

The Impact of Prenatal Diagnosis and Termination of Pregnancy on the Relative Incidence of Malformations at Birth among Jews and Muslim Arabs in Israel*

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ABSTRACT: **Background:** Ultrasound examination of the fetus enables diagnosis of many major malformations during pregnancy, providing the possibility to consider termination of the pregnancy. As a result, in many cases the incidence of malformations at birth does not represent their true incidence. **Objectives:** To determine the impact of prenatal diagnosis and pregnancy termination on the relative incidence of malformations at birth among Jews and Muslim Arabs in Israel. **Methods:** Data on selected major malformations in 2000–2003 were collected from the two large central databases of the Ministry of Health and the Central Bureau of Statistics which contain information regarding births, stillbirths and terminations of pregnancies. **Results:** For many malformations the total incidence was much higher than the incidence at birth. For almost all of the malformations studied, the total incidence was higher in Muslims than in Jews and the differences were further accentuated among the liveborn because of the differences in the rate of pregnancy terminations. **Conclusions:** In order to detect possible influences of environmental or genetic factors on major malformations in Israel, it is critical to look at data including pregnancy terminations, stillbirths and live births.

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KEY WORDS: malformations, prenatal diagnosis, termination of pregnancy, Jews, Muslims

The population of Israel is estimated to be 7,282,000 and is both ethnically and religiously diverse. Jews constitute 80% of the population, while Muslims constitute 15%, Druze 3%, and Christians 2% [1]. Most of the Muslims and Christians are Arabs. There has been an impressive reduction in infant mortality rates among both Jewish and non-Jewish citizens since the creation of the State of Israel in 1948; however, differences remain particularly as a result of differences in the

frequency of congenital malformations and genetic diseases [2]. Significant differences in the rate of malformations at birth between Jews and the Muslim and Druze populations were demonstrated in a study that used the National Registry of Birth Defects during the period 1991–2000 among more than 1.2 million liveborns [3]. However, since major fetal malformations may be diagnosed during pregnancy and often lead to pregnancy termination, the incidence at birth does not always represent the true incidence. The present study was performed to determine the impact of prenatal diagnosis on the rates of selected major malformations at birth among the two major religious communities in Israel – Jews and Muslims.

SUBJECTS AND METHODS

Data were collected from the two large central databases of the Ministry of Health and the Central Bureau of Statistics; these contain information on births, stillbirths and terminations of pregnancies. In Israel almost all infants are delivered in hospitals and the mandatory reporting of all live and stillbirths to the Ministry of Health includes details regarding the presence and type of congenital malformations. Since the year 2000, the mandatory report to the Central Bureau of Statistics of pregnancy termination for reasons of suspected fetal malformations includes details on the type of malformations diagnosed. These data are all coded according to the ICD-10 by a single coder and entered into the appropriate database. When the malformation is part of a syndrome, the code given is that of the syndrome.

Each of the two registries is linked to the Israeli Population Registry in which each liveborn is assigned a unique identification number and includes demographic details, among them religion. The Ministry of Health and the Central Bureau of Statistics registries were compared and duplicate entries were deleted. These consisted primarily of late terminations of pregnancy that are also registered as stillbirths. We report on the total number and rates of congenital malformations for live births, stillbirths and pregnancy terminations using the information from both registries after correcting for duplicates.

* This article represents the opinions of the authors and not necessarily those of the Ministry of Health.

Table 1. Selected malformations in the Israeli Jewish population between 2000 and 2003 among live births, termination of pregnancies and stillbirths

	Numbers of				Rates	
	Live births	TOP	Still births	Total	TOP/Total	Total/10,000 LB
Abdominal wall defects	23	38	2	63	0.61	1.67
Anencephaly	17	154	17	188	0.82	4.99
Anophthalmia	2	2	1	5	0.4	0.13
Atresia esophagus	73	0	2	75	0	1.99
Atresia large intestine	82	1	3	86	0.01	2.28
Atresia small intestine	47	0	0	47	0	1.25
Choanal atresia	23	0	0	23	0	0.61
Cleft lip/palate	116	18	7	141	0.13	3.74
Cleft palate	90	6	1	97	0.06	2.58
Congenital kidney cystic disease	108	18	3	129	0.14	3.43
Diaphragmatic hernia	34	6	3	43	0.14	1.14
Encephalocele	8	25	3	36	0.69	0.96
Exstrophy bladder	5	0	0	5	0	0.13
Hypoplastic left heart	25	40	0	65	0.57	2.89
Prune belly syndrome	2	4	0	6	0.67	0.16
Reduction deformities of brain	7	21	6	34	0.62	0.9
Reduction deformities of limbs	62	17	0	79	0.22	2.1
Renal agenesis	96	27	4	127	0.21	3.37
Spina bifida	41	62	6	109	0.62	0.57
Tetralogy of Fallot	83	20	3	106	0.19	2.81
Transposition of great vessels	40	15	9	64	0.23	1.7
Trisomy 13 and 18	27	38	5	70	0.54	1.86
Trisomy 21*	358*	484		842	0.57	22.36

The stillbirths do not include late termination of pregnancy (Methods).
 *A unique registry exists for trisomy 21 in the Ministry of Health and the numbers at birth include stillbirths.
 TOP = termination of pregnancy

The rates of diagnosis of some of the malformations diagnosed at birth, such as congenital heart malformations, differ among the hospitals. In order to reduce this bias, we included in this study only malformations for which the diagnosis is unequivocal during pregnancy or at birth. Although this correction allows for greater uniformity, it is known that the registries are incomplete due to partial reporting and thus underestimate the rate of malformations in Israel.

Some of the information from these reports is not sufficiently specific due to the use of general terms such as "congenital heart malformations" or "multiple malformations,"

thus contributing further to an underestimation of the number of each malformation. In addition, when the malformations were part of a syndrome they were not included in the study. Since it is not always possible to differentiate in the report between unilateral and bilateral cases of major kidney malformations such as renal agenesis and congenital kidney disease, these malformations include both possibilities.

RESULTS

From 2000 to 2003 in Israel there were 376,627 liveborn Jewish infants and 144,625 liveborn Muslim Arab infants [1]. As expected, Down syndrome and open neural tube defects were the most frequent malformations among both Jews and Muslims [Tables 1 and 2]. For almost each of the malformations studied, the total incidence was higher in Muslims than in Jews [Table 3]. One exception was Down syndrome for which the total incidence among Jews (23.36 per 10,000 live births) was higher than among non-Jews (16.35 per 10,000 live births) as a direct consequence of the higher proportion of Jewish women being pregnant at later ages [1].

In addition, since for each of the malformations studied the rate of pregnancy termination was higher among Jews than among Muslims, almost all the malformations were more frequent at birth among Muslims than among Jews [Table 3]. For Down syndrome this resulted in a false impression that it is more frequent among non-Jews than in Jews.

For many of the malformations studied the rate at birth did not represent even an estimate of the true incidence. The most extreme example was anencephaly. Among Jews the rate of live births with anencephaly (0.45/10,000 live births) was 10.9 times lower than its true incidence (4.99/10,000 live births).

