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RESEARCH ARTICLE

# Policymaking in a plural society: the case of human experiments in medicine in Israel

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**Abstract**
Various processes in recent years have brought about trends of polarization within democratic societies, challenging political stability. Against this backdrop, policy patterns that are being adopted regarding controversial issues are significantly affected by these countries' aspiration to create and maintain a consensus, which may have implications not favoring the public. One such issue is human experiments in medicine (clinical trials), which has been regulated by most countries through primary legislation. As a deeply divided society, Israel has been addressing this issue through regulation and secondary legislation, despite several attempts to have it regulated through primary legislation. This article employs the consociational model alongside Public Choice Theory to explain the adoption of this policy pattern on the issue of human experiments. Based on thematic analysis of semi-structured interviews and existing sources, it sheds light on the normative choice that weighs the merits of primary legislation against the virtues of accommodation and consensus.

**Keywords:** clinical trials; consociational model; consociationalism in Israel; ethics in medicine; human experiments in medicine; public choice theory

## Introduction

In recent decades, Western democracies have been experiencing trends of polarization owing to processes such as globalization and its associated economic changes (Chan et al. 2006; Jenson 2010); changes in social relationships fueled by the development of new information and digital communication technologies (Beauvais and Jenson 2002; Ferlander and Timms 1999); and global migration movements and growing ethno-cultural diversity (Beauvais and Jenson 2002; Chan et al. 2006). The deep cleavages have brought about a process of declining social cohesion, which challenges political stability in these countries.

Against this backdrop, policy patterns that are being adopted regarding controversial issues are significantly affected by these countries' aspiration, despite immobilism, to create and maintain a consensus, which may have implications not

favoring the public. One such issue is that of human experiments in medicine, which has been addressed in Israel by the policy pattern of maintaining the status quo. As an issue that is mainly related to the religious-secular ever-deepening rift, (which overlaps other rifts), any policy change may threaten the political stability, despite the potential of benefiting the public.

Following the brutal experiments the Nazis carried out on human beings in World War II and the "Doctors' Trial" (1947), some ethical principles, later known as the Nuremberg Code, were articulated, constituting a landmark in the development of research medical ethics (Weindling 2004). Even if not directly, the Code may be seen as the foundation on which rests the Declaration of Helsinki[1], the main document framing the ethical aspects of human experiments (Lederer 2004). This document was first published by the World Medical Association in 1964 and has been updated several times; the last update was in 2013. The declaration is based on the right to make an informed decision whether to participate in a research project and therefore asserts that the welfare of the patient overrides the interests of the science and society. As ethical considerations outweigh laws and regulations, the declaration prefers to give a higher protection to the patient.

Many democracies have enshrined the principles of the Helsinki Declaration in primary legislation, and the constitutions of Estonia, Hungary, Poland, Croatia, and South Africa contain explicit provisions restricting non-consensual human experimentation Additionally, within the constitutions of Italy and Greece an explicit provision limits a non-consensual medical treatment (Wargan 2005). The State of Israel, however, has made do with secondary legislation and a circular issued by the Ministry of Health's director-general, this, after several attempts at primary legislation in the 1990s, which came to naught. This situation has implications for the public in terms of protecting the well-being and liberty of the individuals.

This article aims to answer the question: What explains the persistence of the status quo that is adopted in democratic plural societies, against the backdrop of players attempting to change it? As such, a policy pattern may be adopted regarding various issues, the requested explanation should focus on issues which are related to one or more social cleavages, where any change has the potential of harming political stability, in spite of an expected contribution to the public welfare. Therefore, the examination of the case of clinical trials in Israel is beneficial in terms of the question's context. It will be examined in light of the consociational model, complemented by public choice theory, while shedding light on the normative choice that weighs the merits of primary legislation against the virtues of accommodation and consensus, touching upon the complexity surrounding the notion of 'the public interest'.

## Theoretical framework

### Consociationalism

The complexity of stable democracy is composed of its two contradicting needs: while stability in democracies is nourished by social and cultural homogeneity,

[1]https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

representative democracy presumes heterogeneity (Diamond 1993). The answer to this puzzle lies in the pluralist theory of cross-pressures, according to which, cross-cutting social cleavages moderate the intensity of the conflict. This happens because social groups are homogeneous regarding one social cleavage and heterogeneous regarding another, thereby, having their loyalties going in different directions. By the same token, when social cleavages overlap, they reinforce each other, leading to antagonistic subcultures that threaten political stability (e,g., in the early decades of the State of Israel, the national religious sector did not adopt a uniform position regarding the Arab-Israeli conflict, but in recent decades it identifies itself, by and large, as right-wing oriented). However, there are countries where stable democracy and social polarization (i.e. overlapping cleavages) live side by side (Andeweg 2000). The explanation for these deviant cases is embedded in consociationalism, which is at the core of this article as follows.

A consociational democracy characterizes countries that are deeply divided along religious, ethnic, racial, or regional lines, yet, manage to maintain political stability, owing to cooperation at the level of the political elites. That is, the leaders of the rival groups make "deliberate efforts to counteract the immobilizing and destabilizing effects of cultural fragmentation" (Lijphart 1969, p. 212). This power sharing principle has been proven to be the favorable condition that enables plural societies, which are threatened by political instability and even violence, to create and preserve a stable democratic political system that embraces the adversary groups.

The consociational theory was launched in the 1960s, based on classic European cases (the Netherlands, Belgium, Switzerland, Austria, and Lebanon), followed by its application as an analytic tool and/or a normative model in other countries. While the model is mostly associated with Arend Lijphart (1968), Arthur Lewis (1965) concluded that the deeply divided West African societies needed a radical alternative to the majoritarian model, which failed to bring about stabilization. He, therefore, deduced the basic needs for such societies: inclusive broad coalition governments, autonomy for the various ethnic groups and proportional representation. (Lijphart 2002).

