Therapeutic Justice and Vaccination Compliance

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Abstract

Recent decades have witnessed the appearance of multiple grounds for vaccine hesitancy. One of the options to deal with this phenomenon is legislative. Given that vaccination enforcement through law raises allegations of infringement of constitutional rights, interventions seeking to promote vaccination compliance should rather address the factors that influence vaccine hesitancy, which are – by and large – related to trust in health authorities. Trust in health authorities may be promoted by a procedure for compensating the comparatively few vaccination victims reflecting a willingness to acknowledge liability and commitment to social justice.

A qualitative study of the Israeli Vaccination Victim Insurance Law was conducted by the author. The study involved document content analysis (legislative protocols, Court judgments) and semi-structured in-depth interviews with informants representing different legal, medical and ethical perspectives. The thematic analysis found that the Israeli Vaccination Victim Insurance Law and its implementation in Court do not attain their therapeutic potential with respect to the promotion of trust. Barriers to claim submissions and the denial of all claims submitted according to the law do not permit the acknowledgement of liability or the demonstration of the authorities' commitment to social justice.

Recognizing the therapeutic power of the Law may lead to adaptations or amendments promoting trust in the health authorities and subsequently fostering vaccine compliance.

Keywords: public health, trust, vaccination, health law, health policy.

1 Introduction: Vaccine Hesitancy

Vaccines are one of the most successful interventions, having improved health and saved the lives of millions worldwide. However, recent decades have wit-

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nessed a significant increase in hesitancy to undergo vaccinations.[1,2] The World Health Organization (WHO, 2018) has described this phenomenon as 'Vaccine Hesitancy,' a phenomenon related to the acceptance, delay or refusal of vaccines despite their availability. The WHO (2018) states that vaccine hesitancy is complex and context specific, and varies across time, place and vaccines.

Concerns over vaccine safety, reinforced by publications ascribing injuries to vaccination such as a 1974 article which described severe neurological complications following Pertussis immunizations (Baker 2003), or the discredited 1998 Lancet publication of neuropsychiatric dysfunction among children who had previously received Measles, Mumps, and Rubella vaccines (Wakefield et al., 1998), are among the main causes for vaccine hesitancy. Other causes include a general opposition to conventional medicine or an opposition to government intervention in individuals' health decisions. Hesitancy may also arise on account of the fading memory of the severity of vaccine-preventable diseases (Benin et al. 2006; Larson et al. 2014; Offit & Coffin 2003).

In 2011, The WHO Strategic Advisory Group of Experts (SAGE) on immunization identified vaccine hesitant populations as one of its new high-priority topics. A WHO working group on vaccination hesitancy suggested two models addressing the factors that may influence the decision to accept some or all vaccines according to the recommended schedule. According to the Complacency, Convenience and Confidence ('3Cs') model, this decision is influenced by confidence in the effectiveness and safety of vaccines, in the system that delivers them, and in the motivations of the policymakers who decide on the necessary vaccines. The decision is further influenced by complacency where the perceived risks of vaccine-preventable diseases are low; and convenience, measured by the extent to which the physical availability, affordability, geographical accessibility, understandability and appeal of immunization services affect uptake.

According to the second model, the decision whether to accept vaccine recommendations is influenced by historical, socio-cultural, environmental, health system/institutional, economic or political factors; by individual and group influences arising from a personal perception of the vaccine or the influences of the social/peer environment; and by vaccination-specific issues such as the introduction of a new vaccine, its mode of administration or its vaccination schedule (WHO, 2014).

1 A report written by the Knesset (Israeli Parliament) Research and Information Center in 2008 held that Israel too has witnessed a recent decrease in vaccination rates (Weisblai, 2008).

2 A recent example of vaccine hesitancy in Israel took place in 2013 when Polio was detected in Israeli sewage. The recommendation to vaccinate children born after 2004 with OPV had a 79% compliance rate, which was followed by a request from the State Comptroller to "draw conclusions from the low compliance rates in certain Israeli regions" (Report on Child, Adult and Healthcare Worker Immunizations, State Comptroller's Office 2014: 608). In another example, the 2014 rate of HPV compliance in Israel was only 53% for the 1st dose, 50% for the 2nd dose and 15.2% for the 3rd dose (Israeli Ministry of Health Advisory Committee on Infectious Diseases and Immunizations 2015).

2 Vaccination coverage as government duty and power

According to Social Contract theory, the public in a democracy authorizes the government to act for the common good. By corollary, governmental entities possess the duty to protect and promote public health. The government alone is authorized to require conformance with publicly established standards of conduct, although its police powers are limited by the individual rights to liberty, autonomy, property and other constitutionally protected interests (Hobbes, 1961; Gostin, 2000:7). Since the control and containment of infectious disease is essential to public health, the government has the duty and the power to promote vaccination compliance and to reduce vaccine hesitancy.