DISCUSSION

From a public health perspective, analysis of the relative incidence of malformations is important both for planning of services and for the determination of causal factors. In the case of the former, the rate of congenital malformations at birth is the variable that needs to be taken into account. However, in order to detect possible influences of environmental or genetic factors it is crucial to estimate the true incidence of the malformations. The true incidence must include data about terminations of pregnancy since the incidence at birth is strongly influenced by the rate of pregnancy termination for many of the malformations. In addition, since for some of the major malformations such as anencephaly many of the affected fetuses are stillborn, these data must also be added. Only the total rates of congenital malformations thus derived should be used to determine and follow the incidence of malformations in order to detect possible influences of environmental or genetic factors. The present study confirmed that in a country where termination

of pregnancy for malformations is possible, the incidence at birth is a very poor indicator of the true incidence for many of the malformations, and, as already noted, the most extreme example was anencephaly. As a result, while in some countries research on the rate of open neural tube defects at birth is enough to follow the implementation of food fortification with folic acid, in Israel such a study would not be representative. It would not have been possible to demonstrate the results of the 2000 recommendation for folic acid supplementation using only data from live births since no significant changes at birth were observed. Only with data on termination of pregnancies and stillbirths was the reduction in the incidence of open neural tube defects in Israel demonstrated [4]. In contrast, for malformations that are rarely diagnosed during pregnancy – such as cleft palate, choanal atresia or small intestinal atresia – incidence rates at birth are similar to the true incidence in the population.

In the present study the differences in the rate of pregnancy termination between Jews and Muslims were evident. The differences were present both for a severe and lethal malformation such as anencephaly (82% terminated among Jews and 60% among Muslims) and less severe malformations such as spina bifida (62% and 32%) or Down syndrome (57% and 24%). While among Jews more than 50% of pregnancies were terminated for 9 of the 23 selected malformations, among Muslims anencephaly was the only malformation for which more than 50% of the cases were terminated. Among Jews the rate of pregnancy termination for malformations was less than 50%, either because the malformation was difficult to diagnose or because the malformation itself was relatively mild. In the case of severe malformations such as renal agenesis and cystic malformations of the kidneys, it is probable that the relatively low rates of pregnancy termination are due to the inclusion of cases with unilateral malformations that allow for normal life. In contrast, among Muslims the pregnancies with a malformation were terminated for 16 of the 23 selected malformations in less than 10% of the cases.

What are the reasons for the difference in the rates of pregnancy termination for malformations in these two populations? Among the malformations that are diagnosed during pregnancy the differences in the rate of pregnancy termination between the two religious communities are mostly due to differences in religiosity [5]. According to Jewish Law, interruption of pregnancy is mostly forbidden after 40 days of pregnancy, whereas Islamic Law absolutely forbids termination of pregnancy after the 120th day of pregnancy. However, among Jews the majority of the population is secular and considers termination of pregnancy legitimate. As a result, as seen in the present study, for the most severe malformations the rates of termination of pregnancy are within a similar range (between 69% and 54%). On the other hand, the general Muslim population is traditionally religious, and

Table 2. Selected malformations in the Israeli Muslim Arab population between 2000 and 2003 among live births, termination of pregnancies and stillbirths

	Numbers of				Rates	
	Live births	TOP	Stillbirths	Total	TOP/Total	Total/10,000 LB
Abdominal wall defects	11	10	1	22	0.45	1.52
Anencephaly	17	76	34	127	0.6	8.78
Anophthalmia	2	0	0	2	0	0.14
Atresia esophagus	45	1	1	47	0.02	3.25
Atresia of large intestine	48	0	1	49	0	3.39
Atresia of small intestine	33	0	0	33	0	2.28
Choanal atresia	11	0	0	11	0	0.76
Cleft lip/palate	83	6	0	89	0.07	6.15
Cleft palate	39	1	1	41	0.02	2.83
Congenital kidney cystic disease	63	9	6	78	0.12	5.39
Diaphragmatic hernia	31	2	0	33	0.06	2.28
Encephalocele	16	6	4	26	0.23	1.8
Exstrophy bladder	3	0	1	4	0	0.28
Hypoplastic left heart	27	4	0	31	0.13	2.14
Prune belly syndrome	3	0	0	3	0	0.21
Reduction deformities of brain	10	4	2	16	0.25	1.1
Reduction deformities of limbs	43	5	1	49	0.1	3.39
Renal agenesis	29	3	3	35	0.09	2.42
Spina bifida	66	32	3	101	0.32	6.98
Tetralogy of Fallot	52	3	1	56	0.05	3.87
Transposition of great vessels	39	1	0	40	0.02	2.77
Trisomy 13 And 18	8	5	3	16	0.31	1.11
Trisomy 21*	179	57		236	0.24	16.35

The stillbirths do not include late termination of pregnancy (methods)

The data for trisomy 21 are obtained through a different registry for the non-Jewish population and the numbers at birth include stillbirths

TOP = termination of pregnancy

the birth of a malformed child is often accepted as God's will and an event that should not be interfered with. Indeed, the rates of pregnancy termination are relatively low even for severe malformations.

However, an important question that must be addressed but cannot be resolved by the present study is whether the differences in the rate of pregnancy termination represent only a difference in the approach to pregnancy or are also due to differences in the ability to arrive at a diagnosis during pregnancy. In the example of anencephaly, since almost all the cases are diagnosed during pregnancy, the differences in the rate of termination among the two groups are mainly explained by differences concerning the approach to termination. However, for other disorders such as cardiac malformations the ability to reach a prenatal diagnosis depends on the

Table 3. Selected malformations in the Israeli population between 2000 and 2003: comparison of the rates at birth and total rates between Jews and Arab Muslims*

	Live births rates			Total rates		
	Muslims	Jews	M/J ratio	Muslims	Jews	M/J ratio
Anencephaly	1.18	0.45	2.6 (1.3-5.1)	8.78	4.99	1.8 (1.4-2.2)
Atresia esophagus	3.11	1.94	1.6 (1.1-2.3)	3.25	1.99	1.6 (1.1-2.4)
Atresia large intestine	3.31	2.18	1.5 (1.1-2.2)	3.39	2.28	1.5 (1.0-2.1)
Atresia small intestine	2.28	1.25	1.8 (1.2-2.9)	2.28	1.25	1.8 (1.2-2.9)
Cleft lip/palate	5.74	3.08	1.9 (1.4-2.5)	6.15	3.74	1.6 (1.3-2.1)
Cleft palate	2.70	2.39	1.1 (0.8-1.6)	2.83	2.58	1.1 (0.8-1.6)
Congenital kidney cystic disease	4.36	2.87	1.5 (1.1-2.1)	5.39	3.43	1.6 (1.2-2.1)
Diaphragmatic hernia	2.14	0.90	2.4 (1.5-3.9)	2.28	1.14	2.0 (1.3-3.5)
Encephalocele	1.10	0.21	5.2 (2.2-12.2)	1.80	0.96	1.9 (1.1-3.1)
Abdominal wall defects	0.76	0.61	1.2 (0.6-2.6)	1.52	1.67	0.9 (0.6-1.5)
Hypoplastic left heart	1.87	0.86	2.8 (1.6-4.9)	2.14	1.73	1.2 (0.8-1.9)
Reduction deformities of brain	0.69	0.19	3.7 (1.4-9.8)	1.10	0.90	1.2 (0.7-2.2)
Reduction deformities of limbs	2.97	1.65	1.8 (1.2-2.7)	3.39	2.10	1.6 (1.3-2.3)
Renal agenesis	2.01	2.55	0.8 (0.5-1.2)	2.42	3.37	0.7 (0.5-1.0)
Spina bifida	4.56	1.09	4.2 (2.8-6.2)	6.98	2.89	2.4 (1.8-3.2)
Tetralogy of Fallot	3.60	2.20	1.6 (1.2-2.3)	3.87	2.81	1.4 (1.0-1.9)
Transposition of great vessels	2.70	1.06	2.5 (1.6-4.0)	2.77	1.70	1.6 (1.1-2.4)
Trisomy 13 and 18	0.55	0.72	0.8 (0.4-1.7)	1.11	1.86	0.6 (0.4-1.0)
Trisomy 21	1.23	0.92	1.3 (1.1-1.6)	16.35	22.36	0.7 (0.6-0.8)

*Includes only those malformations in which there were more than 5 cases among either Jews or Muslims

type of examination that was performed during pregnancy. Therefore, it is probable that at least some of the differences observed for malformations such as hypoplastic left heart (62% terminated among Jews and 13% among Muslims) or transposition of great vessels (23% and 2%) are secondary to differences of either availability or use of the medical services between the two populations.

