Immunization in Light of Halacha: The Case of Viral Hepatitis B

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Background

Immunization programs

The Israeli Ministry of Health recommends that its residents be immunized against dangerous contagious diseases. according the recommendations of the advisory Committee Diseases and Vaccinations of Infectious Department of Epidemiology, and the policies of the Centers of Disease Control of the United States, Canada and Europe. As such, the Israeli National Health Insurance Act (1994) includes routine immunization as part of the health preventative services to which all residents are entitled. Although routine immunizations are not legally mandatory in Israel, but only strongly recommended, approximately 94% of the Israeli population adhere. Nevertheless, among segments of the population who do not frequent public health clinics, rates of immunization are considerably lower than average and what is more worrisome, on the decline. Of interest, in the United States and many other developed countries, adherence to the national vaccination protocol is a prerequisite for acceptance into the school system. ^{1,2,3}

The professional medical community considers the development of immunizations one of the greatest achievements in health care; it has prevented the spread of many deadly diseases effectively and efficiently. The first immunization, developed by Dr. Edward Jenner against smallpox in 1798, eventually eradicated the disease world-wide. The last recorded case was in 1977.⁴

Most immunizations prevent diseases highly prevalent in pediatric populations and are thus given at very young ages. They have nevertheless been

The immune suppressed infant in serious contraindicated effects

- are nevertheless protected due to "herd immunity" and co

found safe to administer even in newborns. Serious side effects are extremely rare and contribution to public health

is highly significant in disease prevention. Two cases in point: Immunization against hepatitis A begun in 1999 reduced prevalence of the disease by 90% in a short time. On the other hand, the temporary suspension of immunization against mumps in 1987-1988 quickly returned the rate of disease back to its former level (from 20 out of 100,000 to 160 out of 100,000). ^{5,6,7}

Under conditions in which the vast majority of the population is immunized, those not immunized – for

http://www.who.int/mediacentre/factsheets/fs288/en/index.html.

Weissblai A., The immunization program in Israel, 2008: http://www.knesset.gov.il/mmm/data/pdf/m01975

Rishpon S, Immunization protocol in Israel: where is it headed?, Aleph Bet Magazine for public health nurses, May 2009: pp. 3-33.

Omer SB, Salmon DA, Orenstein WA, deHart MP, Halsey NA, Vaccine refusal, mandatory immunization, and risk of vaccine preventable diseases in the United States, *New England Journal of Medicine*. 2009; 360(19) 1981-1988.

WHO (World Health Organization), Immunization against diseases of public health importance. The benefits of immunization, *Media Centre*, 2005, Available at:

⁵ Breitbart D., Immunizing children, a comparative view, Knesset, Center for information and research, 2004:

http://www.knesset.gov.il/MMMdata/docs/m00947.doc

State of Israel Ministry of Health, Sixty years of health in Israel, Israel Center for Disease Control, Publication 316, December, 2008: http://www.health.gov.il/Download/pages/60_eng.pdf

Amitai Y., Slater P., Leventhal A., Immunization in the 21st century: effectiveness, safety and the case against, Department of Public Health – mother, child and adolescent/ epidemiological unit, June 2004: http://www.knesset.gov.il/MMMdata/docs/m00947.doc

example the immune suppressed infant for whom immunization is contraindicated – are nevertheless protected due to "herd immunity". This phenomenon occurs because of the relatively small number of individuals left to harbor and transfer the disease. If the rate of the immunized individuals, however, falls below below the critical level, due for example to a decrease in adherence or an influx of immigrants harboring the disease, epidemics are apt to erupt. A case in point: In 2000 the rate of individuals immunized against pertussis declined considerably, resulting in a 500% increase in prevalence. ^{8,9,10}

Studies, accumulated over the past decades have provided robust scientific evidence for immunization safety. ¹¹ Despite the data, there are individuals who have reservations about the safety and advantages of

immunizations as a whole, with respect to the optimum time for their administration, or regarding which populations should be included (*i.e.*, only those at high risk for contracting the disease). Some are opposed

due to their belief in the power of the body to heal itself and the preference for this natural process over "artificial" means of healing. A correlation was in fact found between those seeking healthcare from complementary and alternative medicine practitioners and refusing immunizations. ¹² Others are opposed because they fear that immunizations are harmful or are looking for a simple explanation for their child's otherwise unexplainable ill health. A case in point is

the United Kingdom, following research that attempted to implicate this vaccine as being causally related to autism. Although the prestigious medical journal in which the study appeared eventually retracted it and despite the fact that the research was proven to be fraudulent, fear lingers on as does the groping for pat explanations for mishaps. Autism activist groups still maintain there is a connection. In a similar vein, consumers have fallen prey to unsubstantiated internet and other media claims regarding the toxicity of certain stabilizers and preservatives contained in immunizations. It is remarkable that today's parents have for the most part not been exposed to the diseases for which immunization exist, and thus have no first hand

the MMR (measles, mumps, rubella vaccine) scare in

knowledge regarding the devastation they can wreak. 16 Another perhaps partially legitimate concern is the inadequacy of information given to parents with respect to the serious

potential side effects, regardless of how rare; this is perceived by some as a violation of parents' rights to informed consent and true autonomy in decision making, as put forth on the Patients' and children's bill of rights. ^{17,18,19} In a large study done by Maayan Metzger *et al.* ²⁰ of post-partum women in Israel the study group opposing immunizing newborns against

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which immunization exist, and thus

have no first hand knowledge regarding

the devastation they can wreak

Barak A., Background document for the discussion of child immunization. The committee for the promotion of child welfare; 2000: http://www.health.gov.il/download/pages/zihumiyut 20.pdf

Vaucher P., Designing phase III or IV trials for vaccines: choosing between individuals or cluster randomized trial designs, *Vaccine*, 2009; 27(18):1928-31.