The International Covenant on Economic, Social and Cultural Rights (adopted by the General Assembly of the United States on 16 December 1966) states (in Part III, Article 12) that: "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: [...] (c) the prevention, treatment and control of epidemic, endemic, occupational and other diseases."

In line with the aforementioned Social Contract theory and the Covenant on Economic, Social and Cultural Rights, all 50 US states have laws that require vaccinations for school admissions. Exemptions vary from state to state, although all school immunization laws grant exemptions to children for medical reasons, and almost all states grant religious exemptions for people who possess religious beliefs that prohibit immunization. In Canada, three provinces (Ontario, New Brunswick and Manitoba) require proof of immunization for school admission. Exceptions are permitted on medical or religious grounds and for reasons of conscience (Walkinshaw 2011). In France, the Code of Public Health (Le Code de la santé publique, article L.3116-4) prescribes up to six months' imprisonment and fines of up to € 3,750 on those who fail to comply with mandatory vaccinations, and in Italy the law requires children to receive 10 vaccinations as a precondition for school enrollment and imposes fines of € 500 to € 7,500 on parents who refuse to vaccinate their children (Yang and Reiss, 2018). Australia's New Tax System (Family Assistance) Act 1999 provides that family tax benefits, child care rebates and child care benefits can only be paid to children who meet immunization requirements. A person may have a medical exemption to vaccination if they are undergoing treatment that compromises their immune system. As of July 1, 2018 parents who don't vaccinate their children will lose part of their biweekly support payments.

Israel joined the International Covenant on Economic, Social and Cultural Rights on October 3rd, 1991. Moreover, the Israeli Basic Law: Human Dignity and Liberty, enacted in 1992, recognizes the right to health as a civil right, holding (in §4) that 'All persons are entitled to the protection of their life, body and dignity' (Book of Laws no. 1391, 1992: 150). Israeli Court decisions have interpreted the right to bodily integrity to include the right to healthcare, which the government

must both protect and positively provide (Luzon v. The State of Israel, 2008; Physicians for Human Rights v. The Finance Minister, 2004; Gross, 2013).

In an attempt to deal with vaccine hesitancy and improve vaccination coverage, the Israeli Social Security Law of 1995 was amended in 2009 such as to require vaccinations in accordance with Ministry of Health recommendations in order to receive an additional child allowance. In the course of the deliberations on the amendment, Ministry of Finance representatives supported this financial sanction and stressed that it had proven effective in other countries. The Ministry of Health representatives, in turn, added that Israel's unvaccinated population was the reason for disease outbreaks, and that providing parents with a vaccination incentive might promote compliance. However, the additional child allowance was later cancelled, and the amendment to the Israeli Social Security Law was repealed by the Israeli parliament before its implementation.

3 Drawbacks of Coercive Vaccination Laws and the Importance of Promoting Trust in Health Authorities

The implementation of laws that enforce vaccination is often complex and raises allegations of infringement of constitutional rights.

In the US, opposition to ordinances requiring presentation of a certificate of vaccination to attend a public school or other place of education was followed by court litigation. Rosalyn Zucht filed a Court petition claiming that 'the ordinances deprive her liberty without due process of law by, in effect, making vaccination compulsory, and also that they are void because they leave to the board of health discretion to determine when and under what circumstances the requirement shall be enforced, without providing any rule by which that board is to be guided in its action and without providing any safeguards against partiality and oppression' (Zucht v. King, 1922).[3]

In Israel, a Supreme Court petition was submitted against the implementation of the aforementioned 2009 amendment to the Social Security Law, requiring vaccination in order to receive an additional child allowance (Adalah Legal Center v. The Ministry of Labor and Social Affairs, 2013). The petitioners claimed that depriving families with an unvaccinated child of the additional child allow-

3 The court held that "these ordinances confer not arbitrary power, but only that broad discretion required for the protection of the public health" (Zucht v. King, 1922).

ance is a violation of their constitutional rights to dignity, autonomy and equality.[4]

Given the complexity of enforcing coercive vaccination laws and the associated courtroom confrontations with policymakers that give rise to controversies and polarization, interventions seeking to promote vaccination compliance should rather address the factors that influence vaccine hesitancy, which are – by and large – affected by trust in health authorities.

Trust in health authorities is relevant to public confidence in the effectiveness and safety of the recommended vaccines, in the system that delivers them, and in the policymakers' motivations. Moreover, trust may also diminish complacency by leading to public acceptance of health authorities' disease risk evaluations (Gostin, 2000:94)[5]. According to Gilles et al., 'public trust in medical and political authorities is emerging as a new predictor of compliance with officially recommended protection measures' (Gilles et al., 2011).[6]

4 A Trust-Building Procedure for Compensating Vaccine Victims

An opportunity to promote public trust in health authorities and thus the promotion of compliance with recommended vaccinations may be found in an attentive and empathic procedure for compensating vaccination victims which would express policymakers' acknowledgement of their liability for vaccine damages, and their commitment to social justice (Okimoto & Tyler, 2007).