The consociational democratic model formulated by Lijphart was inspired by Gabriel Almond's (1956) classic typology of political systems in regard to political stability. According to him, there are two democratic types: the Anglo-American and the Continental European systems, which differ in their political culture and role structure (the way in which the structures of the political system function and adjust with its surroundings and with the other systems). The former, which is associated with stability, is characterized by a secular homogenous political culture and a highly differentiated role structure (autonomous parties, interest groups, and media), while the latter, associated with instability and immobilism, is characterized by fragmentation of political subcultures, that is, plural societies, where the roles are embedded in the subcultures alongside mutually dependent parties, groups and media (Almond 1956; Almond and Bingham Powell 1966).

Almond (1956) mentioned a third category of the Western democratic system, consisting of the Scandinavian and the Low Countries, which was neither given a distinct label, nor was it illustrated in detail. Lijphart named these deviant cases, which demonstrated political stability within divided societies, 'consociational democracies', and aimed at improving and elaborating this type. In addition to the two criteria influencing political stability, that is, political culture and role structure,

Lijphart identified a third one: the behavior of the political elites. The leaders of the adversary subcultures may choose to adopt competitive behavior, thereby aggravating instability, or they can make "deliberate efforts to counteract the immobilizing and destabilizing effects of cultural fragmentation" (Lijphart 1969, p. 212). Thus, they may bring about political stability despite plurality. In fact, the essential characteristic of consociational democracy is not about institutional arrangement, but rather an overarching cooperation at the elite level.

An analysis of successful consociational democracies raised several favorable conditions for the establishment and maintenance of this type of political system, among these are a multiple balance of power among the subcultures; external threats; a relatively low total load on the system; prior traditions of elite accommodation (Lijphart 1968, 1969, 1977).

The consociational model can be defined by four main elements, all constituting deviation from majority rule and reflecting the principle of power sharing. The most important of all is government of a 'grand coalition', that includes all leaders of the significant segments, who bargain between themselves over differing social outlooks/views. It is related to the 'size principle', which is based on game theory assumptions. According to Riker and Niemi (1962), where players are rational close friends, who perceive a game as a game, accept the zero-sum condition, and have perfect information, only minimum winning coalitions occur. By contrast, groups of people who are not familiar with each other, and therefore, experience significant uncertainties, don't adopt the perception of a game but rather "consideration of maintaining the solidarity of the group and the loyalty of members to it" (Riker and Niemi 1962, p. 32). Thus, they tend to form larger winning coalitions. In political life, the size principle is operative either when the participants perceive politics as a game (homogenous society) or as an all-out war. In intermediate situations, there is pressure to enlarge the coalition. Moreover, Almond holds that since the risks are often higher in plural societies, a situation of a game (government versus opposition) is less recommended whereas a grand coalition is far more suitable (Almond 1956). Thus, in heterogeneous societies, especially in those divided by ethnic/ religious/ideological/cultural cleavage, where governments usually don't change and the excluded minorities may lose loyalty to the regime, coalitions should be more inclusive (Lijphart 1977).

As a grand coalition does not guarantee minorities' full defense during decision-making, especially when their crucial interests are at stake, the consociational model adds the second element, a mutual veto. Lijphart explains that a tyranny of the minority is not likely, as the very recognition of being granted this right, will bring about a minimal use of it.

The third element dictates proportionality in political representation, civil service appointments, and resource allocation. It removes several divisive problems from the decision-making process thereby facilitating the government's burden. The last element is segmental autonomy and federalism, where the minority rules over itself in areas which concern it exclusively.

Throughout the years, this theory has been gathering renewed interest and importance, as a means of peaceful conflict regulation, in light of polarization trends within societies worldwide (see, for example, Cole 2015; McCulloch and McGarry

2017; Howe 2019). The model's relevance has also been recognized following the wave of power sharing democracy (see, for example, Hartzell and Hoddie 2007).

Nevertheless, the consociational model has been criticized ever since its very beginning. The classic major claims made against it are as follows: poor democratic quality; the difficulties of policymaking; clientelism; the reinforcement of socio-cultural divisions, and the view of elites as the solution and citizens as the problem (Bogaards et al. 2019). Lijphart addressed these claims, but recognizes the potential for immobilism and instability due to a slow decision-making as a result of a grand coalition and overuse of the veto. However, the European experience indicates that immobilism is preventable (Lijphart 1977).

Ever since the days of the British Mandate, the Israeli society has been characterized as deeply divided by several cleavages (Horowitz and Lissak 1992). Horowitz and Lissak (1978) identified consociational principles in their study of the Jewish political community before independence, while Gutmann (1977) perceives the consociational model as being applied mainly to the issue of religion–state relations, starting in the period after independence, as a conscious decision made by Israel's first prime minister, David Ben-Gurion (Don-Yehiya 1997), continuing ever since (Lipshits and Neubauer-Shani 2019).

Similarly, Lijphart (1977) pointed to the presence of mutual veto, proportionality, and quasi-federalism in the context of favorable conditions for the consociational model. He underscored the use of veto power by the religious camp, which successfully served to prevent any significant change regarding state funding of the religious educational system and regarding the jurisdiction of the religious authorities over personal status law. However, in recent decades, the grand coalition principle can be identified as well (see, for example, Galnoor and Blander 2013).

The issue of clinical trials has ethical, religious, legal, and economic aspects, all which contribute to it being highly controversial. However, as this article demonstrates, the most prominent cleavage that is being expressed in this venue is the religious cleavage. Considering that Israeli society is characterized by overlapping cleavages, rather than cross-cutting ones, placing such an issue high on the policy agenda has the potential of destabilizing the political system. However, as the field of state-religion relationship in the state of Israel has been addressed by consociationalism over the years, the cooperation at the elite level serves best in explaining the policy of maintaining the status quo.

