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Legal aspects related to the access of natural family planning services: patient's right to accurate and impartial information

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Abstract

Natural family planning methods historically were considered as a separate group of family planning methods as opposed to conventional contraception methods. In the 60's of the last century family planning have become an international demographic policy issue and lately it was included into the international public health agenda. Since that time natural family planning experienced a radical transformation in conceptual terms, accompanied by terminological chaos. In the last two decades the term of natural family planning as autonomous concept was almost completely eliminated from the language of international intergovernmental organizations, such as World Health Organization. Natural family planning methods terminologically now are incorporated into the concept of contraception, contrasting them with the so-called „effective modern contraceptive methods“. Two relevant conclusions could be drawn from that. Firstly, these above mentioned terminological innovations arise from working definitions developed by various internal working groups, lack transparency and thus they may not be formally considered as legally or politically binding international community. Secondly, the marginalization of effective natural family planning methods from the agenda of healthcare and the exclusive promotion of “effective modern contraception“ work against the rights and the interests of patients to receive unbiased and comprehensive information about healthcare services and to make an autonomous decision.

Keywords: natural family planning (NFP); contraception; patient's right to information; informed choice;

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1. Introduction

Scientific and empirical evidence makes a reasonable claim that the effectiveness of natural family planning (NFP) is "competitive" to conventional contraception, since it has no side effects to the health of the person and it is cheap. Moreover, unlike conventional contraception, NFP methods could be reasonably used as a means of achieving pregnancy, particularly in solving infertility problems. However, for various reasons NFP is marginalized in public health practice in favor of contraceptive use in the era of reproductive freedom. NFP is often stigmatized by beliefs it is only used by the religiously devout, or it is simply not effective.

If in general NFP is in no way inferior to the conventional contraception, or to some extent even superior, it is licit to claim that persons have a legal right to obtain unbiased information about both the NFP methods and contraception from their healthcare providers. Consequently, public health and healthcare institutions must pay due and non-discriminatory attention to NFP in providing family planning policy.

1.1. Natural family planning – basic facts

NFP is a general term that applies to various methods that have been developed to help women and men determine the fertile and infertile times of a woman's monthly cycle. The scientific basis of NFP methods is sound, as they are based on the observation of signs and symptoms which reflect endocrine changes occurring in fertile cycles (Derzko, 1986). NFP covers two groups of methods: the "modern" and the "old". "Modern" NFP includes ovulation and symptothermal methods, which are used for more than 30 years. Calendar and basal body temperature methods are considered as the "old" ones since these methods were developed in the beginning of the twentieth century. The efficacy of "modern" NFP methods if they are used properly and consistently is proven to be very high - 97-99% and could be considered comparable to all conventional contraceptives, such as drugs, devices, and surgical procedures. (Trussell, 1998; Frank-Herrmann et al., 2007).

Scientific and empirical evidence of NFP effectiveness allows claiming that they are highly "competitive" with conventional contraception, not to mention unique characteristics of these methods - absolute absence of side effects, successful application of these methods in achieving the desired pregnancy when infertility problems are diagnosed or their extremely low cost (Pallone & Bergus, 2009).

Published studies suggest other social benefits of NFP: a nonrandomized survey in the United States found a very low divorce rate - 2 in 1000 - among individuals using these methods only as compared with the total population indicators (Wilson, 2002). Four percent of those who had used conventional contraception previously had been divorced. Other published studies associate modern NFP methods with a lower incidence of induced abortion (Che, Cleland & Mohamed, 2004).

1.2. Recent developments related to the use of the term "natural family planning"

Family planning was included into the global public health agenda when hormonal contraceptives were introduced into the market in parallel to the causal association of maternal mortality with high fertility rate that family planning could help to address (Seltzer, 2002). The key institutional player at the global level World Health Organization (WHO) defines family planning as "the ability of individuals and couples to anticipate and attain their desired number of children and the spacing and timing of their birth" (WHO European Regional Office, 1999 & 2001). The term of family planning has historically involved two groups of techniques: natural (or fertility awareness based) methods of family planning and other family planning methods, which are widely referred to contraception. WHO provided with the official definition of natural family planning the last time in 1988. According to this definition NFP

is understood as “methods for planning or preventing pregnancies by observation of naturally occurring signs and symptoms of the fertile or infertile phases of menstrual cycle” (WHO, 1988). At the same time WHO unambiguously stressed that „[i]t is implicit in the definition of natural family planning, when used to avoid conception that drugs, devices and surgical procedures are not used” and that “NFP is a technique to determine the fertile period and is not a method of contraception” (Report on a WHO Workshop, 1987). Thus, it was recognized at the conceptual level that the essential difference between NFP and contraception lays at the level of values, i.e. by controlling sexual behavior. Meanwhile, fertility awareness and behavioral control are virtually unnecessary elements for contraceptive use (Narbekovas, 2003).