4 In a decision delivered in June 2013, all three judges agreed that the constitutional right to dignity and the constitutional right to autonomy were not violated in this case. As for the constitutional right to equality, Justice Hayut held that legislators are authorized to relate differently to parents who vaccinate their children as opposed to those who refuse to do so. Justice Arbel, on the other hand, was of the opinion that the above distinction is immaterial to the child allowance's initial purpose – the assurance of minimal financial conditions for survival, meaning that the right to equality is indeed being violated in this case. Nonetheless, Justice Arbel also concluded that this constitutional right violation complies with the stipulations laid down in the Limitation Clause (§8 of the Basic Law: Human Dignity and Liberty). Justice Barak-Erez did not positively hold that depriving the additional child allowance from families with an unvaccinated child represents a violation of the right to equality, but agreed with Justice Arbel that the law's amendment complied with the stipulations provided in the Limitation Clause. In her opinion, the amendment has a proper purpose (to protect unvaccinated children and promote public health). Furthermore, there is high probability that a financial sanction would be effective and promote vaccination compliance, and the intervention is both minimally infringing and proportionate since it has been balanced by the parents' right to opposition and appeal (Adalah Legal Center v. The Ministry of Labor and Social Affairs, 2013).

5 For the importance of trust in health authorities, see also Hall, 2002; Gatter, 2004; Armstrong et al. 2006.

6 Promoting trust in health policy makers would probably not promote vaccination compliance in cases where vaccine hesitancy is due to historical socio-cultural, environmental, economic or political factors, or when hesitancy derives from convenience (physical availability, affordability, and geographical accessibility). However, measures for increasing public trust might promote vaccination compliance in cases where hesitancy results from uncertainty regarding the communicable diseases' severity or vaccine efficacy and safety as described by the health authorities.

However, as an adversarial procedure following torts law involves a confrontation between the victim and the health authorities, this procedure fails to promote trust between the public in general or the injured parties in particular and the policymakers who recommended vaccination. Moreover, concerns over the implications of full information disclosure prevent the authorities from holding an open discussion with injured parties and diminishes trust. Finally, the high burden of proving both negligence and causal connection between the vaccine and the injury, which usually bars compensation, conveys the impression of the health authorities renouncing their responsibility (Looker & Kelly, 2011; Evans, 1999).

Proceedings other than adversarial tort litigation were recently undertaken in Israel in other areas of physical injury. In 2006, for example, and as part of a compromise arrangement, a committee was established for compensating women who suffered from injuries attributed to Diethylstilbestrol (DES) given during pregnancy in the mistaken belief it would reduce the risk of pregnancy complications and losses. The injured women were not required to prove negligence and a causal connection in every case. In another example, a class action against the distributors of Eltroxin (a medication to treat thyroid hormone deficiency) was authorized in 2015. Here, too, a compromise arrangement was formulated for compensating victims who suffered from side effects attributed to the drug without requiring proof of negligence or a causal connection in every specific case. Nonetheless, despite the fact that compromise agreements may waive the requirement of proof of negligence and permit prompt compensation, they usually do not involve full information disclosure or the acknowledgement of liability and therefore do not introduce the opportunity of promoting trust.

An additional form of alternative dispute resolution that could be employed in cases involving vaccine injuries is mediation. Since the mediation procedure is confidential, it would allow the health authorities to disclose information, acknowledge liability and even apologize for the damages caused by the vaccine without being concerned about the legal implications of doing so (Alberstein & Davidovitch, 2011). However, and despite possessing the potential to promote the injured parties' trust in the health authorities, a confidential acknowledgment of liability in a specific case would not contribute to the promotion of the collective trust.

Promoting collective trust requires the kind of open public procedure that is employed in litigated trials (court judgments are usually published even though the litigants' names may be redacted). The deliberation of vaccine injury compensation in court is carried out in many industrial countries according to no fault laws of compensation for vaccine victims (Keelan & Wilson, 2011). The wording and implementation of no fault legislation such as to reflect the health authorities' willingness to acknowledge liability and their commitment to social justice may result in the therapeutic outcome of increased trust. The trust gained by the implementation of a compensation law for vaccine victims might thus increase the overall level of trust in the health authorities and vaccine recommendations.

Imbuing the law with the ability to promote trust follows the therapeutic jurisprudence perspective, which regards the law as more than a tool for imposing

sanctions; rather, it argues, the law is also a social force that produces behaviors and consequences. As noted by several scholars, 'therapeutic jurisprudence invites us to think instrumentally and empirically about the law, rather than in terms of intrinsic rights or a priori principles' (Hall, 2002; Davidovitch & Alberstein, 2008; Wexler, 2014).