In conclusion, when looking at the rate of malformations in a country such as Israel where interruption of pregnancy is allowed, it is critical to look at data including pregnancy terminations, stillbirths and live births to detect possible influences of environmental or genetic factors on major malformations.

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Surveillance of Neural Tube Defects in Israel: the Effect of the Recommendation for Periconceptional Folic Acid

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Key words: neural tube defects, anencephaly, spina bifida, encephalocele, folic acid, prevention

Abstract

Background: Open neural tube defects are among the most common severely disabling birth defects. Secondary prevention by early diagnosis during pregnancy and abortion of affected fetuses lead to a marked reduction of NTD incidence at birth. For primary prevention of these defects, in August 2000 the Israel Ministry of Health issued guidelines recommending a daily 0.4 mg folic acid supplement for all women in their childbearing years with special emphasis on the 3 months preceding conception and the first trimester of pregnancy.

Objectives: To compare the epidemiologic characteristics of NTD in Israel before and after the guidelines for folic acid supplementation.

Methods: A national registry of NTD was begun in 1999. Since the Ministry of Health published the recommendation for folic acid supplementation in mid-2000, the years 1999–2000 represent the status prior to the recommendation and the years 2002–2004 the status after.

Results: A marked decline in the rate of spina bifida was observed in the last 3 years (from 4.9 to 2.7 per 10,000 live births among Jews and 9.5 to 6.2 among Arabs and Druze). There was no apparent reduction for anencephaly.

Conclusions: Following the Ministry of Health guidelines on folic acid supplementation for women in the reproductive age, a marked reduction in the rates of NTD was observed. In light of this apparent success, continuous efforts should be made to increase the percentage of women taking the supplementation and, especially, to introduce folic acid fortification.

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termination of affected pregnancies. The studies of Smithells et al. [2], confirmed by other clinical trials, showed that supplements containing folic acid, when consumed by women before conception, could reduce the rates of neural tube defects. Accordingly, professional organizations and governmental agencies promoted the use of folic acid supplements before and during pregnancy to prevent neural tube defects. In some countries like the United States and Canada, the recommendations of supplementation are integrated with a policy of folic acid food fortification [3]. In Israel, the Public Health services in the Ministry of Health issued a circular in August 2000 containing guidelines with recommendations for 0.4 mg folic acid supplement in the preconceptional period and during pregnancy [4]. The subject was also introduced by a campaign to doctors and nurses in the well-baby clinics run by the Ministry of Health and to the four health management organizations, various professional organizations, and the public via the media [5]. Although most cereals for breakfast in Israel as well as a few types of bread are fortified also with folic acid, fortified foods represent only a small part of the diet of the majority of the population [6].

Data on the total rates of NTD (including those of terminated pregnancies) in Israel have been available since 1999 when a national registry of NTD was initiated [7]. The registry therefore includes data before and after the recommendations on folic acid supplementation, allowing monitoring and evaluating the implementation and outcome of the project.

Subjects and Methods

Reporting newborns with malformations is obligatory in Israel; the registration uses the child's ID number. In 1999 all the medical units involved in the diagnosis of NTD either during pregnancy or at birth were informed of the establishment of a national registry and were asked to participate. The major participants came from the hospitals' ultrasound units, genetic units, triple test laboratories, and departments of pathology. In addition, data were extracted from the National Registry of Malformations for live-born as well as stillborn infants. Many of the cases were reported twice or more to the NTD registry, however the ID numbers prevented multiple entries of cases.

While the registry includes syndromic NTD the data presented

For Editorial see page 649

Open neural tube defects are among the most common severely disabling birth defects [1]. A general declining trend in the incidence of NTD at birth has been observed in many countries because of a primary prevention causing reduction in the total incidence and/or due to secondary prevention by screening and

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NTD = neural tube defects

here refer only to non-syndromic NTD, and were categorized in four groups: anencephaly, spina bifida, encephalocele, and unknown. The cases were classified according to the ethnic religious affiliation of the parents. The major religious groups in the Israeli population are Jews (81%), Muslim Arabs (15%), Christian Arabs (2%), and Druze (2%) [8]. The newborn population in 1999–2000 comprised 69.1% Jews, 26% Muslim Arabs, 2.1% Christians and 2% Druze.

Because the recommendations for preconceptional supplementation with folic acid were issued in mid-2000, the first weeks of the pregnancies that ended in 1999 and 2000 preceded publication of these guidelines. The pregnancies ending in 2002–2004 were after the recommendations. The year 2001 includes pregnancies whose first weeks were both before and after the recommendations and the data for 2001 were therefore not included in the comparisons.

Fluctuations in the rates of NTD are observed in all populations, often without apparent causes. In order to minimize the fluctuation in rates observed from year to year for the analyses, the data were grouped as before the recommendation for supplementation (1999–2000) and after supplementation (2002–2004). In addition, no statistical analysis was performed and the results are presented as pointing to a trend.

Results

The total numbers of NTD were stable in 1999 and 2000 and a decline occurred from 2002 [Table 1]. The mean total number of NTD was 103 for Jews and 93 for non-Jews in 1999–2000, and declined to 81 for Jews and 74 for non-Jews in 2002–2004. During the years the rate of pregnancy terminations for neural tube defects remained in similar ranges for the various ethnic groups: significantly higher for Jews (range 69–79%) than for Arabs and Druze (range 40–56%).

From the analyses of data grouped as before the recommendation for supplementation (1999–2000) and after supplementation (2002–2004) the trend was to a reduction in NTD rates [Table 2]. The NTD rates in the period 2002–2004 declined as compared to 1999–2000 in the two religious groups: from 11.7 to 8.1 per 10,000 live births among Jews (31% decline) and from 22 to 16.7 per 10,000 live births among non-Jews (24% decline). The reduction was from 21.1 to 18 per 10,000 live births among Druze and 16 to 8.8 per 10,000 among Muslims not including the Bedouins. Almost no changes were observed among the Christians, and in the Bedouin subgroup of Muslim Arabs there was even an elevation in the rates from 25 to 28 per 10,000 live births.

The main change observed was a reduction in the rates of spina bifida [Table 3] – from 4.9 to 2.7 per 10,000 live births among Jews (44% decline) and 9.5 to 6.2 per 10,000 live births among Arabs and Druze (34.4% decline). There was almost no change in the rates of anencephaly in both groups: from 5.3 to 4.9 per 10,000 live births among Jews and 8.9 to 8.2 per 10,000 live births among Arabs and Druze.

Discussion

Open neural tube defects are among the most common severely disabling birth defects [1]. In Israel it has been demonstrated

Table 1. Neural tube defects per year among Jews, Arabs and Druze*

	1999	2000	2001	2002	2003	2004
Jews	24/99 (76%)	31/107 (71%)	31/99 (69%)	19/73 (74%)	18/87 (79%)	25/84 (70%)
Arabs and Druze	47/92 (51%)	49/94 (52%)	58/96 (40%)	38/80 (52%)	34/77 (56%)	22/71 (55%)

* For each year, the numbers in the table are the number of children born with NTD (live births + stillbirths)/total numbers of NTD. Stillbirths refer to intrauterine deaths only and do not include late terminations of pregnancies.

Numbers in parentheses are the percentages of NTD in which the pregnancy was medically interrupted.