Mei-Ami N., Background document for the discussion of child immunization. Committee for children's rights, Knesset Center for information and research, 2004: http://www.knesset.gov.il/MMM/data/docs/m00844.doc

Maayan-Metzger A, Kedem-Friedrich P, Kuint J, To vaccinate or not to vaccinate – that is the question: why are some mothers opposed to giving their infants hepatitis B vaccine?, Vaccine, 2005; 23(16):1941-1948.

http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html#2
 Downey L, Tyree PT, Heubner C.E., Lafferty W.E. Pediatric vaccination and vaccine preventable disease acquisition. *Maternal Child Health* 2010; 14(6): pp. 922-930.

Wakefield AJ, Murch SH, Anthony A, Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children, *Lancet* 1998; 351:637-641

Editorial: Wakefield's article linking MMR vaccine to autism was fraudulent

http://www.myfoxboston.com/dpp/morning/vaccine-autism-link-newinvestigation-20110511

Kennedy, A, Brown, C, Gust, D, Vaccine Beliefs of Parents who Support and Oppose Mandatory Vaccination. *Public Health Reports*, 2005; 120:252-258.

Hak E ,Schonbeck Y, Demelker, H VanEssen, GA, Saunders EA, Negative attitude of highly educated parents and health care workers toward future vaccinations in the Dutch childhood vaccination program, Vaccine, 2005; 23:3103-7.

Gullion JS, Gullion G, Deciding to opt out of childhood vaccination mandates, *Public Health Nurse*, 2008; 5(5):401-408.

Salmon DA, Moulton LH, Omer SB, Dehart MP, Stokely S, Halsey NA, Factors associated with refusal of childhood vaccines among parents of school-aged children: a case-control study, *Archives of Pediatric Adolescent Medicine*, 2005; 159(5):470-6.

²⁰ See note 11 *supra*.

viral hepatitis B was significantly older (on the average of two years), better educated (on average of 2 years additional education) than the compliant control groups. The percentage of opposed women also reported higher incomes than controls (92% above average income as opposed to 63% above average, respectively). Reasons cited for opposition were both the trauma of the injection and the potential danger of immunizing so early in life.

Viral hepatitis B presents a global health danger; about 350 million people are chronic carriers of the disease. 21 In the Middle East 3% to 5% of the population are carriers, placing the region in an intermediate level of endemicity; ²² in 1992, between 2% and 2.5% of Israeli residents were carriers. 23 The said virus is found in blood and bodily secretions and is easily transmitted through contact, including contaminated needles (common in drug users). It is, in addition, transmitted sexually and prenatally through the placenta, the latter accounting for 30 to 50 percent of cases of disease contraction globally.²⁴ It is remarkable that although there is similarity in the channels through which hepatitis B and HIV viruses are transmitted, hepatitis B is 50-100 folds more contagious, as assessed by the United States Center for Disease Control.

Hepatitis B virus, which multiplies in the liver, can cause a carrier state without creating awareness in the carrier himself. It may also create an acute disease state (after an incubation period of a few months' time) that is often accompanied by fever, weakness, pain, nausea and vomiting, anorexia, rash and jaundice. It is nevertheless remarkable that in children especially, even the acute disease state may be present

Hepatitis Central, 2009. Available at: http://www.hepatitis-central.com/hbv/hepbfaq/intro.html

without signs and symptoms.²⁵ Approximately 5 to 10% of those acutely ill will develop chronic manifestations, resulting in cirrhosis and hepatic cancer; 620,000 individuals around the globe die each vear from these diseases. ²⁶ Hepatitis B chronic disease leads to a heavy economic toll in terms of medical care, work absenteeism and shortened life span. In infants, although acute disease is rare, 90% of acute will progress to chronicity, a significantly higher percentage than among adults.²⁷ A prospective study conducted in Taiwan revealed that 25% of infants and children that contracted viral hepatitis B eventually died of cirrhosis or cancer. ²⁸ Although it is possible to diagnose different manifestations of the disease via serological markers, antibody/antigen and HBV-DNA levels, and liver function tests, ²⁹ treatment options are only partially effective. In most cases, the viral multiplication process is slowed down; cure is not achieved. 30,31 All these conditions make immunization, and at a very early age, vitally important.

The vaccine against viral hepatitis type B

The natural form of the vaccine came into use in the 1970s; this gave way in the end of the 1980s to a genetically engineered vaccine produced from viral particles. The latter is cheaper, prevents the

Pyrosopoulos NT, Rajender K, Hepatitis B, emedicine. Jan 19 2009. Available at:

http://emedicine.Medscape.com/article/177632-overview

Ginsburg GM, Shouval D, Cost-benefit analysis of a nationwide neonatal inoculation program against hepatitis B in an area of intermediate endemity, *Journal of Epidemiology and Community Health*, 1992; 46(66):587-594.

Lee C, Gong, Y, Brok J, Boxall E H, Gluud, C, Effect of hepatitis B immunization in newborn infants of mothers positive for hepatitis B surface antigen: systematic review and meta-analysis, *British Medical Journal*, 2006; 332 (7537):328-336.

Mast E, Margolis H, Fiore A, Brink E, Goldstein S, Wang S, Moyer, L, et al., A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States. Recommendation of the advisory committee on immunization practices part I: Immunization of infants children and adolescents, Morbidity and Mortality Weekly Report, 2005; 54/RR-16:1-39. Available at:

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416al.htm

Implementation of newborn Hepatitis B vaccination-worldwide, 2006, Morbidity and Mortality Weekly Report, Nov 2, 2008 57(46) 1249-1252. Available at:

http://www.cdc.gov/mmwr/preview/mm5746a1.htm

McMahon, BJ, Alward, DB, Hall D, Heyward W, Bender T, Francis D, Maynard J, Acute hepatitis B virus infection: relation of age to the clinical expression of disease and the subsequent development of the carrier state, *Journal of Infectious Diseases*, 1985; 151:599-603.

Poland GA, Jacobson RM, Prevention of hepatitis B with the hepatitis B vaccine, New England Journal of Medicine, 2004; 351 27:2892-2841.

²⁹ See notes 17 and 21 *supra*.

Hoofnagle, JH. Hepatitis B- preventable and now treatable, New England Journal of Medicine, 2006; 354: 1074-1077.