5 An Examination of the Israeli Vaccination Victim Insurance Law – Wording and Implementation

A qualitative study of this law was conducted by the author. The study involved documents, content analyses (legislative protocols, court judgments) and thirteen semi-structured in-depth interviews with informants representing different legal, medical and ethical perspectives on this issue.

The interviewees included lawyers involved in vaccine injury lawsuits, a judge who was formally assigned to rule in claims submitted under the Vaccination Victim Insurance Law, public health specialists, parents who claimed that their child's injury could be attributed to a vaccine and medical ethicists.

The informants represented a purposive sample selected according to the relevance of their knowledge and experiences to the research questions. They were interviewed according to an interview guide that contained pre-determined open-ended questions based on the existing vaccine compensation literature (Keelan & Wilson, 2011; Kutlesa, 2004).

During the interviews, informants addressed the predetermined questions but were also permitted to add new themes they perceived as relevant without interruption. Each interview lasted approximately 90 minutes and was recorded and transcribed verbatim.

Data analyses began by a repeated reading of every document and interview protocol to obtain a sense of the whole. In line with the grounded theory approach, 'meaning units' that emerged from the texts were marked, coded and then combined into categories. The data were then collected, coded and analyzed simultaneously with respect to all categories. Any new themes that emerged from this analysis were then integrated iteratively into the interview guide before proceeding with further interviews.

The analyses were also conducted reflexively to minimize the likelihood that the author's prior experience would influence the systematic structuring of codes and categories. Comparing the results between data collecting methods, interviews and documents content analyses, ensured comprehensiveness. Credibility was established through persistent observation and peer debriefing.

The thematic analysis found that the Israeli Vaccination Victim Insurance Law was passed further to Israeli judicial calls for legislation that would allow the Courts to compensate vaccination victims without involving the law of torts. In 1987, an Israeli District Court denied compensation to a baby who was diagnosed with epileptic syndrome (Lennox-Gastaut) after receiving combined vaccines against diphtheria, tetanus and pertussis (DTP). The court held that the claimants could not prove the causal connection between the vaccination and the syn-

drome. However, the Court also advised legislators to consider legislation that would lower the vaccination victims' burden of proof and allow them to receive compensation despite their inability to meet the requirements of tort law (Lifshitz v. The State of Israel, 1987).

In another case, a 4-month-old baby named Juhar Alturi was vaccinated with DTP and suffered from neurological symptoms ten days later. In her tort suit against the State of Israel, counsel for Juhar Alturi claimed that the recommendation to vaccinate children with the DTP vaccine was negligent as the vaccines place children at risk of harm. The District Court rejected the allegation and held that the decision to vaccinate children with the DTP vaccine was reasonable and that there was no proof of negligence. Moreover, the Court held that there was no proof for a causal connection between the vaccine and the claimant's injury (Alturi v. The State of Israel, 1987). An appeal submitted by the claimant was denied by the Supreme Court, but the Court added that legislators were advised to consider legislation that would compensate vaccine-injured individuals, given the lack of a tort-based remedy for the claimant (Alturi v. The State of Israel, 1993).[7]

The Vaccination Victim Insurance Law was thus passed in 1989. According to this law, the State of Israel is required to insure every individual who was vaccinated with the following vaccines: DTP, Polio, MMR, Hemophillus Influenza, Hepatitis B, or vaccines given as a result of a public health authority decision with a view to protecting the public from an epidemic.

Furthermore, the State is required to pay indemnification(s) to the beneficiary(ies) regardless of whether or not negligence was involved. An expert committee consisting of two physicians and a judge decides whether there was a causal connection between the vaccine and the injury, and evaluates the degree of the claimant's disability. Injured parties are also granted the right to choose whether to submit their claims according to the Vaccination Victim Insurance Law or according to tort law. However, it is prohibited to sue for compensation both ways.

According to the Law's explanatory remarks and to Israeli parliamentary deliberations, legislators believed that acknowledging liability for vaccine damages would promote vaccination compliance: *'The State's commitment to the compensation of vaccination victims is essential to the continuity of the vaccination coverage in Israel'; 'If the Ministry of Health or other such authority does not take*

7 While the decision was given after the enactment of the Vaccination Victim Insurance Law, it nonetheless demonstrates its rationale in the Israeli case.

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responsibility, parents might recoil from vaccinating their children and the consequences will be drastic."[8]

Yet, information provided by the state-owned insurance company Inbal for the period 1997-2011 (14 years) indicates that a mere 41 claims were submitted under this Law and that indemnification was paid only in seven of these (17%). A 2008 observation by an expert committee chairperson noted that the committee had never ruled in favor of the victims such that the few indemnifications paid were on an *ex gratia* basis further to a settlement agreement.[9]

The study's in-depth interviews revealed that the Israeli Vaccination Victim Insurance Law erected barriers to claim submissions that diminished trust in health authorities' willingness to acknowledge liability and in their commitment to social justice.