### *Policymaking as reflected in public choice theory*

The theory of public choice revolved around the central claim of Buchanan and Tullock (1962) that the individuals in the public arena are self-interested and utility maximizers (Kimenyi and Mukum Mbaku 2019). Therefore, any policy decision is based upon the relationship between the politician and the electorate, characterized by the dynamics of demand and supply mechanism.[2]

[2]In the course of time, public choice theoreticians have made changes and additions to the basic economic reasoning, following their realization of some differences regarding the situation in politics compared to the situation in economics (Tullock, 2019).

The basic model holds that the politician's main interest (sometimes exclusively) is maximizing their chance of being reelected, and they therefore strive to advance a policy that will meet the preferences of the majority of the electorate. In order to do so, the politician chooses to promote a policy that reflects the position of the median voter (Downs 1957).

Moreover, the natural tendency of politicians is to adhere to an existing policy and maintain the status quo if there is no significant demand by the public that calls for a change (Hirschman 1995). This is a partial explanation for why, in many cases, public policy is not formulated until the situation becomes catastrophic. The second part of the explanation lies in the problem of collective action, as analyzed by Arrow 1963).

According to public choice theory, public policy is similar to a public good, whereby most people will tend not to cooperate in supplying the good but will consume as much of it as they can ("free rider"), and therefore, none of the players cooperates with the others (Olson 1965; Axelrod 1984). The result is a lack of policy on the one hand and a lack of interest in creating public pressure to change the situation on the other. In the absence of demand by the general public, there is an increase in the power of blocs that succeed in overcoming the problem of collective action and form interest groups with a significant impact on public policy (Farber 2017).

The research dealing with the interaction between interest groups and the politicians they seek to influence is based on the premise that politicians need electoral or financial support in order to benefit their electorate and improve its welfare. This support is provided to them by interest groups that receive in exchange a policy they favor, often at the expense of the majority (Buchanan and Tullock 1962; Ekelund and Tollison 1980; Levy and Peart 2020). Recently, the need for information provided by interest groups has been gathering importance, as well (Lohmann 1995).

Like politicians, bureaucrats can trade in their public power and promote public policy that benefits socially influential groups and organizations, in exchange for promoting their own personal benefit (budget, securing their future in the business sector after completing their term in the public sector, etc.) (Niskanen 1971).

Thus, public choice theory holds that public policy does not reflect the public interest but is only being marketed to the public as if it had been decided for its benefit, while in fact improving the situation of individuals and/or groups, whose investment in public lobbying paid off in benefits to themselves (Nachmias et al. 2019). Notwithstanding, Tullock (2019) emphasizes that it would not be true to say that these policies have never achieved anything beneficial for the state overall.

Following public choice theory, it can be argued that public policy is the result of interactions between four actors: politicians, interest groups, bureaucrats, and the general public, taking place within structural conditions (Mizrahi and Meydani 2006). In this sense, public choice theory adds a supplementary perspective on how consociationalism played out among the various actors and provides a way of exploring its implications for each of them.

While consociationalism has a bias towards the status quo, since coalition government is the norm and consensus is required for policy change, public choice theory is more consistent with a view of politics as involving incremental change or, under certain conditions, punctuated equilibrium, rather than stasis. Therefore, it is a theory about the drivers of change.

This article proposes consociationalism as the primary explanation for the persistence of the status quo in Israel, that is, why a legislative change did not take place, and makes use of public choice theory, in order to study how the various drivers did not operate to produce change in this context. This difference is reflected in the role of political parties in each of these theories, where both approaches regard the views of voters as fixed. As public choice theory sees political parties mainly as marketing instruments for leaders seeking election/re-election (Downs 1957), when politicians' interest calls for a policy change, the parties' resources are mobilized for that purpose. By contrast, the consociational model views political parties as the crucial conveyors of different societal outlooks leading to inter-party bargaining within government (Lijphart 1977). Therefore, the parties may not want or be able to implement a policy change when politicians' interest calls for a policy change initiated by politicians.

Despite the opposing directions these two theories take, they may share similar results in terms of the public interest. As the consociational model strives to benefit the public by providing it with political stability, it entails avoiding policy change in various controversial issues which may harm the public. This result may also stem from active players who, in pursuing their narrow interests, make a policy change as illustrated by public choice theory. However, in the case of clinical trials in Israel, a policy change could have benefited the public interest. Therefore, the failure of the drivers to produce change, coupled with the norm of power sharing, provides an explanation not only to the persistence of the status quo but also for the harm to the public interest.

### *Methodology*

The present study is a qualitative one, based on two data collection tools that helped identifying the structural conditions of the human experiments' arena in Israel, as well as the players' interests and their patterns of activities: a series of semi-structured interviews and a thematic analysis of existing sources. Fifteen face-to-face interviews were conducted with respondents who were selected based on their deep acquaintance with the topic, whether by virtue of their official position or following their high public involvement in the issue (convenience sample). Several respondents, upon request, recommended other interviewees who could expand on or add to the information that emerged during the interview (snowball sample).

The Interviewees:

Interviewees were two representatives of interest groups dealing with patients' rights; one representative of the manufacturers' association; the chair of the ethics board of the Israel Medical Association. Also interviewed were four politicians involved in the issue and a legal advisor of a parliamentary committee; a rabbi who deals with ethic-medical issues; two members of the supreme Helsinki Committee; an ethicist and a physician-ethicist; a representative of the Pharmaceutical Division in the MoH.