Table 2. Rates of NTD* in the different religious groups (per 10,000 live births)

	Jews	Christians	Druze	Muslims**	Bedouins
1999–2000	11.7	12	21.1	16	25
2002–2004	8.1	11	18	8.8	28

* Including all the NTD

** Not including Bedouins

Table 3. Rates of NTD per 10,000 live-births at different time periods

	1958–1968	1999–2000	2002–2004
Jews			
Anencephaly	8.6	5.3	4.9
Spina bifida	6	4.9	2.7
Total*		11.7	8.1
Arabs and Druze			
Anencephaly		8.9	8.2
Spina bifida		9.5	6.2
Total*		22.0	16.7

* Including all the NTD

that the prevalence is particularly high among Muslim Arabs and Druze [7]. The disparities between the different religious groups probably represent a combination of genetic differences with environmental and cultural factors. The living conditions of the Bedouins in the Galilee are close to those of the other Muslims in the region but mostly different from the Bedouins in the Negev Desert. However, a similar high prevalence of NTD is observed among the Bedouins living either in the Galilee or in the Negev.

In Israel most NTD are diagnosed during pregnancy, and between 40% and 79% are terminated [Table 1]. Therefore, while in the past, Israeli surveys of the NTD prevalence were performed at birth, nowadays it is imperative that such surveys include also termination of pregnancies. A comparison of the NTD rates among Jews in 1958–1968 at birth [9] with those from 1999–2000 including termination of pregnancies revealed a 20% decline (from

14.6 to 11.7 per 10,000 live births) [Table 3]. Since complete data were not available for the 30 year period between the two surveys, it is difficult to determine whether the decline was progressive or occurred only in recent years. However, the national registry shows that the number of cases of NTD was very stable for 3 years prior to publication of the new recommendations, i.e., from 1999 to 2001, in Jews as well as Arabs and Druze. A decline in NTD rates was observed beginning in 2002. From 1999–2000 to 2002–2004 the total rates declined by 31% among Jews (11.7 to 8.1 per 10,000 live births). In the same periods a 24% decline was observed among Arabs and Druze (from 22 to 16.7 per 10,000 live births). The reduction in NTD rates occurred in each religious group, except for the Bedouins in the Muslim group (respectively 25 and 28 per 10,000 live births). The observation that the decline in NTD rates occurred in all religious groups supports the assumption that the reduction is not an artifact such as lower reporting in recent years. The decline was noted in both registries – stillbirth and live-born, while the data for each were obtained from independent sources. In addition, a 30% decline in the number of pregnancy terminations due to NTD was observed in recent years (Central Bureau of Statistics, unpublished data). It should be emphasized that reports of pregnancy termination including its indication is obligatory by law; however, since the data are collected anonymously they are not used in our registry. The observation of a significant decline in NTD obtained from several independent sources supports the assumption that the decline in the NTD rates is real.

In parallel to the recommendations for folic acid supplementation, several surveys were conducted on awareness, knowledge and practice of folic acid consumption in pregnant women in Israel, demonstrating significant changes in the habits of the population. In 2000, before the recommendation, only 17.6% of the women knew about the effects of folic acid, and 5.2% took it as recommended. 2 years later the numbers rose to 77.7% and 30.5% respectively [5]. The preliminary results of a similar survey in 2005 indicate a further rise in the preconceptional use of folic acid to 35%. Therefore, the observations of stable rates in the years preceding the recommendation and the progressive decline in NTD rates accompanying both the increased knowledge of women on the importance of folic acid and the increased intake suggest that a direct link exists between the two.

Another observation supporting the effect of folic acid is that the most significant decline (31%) occurred among Jews, who also had the highest consumption of folic acid (34.8%). Among Arabs and Druze there was a 24% decline in NTD and the folic acid consumption was 21.2%. As already mentioned there were no changes in the rates of NTD among the Bedouin. Since data on their folic acid consumption are insufficient it cannot be determined whether this is due to the low intake or to differences in genetic background resulting from consanguineous marriages in the community.

An intriguing observation from other studies as well is that the reduction in NTD rates is more significant for spina bifida than for anencephaly in all religious groups. In the 3 years following the recommendation a 41% reduction occurred among

Jews (from 4.9 to 2.7 per 10,000 live births) and 35% among non-Jews (from 9.5 to 6.2 per 10,000 live births). Changes in the rates of anencephaly were minimal among both Jews (from 5.3 to 4.9 per 10,000 live births) and non-Jews (from 8.9 to 8.2 per 10,000 live births). One possible explanation may be the use in recent years of the nuchal translucency test for Down syndrome screening, whereby anencephaly can be diagnosed very early in pregnancy. Many of these early-affected pregnancies would otherwise have been spontaneously aborted and not diagnosed. This early ultrasonographic diagnosis led to an increase in the total numbers of anencephaly in recent years, masking in part the reduction. However, this explanation accounts for only a small portion of the difference in the decline of rates between anencephaly and spina bifida. Another possible explanation is that higher amounts of folic acid are needed to prevent the more severe defects [10]. A third possibility, namely, that anencephaly is more sensitive than spina bifida to folic acid, may also be raised. Already before the folic acid recommendation a 35% decline in the rates of anencephaly was noted among Jews, while for spina bifida the reduction was only 18%. It may well be that socioeconomic changes in Israel in the period between the two surveys, with concomitant improvement in diet before and during pregnancies led to a drastic reduction in the rates of anencephaly and a moderate reduction in spina bifida. Only with the folic acid supplement did a significant reduction occur in the rates of spina bifida while the reduction in anencephaly was moderate. Similar observations were made in the U.S. [11,12]; however, in Ireland for instance a significant decline occurred in the 15 years preceding the folic acid recommendation both for anencephaly and spina bifida [13]. In Chile, a third type of observation was made – no changes in NTD rates before folic acid supplementation, whereas afterward a decline occurred in both malformations [14]. It is possible that in those populations different nutritional status, socioeconomic conditions as well as genetic background contribute to these diverse observations.

In a recent study covering birth defect registries from various countries and including a total of more than 13 million births, there was no detectable change in NTD rates associated with recommendations to consume folic acid [15]. Either the rates were unchanged or the rate of decline was similar to that observed during the period before the recommendations. The authors attributed this to the fact that the recommendations were not effectively implemented and therefore did not induce a sustained change in behavior in a sufficiently large proportion of women to cause measurable effects. The present study confirms other observations that if the recommendations are accompanied by effective implementation leading to an increase in the intake of folic acid, the supplementation is effective in reducing the NTD rates.

However, to a certain degree, it is very difficult or even impossible to increase the rate of utilization of folic acid supplements [16]. Therefore, the next step should be mandatory food fortification, the success of which has been demonstrated in various countries [17]. The importance of food fortification in Israel has been emphasized and planned in parallel with the effort

to increase folic acid intake [6,18]. However, several unexpected events slowed the process and general folic acid fortification has not yet been implemented.

In light of the apparent success of folic acid in reducing NTD rates in the different communities living in Israel, continuous efforts should be made to increase the percentage of women taking the supplementation and, particularly, to institute folic acid fortification.

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Preconceptional folic acid utilization in Israel: Five years after the guidelines

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Abstract

Objective. In Israel, a national survey was conducted in order to assess the efficacy of the ongoing national folic acid (FA) campaign launched in 2000. The Ministry of Health had issued official guidelines in August 2000 recommending daily FA supplementation for all childbearing age women.

Methods. In 2005, structured interviews of pregnant and postpartum women were conducted by the nursing staff of the Maternal Child Health Clinics administered by the Public Health Service. The results of the 2005 survey are compared with similar surveys done in 2002 and 2000 (baseline).