Submission of claims under this Law is complicated: injured parties must apply to both the Health Minister and to the state-owned insurance company Inbal, and enclose an expert medical opinion supporting their claims. Technically an expert opinion is not mandatory, but vaccination victims are led to understand they will be unable to prove their cases without it. This unofficial requirement for an expert opinion bars some claims due to their high costs and to the difficulty locating experts who will write anti-vaccination opinions. The complexity of claim submissions may thus lead some to assume that the health authorities introduce difficulties deliberately to impede or prevent the payment of compensation:

> 'The law itself doesn't require anything, but the Ministry of Health requires an expert opinion when you approach them … that isn't right … the law's doors shouldn't be closed to someone who cannot afford an expert opinion … the law is unlike tort litigation'; 'People feel that the Health Ministry creates difficulties for claims' submission … not everyone is legally literate.'

Another barrier to claim submissions is the prohibition on submitting a tort claim if a claim was handled according to the Vaccination Victim Insurance Law. This

8 Another justification offered for compensating vaccine victims among the author's interviewees was the fact that vaccine policy is determined by the state and therefore justifies the awarding of compensation to those who followed state recommendations: *"The state recommends it to all parents and therefore must compensate them in case something goes wrong"; "Vaccination isn't mandatory, but there is a silent requirement that people get vaccinated"; "We must follow the State's vaccine program without knowing what the vaccine is made up of… the State knows the risks and should take responsibility"*. The informants also justified compensation as vaccination is an altruistic action: *"the state has a moral obligation to compensate an injured child who sacrificed his health for the public's benefit."* Others related to the fact that vaccines are given to healthy people: *"the child was perfectly normal and now he is a total loss, gone;"* or to the severity of vaccine injuries: *"In most cases, the plaintiffs are children with 100% disability."* A final group of justifications for compensation related to the small number of victims not giving rise to a financial burden on society: *"We need not worry about multiple claims as there are very few vaccine-related injuries every year."*

9 In the US, for example, compensation was awarded in 57% of cases involving claims of injuries caused by DTaP vaccines; in 52% of claims of injuries caused by MMR vaccines, and in 54% of claims of injuries caused by the Hepatitis B vaccine (Health Resources and Services Administration, US Department of Health and Human Services – Data and Statistics).

prohibition was perceived by the injured parties as a factor that prevented them from exercising their full rights and meant to silence them with inadequate compensation and no acknowledgment of liability for their damages:

> 'Injured parties must gamble, because they cannot know in advance whether the case can be proven in court and result in a far greater award of compensation;' 'They compensate you in order to shut you up, and you can't sue the authorities even though they are the ones responsible for the injury'.

The adversarial handling of claims submitted under the Law was noted as another barrier to vaccine injury claims. The dispute between the injured and the Ministry of Health's representatives, which includes cross-examination and attempts to contradict the injured party's arguments, makes them feel as if the Vaccination Victim Insurance Law was nothing but lip service, and that the health authorities will do everything to prevent them from receiving any compensation:

> 'People are busy with their injury … everyone knows this is a long battle and no one wants to get into legal battles which cost time and money.'
>
> 'People feel the health authorities don't really intend to compensate them and that the law is just a ruse;' 'Why should I confront someone who doesn't want to compensate me? The other side would always be stronger than me … either I hire a lawyer and pay him more than I can get, or face a 'shark' lawyer who would eat me alive.'

Finally, claimants realized that any compensation awarded would not cover their losses even if their claim is accepted, as Vaccination Victim Insurance Law awards a low lump sum determined according to the degree of permanent medical disability. Accordingly, vaccination victims prefer to submit tort claims, where they can be compensated for pain and suffering, medical expenses and loss of wages or for amounts paid for assistance from third parties even in cases of temporary disability. The lack of compensation for the above damages in claims submitted under the Law suggests that the health authorities are not concerned with the victims' needs or with social justice:

> 'The compensation doesn't even cover three months' worth of medical treatments … as long as the amounts paid according to the law are so small, I would rather try to submit my claim in court;' 'This is a social law, but it doesn't compensate for hospitalization, loss of working days or anxiety if the injured party has fully recovered'; 'I expect to be compensated at a level that would enable reintegrated in society.'

In addition to barriers to claim submissions, trust in health authorities is also diminished in light of the fact that the committee appointed to discuss vaccine injury claims has never decided in favor of a claimant.

Informants were of the opinion that the committee could never rule that a recommended vaccine caused damage since the committee members were also

employed by the Ministry of Health. Moreover, and since they were simultaneously engaged in promoting immunization, they would probably be concerned that ruling in favor of a claimant and confirming that an injury was caused by a vaccine might discourage others from vaccination. Some informants further suggested that the Ministry of Health, which appointed the medical experts, chose those who supported vaccination and did not believe that there was a causal connection between a vaccine and an injury:

> 'I [could] sue the Ministry of Health, but every member of the committee is employed by the Ministry… they can't rule against their employer;' 'An expert employed by the Ministry of Health would be rebuked if s/he suggested a causal connection between a vaccination and an injury;' 'If the committee compensated claimants, the public might relate injuries to vaccines… these are very bad implications.'