The interviews took place between December 2020 and July 2021, each lasting approximately one hour, and were conducted on zoom or by phone. The participants were informed about the general research goal, that is, to explain the policy of the absence of primary legislation regarding the issue of human

experiments. As most of the interviewees asked to remain anonymous, references to them will be by identification numbers when presenting case-study interview information. As few of them agreed to be quoted, we will bring their saying under their name.[3]

Limitations of the data: none of the representatives of Pharma Israel (interest group) agreed to be interviewed, and neither did former and present director generals in the MoH. A former chair of the Ethics Board of the Israel Medical Association refused as well.

Following the interviews, and due to the refusal of several players to cooperate, this study used additional qualitative data that comes from existing sources (primary and secondary) dealing with human experiments issues, between 1995–2020. This includes all of the extant Science and Technology Parliamentary Committee (hereafter: ScTPC) protocols, bills, daily newspapers, academic publications, and various Internet publications. These sources completed data that did not appear in the interviews and helped to cross-reference data that emerged in the interviews (triangulation) (Kasen and Cromer-Nevo 2010). Combining the findings from interviews and written sources allows a presentation of an in-depth analysis.

The article employs a thematic analysis (Krippendorff 2013) identifying and analyzing central themes throughout the interviews and the written data. In order to ensure trustworthiness, as Rolfe (2006) suggested, the main criterion for the evaluation of qualitative studies would be, both authors identified themes in parts of the materials independently, then compared results and settled disagreements to ensure reliability.

## Case study

### *Human experiments in medicine – a brief survey of developments in Israel*

In Israel, there is a law regulating experiments on animals, yet none on human beings has been legislated. The chief relevant legal framework is the Public Health Regulations (Medical Experiments on Human Subjects) 1980 enacted in 1980 pursuant to section 33 of the Public Health Ordinance, 1940. The regulations adopt the principles of the Helsinki Declaration in its 1975 version. Subject to these regulations, in 1999 the Pharmaceutical Division of the MoH published the Procedure for Experiments on Humans (MoH Director-General Circular 1999), which regulates the procedural rules regarding the conducting of human experiments. This procedure was last updated in 2016.

In accordance with the regulations, two types of committees were established: the Helsinki Committee of the hospital (an institutional committee) whose approval is required for every human experiment performed at the hospital, and the Supreme Helsinki Committee for Genetic Studies in Human Subjects, which also serves as the Helsinki Committee for experiments conducted by the MoH. The regulations and the Director-General's circular do not cover the entire range of issues related to the

[3]Interest groups-interviewees no. 1–4; Legal advisor of the Science and Technology Parliamentary Committee- interviewee no.5; Politicians- interviewees no. 6–9; Rabbi-interviewee no. 10; Supreme Helsinki committee- interviewees no. 11–12; Ethicists-interviewees no. 13–14; Bureaucrat of MoH-interviewee no.15.

topic. For example, they only relate to public hospitals, not to experiments conducted outside of these facilities. This includes, for example, universities and the Weizmann Institute, although each of these bodies has an institutional committee.

Furthermore, these regulations do not directly define frameworks of authority or people subject to authority and therefore do not outline special conditions for conducting experiments on them. The procedure does define "special populations" and places additional restrictions on conducting research in them, but soldiers and prisoners are not defined as "special populations."

In 2005, the State Comptroller published a report on the supervision of medical trials in humans, which focused on hospitals where the elderly and the mentally disabled are hospitalized. The findings showed that in all related events, the subjects were given informed consent forms to sign, which were missing information essential to making a rational decision about whether to participate in the trial. The Comptroller instructed that substantive changes must be made to ensure that experiments would be performed according to the Helsinki Declaration and to the rules set down in the regulations and procedure, and to set out detailed rules regarding matters yet unresolved, such as obtaining informed consent when subjects are suffering from cognitive impairments (State Comptroller, 2005).

In 2007, the media exposed that in the years 1999–2005, an experiment was conducted on soldiers to test a vaccine against anthrax ("Omer 2"). Following the publication and two petitions to the High Court, a review committee was set up, whose findings showed that problems occurred at all stages of the experiment (Siegel-Itzkovich 2009).

In the last decade and a half, a number of bills have been submitted which were aimed at regulating the issue of medical experiments in humans. The MoH has been preparing drafts for a bill since 1997, but it was only in 2007 that one was brought to first reading, and the discussion was transferred to a joint parliamentary committee (ScTPC and welfare and health committee).

In 2005 (the 16th Knesset), a private bill was submitted by MK Orit Noked and a group of Knesset members (P/ 3241/16), to which the Rule of Continuity was applied, and it was discussed in the 17th Knesset together with two private bills that were approved in a preliminary reading (P/ 625/17) by MK Shlomo Breznitz and (P/ 1534/17) by MK Zevulun Orlev and with the government bill (M-321). With the dissolution of the 17th Knesset in 2009, however, the law of continuity could not be applied to private bills anymore while applying it to a government bill required government initiative.

Since then, the following bills have been tabled but not been brought even for a preliminary reading: in the 18th Knesset, P/2109/18 (MK Zevulun Orlev), P/1854/18 (MK Meir Sheetrit); in the 20th Knesset P/ 3210/20 (MK Zeev Binyamin Begin). Later in the 20th Knesset, the legal office of the MoH drafted a new bill, but it was not brought to the Knesset.

The empirical implications of the absence of primary legislation are violating the directives enshrined in the regulations does not constitute a criminal offense, in contrast to those derived from primary legislation, and therefore, the level of punishment and deterrence is low. Furthermore, there is potential for direct harm to the research subjects: adverse effects of the drug on their health (especially in trials conducted outside of hospitals), invasion of privacy, and the absence of an agency to

apply to if the drug company fails to continue delivering the drug after the trial period, despite the creation of a Control unit at the pharmaceutical division of MoH, in 2014.