Agganwal R, Ranjan P, Clinical Review: preventing and treating hepatitis B infection, *British Medical Journal*, 2004; 329(6): 1080-1086.

possibility (remote as it may theoretically be) of contamination from plasma, 32 and achieves higher levels of antibodies. 33,34 Both forms are however, at least 95% effective in preventing hepatitis B.35 The recommendation of the World Health Organization (adopted by 160 nations in 1997, and over 171 by 2005) is universal immunization of the population via three separate vaccines administered in infanthood. Countries in which the disease is endemic are recommended to give the first vaccine in the series as close to birth as possible, with the next two being administered after 1-2 months and at 6 months, respectively. 36 In countries where immunization was habitually practiced, rates of disease decreased by 70% over about a decade.³⁷ Israel adopted universal immunization in 1992. It is remarkable that during the previous decade, in which only populations at risk (i.e., health personnel, drug users) were immunized, success in lowering disease rates was not achieved.38

A meta-analysis conducted by Lee, Gong, Brok, Boxall and Gludd³⁹ revealed that immunizing newborns in the United States lowered the risk of contracting the disease by 72% (O.R. 0.28 (CI: 0.4-0.2) and the incidence from 8.2 out of 100,000 in 1990 to 2.1 out of 100,000 in 2004.⁴⁰ In Israel, the incidence dropped from 2.8 in 1992 to 1.2 in 2004. On the other hand, in Britain, a country that has to date not adopted universal immunization of newborns, there was an upward trend of disease incidence – from 1 to 1.5 cases in 100,000.⁴¹

MacGregor I, Screening assays for transmissible encephalopathies (TSEs), Vox Sang 2004; 87:(suppl 2): 3-6. There is great importance in immunizing newborns, preventing them from contracting the disease from carrier moms during the perinatal period. As has been noted the younger the age of acquiring the disease, the higher the chance that it will become chronic. Immunizing at the start of life also diminishes the reservoir of potential carriers and their ability to infect others in the future.⁴² The immune status achieved with immunization lasts a long time, some claim for life.⁴³

The United States Center for Disease Control recommends screening pregnant women for viral hepatitis B as part of their routine prenatal care. Newborns of woman found to carry the virus in the screening procedure are moreover, recommended to receive (in addition to the active vaccine!) HIBG (Hepatitis B immunoglobin) to induce passive immunity. 44 Israel did not adopt this policy because most female carriers have a combination of Anti-HBe antibodies and low HBV-DNA viral loads. In this situation, giving active immunization is effective protection in 95% of the cases without HIBG. Screening compounded with administering passive immunization significantly increase costs, and in this case would not be economically justifiable. At this point, Israel's policy with respect to immunizing against the virus has been determined to be costeffective on the basis of an epidemiological study predicting a 40 year period. Preventing disease is 2.8 times cheaper than treating those that are anticipated to contract the disease and paying for lost work hours and decrease life span; the savings are estimated to be in the millions of dollars. 45 These figures do not take into account variables that are difficult to quantify, such as stress, pain, and anguish of the sick and their families. They also do not relate to the saving that will accrue from diminished population screening

³³ See note 24 *supra*.

Liu Y, Liu X, Kuang J, Comparing immunogenicity and efficacy of two hepatitis B vaccines in newborn infants of hepatitis B surface antigen (+)/ hepatitis B antigen (+) carrier mothers (abstract only), Zhonghua fu chan ke zazhi, 1999; 34(8); 470-2.

³⁵ See note 28 *supra*.

³⁶ WHO, Immunization, Vaccines and Biologicals, Hepatitis B, 2009. Available at:

http://www.who.int/immunization/topics/hepatitis_b/en/index.html

³⁷ See notes 31, 32, 33 *supra*.

See note 26 *supra*.

See note 24 *supra*.

⁴⁰ See note 25 supra.

Diseases warranting reporting: 54 years of monitoring, 1951-2004, available at:

http://www.health.gov.il/download/pages/zihumiyut20.pdf

⁴² See note 25 supra.

⁴³ See note 31 supra.

Center for Disease Control, Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination recommendations of the immunization practices advisory committee (ACIP), Morbidity and Mortality Weekly Report, 1991; 40 (no. RR_13):1-19. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm.

⁴⁵ See note 23 *supra*.

over time once immunizations are universal for newborns. 46 Evidence for cost – effectiveness of universal immunization has emerged for other countries with intermediate levels of endemicity. 47

Over 500 million individuals world-wide have been immunized against the virus and aside from short-lived inflammation at the injection site and fever side effects were very rare. There have been only isolated cases of anaphylaxis, with a rate of 1 to 1.1 million, none of which resulted in death.⁴⁸ There were reports of reversible neurological problems at a rate of 5 to 100,000 occurring shortly after the immunization; no causal connection between the two events was evident.⁴⁹

Due to the concern that was raised with respect to a connection between the hepatitis B vaccine and demyelinating nervous diseases, a special committee appointed by the United States Institute of Medicine carefully reviewed the relevant research conducted up to the year 2002, and concluded that the evidence points to the lack of causality between immunization and the outbreak of multiple sclerosis or its relapse. ⁵⁰

Among the studies reviewed was the well-known Nurses Health Study conducted in 2001;⁵¹ it spanned two generations of hundreds of thousands of nurses in ten different American states, relating to varied health measures. One hundred and ninety nurses diagnosed with multiple sclerosis by their physicians

English, P, Should universal hepatitis B immunization be introduced in the UK?, Archives of Diseases in Children, 2006; 91:286-289.

and Posner's criteria⁵² were identified. Each one of these was in turn matched with six others, similar in terms of socio-demographic data, to make up a control group. One out of the six chosen for the latter group was diagnosed with cancer; this neutralized the bias which may result from a tendency of healthy individuals to forget health related data (including immunizations). Nurses were asked whether they were immunized against hepatitis B; positive responses were checked against medical records and negative ones were taken at face value. It is remarkable that the subject response rate ranged between 88% and 95% and variables that may have impact on contracting the illness such as geographic location and ethnicity were controlled for in the statistical analysis. No connection was found between immunization and subsequent outbreak of multiple sclerosis.