Results. In the 2005 survey ($n=1860$), FA awareness, knowledge, timing knowledge and preconceptional utilization were 90.3%, 80.8%, 74.6% and 34.0%, respectively. Education was significantly associated with compliance: only 13.6% of women with <12 years of education utilized FA preconceptionally versus 48.1% of women with ≥ 16 years.

In the 2002 survey ($n=1661$), FA awareness, knowledge, and preconceptional utilization were 85%, 77.7% and 30.5%, respectively. In the 2000 survey ($n=1719$), FA awareness was 54.6%, knowledge was 17.6% and preconceptional utilization was 5.2%.

Conclusions. The national preconceptional FA campaign in Israel has resulted in significant increases in awareness, knowledge and preconceptional utilization.

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Keywords: Folic acid; Preconceptional health; Neural tube defects; National survey; Israel

Introduction

Conclusive evidence that perceptive folic acid (FA) is essential in the prevention of neural tube defects (NTDs) has been available since 1991 (MRC, 1991). In 1999, Berry et al. provided irrefutable evidence that confirmed the efficacy of a 400 μg daily dose.

Terminations of pregnancy as a result of improved prenatal diagnostics have led to a decreased incidence of NTDs at birth. In order to ascertain the “true” incidence of NTDs the Ministry of Health’s (MOH) Department of Community Genetics established an “NTD” registry in Israel in 1999. Reports from

ultrasound clinics, genetic laboratories and units, and pathology departments are cross-referenced with the national birth registry, stillbirth and abortion (spontaneous and induced) records.

The rate of NTDs in 1999–2000 was 1.2 per 1000 in the Jewish population and 2.2 per 1000 live births in the Arab population. Live-born, stillborn infants and electively terminated pregnancies were included in the analyses. The incidence of spina bifida (reflected within NTDs) was 0.49/1000 Jews and 0.98/1000 Arab live births (Zlotogora et al., 2006).

A baseline national survey conducted in June 2000 ($n=1719$) revealed FA awareness, knowledge and preconceptional utilization at 54.6%, 17.6% and 5.2%, respectively. Survey results endorsed the need for a national FA policy.

In August 2000, guidelines were issued recommending a daily 400 μg FA supplement for all women in their childbearing years with emphasis on the 3 months preceding conception and throughout the first trimester (MOH, 2000). National guidelines

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for a 4 mg preconceptional FA supplement to prevent NTD recurrence have been in effect since 1994 (MOH, 1994).

A national FA campaign was launched concurrently with the issue of the 2000 guidelines. A detailed description of the original campaign was reported earlier (Amitai et al., 2004).

In 2002, the first post campaign survey was conducted ($n=1661$). Folic acid awareness, knowledge and preconceptional utilization were 85%, 77.7% and 30.5% (Jewish 35%, Arabs 21%), respectively (Amitai et al., 2004).

Data from the NTD registry (2002–2004) reported a concurrent decline in open NTDs (Jews 33%, Arabs 23%) and spina bifida (Jews 45%, Arabs 35%; Zlotogora et al., 2006).

As a result of the 2002 survey, we began targeting specific populations at risk for NTDs. Southern district Bedouin have a high fertility rate (7–8) and the highest incidence of NTDs (3/1000) (Friedlander, 2002; Zlotogora et al., 2002). Programs targeting this population were developed in conjunction with Ben Gurion University. Bedouin women were trained as health educators and employed in various outreach programs.

Ultra orthodox Jews in the Tel Aviv district were targeted due to their high fertility rate (7.0) (Friedlander, 2002) and religious objections to terminations of pregnancy despite congenital defects. Programs were developed in conjunction with the approval of local rabbis. A nurse functioned as the FA liaison with local existing women's groups; providing lectures and handouts and weekly rounds at the postpartum convalescent facility.

An annual national FA awareness week was established in January 2005. The week is highlighted by intensive radio advertisements and the distribution of FA pamphlets to all women in their childbearing years by sick fund and drugstore pharmacists. During each of these weeks a total of 125,000 pamphlets were distributed (live births in Israel per annum are 143,000).

The focus of this report is the March 2005, third national FA survey.

Methods

Pregnant and women up to 2 months postpartum who presented to the MCHCs (Maternal Child Health Clinics) for either prenatal, postpartum or infant care were the target population.

A total of 2256 Hebrew and Arabic multiple-choice questionnaires were distributed via district health offices to 515 MCHCs throughout the country. Nurses conducted structured interviews on the first 3–5 eligible women who presented at the MCHC during the survey period.

Awareness, knowledge of FA, timing knowledge and utilization, were used as dependent variables. Awareness was defined as ever having heard of FA. Knowledge of FA was defined as knowing that "FA prevents a number of birth defects". Timing knowledge was defined as knowing that "FA should be taken preconceptionally and throughout the pregnancy". Utilizing FA preconceptionally on a regular basis was defined as having taken FA; "at least 4 days a week" in the month preceding the current pregnancy. Women were asked to delineate the source of their FA information. Also, women were asked when they began prenatal care and whether they had taken FA prenatally.

Religion, age, education, parity and sources of information were used as the main independent variables. Education was defined by years of schooling. Parity for pregnant women was adjusted upward in order to reflect the current pregnancy.

Statistical analysis was performed using SPSS 13. Regression analysis incorporated the Hosmer and Lemeshow test for best fit model. Confidence intervals were computed at the 95% level.

Results

A total of 1860/2256 (82.4%) questionnaires were returned. Demographic data are presented in the Table 1.

Religion was classified as Jewish, Moslem Arab (excluding Bedouin), Bedouin, Christian Arab, Druze and other. Religion was delineated by 1830 respondents (1123 Jewish and 707 Arab women).

Moslem Bedouin women had significantly more children and less years of schooling than Druze, Christian and non-Bedouin Moslem women. Christian women had significantly more years of schooling than Moslem and Bedouin Moslem women.

There was no significant difference between the four Arab sub-populations in FA awareness, knowledge, timing knowledge and utilization. The four groups, given the small individual numbers, were therefore combined into one and referred to as Arab (Table 1).

FA awareness, knowledge, timing and utilization

In the 2005 survey, FA awareness, knowledge, timing knowledge and preconceptional utilization were 90.3%, 80.8%, 74.4% and 34.0%, respectively (Table 1). A subset of 61 (3.3%)

Table 1
2005: Selected sociodemographic characteristics of women, folic acid awareness, knowledge, timing knowledge, preconceptional and prenatal utilization as defined by religion in Israel

Arab						Arab	Jewish ^a	Arab to Jewish, <i>P</i>	Total: Arabs and Jews
	Moslem Non-Bedouin	Moslem Bedouin	Christian	Druze	<i>P</i>				
<i>N</i> (%)	450 (24.2)	90 (4.8)	84 (4.5)	83 (4.5)		707 (38.6)	1123 (61.4)		1830
Age ^a , mean (SD)	27.0 (5.3)	27.0 (5.1)	28.4 (5.0)	27.7 (5.4)	<0.001***	27.3 (5.2)	29.2 (5.0)	<0.001***	28.5 (5.2)
Children ^a , mean (SD)	2.6 (1.5)	3.2 (2.2)	1.8 (.9)	2.4 (1.4)	<0.001***	2.5 (1.6)	2.3 (1.7)	0.008**	2.4 (1.6)
Education ^a , mean (SD)	12.4 (2.7)	10.4 (4.5)	13.7 (2.3)	12.8 (3.2)	<0.001***	12.4 (3.1)	14.0 (3.9)	<0.001***	13.4 (3.7)
Awareness (%)	82.0	78.7	89.3	81.9	0.298	82.8	95.2	<0.001***	90.3
Knowledge ^a (%)	80.6	75.0	72.7	30.1	0.374	77.6	82.6	0.013*	80.8
Timing (%)	68.6	61.1	68.8	71.2	0.572	67.6	78.3	<0.001***	74.4
Utilization (%)	25.6	27.8	26.2	30.1	0.845	26.4	39	<0.001***	34.0
Prenatal utilization (%)	73.8	71.6	81.0	76.0	0.152	74.9	79.0	0.048*	77.4

^a Jewish women were significantly: older than Arab women, had less children, more years of education, increased FA awareness, knowledge, timing and preconceptional utilization.

women had utilized FA preconceptionally, but only 1–3 days a week.