As early as 1986 within WHO European Regional Office terminological changes regarding NFP are taking place (Juškevičius, 2011). The term of NFP becomes gradually replaced by more neutral term of “fertility awareness methods” because the adjective “natural” would imply they are better than other methods that are seen “unnatural” and, therefore, bad. At the same time it is avoided to emphasize its advantages and respectively negative aspects or medical side-effects of contraceptive methods. Another reason that stimulated terminological change was a presumably strong connotation with religion, especially when it comes to the abstinence during fertile times. On the practical level a „secular version“ of FNP is favored as an option together with barrier contraception methods. Ultimately, FNP is advised as an auxiliary option when other contraceptive methods are not available. In parallel with the NFP terminological metamorphosis the term of „modern contraception”, generally referred to hormonal contraceptives was introduced in the official practice and scientific literature. Starting 2001 the term of NFP disappeared from the language of WHO European Office and consequently NFP methods were renamed to “fertility awareness methods” or to “periodic abstinence during fertile periods” and ... attributed to contraceptive methods! From now, at least at the European level “[f]amily planning is achieved through contraception defined as any means capable of preventing pregnancy...” (WHO European Regional Office, 1999 & 2001).

To our knowledge WHO has never explained officially such a conceptual shift. The introduction of the term “modern contraception” would suggest an idea, that NFP methods are ineffective and somewhat scientifically outdated, though WHO in its key guidance documents so called 4 Corner stones of family planning guidance avoids direct questioning the efficacy of NFP methods. Although, the scope of these documents is to base family planning practices on the best available evidence, for example, Medical eligibility criteria for contraceptive use (2010) dedicates to these methods only 3 pages with no bibliographical references to scholarly literature while to the methods of contraception are given the rest 106 pages with 960 references. The distinction between modern and older NFP methods can be lost on the uninformed. For example, Selected practice recommendations for contraceptive use (2004) dedicates only 1 page out of 170 to the NFP and specifically to the least reliable and the outmoded so called „calendar“ method with its 24 percent failure rate. Thus, such a deliberate semantic obscurity of NFP methods in contrast to “effective methods of modern contraception” leads to general perception of FNP as “natural contraception” or even, as Wikipedia informs, as “family planning methods approved by the Roman Catholic Church.” However, from the formal point of view these terminological innovations of WHO have some significant legitimacy defects. Firstly, they are in sharp contrast to WHO official definition on NFP from 1988 (WHO, 1988) which was never officially abandoned. Secondly, the said changes associated with NFP terminology took place in WHO regional office - definitions and indicators used in European region formally do not bind WHO activities in other regions or at the universal level. Thirdly, definitions and indicators used in WHO European regional office have working character. Working definitions are temporary definitions per se that are chosen for an occasion (usually within internal working groups having a specific task) and may not fully conform with established or other authoritative definitions, therefore not necessarily reflecting scientific or societal consensus. And finally, these terminological innovations may not be formally considered as legally or politically binding the global agenda of public health.

2. Patient Information Issues

Patient's right to the information is a crucial one within a health practice, especially when both the patient and healthcare provider contribute to the medical decision-making process. It is an already well-established health law rule both at a national and international level. Healthcare professionals provide patients with unbiased information on the nature of the treatment or advice and on the available alternatives. Patients, on the basis of information provided by the physician, are supposed to choose the most acceptable option that corresponds with their personal conscience and preferences. That stems from the essential ethical and legal principle of patient's autonomy that governs the physician-patient relationship - the patient's autonomy can be effectively exercised only if the patient possesses enough information to make an informed choice. In such a way healthcare practitioner has both moral and legal duty to convey honestly information to the patient on the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option. National legislations or case law in the field of healthcare normally stipulate, for example, the right of patients to be fully informed about all treatment methods and procedures, the right to refuse treatment, the right to confidentiality, etc. (e.g. Law on the Rights of Patients and Compensation of the Damage to their Health of the Republic of Lithuania, 1996).