Besides concerns over the specialists' objectivity, informants also argued that vaccine damage claims are rejected due to the requirement of demonstrating medical causality between the vaccine and the injury.

An example of this can be found in the case of Plonit v. The Ministry of Health, 2002: In 1994, a 2-month-old baby received a DTP vaccination. A few hours later, her mother noticed that the baby had convulsions. The baby was later diagnosed with severe neurological damage, as well as cognitive and motor deficiencies associated with 'West Syndrome.' The child's parents filed a claim against the Israeli Ministry of Health under the Vaccination Victim Insurance Law and claimed that the vaccine was a trigger for the syndrome's onset, given that the child was otherwise symptom free. The expert committee appointed under the Law with a view to determining a causal connection (or lack thereof) between the vaccination and the baby's symptoms concluded that the short duration between the vaccine and the symptoms' appearance does not constitute evidence of a causal connection.

Another claim submitted in 2008 concerned the alleged connection between MMRV and HIB vaccinations and SIDS (Sudden Infant Death Syndrome). Although the death occurred a few hours after the vaccines were given, the expert committee determined that this did not constitute a causal connection (El Hoashala v. Jerusalem Health Department, 2008).

Informants noted that the requirement of proving a causal connection between the vaccine and the injury bars compensation *'as every injury attributed to a vaccine can also have other causes.'* They also argued that scientific studies had never proved a causal connection between vaccines and medical injuries, meaning that causality could never be proven in claims submitted according to the Law: *'All studies demonstrate that injuries are not the outcome of vaccines…'*

6 Building Trust in Health Authorities

In line with the principles of therapeutic jurisprudence, the wording and implementation of the Vaccination Victim Insurance Law has the potential to promote trust in health authorities if interpreted as an acknowledgement of liability and as an expression of commitment to the injured parties' and the public's welfare.

Such trust building can begin with the simplification of the claim filing process. In this respect, Israeli legislators might follow the United Kingdom's Vaccine Damages Payment Scheme, in which filing claims requires either the individual or a healthcare professional to complete a simple form. Expert medical advice is provided by the Medical Advisory Service, which provides advice to all medicine-related claimants. An expert opinion on the injured party's part is therefore not required (Vaccine Damage Payments Act, 1979).

In addition to a simple claim-filing process, the injured party should also be allowed to submit a tort claim after receiving compensation according to the Vaccination Victim Insurance Law. Offering the option of submitting a claim under the Law as well as a tort suit may eliminate the claimants' perception of being deprived of their right to additional compensation from the health authorities if the latter have acted negligently. In order to prevent a case in which an injured party is compensated twice for the same damages, the law may assert that the compensation received under the Law would be deducted from compensation awarded in the tort suit.

As for the adversarial litigation which makes claimants feel as if the Health Authorities are confronting them and not acknowledging liability, it should be noted that the Law does not mandate adversarial litigation. Yet, the procedure has come to resemble adversarial litigation since the Ministry of Health is represented by lawyers appointed by the state-owned insurance company Inbal. Informants argued that legal representation is essential to both the claimant (in order to ensure all relevant arguments were raised) and the health authorities (in order to uncover all medical information).

Nonetheless, therapeutic outcomes might still result from claim hearings, building trust in health authorities despite the presence of lawyers for both parties, if the committee members charged with deliberating the vaccine injury claim handle the hearings with compassion and sensitivity, and - when appropriate - encourage health authorities to acknowledge liability and compensate claimants. Alternatively, legislators may hold that the parties may not be represented by lawyers, but simultaneously invest the committee appointed in every case with inquisitional powers as well as the authority to disclose all relevant information and to discuss all relevant arguments. An administrative system equipping committee members with broad inquisitional powers would allow the committee to

deliberate on claims in a timely fashion and would promote trust in the health authorities' willingness to examine the case objectively.[10]

Authorizing the committee to adjudicate compensation according to the injured parties' needs (rather than a lump sum payment determined by the extent of assessed permanent disability) might also promote trust in health authorities and their commitment to social justice. In this case, it may be argued that compensation according to the Vaccination Victim Insurance Law aims to acknowledge the injury and not necessarily to attain *restitutio in integrum* (restore the injured party's original condition), and therefore that a low lump sum is justified as compensation. This is commensurate with the small premium paid for insuring all vaccinees and for waiving the requirement of proving negligence. However, awarding compensation insufficient to cover all the injured parties' needs (e.g., medical or paramedical treatments, third party assistance, loss of wages) would probably fail to restore trust in the health authorities' willingness to acknowledge full liability for vaccine-related injuries.