Since 2002, the first survey in which religion was recorded; the Arab population has exhibited significant gains in FA awareness, knowledge and utilization respectively, from 73.5%, 66.8%, 21.5% in 2002 to 82.8%, 77.6% and 26.4%, respectively, in 2005. An increase in FA awareness and utilization from 91.0% and 34.8% in 2002, to 95.2% and 39.0%, respectively, in 2005 was also observed among Jewish women.

Jewish and Arab populations differed significantly in their age, number of children, years of schooling and FA awareness, knowledge, timing and utilization (Table 1).

Factors associated with awareness, knowledge, timing and utilization education

A majority of the women in our current survey (87.2%) had at least 12 years of education and 24.9% had completed 16 or more years. Awareness, knowledge, timing and utilization increased significantly and were all correlated with years of education ($P<0.001$) (Fig. 1). The primary factor associated with FA timing was having at least 12 years of education ($P<0.001$, OR=6.46, CI: 4.2–9.9).

Age

Age was not significantly associated with any FA variable in the 2005 survey,

Correlation between folic acid awareness, knowledge and utilization

Women who did not take FA preconceptionally were overwhelmingly (90.3%) unaware of the correct timing and 84.9% did not know that FA prevents birth defects.

The primary correlates associated with FA preconceptional utilization as determined by the best fitting model using the Hosmer and Lemeshow test (sig=0.966) were FA timing

($P<0.0001$, OR=5.64, CI: 4.0–8.05) and knowledge ($P=0.0002$, OR=2.0, CI: 1.4–2.8).

Information sources and FA utilization

Two sources of information that were significantly related to utilization were the internet ($P<0.0001$, OR=2.4, CI: 1.6–3.5) and the physician ($P<0.0001$, OR=2.2, CI: 1.8–2.8).

The internet was cited by relatively few women [$n=140$ (8.3%)] as an information source. This group however had the highest rates of FA knowledge ($P=0.005$, OR=3.4, CI: 1.5–8.0), timing ($P=0.002$, OR=2.6, CI: 1.4–5.0) and preconceptional utilization ($P<0.001$, OR=2.9, CI: 1.9–4.3).

The physician (66.6%) and nurse (49.9%) were the major sources of information among women who utilized FA preconceptionally. For Arab women the nurse had been the primary source of information (75.3%), while for Jewish women it was the physician (72.2%). Physicians, as a source of information correlated with FA timing ($P=0.001$, OR=1.5, CI=1.2–1.9) and preconceptional utilization ($P<0.001$, OR=2.13, CI: 1.7–2.7), though not with knowledge ($P=0.224$, OR=1.2, CI: 0.9–1.6).

Nurse counseling was associated with knowledge ($P<0.001$, OR=1.8, CI: 1.3–2.4).

Prenatal FA utilization

Prenatal FA utilization at any stage was 77.4%. In addition to the women who had utilized preconceptional FA, 206 (11.1%) women began their prenatal FA by or before 6 weeks gestation.

Discussion

Five years into the national FA campaign; preconceptional utilization has increased from 5.2% (2000) to 34% (2005), awareness has exceeded 90%, more than 80% know that FA is essential in the prevention of birth defects and more than 70% know that in order to be effective FA must be taken preconceptionally as well as during the pregnancy.

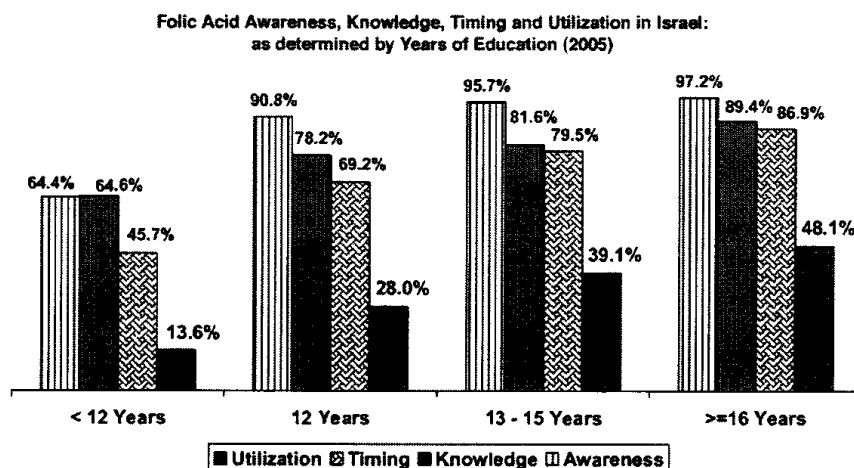


Fig. 1. Folic acid awareness, knowledge, timing and utilization in Israel: as determined by years of education (2005).

Education is significantly correlated with FA utilization. To achieve client empowerment, it is necessary to provide the knowledge that can influence attitudes and impact on behavior. Women must know not only that FA prevents birth defects but that it must be taken preconceptionally. In the present study, timing was a stronger indicator of *preconceptional* utilization than simply knowledge of the benefits, and logically so, since timing is the essential component of *preconceptional* compliance. "Providing knowledge can only reap the fruit of compliance in a society where governments, private interests, and other sectors work together to support individuals making healthy choices" proclaims the WHO, 1986 Ottawa Charter for Health Promotion. Ideally, MCHCs and pharmacies should be local, accessible and run culturally sensitive community outreach programs. Supportive environments, access to information, life skills and opportunities for making healthy choices are the building blocks that can empower women to achieve their fullest health potential (WHO, 2005).

Prenatal FA compliance in Israel was over 75%. This indicates a positive attitude towards vitamins and a population willing to comply with health messages. Once women are part of the health system, the system is effective, across the board in communicating the message. The ideal then would be to convert the entire health system and not just the prenatal system into a "preconceptional" health system that advocates ongoing health promotion and FA utilization throughout the childbearing years. Preconceptional health is part of general health promotion. A woman's health status before her pregnancy is a major determinant of the outcome of her pregnancy, the health of her newborn, and her own long-term prognosis.

The wide gap between FA knowledge and utilization is a common finding in many countries. As a general rule, patients tend to comply better with curative treatment for actual disease, than with preventive treatment for potential conditions. Approximately 50% of pregnancies are unplanned which makes achieving a high preconceptional FA utilization rate even more challenging.

All providers who routinely interact with women, including general practitioners, nurses, pharmacists, phlebotomists, gynecologists, pharmacists and pediatricians should be enrolled in the endeavor. Every birth control consultation is a potential birth and every childhood immunization is an opportunity for parental health education.

Limitations

The questionnaire was not anonymous and might have led to over-reporting compliance; however, the same technique has

been used in all 3 surveys and, therefore, any increment is probably real and not an artifact.