A few years after the Nurses Health Study, Milkaeloff *et al.* studied 143 children diagnosed with multiple sclerosis tracked down via nation-wide French treatment centers. ⁵³ As almost all cases in the country are treated within this medical framework, these children for all practical purposes made up the entire target population. The control group consisted

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of 1122 children, nationally and randomly selected and matched in terms age, gender, family status, and geographic location. The research spanned 7 years and examined the risk of

contracting multiple sclerosis from 6 months to 3 years (at different points of time) and a lifetime after immunization. Only children whose immunization records could be located for self report verification of

⁴⁷ Aggarwal R, Ghoshal UC, Naik SR, Assessment of cost effectiveness of universal hepatitis B immunization in a low-income country with intermediate endemicity using the Markov model, *Journal of Hepatology* 2003; 38:215-22.

⁴⁸ See note 20 supra.

Shaw FE, Graham DJ, Guess HA, Milstein J, Johnson J, Schatz G, Hadler S, et al., Post marketing surveillance for neurologic adverse events reported after hepatitis B vaccination – Experience of the first three years, American Journal of Epidemiology 1988;127:337-52.

Stratton K, Almario D. McCormick, MC. Eds. Safety review committee. Immunization safety review: Hepatitis B vaccine and demyelinating neurological disorder – Executive summary, *Institute* of Medicine, 2002. Available at: https://www.nap.edu/catelog/10393.html.

Ascherio A, Zhang SM, Hernan MA, Olek MJ, Coplan PM, Brodovitz, K, et al., Hepatitis B vaccination and the risk of multiple sclerosis, New England Journal of Medicine, 2001; 344:327-32.

Poser CM, Patty DW, Scheinberg, L, McDonald WI, Davis FA, Ebers GC, et al., New diagnostic criteria for multiple sclerosis-guidelines for research protocols, Annals of Neurology, 1983; 13(3):227-231.

Mikaeloff Y, Caridade G, Rossier M, Samy S, Tardieu M, Hepatitis B Vaccination and the Risk of Childhood-onset multiple sclerosis, Archives of Pediatric Medicine, 2007; 161(12):1176-1182.

immunization for hepatitis B were included in the study; no differences, however emerged, between this group and those for whom there was no verification and were therefore excluded from the study. Statistical analysis controlled for the presence of other risk factors such as autoimmune disease and a family history of multiple sclerosis. No correlation was found for any of the time periods between immunization and contraction of the multiple sclerosis.

It is remarkable that in not a single one of the empirical studies conducted to date, did any connection emerge between newborn immunization and mortality or morbidity. In the research conducted by Erickson *et al.* in 2004, causes of mortality at age 29 days was examined in 350,000 newborns; no difference was found between those immunized and those not immunized against hepatitis B. ⁵⁴

Lewis *et al.* compared 3302 immunized newborns with 2353 that had not received the vaccine, with respect to adverse reactions of fever, septicemia (and rule out work up), allergic reactions and neurological disturbances for 21 days after birth. No differences were found between the two groups except that rates for sepsis workup were higher for those not immunized.⁵⁵

II. Introduction to Halachic Considerations

1. The obligation to care for one's health and that of one's child

Every individual is *halachically* obligated to preserve his own life. This derives from *Deuteronomy* 4:15: "Take good heed to yourselves (*V'nishmartem meod l'nafshotachem*)…"⁵⁶ and from *Deuteronomy* 4:9: "Only take heed to thyself, and keep thy soul diligently (*Hishamer lechah u'shmor nafshechah*

Erikson EM, Perlman JA, Miller, A, Marcy SM, Lee H, Vadheim C, Lack of association between hepatitis B immunization and neonatal death: a population based study from the vaccine safety datalink project, *Pediatric Infectious Diseases Journal* 2004;23(7):656-62.

meod)..."⁵⁷ Although on face value these verses refer to spiritual preservation, e.g., refraining from idolatrous practices, Chazal additionally attribute to them an admonition against endangering one's physical existence.⁵⁸ In a similar vein, Ralbag in his commentary on Proverbs (23: 13) "Don't withhold reprimand from your child, if you punish him with a rod he will not die" (translation, c.g.), purports that this verse refers not only to parents' responsibility for their child's spiritual welfare (even at the expense of inflicting temporary pain) but also for their physical wellbeing - protect your child's existence in this world from premature death, so that he may live to earn the world to come, explicates Ralbag. Vaccinating children in their youth underscores this interpretation. Rabbi Tzvi David Hoffman (Responsa Melamed L'Hoeel 2: 104) responds to a case in which parents, on "behalf" of their child, refused a surgical procedure necessary to save his life with the following categorical statement: We have not found anywhere in the Torah that a mother or father has the right to endanger their child's life and deprive him of indicated medical care.⁵⁹

The religious obligation to embrace health care is circumscribed to evidence based treatment, proven effective and safe by scientific research as recognized as such by the professional medical community. *Tosfot Yom Tov (Mishna Yoma* 8:6), (*Mishna Yoma* 8:4), and *Shulchan Aruch (Orach Chaim* 301: 80) connote "refuah bedukah", or "refuat mumchim" as

Lewis E, Shinefield HR, Woodruff BA, Black SB, Destefano F, Chen RT, Ensor R, Safety of Neonatal hepatitis B vaccine administration, Pediatric Infectious Diseases Journal 2001; 20:1049-54.

Unless stated otherwise, biblical translations taken from Koren's, The Jerusalem Bible, Jerusalem 1982.

Rambam actually derives from *Hishamer lechah u'shmor nafshecha meod* the responsibility an individual has to protecting the life of fellow man. In *Hilchot Rotzach u'Shmirat Hanefesh*, he brings this *pasuk* as an additional proof text to *lo taamod al dam raiacha* for the obligation of fencing in one's roof, covering up an open pit and removing other dangerous pitfalls on one's property (See *Sefer Assia* vol. 5, p, 238, footnote 7, editor).

The Talmud in Tractate Berachot (32: 2) tells of a pious man who refused to stop in the middle of his prayer in order to greet a member of the royalty. The latter used these biblical texts as proof that the man did not act in accordance with halacha. Minchat Chinuch raises the possibility that there was an oral tradition regarding the relevance of these texts to protection of one's physical existence.