Regarding the objectivity of the expert committee members appointed by the Minister of Health: although sovereign in their decisions, it is important that justice not only be done but also seen. Informants have suggested that the expert committee also include claimants' physicians who can attest to pre-injury health. It was also suggested that the committee's experts not include physicians employed by the Ministry of Health responsible for promoting vaccinations, and that the appointment of committee members be made by an external and objective entity.

Other measures that would increase the appearance of justice would include the institution of public access to the committee's decisions and the publication of cases in which claimants were awarded *ex gratia* compensation. In order to minimize the false interpretation of committee decisions, the authorities should communicate these decisions to the public in a transparent, clear, and accessible manner, and should monitor the public understanding of vaccine-related injury cases and redress misinterpretations.

Finally, as difficulty in proving causality appeared as a salient factor for diminished trust, a thorough discussion is required into this issue.

The Vaccination Victim Insurance Law does not specify the manner in which claims committees should determine the causal connection between vaccine and injury. Some informants suggested that causality should be seen if there is greater than 50% probability in line with the admissibility criteria pertaining to legal evidence. Other informants were of the opinion that causality should only be determined according to scientific criteria, which includes the requirement for specific-

10 Most no-fault programs for vaccine injury indemnification provide for an administrative review of the injury: an expert committee is provided with the claimants' medical documents and has the authority to interview or examine the claimant. The compensation is determined through the use of standardized coding. It is only in the US that the deliberation of vaccine injury claims (when the "Injury Table" criteria described hereunder are not satisfied) resembles civil litigation: both the injured party and the Secretary of Health and Human Services are represented by lawyers and argue their case before a Special Master (Keelan and Wilson, 2011).

ity (disease with no other likely explanation) as the committee's medical experts must support their decisions with science.

The controversy regarding causation requirements was addressed in Israel by the committee appointed to discuss the health implications of allowing soldiers to dive in the Kishon river. This river had been contaminated by toxic sediments (from fertilizers, pesticides, urban waste and industrial deposits) for many years. Nonetheless, Israeli Naval Commando soldiers practiced diving in the polluted river and were sometimes even made to drink its water as a disciplinary measure. A high incidence of cancer was subsequently diagnosed among the divers. The committee appointed to investigate the case found that the data indicating higher rates of cancer among these divers did not demonstrate sufficient statistical significance and therefore concluded that there was no causal connection between diving in the Kishon and contracting cancer (Golan, 2010).

The minority opinion of Israel Supreme Court Chief Justice emeritus Meir Shamgar held that causation should be determined according to reason, logic and experience. Chief Justice Shamgar, who followed the legal guidelines pertaining to the 'preponderance of evidence,' argued that the proven fact that the divers were exposed to the toxic water was sufficient to establish a causal link between the exposure and their illnesses.

In 2004, Chief Justice Shamgar's minority opinion became a guiding judgement in the matter of Krishov v. Kibutz Maayan Zvi. Itzhak Krishov had worked at the Kibbutz's garage since 1972 and had been routinely exposed to asbestos. He was diagnosed with Non-Hodgkin's Lymphoma (NHL) in 1985 and attributed his illness to his continual exposure to toxic asbestos. The majority opinion in the Israeli Supreme Court was that the Court was authorized to examine the evidence according to either scientific guidelines or inductive reasoning pertaining to life experience and common sense. In this case, the court held that as it is well known that asbestos might cause cancer, and the claimant contracted NHL following his long-term exposure to asbestos, reason supports the assertion that there is causal connection between the exposure and the illness.

The US Court of Federal Claims addressed the burden of proving causality in vaccine injury cases and held that when a vaccine injury does not meet the 'Injury Table' criteria, the presentation of causation must satisfy the 'preponderance of evidence' standard, the same standard ordinarily used in tort litigation. However, claimants can meet the standard by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. If the claimant satisfies this burden, she is 'entitled to recover, unless the government shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.' The Court also indicated that, in finding causation, a fact finder may rely upon 'circumstantial evidence' rather than conclusive scientific evidence (Althen v. HHS, 2005; Hooker v. HHS, 2016).

Another possible way of determining causality in vaccine injury claims is the standard of 'proportional liability,' replacing the 'preponderance of evidence' rule. This standard would allow courts to impose partial liability despite the absence of

the 50+% probability criterion to determine a causal connection. The Israeli Supreme Court has adopted the standard of proportional liability in cases where a tortfeasor repeatedly places a group of injured parties at risk (Carmel Hospital Haifa v. Eden Malul, 2010; Rosenberg, 1984), but it may also be considered when implementing the Vaccination Victim Insurance Law - which was originally intended to facilitate claimants' access to compensation.

