 2007.

| Type of drug | Self-medication | | Medical Indication | | Total |
|---|---|---|---|---|---|
| | N* | % | N* | % | |
| Vitamins | 2 | 0.7 | 279 | 99.3 | 281 |
| Analgesic/ antipyretic | 10 | 13.2 | 66 | 86.8 | 76 |
| Anti-inflammatory agent | 14 | 58.3 | 10 | 41.7 | 24 |
| Antihypertensive | 1 | 4.5 | 21 | 95.5 | 22 |
| Antibiotic | 0 | 0 | 19 | 100.0 | 19 |
| Antacid | 4 | 80.0 | 1 | 20.0 | 5 |
| Anticonvulsant | 0 | 0 | 3 | 100.0 | 3 |
| Antihypertensive | 0 | 0 | 2 | 100.0 | 2 |
| Corticoid | 0 | 0 | 1 | 100.0 | 1 |
| Antirheumatic | 0 | 0 | 1 | 100.0 | 1 |
| Others | 5 | 29.4 | 12 | 70.6 | 17 |

* Number of times the type of drug was used.

Regarding prenatal care, 96% of the postpartum women in our study underwent prenatal care, while only 4% did not. 43.3% of the pregnant women did not undergo prenatal care or underwent inadequate prenatal care (zero to five antepartum visits) and 56.7% of them underwent adequate prenatal care (six or more antepartum visits). The quality of prenatal care was not related to the teratogenic potential of the drugs taken during pregnancy ($p = 0.064$).

Table 4 relates prenatal visits to teratogenic risk.

Smoking is present in 11.3% of pregnancies, and in 75.7% up to the end of pregnancy. 16% of them drank alcoholic during pregnancy, with 59.6% of them keeping this habit until the end of the third trimester of pregnancy. There was no statistically significant association between alcohol consumption and smoking during pregnancy and the occurrence of fetal malformations.

In the present study there were 11 cases (3.4% of the sample) of congenital malformations. A possible association between the presence of fetal malformation and teratogenic risks during pregnancy was investigated, related to the use of drugs with such potential during pregnancy (Table 5).

No statistically significant results were found linking teratogenic risk to the presence of congenital malformation.

## DISCUSSION

Since no drug is free from toxicity to the mother or fetus, and may cause teratogenic risk such as abortion, death or congenital malformations, medicalization associated with irrational use of drugs in pregnancy can be considered a public health problem. However, few studies aimed at the measurement and assessment of the consumption of medicines and other drugs during pregnancy, especially in the Northeast of Brazil.

Regarding the consumption of medicines by pregnant women, the result obtained in this research was higher than the 83.4% of pregnant women who reported taking at least one drug in Paraná[7] and 86.6% in Natal, with a similar average of drugs per pregnant woman [8].

Regarding the most consumed types of drugs, the results obtained were similar to those found in another study where antianemics represented 55.1% of the drugs consumed, analgesics, anti-inflammatory agents and antipyretics corresponded to 19.0% and antibiotics to 7.2% [9].

Concerning self-medication, this research found lower values than those obtained in other studies. A study in Natal revealed that 12.2% of the participants took at least one medication without medical indication, especially dipyrone and acetyl salicylic acid. The studies also highlight that the

**Table 3** – Teratogenic risk according to sociodemographic variables. Fortaleza, CE, 2007.

| Variable | Total | Low Teratogenic Risk | | High Teratogenic Risk | | P Value |
|---|---|---|---|---|---|---|
| | | N | % | N | % | |
| **Age** | | | | | | |
| ≤ 19 years | 81 | 54 | 66.7 | 27 | 33.3 | |
| 20 to 34 years | 192 | 116 | 60.4 | 76 | 39.6 | 0.295 |
| 35 to 45 years | 26 | 13 | 50.0 | 13 | 50.0 | |
| Missed | 27 | | | | | |
| **Marital Status** | | | | | | |
| Single | 66 | 33 | 50.0 | 33 | 50.0 | |
| Married | 73 | 52 | 71,2 | 21 | 28.8 | 0.037 |
| Stable Relationship | 159 | 98 | 61.6 | 61 | 38.4 | |
| Missed | 28 | | | | | |
| **Schooling** | | | | | | |
| Completed elementary education | 172 | 101 | 58.7 | 71 | 41.3 | 0.281 |
| Started secondary education | 128 | 83 | 64.8 | 45 | 35.2 | |
| Missed | 26 | | | | | |
| **Origin** | | | | | | |
| Fortaleza | 245 | 147 | 60.0 | 98 | 40.0 | |
| Inland of the state | 16 | 10 | 62.5 | 6 | 37.5 | 0.544 |
| Metropolitan region | 39 | 27 | 69.2 | 12 | 30.8 | |
| Missed | 26 | | | | | |
| **Occupation** | | | | | | |
| Does not work | 38 | 20 | 52.6 | 18 | 47.4 | |
| Works at Home | 168 | 108 | 64.3 | 60 | 35.7 | 0.377 |
| Works Outside | 94 | 56 | 59.6 | 38 | 40.4 | |
| Missed | 26 | | | | | |