This response was rendered as a reply to a query regarding performing surgery on a child, minimally endangering the child's chayai shaah, but giving him a very good chance for chayai olam. In the case of immunizations, there is miniscule endangerment of chayai shaah for almost complete guarantee of chayai olam vis-à-vis the particular disease.

being *halachically* binding.⁶⁰ They define these as treatments that are both rational and clinically successful. Immunization protocols, as we have seen, certainly fall into this category.

Historically, halacha first related immunizations in the late 18th century, in the wake of a pandemic outbreak of smallpox decimating 30% of the world's population. Dr. Edward Jenner, as will be recalled, succeeded in developing a vaccine against the deadly virus. The vaccine harbored a mortality rate of 1 in 1000. Rabbi Israel Lifshitz (author of the Tiferet Yisrael commentary on the Mishna) perceived Dr. Jenner as one of the saints of the nations.⁶¹ Although there was ostensibly a halachic issue regarding the vaccine in light of its risks, Rabbi Lifshitz and most of the poskim of that generation, deemed it obligatory to immunize. He makes the following case (Mishna Yoma 47: Boaz 3): Even though the vaccine causes 1 in 1000 to die, smallpox itself is a much greater and more immediate risk; one is permitted to take a smaller risk in order to avoid a greater one. 62 Rabbi Abraham Nansich, who himself lost two children to smallpox, perceived the discovery of the vaccine as divinely inspired. In his discourse entitled Aleh Terufah (Leaf of Healing) he writes:

Due to God's great mercy on his creation, he put a stop to the destruction of life by inspiring the physicians of the era with the wisdom to discover a treatment entailing almost no danger...

Aleh Terufah 1a

One in 1000 deaths is considered a negligent number when taking into account the great benefits... whoever avails himself of the vaccine it will not be considered a sin but rather a fulfillment of the mitzva *v'nishmartem meod l'nafshotachem*...

Aleh Terufah 6a

Rabbi Nansich *halachically* categorized the child living in the shadow of the smallpox plague as a *Choleh Shebefanainu* – in a sense, already ill – due to the near and present danger of contracting the deadly virus (*Aleh Terufah* 6a). This confers on the child the *halachic* status of *Pikuach Nefesh*. ^{63,64}

It must be emphasized that the accompanying immunization in the 1800s were of much greater magnitude than those of the 21st century. As will be recalled, significant adverse effects of the immunization against hepatitis B are at a rate of one case to 100,000, with no morbidity. Truth be told, the odds of contracting this virus in Israel are significantly lower (prevalence is 2% population) than getting smallpox in the 1800s. Nevertheless, Situations in which increasing numbers of individuals, lulled into a false sense of security due to low prevalence of a given disease, refrain from immunization are, moreover, potentially dangerous. Low disease prevalence is due to the immunization of a high percentage of the population. The "herd immunity" that results breaks the chain of contagion. If the number of individuals immunized falls below the critical mass, dangerous epidemic may ensue.

Talmud tractate *Shabbat* (32a) teaches that an individual should always refrain from presence in a dangerous place, asserting that surely a miracle will occur for me. If a miracle does occur, it will be deducted from the bank of merits the individual can draw upon. A person should not rely on a miracle for two reasons: the miracle may not materialize, and if it does, it would still have been proper not to evoke the

In footnote 16, commentating on the *Bartenurah*, who rules that it is forbidden to feed someone bitten by a dog from its liver, even though he is in danger, because the treatment is not considered effective.

⁶¹ Eisenberg, D, MD, "The Ethics of Smallpox Immunization", 2009. Available at:

http://www.aish.com/ci/sam/48943486.html

These words were said in reference to a question that arose regarding whether is was permissible to undergo treatment that could potentially result in death for a good chance at gaining chayai olam.

Nansich A., Aleh Terufah, London:1785, Rare Book Room, Jewish Theological Seminary Library, cited by Prouser, J., Compulsory Immunization in Jewish Day Schools (Accessed 2009):

http://mysite.verizon.net/bizeg2z8/Teshuvah%20Vaccine%20Policy.pdf Reichman, E., *Halachic* Aspects of Vaccination. *Jewish Action online, Magazine of the Orthodox Union* (Accessed 2009): http://www.ou.org/index.php/jewish_action/article/46479

Dr. Edward Reichman, *Medical and Jewish Law*, Chapter 12, pp. 163-176; Dr. Edward Reichman, The Impact of Medical History on Medical Halacha (Accessed 2009):

http://www.yasharbooks.com/medjewlaw.pdf

Rabbi Yehuda Eizenstein, in the *Encyclopedia Otzar Yisrael*, s.v. *Abaabuot*, relates that in the city of Hag in Holland some rabbis were indecisive with respect to vaccinating against smallpox, as it was something new their forefathers had not even imagined as a possibility. It was in response to this that Rabbi Nansich wrote his book.

need for a miracle but guide one's actions by natural processes. Maimonides, in *Hilchot* Rozeach U'Shmirat Hanefesh iterates that the sages prohibited many things because they endanger life and that whoever violates this prohibition by endangering himself or fellow man is punished with Makot Mardut (stripes for being rebellious). Maimonides clarifies that lest we erroneously claim that harming ourselves is no one else's business, it is, firstly, a serious transgression and secondly, a matter not only for the heavenly Beit Din, but also the terrestrial one. Shulchan Aruch (Choshen Mishpat 427) cites examples of things from which one is obligated to refrain because they are dangerous. Specifically with respect to contagious diseases, Rema in the name of Bet Yosef (Yoreh Deah 116) obligates one to flee a city stricken by a "plague". These words were written before immunizations were discovered; it is safe to assume that Shulchan Aruch would have substituted the obligation to flee with the obligation to immunize as a superior act, given the fact that the nature of contagious diseases is to spread geographically.