In addition to possible direct damage, one may point out the loss caused by the absence of a law relating to lacunae in the existing situation. That is to say, if non-hospital institutions were also included, additional studies that do not require a laboratory in a hospital could be encouraged, as well as important studies in DATA that can be conducted on a larger scale (interviewees 2,3).

### *The structural conditions of human experiments in medicine in Israel*

Although each player has essential interests in a particular interaction, both specific preferences and actual behavior are influenced by structural conditions (Mizrahi and Meydani 2006). Therefore, when analyzing the interaction between the various players that led to the policy in this regard, one must first identify the structural conditions that constitute the contours of this policy arena.

This research found four structural conditions which shape the policy arena on the issue of human experiments in Israel, namely the status of medical science in Israel; the weakness of the Ministry of Health; the 'horror narrative'; and the Jewish law's approach.

*The status of medical science in Israel.* Medical science was perceived by Zionist political leaders as a prerequisite for the success of the Jewish settlement in Israel and as part of the idea of a progressive and just society. With the establishment of the State and during its years of existence, science, and medical science in particular, has been accorded a central role in the political-social way of life in Israel (Shvarts 2008).

The research analysis shows that medical science sought to position itself as part of the emerging state leadership, and medical-scientific practices as an integral part of the social and political control mechanisms in Israel (Eyal 2017). Moreover, Rozin and Davidovich's (2009) study of the Medical Association shows that physicians saw themselves as 'an elite serving the nation'. In addition, scientists believed that through science it would be possible to meet all the needs of the people (Filc 2005, 2009). At the same time, the state used medical science as a means of defining its sovereignty and strengthening its authority.

Physicians used the scientific discourse to establish an agenda consistent with their professional worldview (Rozin and Davidovich 2009) and thus succeeded in preserving their status and exclusive control over the conduct of the profession. In this way, physicians were not required to give an explanation regarding their professional activity (Rose 2001).

Over the years, the independence of medical science has been somewhat challenged, but has still been maintained. This status is manifest especially compared to the lack of cohesion of the state (Eyal 2017).

*Weakness of the ministry of health.* In light of the extensive power of medical science and its practitioners from pre-State days, the relative weakness of the Ministry of Health over the generations stands out. Considering the serious health problems that accompanied the many immigrants who arrived from underdeveloped

countries, none of the members of the provisional government wanted to take responsibility for handling health problems. As a result, Ben-Gurion put pressure on the representative of the United Religious Front, who was appointed Minister of the Interior, to take on the additional responsibility for health and welfare. Ben-Gurion's treatment of the Ministry of Health as secondary established it as an inferior ministry, which carries with it no political credit while it is called upon to deal with the difficult and fateful problems (Shvarts 2002, 2009).

Another source of the ministry's weakness lies in the existence of two dominant bodies in the health system before the state was established: The Israel Medical Association and with it the Workers' Health Fund (controlled by the *Histadrut*, the main trade union), which was the central and strongest health organization in the State of Israel. Therefore, to realize his vision of statehood, Ben-Gurion resorted to nationalizing the health care system, which was to take the Worker's Health Fund (WHF) out of the *Histadrut's* control, and consequently weaken the *Histadrut* as a competing political factor. The appointment of a health minister not from among the workers' parties made this step possible. The *Histadrut* and the health fund, however, demanded that the former medical director of the WHF be appointed to the position of director-general of the MoH, in order to prevent any future damage to the status of the WHF in the State of Israel (Zalmanovitz 1981).

This situation of opposing forces in the MoH, pulling in different directions and committed to different political systems, largely enervated the ministry's ability to build its status as the main factor managing the health care system in the nascent state of Israel, and created the image of a subordinate, weak political factor (Tsahor 1997). The way the Ministry of Health was shaped has influenced its prestige and power ever since as reflected in various ways, which will be discussed below.

*Horror narrative.* The transformation of the Holocaust into a national entity has had an impact at many levels these days. The term 'horror narrative' developed in the wake of the Nuremberg Trials, representing the view that medicine as practiced by the Nazis is a moral horror evoking extreme revulsion and existential fear, and all social and legal means must be taken to prevent its recurrence.

The horror narrative led to the framing of "Nazi medicine" as a terrifying and anomalous phenomenon, located on a plane that is different and parallel to conventional-normal medicine. This prevents any connection between the horrors of the Holocaust and experiments carried out using actual technologies to advance medical science: in other words, a dichotomy has been created that stands in contrast to the 'perception of continuity', whereby Nazi medicine is on the same plane as conventional 'normal' medicine.

This framing creates a situation that protects conventional medicine from any comparison to medicine that is professionally and morally reprehensible and thus reduces apprehension that medicine in Israel in general, and the field of human experiments in particular, could decline into realms of moral horror (Malul 2018; Malul et al. 2019–2020).

*Jewish law approach.* There is no halakhic (Jewish law) prohibition on conducting human experiments whose purpose is advancing medicine, and in fact, Judaism's approach is, in general, positive and supportive, because the imperative to value and preserve life are among its paramount values. A number of halakhic-philosophical

principles guide the Jewish approach to the question of research on human subjects, for example, the sanctity of human life; the interdiction against suicide and self-harm; the obligation to avoid dangers; the obligation to save others from harm and more (Jakobovits 1976). Thus, the halakhic approach depends on the definition of these principles and the balance between them, based on the research data, and this varies according to the data, the risks entailed, and the nature of the subjects (Steinberg 2006). In fact, the balances in the halakhic literature are very similar to the balances in the general ethics literature (Interviewee 10).