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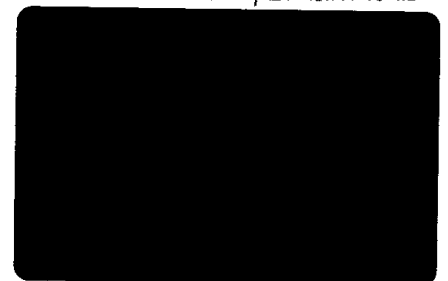
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- בשנת 2005: מדגם אקראי של כ-1,300 בני 21 מקרב האוכלוסייה היהודית והערבית
- בשנת 2007: 2,053 מדגמים בני 21 ומעלה

מבוא

בעידן המודרני בו האזרח מודע ואחראי על בריאותו, טיפול עצמי, הכולל טיפול תרופתי עצמי, מאפשר לו לשלוט על בריאותו באופן רחב ומושכל יותר ומאפשר למערכת הבריאות להקטין את הנטל הכלכלי עליה. שינוי מעמדן של תרופות ללא מרשם (תל"ם), (Over-the-Counter (OTC), מתרופות רוקח לתרופות מדף קובעת מחדש את אחריותו ותפקידו של הרוקח, הצרכן ומערכת הבריאות. מערכת הבריאות מחויבת לבריאות הציבור והפרט ועל כן, בנוסף לאחריותה להעביר מידע רלוונטי באיכות גבוה לציבור בנושא שימוש מושכל בתרופות, עליה לבדוק האם לשינוי השפעה בריאותית-כלכלית על הפרט, הרוקח ומערכת הבריאות ולהערך בהתאם.

תרופות ללא מרשם מחולקות בעולם לשתי קטגוריות – תרופות רוקח הנמכרות בבתי מרקחת בלבד בנכחות רוקח, (P) pharmacy-only, ותרופות מדף הנמכרות בד"כ מחוץ לבתי מרקחת וללא נכחות רוקח, (GSL) general sales list.

תל"ם מיועדות בעיקר למניעה או טיפול בבעיות קליניות שכיחות, קלות לאבחון עצמי, שאינן בעלות סימפטומים דומים למחלות קשות ואינן מסכנות חיים. כבר מאמצע שנות השבעים קיימת מגמת עלייה במדיניות הרשויות בשינוי מעמדן של תרופות מרשם לתרופות ללא מרשם. חשוב להדגיש שע"פ מחקרים שונים שינוי מעמדן של תרופות לא גרם לצריכה מוגברת ושימוש לא הולם.

מחד, המידע הזמין הרב המסופק בערוצי התקשורת השונים מאפשר לצרכן למלא תפקיד אחראי פעיל באבחנה וטיפול במצבו הבריאותי, ומאידך דורש ממשד הבריאות להוות גורם מעצב שיוביל מידע איכותי לציבור.

ארה"ב הנה המדינה הליברלית ביותר בתחום התל"ם, הנמכרות בכל עסק הרשאי למכור מזון, בתי מרקחת, תחנות דלק, דוכני עיתונים וכדומה. בניגוד לארה"ב, ברוב מדינות אירופה, כאשר תרופות מרשם משנה מעמדה לתל"ם, היא נמכרת אך ורק תחת פיקוחו של רוקח או אדם שהוכשר לכך.

סקירת המצב בישראל בנושא התל"ם:

סעיף 26(א) לפקודת הרוקחים התיר לרוקחים לנפק תרופות אך ורק לפי מרשם חתום בידי רופא. בשנת 1994 תוקנה פקודת הרוקחים, ונוסף סעיף 26(ג), שהתיר לרוקחים לנפק תרופות בבית מרקחת ללא מרשם רופא. תיקון זה היה ההתייחסות הראשונה של המחוקק לתרופות ללא מרשם. בשנת 1999, במסגרת תיקון מס' 7 לפקודת הרוקחים, תוקן סעיף 26(ג), ונוספה לו הסיפא המתירה לרוקח לייעץ באשר לבחירתה של תרופה ששיווקה לא הותנה במרשם רופא בידי המטופל. הוראה זו העניקה לראשונה לרוקח מעמד מיוחד בהליך ניפוק תל"ם, שנועד לאפשר מתן סיוע מקצועי למטופלים המתלבטים באשר לבחירת תל"ם מסוגים שונים. במסגרת תיקון מס' 10 לפקודת הרוקחים בוטל לחלוטין סעיף 26(ג). לעומת זאת, נוסף סעיף 22(א1), לפיו "רוקח יהיה רשאי לייעץ בבית מרקחת באשר לשימוש בתכשיר". סעיף זה מרחיב באופן משמעותי את סמכות הייעוץ המפורשת של רוקחים בנוגע לשימוש בתכשירים, והיא חלה כיום בפירוש גם על תרופות מרשם. סעיף 42(ג), שנוסף לפקודה, הינו ההוראה המרכזית בתיקון מס' 10, אשר קובע כי לשם הגנה על בריאות הציבור יקבע שר הבריאות כללים למכירה קמעונית של תל"ם שלא בבית מרקחת או שלא בידי רוקח. סעיף זה מצמצם את קטגוריות הרישוי לשתיים – תל"ם החייב להימכר בבית מרקחת בידי רוקח ותל"ם שאינו כפוף לכל מגבלה. הנימוק העומד ברקע תקון מס' 10 לפקודת הרוקחים הוא השאיפה להגביר את התחרות במכירת תרופות ללא מרשם על ידי מתן אפשרות לגופים שאינם בתי מרקחת למכור אותן לציבור. יחד עם זאת הערכתנו היא כי מדובר בתיקון שהשלכותיו חורגות מההקשר הכלכלי, והוא עשוי להיות בעל השלכות מרחיקות לכת על דפוסי השימוש בתרופות בפרט ועל מערכת הבריאות בכלל.

הוצאות משק בית על תרופות בשנת 2002:

בישראל בשנת 2002, ההוצאה הממוצעת לבריאות במשק בית ממוצע עמדה על 498 שקלים לחודש, מרכיב התרופות היווה 107.6 שקלים מסה"כ ההוצאה. מתוך דוח ניירות עבודה לשנת 2002 עולה שמשק בית ממוצע בישראל צרך תרופות מרשם ב- 58 שקלים לחודש, תל"ם ב- 17 שקלים לחודש ו- 31 שקלים על תרופות בצ"נ (בלי ציון נוסף) (דוח ניירות עבודה 2002, הלמ"ס).

מטרת המחקר

לבחון את השינוי שחל בדפוסי השימוש בתל"ם בעקבות הוצאתם למכירה מחוץ לבתי מרקחת לאורך זמן.

שיטות

מדגם מייצג של אוכלוסיית מדינת ישראל ישמש למחקר זה. בעזרת שאלון מובנה (מצ"ב) וראיונות טלפוניים יבחנו גורמים המשפיעים על צריכת תרופות, כגון, הרוקח, פרסום ועונתיות. גורמים אלו יבחנו בשתי נקודות זמן: לפני הרפורמה ולאחר הרפורמה.

תוכנית המחקר:

שלב א: לפני הרפורמה

1. דגימה של אוכלוסיית מדינת ישראל בעזרת תוכנת דבש.
2. בעזרת שאלון מובנה יאספו טלפונית נתונים הכוללים משתנים המאפיינים את הרגלי צריכת תרופות ללא מרשם רופא באוכלוסיית ישראל, כמו כן, יאספו נתונים על משתנים סוציודמוגרפיים.
3. יצירת בסיס מידע והכנתו כבסיס נתונים משותף לעיבודים סטטיסטיים.
4. אפיון המצב טרום החלת הרפורמה.

שלב ב : מעקב לאחר הרפורמה

1. דגימה של אוכלוסיית מדינת ישראל בעזרת תוכנת דבש.
2. בעזרת שאלון מובנה יאספו טלפונית נתונים הכוללים משתנים המאפיינים את הרגלי צריכת תרופות ללא מרשם רופא באוכלוסיית ישראל, כמו כן, יאספו נתונים על משתנים סוציודמוגרפיים.
3. יצירת בסיס מידע והכנתו כבסיס נתונים משותף לעיבודים סטטיסטיים.
4. עיבודים והצגה תיאורית של הנתונים לאחר הרפורמה.
5. עיבודים סטטיסטיים הבודקים את השינויים שחלו בהתאם לתוכנית המחקר המבטאים את אפקט השינוי בעקבות הרפורמה.