Halacha requires that a person avoid risk even when its odds are small. Tractate Chulin (10a) sites the following principle from the Braitah: "One must be more stringent with respect to avoiding danger

than transgressing prohibitions". With respect to the latter, one may assume the outcomes of the majority of cases, not so with respect to mortal danger (Tractate *Yoma* 44b). The Talmud

Even if an individual is not part of a population at risk to contract a certain disease for which a safe and effective vaccination is available he is nevertheless obligated to be immunized

(Chulin 9a) offers a case in point for illustration: A wolf took the intestines of a ritually slaughtered animal and subsequently returned them punctured, the animal maintains its Chezkat koshrut and is not designated as a treifah due to the remote possibility that a hole was present in the animal prior to the Shechitah and went unnoticed. On the other hand, if a bird pecks a hole in a date or a mouse in a watermelon, the fruit is forbidden, due to the

possibility, however remote, that there was already a prior hole made by a snake, rendering the fruit potentially dangerous. Saving oneself or fellow man from danger moreover, is obligatory even at the expense of transgressing the commandments (excluding murder, idolatry, or cardinal sexual prohibitions). In this vein, it is remarkable that Rabbi Shlomo Zalman Auerbach permits immunizing on Shabbat (a Rabbinic transgression) in a case where the next opportunity to immunize is far off, and withholding the vaccine presents a danger, even remote, to life.⁶⁵

It follows that even if an individual is not part of a population at risk to contract a certain disease for which a safe and effective vaccination is available he is nevertheless obligated to be immunized. If we take the case of hepatitis B, although odds are small, it is possible for anyone in the general population to be pricked with a needle or to receive a blood transfusion contaminated with the virus.

An argument may ostensibly be made in favor of declining immunization as in cases where danger exists on both sides, being passive, e.g., refraining from immunizing is preferable to taking an action. One should perhaps let nature takes its course; perhaps this is even a fulfillment of Tamim tihiyeh im Hashem Elohecha (Deuteronomy 18:13). The Rabbis, however, in fact perceive this verse as prohibiting acting on farfetched scenarios that defy nature.* This certainly does not include immunizing against potentially fatal endemic diseases, especially when requested to comply with routine protocols established by a reputable medical body.66 In the case of adhering to immunization schedule there is the additional fact that the individual is not seeking out the treatment, the initiation is coming from the authorities; certainly there is no lack of t'mimut on his part.⁶⁷

Minchat Shlomo IV 29:2; Minchat Shomo Taninah (2-3): 37; cited by Nishmat Avraham (Orach Chaim 328:17- new edition).

Shemirat Shabbat K'Hilchata, chapter 32, footnote 2.

^{*} Ignoring danger is compared in halacha to closing one's eyes to reality (Rav Moshe Feinstein, Iggerot Moshe, Even Haezer 4:10). [Editor's Note]

Rabbi Menashe Klein, Responsa Mishna Halachot, Part 5, 232.

⁶⁷ See: Bar-Ilan Y, Medical Screening for early detection of disease – Halacha and Hashkafa, Assia; 2010:85-86:12-30.

Rabbi Joshua Neurwirth is of the opinion that every effort should be made to convince an individual to abide by the immunization routine, short of compelling him. *Halachically*, it is necessary to give weight to a person's subjective perception of vaccine danger, even if not upheld by scientific evidence. If however, an epidemic breaks out, immediately endangering the public of which the individual is a part, mandating immunization would be the appropriate *halachic* action for the authorities to take. 68

With respect to the immunization against hepatitis B specifically, there is the extra consideration that it is given to a newborn baby. In cases where it is known

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that the mother is not a carrier of the disease nor is she part of a population at risk, would it be halachically proper to postpone the vaccine at least until the age of 30 days, when the baby sheds the status of a nefel? Evidence demonstrates the vaccine to be just as safe for newborns as month old babies. Furthermore, it is impossible to predict when an infant could be exposed to the virus. Some maternal carrier states are

missed, in which case newborns may already be infected. If these are taken into consideration, the chances of contracting the disease are greater than the chances of developing a serious side effect from the vaccination. newborn An important consideration is the difficulty in keeping track of immunized and not yet immunized infants. Once they leave the hospital, chances are much greater that babies will slip through unimmunized. For all these reasons, there is no halachic justification for postponement.

2. The obligation of the individual to share in safeguarding public health

In addition to the obligation to protect the health of self and one's children, is the obligation to protect

the community, to the extent possible. The Torah mandates that one fence-in his roof (those on which it is customary to walk on), lest we indirectly cause the shedding of blood of one who falls off. Rambam extends this prohibition to include creating any situation that endangers the lives of other individuals (Hilchot Rozeach U'Shmirat HaNefesh Additional commandments relate to proactively saving others already in a dangerous situation, such as Tuchal L'Hitalem (Deuteronomy 22:3). V'Hashavotah lo (Deuteronomy 24:2) and the prohibition against standing by idly while another individual's blood is being spilt (Leviticus 19:15). The latter commandment mandates the exertion of both

> monetary and physical effort (Tur, Choshen Mishpat 426). Immunization, an act through which an individual prevents himself from becoming a potential carrier of a contagious and serious disease, is subsumed under these certainly

> criteria.

There are differences of opinion among the poskim with respect to the extent to which one is to endanger

himself for the sake of another. 69 Kesef Mishneh in the name of Hagahot Maimoniot (Hilchot Rotzeach U'Shmirat Hanefesh 1:14) brings the Yerushalmi's vantage point: an individual is obligated to expose himself to potential danger in order to save a fellow man who is in clear danger. 70 The Radbaz (Responsa 3a 52:527) is of the opinion that one is obligated only to incur the level of danger for his fellow's life as he would be willing to incur for his livelihood. In this regard, Chafetz Chaim (Mishna Berurah 329: 19) admonishes us not to be overly protective of ourselves, lest by doing so we bring upon ourselves a situation where the shoe will be on the other foot, so to speak, and our fellow will be overly cautious and refrain from saving us. Rabbi Unterman (Shevet

Eisenberg, D. The ethics of the smallpox immunization - a Jewish perspective on the controversial issues surrounding immunization (Acessed: 2009): http://www.aish.com/ci/sam/48943486.htm

Steinberg, A., Encyclopedia of Halacha and Medicine, 2006 s.v. Sikun Atzmi, pp. 746-end.