### *The players – interests, patterns of activity and interactions*

The activities and motives of the four players, namely the public, politicians, bureaucrats, and interest groups, each striving to maximize their benefit within the structural conditions, contribute to the policy pattern adopted regarding the issue of human experiments as follows.

*The public.* Ever since human experiments have been conducted in Israel, the public has been usually indifferent to the issue. Such behavior can be accounted for by the fact that being included in a human experiment is a relatively rare situation, which most individuals do not encounter during their lifetime. Additionally, there is a relatively high trust in science and in physicians. An alternative explanation for the lack of demand on the part of the public relates to the number of direct losers that results from avoiding primary legislation.

As Dr. Karni, chair of the Ethics Board at the Israel Medical Association, asserts: "Nowadays, there aren't human experiments that physically harm patients. Today, the risks have to do more with privacy (big data and the like), which touches upon the issue of informed consent." In this regard, it may be argued that in the era of social networks, (young) people's attitude towards their privacy has become more relaxed, and therefore, even without their specific consent to the use of their personal details, they don't perceive it as a harmful violation of privacy.

In cases of human experiments, not related to big data, where no physical damage has been caused, the participants naturally don't perceive themselves as "losers," even without informed consent. The only case where we can consider certain direct cost/damage to the subjects occurs when pharmaceutical companies promise to supply the medicine after the trial has finished but do not keep their promise, even though the patient's health depends on it. This is not a common occurrence, and in any case, these subjects are not able to mount a struggle on their own behalf, owing to lack of resources, for example, budget, time, or health (Eyal 2017).

In sum, it appears that the lion's share of those participating in human experiments are not harmed and/or do not feel harmed, and therefore, the public makes no real demand for a policy change.

*Politicians.* Given that the issue of human experiments is not on the public agenda, the politicians choose to leave it off their agenda as well. Indeed, very few politicians have been involved in the issue throughout the years. Moreover, all who were engaged in it acted by virtue of their duty as chairpersons of the ScTPC, rather than because of their own initiative. Corroboration for this lack of interest can be found in one discussion held by the ScTPC (1997), where the MKs who were present had

been told that there was a law regulating clinical trials in animals but no such law for human beings. This did not even draw their attention (Asa Kasher, interview).

MK Zvulun Orlev became aware of the issue as chair of the ScTPC (2006–2008). He felt that the governmental bill was too wide-ranging to have a chance of being passed. He tried to convince the MoH to narrow the bill, while initiating his own limited one (2006), which touched upon critical points only. Having been part of the opposition, he had looked for partners inside the coalition in order to promote the bill but found out that it was not on their agenda. In 2010, he initiated another bill and proposed the Minister of Health, Ya'acov Litzman an ultra-orthodox MK, to form a team of rabbis who are familiar with the medical world, to regulate the issue in a way that would be consistent with Jewish law. Litzman declined the offer (Orlev, interview).

Another MK who initiated a private bill by virtue of his duty as chair of the ScTPC (2009–2013) was Meir Sheetrit. However, he had been involved with enacting the Genetic Information Law, 5761–2000 which he initiated and linked closely to the issue of genetic human experiments. He did not cooperate with other MKs in this regard.

The last chairperson of the ScTPC (2015–2019) who engaged with the issue was Uri Maklev, an ultra-orthodox MK. At first, he tried to promote the 2007 governmental bill, but as he realized that it was being held up by the MoH, he decided to turn it into a private bill, which was introduced by MK Binyamin Begin in 2016. The rationale behind this decision was avoiding the need to receive the approval of the Ministerial Committee for Legislation. Maklev asserted that he had chosen Begin since he was a scientist, available, and agreeable (Maklev, interview). However, one may attribute it to Maklev's being an ultra-Orthodox Jew who did not feel comfortable dealing with the issue. At any rate, Maklev kept track of the process, all the while helping by convening the committee and participating actively in its discussions.

MK Begin was very active in promoting the bill, not before he had received the consent of the leading players to do so (ScTPC Protocols 2017: 4). He participated in the discussions of the supreme Helsinki committee, met with various players in the arena, scheduled discussions and concluded that there were very small gaps between the players, which could have been bridged easily. Several months later, when Begin realized that the MoH was not going to support the bill, he "was furious" and made no additional attempt to advance the issue (Begin, interview).

*Interest groups.* There are several interest groups in the human experiments arena; the first three are non-profit organizations that pursue patients' rights, and all of them support primary legislation on the issue. However, since none of them is exclusively dedicated to it, their engagement is sporadic and they did not develop any cooperation on this issue. As representing the public, this pattern aligns with the indifference that characterizes the public.

The first, "Physicians for Human Rights," focuses its activity on the most vulnerable populations in society, namely migrants, soldiers, Palestinians, and prisoners. It started to become involved in the issue around the anthrax event in the IDF (2007), where it petitioned the High Court of Justice and later on led to an order of the Army Chief-of-Staff that defines soldiers as a vulnerable population.

Disappointed with its inability to influence the political process in this issue, it directs its efforts toward other players and processes, mainly the UN. Every year, it raises grievances regarding health rights to the UN committee for cultural, social, and economic rights including the absence of legislation on this issue. The committee demands that Israel stipulate how it implements the right to health and contends that it must regulate the issue within a law. The chairperson, Hadas Ziv, characterizes the organization's strategy as "to buzz and occasionally to sting." In contrast to the support it gave the previous bills, "Physicians for Human Rights" is at present more reluctant to support primary legislation, following changes (e.g. competition with developing countries) that entail a much more complicated and detailed law, which may not bring about a positive result in terms of the public interest (Ziv, interview).