ממצאים:

תיאור אוכלוסיית המדגם:

סה"כ רואיינו במחקר זה (שלב I) 1,324 פרטים המייצגים את אוכלוסיית מדינת ישראל, בתקופת הזמן אפריל-מאי 2005. מתוך סה"כ המרואיינים 32.6% היו זכרים ו- 67.4% נקבות, ממוצע הגילאים היה 47.1 ± 16.1 שנים.

רוב המרואיינים היו יהודים (73.7%) וחילוניים (42.5%), מתוך כלל המרואיינים 76% היו נשואים ו- 83.7% דיווחו שיש להם ילדים. ממוצע שנות ההשכלה בקרב אוכלוסיית המדגם הייתה 13.2 ± 4.0 שנים וכ- 40.7% דיווחו על הכנסה נמוכה מההמוצע.

הרגלי צריכת תל"ם:

מתוך 1,324 מרואיינים 72.9% דיווחו על קניית תל"ם באופן כללי, כ- 96.1% קנו תל"ם במהלך השנה שקדמה לסקר ו- 69.2% קנו מעל 3 פעמים במהלך שנה זו, מתוך כלל המרואיינים רק 50% רכשו תל"ם בארבעת השבועות שקדמו לראיון. מתוך כלל המרואיינים שדיווחו על קניית תל"ם בארבעת השבועות שקדמו לראיון 55.7% הוציאו בממוצע מתחת ל- 50 ₪.

הסיבות השכיחות לאי קניית תל"ם בקרב אוכלוסיית המדגם: כ- 60.3% סומכים רק על הרופא וכ- 37.4% פוחדים מתופעות הלוואי. התפלגות הסיבות לקניית תל"ם: 80.4% בגלל הכרה מוקדמת של התרופה, 74.2% בגלל הנוחות, 68.8% סומכים על עצמם, 67.3% בגלל חיסכון זמן ביקור רופא, 51.2% בגלל 'טוב שיהיה בבית', 33.2% סומכים על הרוקח, 32.2% בגלל שהמחיר ללא מרשם דומה למחיר התרופה עם מרשם ו- 31.8% כאשר המרפאה סגורה או אין רופא.

מכלל המרואיינים הקונים תל"ם 85.5% קנו בעצמם את התרופה ו- 48.4% הקנייה נעשתה ע"י בן/ת הזוג, בד"כ קניית תל"ם (74.1%) נעשית באופן בלתי תלוי בקניית מוצרי צריכה אחרים או תרופות עם מרשם.

בנושא ההשפעה על בחירת תל"ם דיווחו 61.4% מהמראיינים שהם מושפעים מאוד מהמלצת הרופא, 85.3% מושפעים מאוד מניסיונם האישי, 25.9% מושפעים מאוד מהמלצת הרקח, בהשוואה לפרסומות, אריזת התרופה והמלצת חברים אשר מרבית המראיינים דיווחו שאינם מושפעים כלל.

כמחצית מהמראיינים שדיווחו על צריכת תל"ם רוכשים את התל"ם בבית המרקחת של קופת החולים, כשליש בבתי מרקחת פרטיים או ברשתות הפארם. בנוסף, כ- 60% מהמראיינים טענו שתל"ם בטוחות לשימוש.

הנתונים הבאים מתייחסים לצריכת תל"ם בשנה האחרונה ושימוש בחודש האחרון לפני הראיון:

סוג התל"ם	צרכני תל"ם בשנה האחרונה (%)	השימוש האישי בתל"ם בחודש האחרון (%)
חום וכאבים	95.3%	56.8%
נזלת וצינון	66.1%	21.4%
משחות לעור	29.6%	12.7%
הפרעות במערכת העיכול	17.8%	7.2%
תרופות להרגעה או שינה	6.8%	4.4%

לסיכום: שלב זה היינו השלב הראשון מבין שני שלבים שמטרתו בחינת פחפיל צרכני תל"ם לפני תחילת הרפורמה. במסגרת שלב זה ראיינו טלפונית, בעזרת שאלון מובנה, מדגם מייצג מאזרחי ישראל. השלב השני מתוכנן להתבצע במהלך השנה הבאה וכתלות כהתקדמות הרפורמה. לאחר סיום ביצוע הראיונות בשלב השני ינותחו הנתונים באופן השוואתי לשם בחינת השינוי שחל בדפוסי השימוש בתל"ם בעקבות הוצאתם למכירה מחוץ לבתי מרקחת לאורך זמן.

עמדת הציבור לגבי תרופות ללא מרשם רופא, 2003

מטרת הסקר 2003: הסקר הראשון בוצע בשנת 2003 מתוך מטרה לבדוק את עמדת הציבור ומוכנותו לרפורמה של מכירת תרופות ללא מרשם רופא (תל"ם) מחוץ לבתי המרקחת. **אוכלוסיית הסקר:** 530 מרואיינים בני 16 ומעלה.

תיאור הסקר

1. סקר המרכז הלאומי לבקרת מחלות נערך טלפונית במשך חמישה ימים: 27-31 ביולי 2003.
2. המדגם הוא אקראי, ארצי ומבוסס על תוכנת "דבש".
3. טעות הדגימה המירבית (95% רווח בר סמך) הינה כ- $\pm 4.3\%$.
4. מאפייני המדגם:
א. הסקר הקיף 530 מרואיינים בני 16 ומעלה ובגיל ממוצע 44, 61.5% מהם נשים ו- 38.5% גברים.
ב. 87% מהמרואיינים יהודים ו-13% ערבים.

ממצאי הסקר

1. 69% מהציבור נוהגים לקנות תרופות ללא מרשם רופא.
2. 24% קנו תרופות ללא מרשם רופא בשבועיים שקדמו לריאיון.
3. 42.5% מהציבור מצדדים במכירת תרופות ללא מרשם רופא שלא בבית מרקחת.
4. מקרב הנוהגים לקנות תרופות ללא מרשם רופא, 84% מושפעים מאוד מניסיונם האישי בעת בחירתן; 78% מהמלצת רופא; 38% מהמלצת רוקח; 19% מהמלצת חברים/משפחה; 6% מפרסומות ו-4% מאריזת התרופה.
5. מקרב הנוהגים לקנות תרופות ללא מרשם רופא, 79% מסתמכים מאוד על הרופא כשהם מעוניינים במידע עליהן (מטרת התרופה, תופעות לוואי, התוויות נגד); 62% מסתמכים מאוד על העלון לצרכן המצורף לתרופה; 47% על הרוקח; 11% על חברים/בני משפחה ו-5% מסתמכים מאוד על מידע מהאינטרנט.
6. כאשר יימכרו תרופות ללא מרשם רופא גם שלא בבתי מרקחת, 60% מקרב הנוהגים לקנות תרופות אלה יעדיפו לקנות בבית מרקחת משכני כאבים ותרופות לטיפול בהצטננות; 67.5% יעדיפו לקנות בבית מרקחת תרופות למערכת העיכול ו-70% יעדיפו לקנות בבית מרקחת משחות לעור.
7. מקרב אלה המעדיפים לקנות תרופות ללא מרשם רופא בבית מרקחת:
8. 78% ציינו כי הסיבה לכך היא מקצועיות וקבלת ייעוץ; 41% ציינו כי הסיבה לכך היא בטיחות/ טיפול נאות בתרופות; 9.5% ציינו את הקרבה לבית/ נוחות ו-7.5% ציינו כי היכרות עם הרוקח היא הסיבה להעדפתם זו.