use of drugs, regardless of the indication source (medical or no-medical) was greater among women with higher education level, who, theoretically, would have more access to information about the risks of drug therapy to the fetus [8]. Another study reports that in 16.4% of the cases, drugs were self-administered during pregnancy and, although 43% of the pregnant women said they were warned of the risks, 50% of the total number of participants decided to self-administer the medications [10].

However, we believe that the percentage of women who self-administered drugs during pregnancy is well below the expected, because our health care system is deficient and the use of non prescription medicines is necessary due to the difficult access of the population to health care units.

The higher frequency of self-medication in the first trimester of pregnancy was observed for anti-inflammatory agents. This is a concerning factor because a considerable part of anti-inflammatory agents are classified into class C for risk of teratogenicity by the FDA, or may pose unknown risks, as dipyrone, frequently reported by the postpartum women. It should be stressed that regarding the susceptibility of the fetus to drugs, a key factor to be considered is gestational age, for during embryonic differentiation or else, in the first trimester, it is believed that some substances are more likely to cause fetal abnormalities[11].

Regarding the consumption of drugs according to the FDA classification, this study showed a higher prevalence of risks A and B, respectively 26.4% and 30.1%. A study conducted in the south of Brazil found among the drugs used by pregnant women, 46.6% belong to category A and 35.9% to category B[9]. However, 20 (5%) pregnancies were

**Table 4** – Teratogenic risk according to the number of antepartum visits. Fortaleza, CE, 2007.

| Variable | Total | Low Teratogenic Risk | | High Teratogenic Risk | | P Value |
|---|---|---|---|---|---|---|
| | | N | % | N | % | |
| **Underwent Prenatal care** | | | | | | |
| Yes | 288 | 179 | 62.2 | 109 | 37.8 | 0,225 |
| No | 12 | 5 | 41.7 | 7 | 58,3 | |
| Missed | 26 | | | | | |
| **Pre-Natal Site** | | | | | | |
| Health Unit | 193 | 122 | 63.2 | 71 | 36.8 | |
| Hospital | 83 | 47 | 56.6 | 36 | 43.4 | 0.183 |
| Private Clinic | 12 | 10 | 83.3 | 2 | 16.7 | |
| Missed | 26 | | | | | |
| **Responsible for Prenatal care** | | | | | | |
| Physician | 132 | 78 | 59.1 | 54 | 40.9 | |
| Nurse | 45 | 25 | 55.6 | 20 | 44.4 | 0.198 |
| Both | 111 | 76 | 68.5 | 35 | 31.5 | |
| Missed | 26 | | | | | |
| **Number of Visits** | | | | | | |
| 0 to 5 | 130 | 72 | 55.4 | 58 | 44.6 | 0.064 |
| 6 to 15 | 170 | 112 | 65.9 | 58 | 34.1 | |
| Missed | 26 | | | | | |

**Table 5** – Teratogenic risk according to the presence of malformation in newborns. Fortaleza, CE, 2007.

| Variable | Total | Low Teratogenic Risk | | High Teratogenic Risk | | P Value |
|---|---|---|---|---|---|---|
| | | N | % | N | % | |
| **Malformation** | | | | | | |
| Absent | 282 | 176 | 62.4 | 106 | 37.6 | 0.309 |
| Present | 9* | 4 | 44.4 | 5 | 55.6 | |
| Missed | 25 | | | | | |

*There were two other cases of fetal malformation, totaling 11 cases. However, the teratogenic risk is undetermined.

exposed to teratogenic risk X, which was mostly related to smoking and/or alcohol consumption.

In the present study, only 8.7% of the postpartum women in the sample were considered of an advanced age (35-45 years) and this was not associated to increased teratogenic risk. However, half of the pregnant women took high-risk drugs or medications. On the other hand, most teenage girls, theoretically more susceptible to exposure to teratogens, had pregnancies with low risk of teratogenicity. The research reported that since adolescence is a period of search for biological, psychological and social maturation, the occurrence of a physical and psychological burden such as pregnancy increases vulnerability to risk actions[11]. Besides, it is worth mentioning that some studies showed a significant change in the profile of pregnant women, with a greater number of them under 15 years in the past decades[12].

Regarding marital status, single pregnant women had greater exposure to potentially teratogenic drugs during pregnancy than women in a stable relationship (married and in a stable relationship), result that can be expected due to the

vulnerability of the situation. Nevertheless, some authors reported a higher frequency of drug use during pregnancy among young married women, poorly educated and unemployed [9].