Due to its lack of resources, alongside other urgent issues, "The Society for Patients" Rights in Israel has not prioritized the issue of human experiments, albeit it works toward enabling as many human experiments as possible by facilitating regulation. Its activity in this regard is directed at cautiously simplifying the informed consent form, in order to prevent causing harm to participants. According to its chair, the organization participates in the discussions of the ScTPC and the MoH (Ben-Ya'acov, interview).

In addition to these interest groups, we find "Pharma Israel," the association representing the research and development-based multinational pharmaceutical companies operating in Israel. Pharma Israel's representatives were present at all the discussions held by the ScTPC, where they did not demonstrate opposition to the idea of legislation, but rather, suggested changes to the bills. However, according to some of the interviewees, their lobbyists have put intense pressure on the parliamentary committee's members, who were not among the bills' initiators, and on senior bureaucrats in the MoH to prevent the legislation. (Interviewees 6, 11, 13).

The Manufacturers' Association of Israel is another interest group involved in this arena, whose interests here are similar to those of Pharma Israel. As most of the companies represented by the association do not conduct human experiments, this issue has not been openly on its agenda, and it refrained from using its lobbyists (Carmel Feldman, interview).

The last interest group is the Israel Medical Association, whose goal is to address all aspects of the medical profession. The relevant body within it is the Ethics Board, which has been chaired in the last 7 years by Dr. Tami Karni. She initiated a forum of all Helsinki committees' chairs where they formulate unified standards and bring issues of concern to the attention of the board. Although it aims for primary legislation, which requires an extended, comprehensive discussion, the board holds that such a process should be conducted only in the right context, that is, when the political system is stabilized, the judicial system is respected, and there are proper working procedures. This delay is tolerable since "... most Helsinki committees' members are reliable and protect the patient's rights." (Karni, interview)

*Bureaucrats.* When discussing the role of bureaucrats in the policymaking process, it is crucial to refer to different levels and types of these players.

First, the Director-Generals of the MoH, who are usually medical doctors, as well as other senior physician bureaucrats in the ministry, seek to maintain their control

of the issue. In 1997, the Committee for Ethics in Science (under the National Council for Civil Research and Development) decided to formulate a bill and asked for the ministry's help. The then-Director-General of the MoH agreed, but several days later, the ministry demanded that the process be initiated and managed within the ministry, with the help of the ethics committee (Kasher, interview).

Alongside physician bureaucrats in the ministry, law practitioners, who constitute the legal Bureau of the MoH, aim at leaving as much control as possible in their own hands. From the late 1990s until 2007, it was working on formulating a comprehensive bill. After it passed the first reading in the plenum, it was discussed in the ScTPC, where politicians and experts demanded various changes that would limit the discretion and independence of the MoH.

In order to proceed with enactment of the legislation after the elections, the government had to initiate it (continuity principle). Most interviewees accuse the senior bureaucrats (both legal and medical) of not acting because of the abovementioned changes that were requested. It appears that from this point onwards, the legal advisor realized that legislation would ultimately harm their interest and therefore adopted a pattern of preventing any legislation (Interviewees 3, 13).

Two strategies were employed by the legal bureau for this purpose. First, following intensive discussions with various players, they updated the procedures, for example turning the institutional forms into standardized forms, shortening the schedule of the Supreme Helsinki committee. As Talya Agmon, the legal bureau's representative in the ScTPC said: "There are things that can be done in the current situation before legislation, and we are doing them . . . we are promoting many things."(ScTPC Protocols 2018). As a result, the motivation to legislate the issue, at the practical level, decreased (Feldman, interview).

Second, when Begin's private bill was raised (2016), the legal bureau hindered the process, without stating that it never had any intention of helping to pass the bill (Begin, Maklev, interviews). When MKs Begin and Maklev realized that the committee had labored over the bill for a whole year and made major progress while the ministry kept holding up the process, they accused the legal bureau of deceiving them (ScTPC Protocols 2017). Agmon responded to the accusation saying: "Reality dictates many changes and there is a lot of dynamics involved in these subjects, and part of it is being held up . . . we have specific constraints and limitations, which I don't want to raise here, because it is not important, it does not matter" (ScTPC Protocols 2018: 25). She also claimed that she thought they had let the committee know that the ministry was interested in a governmental bill, "but there might have been some kind of communication breakdown."

Another level of bureaucrats who function outside the ministry are directors of government hospital, who oversee the human experiments within the hospital, and therefore are interested in creating the most favorable conditions for the pharmaceutical companies, which reward the hospitals handsomely. Together with the doctors (street-level bureaucrats[4]), whose promotion depends on publishing the human experiments' findings, their interest is in relaxing the regulation as much as

[4]According to Lipsky (2010), these are " . . . agencies whose workers interact with and have wide discretion over the dispensation of benefits or the allocation of public sanctions."

possible, rather than making it stricter.[5] During the ScTPC's discussions, these hospital directors explained the importance of shortening the process but did not take an active stance against the bills. However, in informal conversations, they accused legislation supporters of "killing people" and demanded that the scientific community be given their trust (Interviewees 2, 5).

## Discussion

As noted earlier, important aspect of the relationship between consociationalism and public choice theory concerns the role of political parties. Since the majority of the Ministers of Health and the Vice-ministers[6] in the past two decades have been ultra-Orthodox MKs, these parties' stance of finding the primary legislation as somewhat problematic is decisive and may account for the difficulty in reaching a compromise over a policy change. Additionally, in terms of the public policy theory, they concentrate their resources on fighting parliamentary decisions regarding issues that may cause a furor among their electorate (their median voter), such as LGBT rights. It may be also argued that the title: "human experiments on human beings," sounds like a desecration of the value of life to the ultra-Orthodox population, which is largely not science-literate. (Interviewee 7, 10).