In addition to the above options for determining causality, Israeli legislators might also follow the U.S. National Childhood Vaccine Injury Act of 1986, according to which victims of vaccine-related injuries specified in the Vaccine Injury Table may receive compensation. The Injury Table presumes a causal link between the vaccine and the injury if symptoms manifest within the time period specified in the table. The injured party is thus not required to prove scientific causality in its specific case if its injury is specified in the table (Kramer & Gostin, 2011). To avoid undermining the public's perception of immunization safety, health authorities should clarify that these eligibility criteria are based on a possible association and do not confirm causality.

A precedent to the presumption of causal connection already exists in the Israeli Ringworm Victim Compensation Law. This law compensates people exposed to officially-administered radiation (as a treatment for ringworm) who later contracted one of the various diseases known to have a causal connection with radiation received in childhood. Here, too, the injured party is not required to prove causality. It should be noted, however, that the Ringworm Victim Compensation Law, like the Vaccination Victim Insurance Law, is a no-fault scheme legislated in order to assure compensation of victims of public health policy. The justification for establishing presumptions of a causal connection between radiation and certain diseases may thus also apply to certain injuries diagnosed following vaccination.[11]

Easing the burden of proving a causal connection between vaccinations and injuries by relying on reason, circumstantial evidence, proportional liability or presumptions of causality would certainly result in a higher percentage of compensated cases, which would, in turn, express the health authorities' willingness to acknowledge liability and their commitment to social justice.

11 Between 1949 and 1960, immigrants to Israel, many of them from North-American countries, were irradiated against ringworm (radiation was considered a mainstream treatment at the time). As a result of the X-ray treatment, the irradiated immigrants developed scars and malignant tumors. The Ringworm Victims Compensation Law was enacted in 1994. The objective of this Law is to compensate persons who were given radiation treatment by the State and, as a result have suffered one of the diseases listed in the Law's addendum. However, the Law was criticized as granting material reparations to individuals without acknowledging the symbolic social dimensions, without acknowledging liability by a public apology, and without giving victims the opportunity to come forward and present their stories (Davidovitch and Margalit, 2008).

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7 Conclusions

Trust in Health Authorities has been identified as a predictor of compliance with officially recommended protection measures (Gilles et al., 2011). However, laws designed to increase vaccination compliance usually impose sanctions against unvaccinated individuals (or their parents) and do not promote trust in policy-makers' recommendations.

The compensation of vaccination victims through a procedure that would express the health authorities' responsibility for the consequences of recommended vaccines and their commitment to caring for vaccine injury victims in the service of social justice would have the potential of promoting both the victims' and general public trust.

An adversarial procedure following torts law involves a confrontation between the victim and the health authorities and therefore fails to build trust. The deliberation of vaccine injury compensation should rather be carried out within the framework of alternative dispute resolution. However, compromise arrangements do not usually involve full information disclosure and the acknowledgement of liability, which are fundamental for building trust. Confidential mediation (though it may encourage disclosure and the acknowledgement of liability in specific cases) would not contribute to the promotion of collective trust. On the other hand, a public court hearing with disclosure obligations according to a no-fault law of compensation for vaccine victims has the potential to promote both the injured parties' and public trust in health authorities. The potential to promote trust would be satisfied if the wording and implementation of the law reflected the health authorities' willingness to acknowledge liability and their commitment to social justice. The trust gained by implementing a law of compensation for vaccine victims might thus increase the overall level of trust in the health authorities including the level of trust in their vaccine recommendations.

The Israeli Vaccination Victim Insurance Law was initially enacted to promote vaccination compliance (among other non-utilitarian justifications for compensation) without the imposition of sanctions. Unfortunately, the Law's wording and implementation do not fulfill its therapeutic potential to promote trust in health authorities, due to: the barriers to claim submissions, which include the informal requirement of supporting claims with an expert opinion; the prohibition of the submission of an additional tort claim; the adversarial proceedings; and the relatively low compensation awarded. In addition, denial of all claims submitted under the Law on account of insufficient evidence for a scientific causal connection between the vaccine and the injury do not allow the Health Authorities to express their commitment to the injured parties' welfare and to social justice.

A recognition of the Law's influence on public trust may encourage health authorities to implement the law in a more understanding and sensitive manner. For instance, cases should be adjudicated in an administrative procedure which would not subject the claimant to cross – examination by a lawyer representing the health authorities and the threshold for determining a causal connection between vaccine and injury would be lowered. In addition to a different imple-

mentation of the Law, Israeli legislators may consider amending the Law to include a simpler filing process, the option to submit a tort claim after a claim is administered under the no-fault scheme; and empower expert committees to compensate vaccination victims according to their actual needs.

As vaccine hesitancy is largely a product of distrust in the health authorities, efforts toward promoting vaccination compliance should focus on building trust between the health authorities and the public. The compensation of vaccination victims by way of a therapeutic procedure might thus be one step toward building this public trust.

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