Regarding prenatal care, the pregnant women who failed to make the antepartum visits were at higher risk of teratogenic risk compared to those who underwent prenatal care, although without statistical significance. Nevertheless, some studies reported that prenatal care facilitates the consumption of drugs during pregnancy, once patients obtain free medications in the pharmacies [10].

Also, many pregnancies were monitored only by nurses in the prenatal period were exposed to low teratogenic risk (55.5%) because of the characteristics of the drugs taken during pregnancy. In other studies it was reported that nurses are increasingly taking more responsibility in low risk pregnancies[13], and prescription of drugs by nurses is a recognized practice resulting from changes in the role of nurses and in their technical-political significance within the scope of basic care under the SUS (Brazil's Unified Health System)[).

As for smoking during pregnancy, the figures obtained in our study are very similar to those reported in the literature, which is 15.9% in a study also carried out in Fortaleza [15]. Smoking during pregnancy is still very common, in spite of being decreasing from 35.6% in 1982 to 25.1% in 2004[16]. However, data from the referred study may not be reliable because the deleterious effects of smoking are widespread, and pregnant women fear the disapproval of researcher, or even the possibility of being responsible for any damage that smoking may have caused in the newborns.

Regarding the trimester of exposure, most pregnant women continued smoking until delivery (75.7%), a very high rate compared to other studies. A recent study found that the prevalence of smoking during early pregnancy was 41%, and 40% stopped smoking during pregnancy and 25% smoked until delivery[17].

The rate of alcohol use in pregnancy is still lower than the ones found in recent studies. A study conducted with 537 pregnant women in Rio de Janeiro demonstrated that 40.6% of them had used alcohol at some point during their pregnancy, and 10.1% had used alcohol frequently throughout pregnancy[18].

Exposure to alcohol occurred to a large extend during the entire pregnancy and at unknown concentrations. The teratogenic effects of alcohol, like any other neurobehavioral agent, have been documented with in-utero exposures at any gestational period[3].

As for the incidence of congenital malformation, the data are consistent with the literature where it is estimated that 2 to 3% of all babies born alive have congenital defects [19]. Although there is no statistical significance, most cases of fetal malformation in pregnancy were associated to drugs or medications with high teratogenic risk. In a study conducted in Maring with 222 medical records of newborns with malformations, it was observed that in 48.4% drugs classified into classes C, D and X had been consumed during pregnancy, according to the FDA, whereas in 24.3% of the cases the mothers had used medications classified into classes A and B only. In the other cases the risk is unknown [20].

Given the particularities of drug exposure during pregnancy, caution should be taken in the administration of drugs. Therefore, it is essential to identify the situations that really require drug therapy, make sure there is no association between malformations and exposure to the selected drug and measure the acceptable level of safety for the mother and fetus under the drug treatment, assessing the risk-benefit of this exposure. Besides, the pregnant women should be made aware of the importance of not using illegal drugs during pregnancy, to prevent possible damage caused by fetal exposure to these drugs.

The nurses, especially through the Family Health Strategy, actively participate in this process, both in the prescription of standard drugs as in health education, acting as opinion makers and professionals responsible to disseminate reliable information. So there must be awareness of the importance and value of their actions, and efforts should be made to reach the proposed objective: high-quality prenatal care that causes no damage to the mother and the developing embryo.

## CONCLUSION

Based on these results, it is concluded that the medicalization of pregnancy is a reality, since there is a large consumption of drugs during pregnancy without knowledge of the teratogenic risks involved, and marital status single was found to be the socioeconomic characteristic of pregnant

women most exposed to potentially teratogenic factors. Self-medication was little reported by the postpartum women, with a frequency well below the expectations, and the most commonly self-administered drug being anti-inflammatory agents, especially in the first trimester. Since non-prescription drugs are often not considered real medications by patients, even if used to treat a physical complaint, it is possible that the number of medications used as self-administered drugs is underestimated, which is a limitation of this study. In addition to this limitation, there is the fact that maternal memory has been used as the only source of information on the use of drugs, alcohol and smoking in pregnancy.

Alcohol and tobacco have been largely consumed by the pregnant women throughout the gestational period. However, no statistical significance was established between alcohol use and smoking during pregnancy and the occurrence of fetal malformations.

Therefore, the nurses' knowledge about the drugs most commonly used in pregnancy and the frequency of alcohol use and smoking, as well as their teratogenic potential and demographic characteristics most exposed contribute to the planning and targeting of educational interventions to pregnant women, providing greater certainty on the rational use of drugs during pregnancy.

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Received: 13.04.2012
Approved: 30.04.2012

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