In the absence of a demand on the part of the public to change the status quo, most politicians refrain from becoming involved in this issue. This avoidance aligns with the "horror narrative" which is one of the structural conditions of this arena. Since it frames the Nazi human experiments as an anomalous phenomenon, there is no real concern that such activity could be conducted in a democratic setting.

The interest groups, representing the patients, are engaged in the issue only sporadically due to multitasking as well as limited resources and do not cooperate with each other. Coupled with the problem of collective action, this setting enables Pharma Israel to gain more power in the arena and to exert influence on public policy, by employing lobbyists to pressure politicians and bureaucrats. According to some of the interviewees, members of the ScTPC, who were not among the initiators of bills, intentionally refrained from active involvement, following pressure by lobbyists (Interviewees 6, 13).

It is important to note that pharmaceutical companies can give significant indirect financial support in return for a favorable policy. Additionally, as the issue of human experiments is especially complicated, these companies become the exclusive source of information, empowering them even further. As such, both bureaucrats and politicians "trade" with this interest group, thereby skewing the public policy in its favor rather than serving the public interest.

Alongside politicians' avoidance to legislate, medical, and legal bureaucrats in the MoH who are interested in maintaining or increasing their power and work volume, opposed legislation that would infringe upon their control and power over the issue and together with the legal bureau, employed various strategies to prevent it from happening.

[5]It should be noted that not all trials that are conducted within the hospitals are related to pharmaceutical companies.

[6]Traditionally, the Ashkenazi ultra-Orthodox party had been avoiding taking office of a minister, for ideological reasons, therefore, it made do with Vice-Minister position.

As opposed to their power in preventing loss of control over the issue, one also must refer to the legal bureau's failure to have the MoH's bill (2007) passed in its original version. Here we identify weakness that may stem from several sources. Most interviewees argued that the lack of resources from which the ministry has been suffering for years led to mediocre human resources in senior positions, as well as to its susceptivity to pharmaceutical company lobbyists. One of the interviewees noted that "the bureaucrats who are appointed are mostly incompetent, and the physicians in the hospitals are zeros" (Interviewee 3). Another pointed at the massive resignation of senior bureaucrats, which indicates the weakness of the ministry.

As a result, the MoH is not capable of handling such a process, while simultaneously coping with many other challenging issues (Interviewee 1). One of the politicians even claimed that "This ministry does not know how to cope with complexity, and it never succeeds in implementing any of its decisions." (Interviewee 6). Additionally, a bureaucrat in the Pharmaceutical Division pointed to the shortage of law practitioners who would be assigned to the division exclusively, as a significant factor in this failure (Interviewee 15). These arguments are consistent with the structural condition regarding the weakness of the MoH ever since the establishment of the state.

Although this issue has dominant ethical and legal dimensions, which entail serious engagement and decisions by professionals in these fields, the government hospital directors and physicians who participate in the human experiments seek to exclude them. This approach is consistent with the unique status of the medical profession ever since the establishment of Israel, a structural condition which characterizes this arena. Since the medical community has had exclusive control over the profession and maintained its independence from state interference throughout the years, their demand for freedom is not surprising, and neither is the legitimacy granted to this demand. This finding is consistent with that of Eyal (2017), who concludes that the absence of primary legislation demonstrates the authority and power of the medical profession.

## *Conclusion*

The alternative of primary legislation regarding the issue of human experiments in medicine in Israel is effectively excluded from the policy agenda by regulating it using administrative means. In order to explain why the policy of the status quo persists, the article employed the consociational model as the primary explanation, complemented by public choice theory, which added the perspective of how, in the context of consociationalism, the drivers of legislation failed to bring about a change.

The policy impasse appears to start with uncertainties generated for each of the actors around the political bargaining process needed to achieve an intra-party and inter-party consensus. The uncertainties about compromise outcomes appear to disincentivize supporters of legislation from disturbing the status quo, causing them to adopt several improvements within the existing framework that further reduce the chances for legislation. As a result, there is no incentive, financial or other, from any constituency, for the politicians to support change and to market the change to the voters.

Against this backdrop, the public choice perspective adds the structural factors, all of which hindered legislation, resulting in the victory of those who opposed

primary legislation, due to their own interests, over the forces that supported such legislation, which reflects the public interest.

In the case of human experiments in medicine, the normative choice is not simply between primary legislation and regulation but is more complicated, placing the merits of primary legislation as against the virtues of accommodation and consensus in a deeply divided society. This choice touches upon the complexity surrounding the notion of the 'public interest' by making us wonder what it really is. Is it maintaining political stability, which is necessary to realizing democratic rights, by avoiding a policy change which would protect specific vulnerable individuals? Or is it protecting these vulnerable individuals from harm carried out by players who wish to maximize their interests, alongside destabilizing the political system by polarizing the cleavage and by undermining power relations between the players in the clinical trials arena?

While consociationalism is crucial for political stability, maintenance of the status quo may perpetuate ramifications that do not favor the public. In addition to the implications at the empirical level mentioned above, one should consider the normative level as well; in democratic countries, value-based issues should rightly be decided through public debate and by the legislative body, rather than by players who were not elected. In the current situation, the MoH continues to make frequent changes in the conditions of experiments and the use of information in procedures, using processes that do not meet public scrutiny and are lacking in transparency. Other value-based issues are decided by the Supreme Court, which, again, is not elected by the public. For example, following 15 years of establishing committees and publicizing statements by politicians regarding the issue of non-Orthodox conversion to Judaism, (which, in fact, maintained the status quo), the court ruled (2021) that the Law of Return, which grants the right to immigrate and become an Israeli citizen, would apply to this type of conversion as well.

However, if the process of getting approval for primary legislation could destroy consensus, there is a case, according to consociationalism, for maintaining the status quo, that is, proceeding along the regulatory track.

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