2.1. The approach of family planning service providers

Family planning is now considered as a part of healthcare scheme. By the same token, family planning services should be provided in conformity with the same ethical and legal principles which govern healthcare field, including the patient's right to information. In the reality the situation concerning the effective exercise of the right to information in family planning is confusing. Published studies indicate that between 40 and 60 percent of surveyed women report that they are interested in learning more from their physicians about non-hormonal, non-barrier, and non-surgical methods of contraception and that this interest reaches across geographic regions, religions, and socioeconomic and education levels (Leonard, Chavira, Coonrod, Hart & Bay, 2006).

How healthcare practitioners meet such a patients' need? Studies demonstrate that many physicians do not have the knowledge to teach their patients about these methods (Stanford, Thurman & Lemaire, 1999). Most physicians underestimate the effectiveness of NFP and do not give information about modern NFP methods to the patients. A study from Canada has shown that when patients seek contraceptive advice 50% of the doctors do not mention NFP as an option, 24% mention NFP with reservations, 22% mention it as viable option to selected patients, and only 3% mention it as a viable option to most of their patients (Choi, Chan & Wiebe, 2010). Another survey of NFP users has shown that only 1% of them came to use those methods because of the advice of healthcare practitioners (Wilson, 2002). However it would be inaccurate to state about the identical geographical disinterest in or unawareness of NFP: for example, a survey has shown that although uncommonly used in the United States, as many as 20% of married women in other countries use one of these methods (Curtis & Neitzel, 2004). These figures lead to the conclusion, why many women believe NFP methods are not efficacious (Stanford, Lemaire & Fox, 1994), despite the fact that the efficacy of modern NFP methods if they are used properly and consistently is proven to be very high. The professional-patient relationship is built on trust: if the physician is misinformed about both NFP options and their efficacy, and even his/her perceptions of it are negative - patients are not going to choose NFP for themselves, even if they are interested (Beeman, 2010). When provided with positive information about NFP methods more than 1 in 5 women in the United States expressed interest in using one of these methods to avoid pregnancy (Piccinino & Mosher, 1998).

2.2. The approach of medical establishment

However, patient's awareness problem is multifaceted: consider the incredible amount of resources pharmaceutical companies spend on pharmaceutical marketing and the biased approaches of medical establishment. For example, it is estimated that, total pharmaceutical sales in the United States came to around 326 billion U.S. dollars in 2012 while the contraceptives market was worth slightly more than 10 billion (ResearchMoz.us, 2013). In the same year, US pharmaceutical industry spent more than \$27 billion on drug promotion: more than \$24 billion of that amount were channeled to the marketing to physicians and the rest 3 billion - to the advertising to consumers (Cegedim Strategic Data, 2012). Scholarly literature insists that this approach is primarily designed to promote drug companies' products by influencing doctor's prescribing practices (Wazana, 2000).

Rather skeptical attitude of the medical establishment, in particular WHO, on NFP needs more in-depth examination, though it appears to be in line with healthcare's general trend toward medicalization, where the definition of sickness is expanded to include personal problems as medical problems or risks of diseases (Moynihan, Heath & Henry, 2002). On the other hand, one may suggest that such an attitude is significantly associated with the proliferation of public-private partnerships WHO has entered in the form of "official relationships" and "working relationships" with non-governmental organizations (NGOs) and the pharmaceutical industry (Burci & Vignes 2004.). Public-private partnership in the public health sector during last two decades proved to be successful in expanding responses to global health needs, including service delivery, prevention, and research and development of new medicines, especially for neglected diseases (Burci, 2009). However, it also raises delicate issues concerning the transparency of WHO's partnerships with certain NGOs. For example, the International Planned Parenthood Federation, which is officially involved in editing and updating the above mentioned WHO's 4 Corner stones of family planning guidance, has concluded with Schering AG, a German contraceptive manufacturer a global partnership for social marketing of contraceptives (Armand, 2003). The goal of social marketing in that particular strategic partnership between the NGO and pharmaceutical industry is the consolidation of the use of hormonal contraceptives while employing commercial marketing techniques to achieve specific social behavior at the global level. Such a partnership has at least two-fold benefit for the pharmaceutical industry at the expense of patient's rights. Firstly, this approach keeps blurring the line between the commercial and non-profit worlds (Armand, 2003): non-profit status granted to NGOs allows them to bypass regulatory restrictions established for manufacturers and marketing authorization holders on advertising of medicinal products in different domestic legislations. Secondly, the official relationship of the NGO with the WHO whose recommendations on public health and healthcare issues enjoy international prestige and authority is of extreme importance in pursuing specific mercantilist goals, especially given the fact that Article 21 of the WHO Constitution under certain circumstances gives WHO a power to introduce mandatory standards for member states.