Yerushalmi Terumot relates the story of Rav Issi who was captured by pirates. Raish Lakish decided to try to save him, affirming, either I will kill the pirates, or I myself will be killed.

M'yehudah 1: 99) and other poskim are of a similar opinion. Immunizations, including the hepatitis B vaccine, pose only a miniscule threat; an individual is therefore halachically obligated to incur it in order to protect others and the public.

Responsibility for avoiding endangering fellow man is perhaps even more demanding than responsibility toward oneself. In this vein, *Avnei Nezer* (*Orach Chaim* 454:2) states that a person is permitted to travel to a place where some small danger ensues in order to perform a *mitzva*, and rely upon the promise of *shluchei mitzva einam nizokin*. One may not, however, endanger someone else under the guise of this promise. It is therefore prohibited to circumcise a child even if minimal danger is present.

Criteria for what categorizes danger as *Pikuach Nefesh* on a communal level, is more stringent than with respect to a single individual. An illustration of

this principle is found in *Tur* (*Yoreh Deah* 178): Those politically well-connected with hostile authorities are permitted to transgress Torah commandments in order to save the community from

A member of a community has to contribute to meeting its needs, regardless of whether he personally derives direct benefit

future danger (even if not currently present which would be the criteria for transgressing a *D'oraitah* for an individual). Another case in point is the permissibility to extinguish a burning coal in the public domain in order to save the possessions of the public (Tractate *Shabbat* 42:22, Rav Hai Gaon). Violating the Sabbath in this manner is prohibited with regard to possessions of individuals.

A threat, even minimal, of an epidemic to the public is certainly an issue of *Pikuach Nefesh*. The danger must *halachically* be reckoned with; everyone is obligated to do his share to prevent it from occurring. *Tosfot* (Tractacte *Bava Kama* 22b) brings evidence for the greater accountability expected from an individual regarding public danger. The *Mishna* relates a case of a dog that takes into his mouth some pastry together with a hot coal and subsequently sets a barn on fire. The dog's owner is obligated to pay the

full expense of the pastry but only half that of the barn. The Talmud asks why the "owner" of the coal is not fined for not watching over it so that the dog could not grab it. *Tosfot* purport that because the Talmud does not ask a similar question with respect to the owner of the pastry we can infer that greater precaution is expected from an individual regarding things that can be dangerous to the public than cause damage to a sole individual.

Individual responsibility for community manifests itself in another dimension. Immunization in Israel, as will be recalled is not legally mandatory. Most individuals comply, as they trust in the professional medical community. Individuals not compliant with the recommended protocols can undermine this trust and in the long run cause an epidemic. Individuals most at risk for contracting hepatitis B, tend to belong to the lower socio-economic and undesirable echelons of society. If sufficient individuals from the general population refuse immunization, they might likely follow suit, in order to avoid stigmatization. It will be recalled that immunizing only at risk populations was unsuccessful in keeping the disease at bay; universal vaccine was necessary.

An additional consideration regarding individual adherence to vaccination protocol is the moral spuriousness of enjoying herd immunity without contributing to it. To reiterate, vaccinations are safe, causing only minor discomfort, easily accessible, fear of charge, and halachically imperative. There are, moreover, populations such as the immunesuppressed for whom immunization is contraindicated. They rely on the rest of the community to bolster herd immunity and provide them an umbrella of protection. This thus becomes a fulfillment of V'Ahavta l'raiacha kamocha (Leviticus 19:18) and V'chai achicha imach (Leviticus 25:36). Vaccinating is also a declaration of social solidarity and thus fulfillment of Lo tifrosh min hatzibur (Avot 2:4) and collective responsibility embodied in kol yisroel aravim zeh l'zeh.

3. Governmental responsibility and authority to implement vaccination protocols

The commandment of eglah arufah singles out the responsibility of the elders of the community for the wellbeing of its members. In order to abscond themselves of guilt for the death by unknown cause of an individual, they must aver that they did all in their capacity to prevent the mishap. Chazal include a safe environment for travelers within the area of their jurisdiction, food, drink and an escort as necessary. The specific commandment of eglah arufah is not halachically applicable today. Nevertheless, one modern expression of the latter is governmental responsibility to protect its residents against contagious diseases via immunizations. Lest we question the legitimacy of the Israeli government (not a monarchial theocracy) to enforce compliance with its stipulations, suffice it to bring to bear Rav Kook's categorical affirmation in Mishpat Cohen 146 15:1 p. 337. In the absence of a monarchy, the rights of government revert back to the people; democratically elected governing body expressing the people's will is authorized to legislate and enforce its laws.

The *halachic* underpinnings for an individual's obligation to share in the burden of the community derive from two major principles: deriving personal benefit from the efforts of the community and on a meta-physical level, being joined to the community both in fate and destiny. As representatives of the community, the authorities enforce individual contribution to the public good. Bava Batra (7:2) stipulates the obligation of all dwelling in a city to contribute to building a wall and bolted gate, as all will benefit from the protection they provide. Mahari Mintz (Responsa 7) broadens this stipulation to include other communal necessities, each generation according to its need. Perhaps immunization fall into this category, they certainly protect the public no less than a bolted gate through which bacteria and viruses penetrate. The contribution mandated in this case is not monetary but rather a mitzva one performs via one's body.

Rambam (*Hilchot Shecheinim* 5:1) differentiates between things which are obvious communal

necessities, for which every individual can be compelled to make a contribution, and things of an aesthetic value, for which he cannot be compelled. This is in line with the first principle. Yet Rema (Shulchan Aruch, Choshen Mishpat 176:25) in the name of the Mordechai relates: "All who dwell in a city are in a partnership." Indeed in Choshen Mishpat 163:3, Rema and Mahari Mintz give examples such as building and up keeping of a woman's mikvah which may not benefit everyone, yet the benefit is general because indirectly all benefit when communal welfare is maintained. Chatam Sofer makes use of the second principle, affirming that a member of a community has to contribute to meeting its needs, regardless of whether he personally derives direct benefit. Hence emerges the obligation to do one's share regardless of any benefit.

It follows from the second principle that one is *halachically* and morally obligated to immunize for the greater good of the community, even if he perceives no direct benefit. Yet even according to the first principle – he is obligated, as a healthier community will benefit every one of its members, at least indirectly, in many ways. A diminished need to invest precious resources in individuals suffering from prevented disease is just one example.

Bava Kama (7b) teaches that Talmidai Chachamim are exempt from contributing to expenses incurred in communal safety measures. Torah learning is their contribution. In the case of immunizations, the exemption does not hold because no one can take their place in contributing their share. Their physical entity has to be immunized. There is also the additional factor of serving as a model for imitation, as those who honor them will immunize as they do. This will prevent the erosion of herd immunity. Chazon Ish states that in a place where everyone qualifies as a Talmid Chacham, all have to contribute to making the community safe, as there is no one that can take their place, and it is forbidden to rely on miracles.⁷¹

For an elaborate discussion of this point, see Rabbi Yehuda Shaviv's article in *Techumin* 3, pp. 298-306.

Rabbi Shlomo Zalman Auerbach (*Minchat Shlomo* 2, 82:12) rules that when confronting natural disasters, an individual is obligated to protect the community, even if he exposes himself to a level of danger which would free him in the case of protecting another individual. In this case, it is obvious that he gets no benefit from his action, incurring, moreover, personal danger. It is possible to make the parallel to immunizing in cases where there is some danger involved; one must incur it for the protection of the community at large. In cases of emergency, the authorities would have the right and duty to compel him to immunize.

4. Immunization in Light of Budgetary Constraints

Financial resources available for public health and welfare are always scarce and allocation is always a challenge. To what extent and via what criteria should funds be allocated for immunization? How can or can one justify setting utilizing funds for future needs when the critically ill individuals have pressing present needs?

Nedarim 80b queries the priorities with respect to use of a particular city's well water. There is an agreement that the human needs for drinking water of the city come before that of another city, as is the case for animals and laundering. There is, however, a disagreement regarding prioritization in a case where the city needs the water for laundering and others outside the city need it for drinking. Rabbi Yossi maintains that the city's needs for laundering come first; his opinion is designated as the valid one. One explanation offered for this seemingly inhumane ruling is that if the city does not launder it will eventually bring disease upon itself, so in the future its people are also endangered. Others claim that Rabbi Yossi was referring to a situation where those out of the city had another source of water but it was difficult to access. In any event, we do see from this case that there is legitimacy in designating resources for preventative measures. In this vein, allocating funds for immunizations for those individuals who are also entitled to share in resources of the community is a legitimate criteria for resource allocation.⁷²

Gittin 45a rules that it is not permissible to redeem prisoners at a price which exceeds their worth, in order to prevent *duchka d'tziburah* – depletion of the public treasury (there are other interpretations for this term). The public has numerous needs to meet and may not give unjustified weight to save individuals at the expense of being unable to meet other important needs.

Allocating resources for the long term, including preventative care of which immunization is a part is halachically legitimate, contingent upon meeting cost/benefit ratios. Some poskim rule that only populations already alive and to be potentially exposed to disease in the future may be taken into consideration. Rabbi Goren and Rabbi Tendler however, are of the opinion that Israel is an organic whole, and future generations need be taken into consideration as well.⁷⁴

Immunization is efficacious and effective preventative medicine against diseases endemic to Israel. Vaccination policy is updated according to recommendations of disease control centers of major developed countries. Evidence of cost effectiveness of the hepatitis B vaccine was elaborated upon earlier in this article. It will be remembered that the resources preserved are well beyond those expended for the vaccination program. It is remarkable that in Israel, unlike in other countries, blood testing for carrier state of hepatitis B is not drawn in labor and delivery. Although identifying carriers would lower (although minimally) the percent of neonatal disease as passive immunization would be administered in addition to active, the procedure would not be economically justified.¹⁹ It is the government's responsibility to continue following evidence on immunizations as situations are dynamic.

Rappaport S, Priorities of resource allocation of public health funds; for health, *Sefer Assia*, 1992; pp. 46-53.

⁷³ Yam Shel Shlomo, Gittin 84:61.

Rosner F, Allocation of scarce medical resources: the Jewish view, New York State Journal of Medicine, 1983; 83(3) pp. 353-358.

5. Informed Consent of Parents to Immunize Their Infants against Hepatitis B

It is morally and *halachically* imperative to inform parent regarding the immunization. It is therefore incumbent upon those in charge that parents be notified that their newborn will be immunized during the first day of life. Possible adverse effects and their chances need to be communicated. Although this information is to be given as part of prenatal care, it should not be relied upon. Informed consent should be active; it is not sufficient that the parents do not resist actively. The *halachic* bases for these acts are *Kevod Habriyot* and *v'Asita Hayashar v'Hatov.*⁷⁵

Conclusions

- 1. Routine immunizations are an evidence based practice, saving lives.
- 2. Parents are *halachically* obligated to take responsibility for their children's health, including immunization according to protocol.
- 3. The obligation to immunize stands strong even in situations in which the chances of contracting the disease are low.
- 4. The commandment of *tamim tihiyeh im Hashem Elohecha* does not negate the *halachic* obligation to immunize.
- 5. The obligation to immunize stems from the stringent criteria of communal *Pikuach nefesh* and the commandment to take part in carrying the public burden.
- 6. *Talmidei chachamim* need to serve as an example to the public to immunize.
- 7. The authorities are obligated to communicate to parents all pertinent information regarding vaccinations.
- 8. The authorities should not force immunizations on someone in fear of them, as long as no immediate danger ensues to his life, that of his child, or the community at large.
- Steinberg, A., Encyclopedia of Halacha and Medicine, 2006, vol. 2, s.v. Informed consent, pp. 685-686.

- 9. The authorities should mandate that individuals immunize as they are part of the community and benefit directly or indirectly from the vaccination program.
- Cost-benefit ratio must always be considered as there are many health needs that the government funds.
- 11. The policy in regard to immunization should be sensitive at all times to new scientific developments.