2.3. Education issues

Another aspect of patient's informed choice is related to both healthcare providers' and customers' education. Some problematic aspects related with NFP expertise among physicians were indirectly discussed above (see 2.1.). Physicians and nurses have little knowledge of NFP and do not advise or trust the use of NFP as a means of child spacing (Fehring, Hanson, & Stanford, 2001). According to 2011 data, the pharmaceutical and medical device industries provided 32 percent of all indirect marketing funding for continuing medical education courses in the United States (Accreditation Council for Continuing Medical Education, 2011). The support of medical establishment is also very important. For example, WHO publishes for practitioners extensive and periodically updated guidance 4 Corner stones on contraceptive use (last updated in 2010). The last guidance dedicated to NFP was

published by the same organization in 1988, however the edition is virtually inaccessible, though officially it is still in effect.

Meanwhile, NFP user-oriented education programs don't offer the type of economic opportunity that pharmaceutical companies see in contraceptives. They have to rely on modest charity or public funding and, in addition, regularly face legal challenges. For example, various health advocacy organizations in the United States are trying on the grounds of human rights to question legitimacy of federal support to these programs granted by Family Planning Service and Population Research Act of 1970 (Benshoof, 1987-1988; LeClair, 2006). Human rights arguments against NFP education are based on two basic premises: a) NFP education programs are scientifically outdated or misleading, they impede the access to the information on benefits of modern contraception and thus restrict the right to choose respective lifestyle; b) such programs indoctrinate religious ideology and conservative approach to marital and family relationships, thus violating freedom of thought, conscience, and religion. These arguments were employed also in the INTERIGHTS collective complaint against Croatia to the European Committee of Social Rights, where Croatian state authorities were accused of violation of Croatia's international obligations under the 1961 European Social Charter by tolerating informal NFP and abstinence education program TeenSTAR that in the INTERIGHTS opinion threatens sexual and reproductive health of adolescents (INTERIGHTS, 2009). The outcome of the case appears to be so far disappointing for petitioners as no new positive obligations aroused for the states: European Committee of Social Rights recognized that responsible national authorities have broad discretion to design the content of education curricula and to decide on the appropriateness of such programs, taking into account the cultural context.

3. Conclusions

The available evidence suggests that NFP is as an effective family planning option. Despite the fact, that these methods have not gained wide use or even have been marginalized from public health and healthcare agenda, they are still scientifically and socially legitimate options among other family planning options offered by national healthcare systems. Modern healthcare systems operate on the basis of the physician-patient (customer) partnership where a central role is attributed to the informed choice of the patient/customer. The patient has a legal right to receive from his/her healthcare provider information on the available options, including an assessment of the expected risks, side effects, benefits, and costs of each option. Accordingly, healthcare provider has a moral and legal duty to provide such information impartially. Patients, in turn, on the basis of information provided by the physician make an autonomous decision on the most acceptable option that fits their preferences and personal conscience according to their religious values or believes. Healthcare providers not meeting that standard risk their ability to show a duty of care imposed on them was not breached. In the same token, physicians' and other medical personnel's limited knowledge of and experience with NFP methods or reluctance to inform about family planning alternatives inhibit the exercise of the patient's right to complete and unbiased information.

Both national and international medical establishment do not contribute sufficiently to the exercise of that individual patient right, specifically in the field of family planning. First of all, transformation in conceptual terms of FNP accompanied by terminological changes appears misleading – though terminological innovations that arise from working definitions of WHO are in contrast to its official definitions and may not be formally considered as legally or politically binding international community, at the practical level they obfuscate the original meaning of FNP. Secondly, the elimination of effective NFP methods from professional practice and the promotion of „effective modern contraception“ inhibit the exercise of patients' rights and interests to receive unbiased and comprehensive information about healthcare services and to make an autonomous decision.

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