Vaccination Ethics, Week 4: Vaccine Trials, and Triage

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Worth Reading regarding trials

- Eyal, Lipsitch, Smith, *Human Challenge Studies to Accelerate Coronavirus Vaccine Licensure*, Journal of Infectious Diseases 2020:221 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7184325/
- Cioffi, COVID-19: Is Everything Appropriate to Create an Effective Vaccine?, Journal of Infectious Diseases 2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7197522/
- Response to Dr. Cioffi, Journal of Infectious Diseases 2020, https://academic.oup.com/jid/advance-article-pdf/doi/10.1093/infdis/jiaa217/33283826/jiaa217.pdf

1. Ewen Callaway, *Dozens to be deliberately infected with coronavirus in UK 'human challenge' trials*, Nature, 10/20/20 https://www.nature.com/articles/d41586-020-02821-4

Young, healthy people will be intentionally exposed to the virus responsible for COVID-19 in a first-of-its kind 'human challenge trial', the UK government and a company that runs such studies announced on 20 October. The experiment, set to begin in January in a London hospital if it receives final regulatory and ethical approval, aims to accelerate the development of vaccines that could end the pandemic.
Human challenge trials have a history of providing insight into diseases such as malaria and influenza. The UK trial will try to identify a suitable dose of the virus SARS-CoV-2 that could be used in future vaccine trials. But the prospect of deliberately infecting people — even those at low risk of severe disease — with SARS-CoV-2, a deadly pathogen that has few proven treatments, is uncharted medical and bioethical territory.

Self-Endangerment for a Benefit

2. Use of Unproven Medicine https://www.yutorah.org/lectures/lecture.cfm/954448/

3. Rabbi Mordechai Halperin, **האם מותרת השתלת לב על פי ההלכה?**, Assia 5 (1986)

In normal surgeries [unlike heart transplants] the patient is considered alive, meaning he has the ongoing status of 'alive' the entire time, but he enters a state of danger in the course of this normal surgery. But a patient may introduce himself into danger, when the chances of healing are good.

4. Rabbi Mayer Twersky, **לך עמי בא בחדריך**, 27 Iyar 5780

It is true and correct that one may distinguish between a temporary threat and a threat which has taken root and created a new reality ("new normal"). Where the threat is temporary, perhaps one is required to wait and hide "until the wrath passes." But where the threat has become embedded in the fabric of life (along the lines of the dangers of childbirth, for example), it is not possible to wait for it to pass. One definitely must live life while dealing with the threat…

Self-Endangerment to Save Others

5. Jerusalem Talmud, Terumot 8:4

Rabbi Issi was captured in a dangerous area. Rabbi Yonatan said, "Let the corpse be wrapped in its sheet." Reish Lakish said, "I will kill or I will be killed! I will go save him by force!" He went and appeased them; they returned him.

6. Rabbi Shlomo Zalman Auerbach (20th century Israel), Minchat Shlomo (newest edition) II 82:12

When the community is pursued by bears and lions, and they need to fight them and chase them out, then perhaps, aside from the fact that this is considered life-saving, and [therefor] there is a mitzvah for each person to desecrate Shabbat and the like to save lives, perhaps it is also considered [obligatory as] a "mitzvah war". Although we lack a king or court [with the power to compel war], still, the town council could compel and endanger the lives of

individuals, as with war, even where an individual would not be obligated to save lives. And if we are correct in this, then perhaps war against illnesses which lie in wait for people, as well, would be like a mitzvah war. And if we would merit that all would be done [in trials] per the Torah, perhaps a court would see the need to test medicines as a mitzvah war of saving lives. Therefore, in our day, even though it is not done according to Torah, still, since it is done via great experts with great care, logically, there is no prohibition against volunteering for this.

7. Rabbi Asher Weiss (21st century Israel), **מנחת אשר בתקופת הקורונה** #5
Still, it appears that this is so even in our case, that as long as it benefits the community, it is appropriate for a group of people whose heart moves them, to volunteer for roles involving some danger.

8. Rabbi Yosef Karo, Rabbi Moshe Isserless (16th century Israel, Poland), Shulchan Aruch, Choshen Mishpat 12:1
Rabbi Karo: If two parties come before you for judgment, one is gentle and one is harsh, then until you hear their words, or after you hear their words but you don't know which way the law leans, you may tell them, "I won't deal with you," as perhaps the harsher one may be found liable and may pursue the judge. But once you hear their words and know which way the law leans, you may not say, "I won't deal with you." And if he is publicly appointed, he is obligated to deal with them.
Rabbi Isserless: … And one authority has written that in any case, we do not protest against transgressors today, because it is dangerous, lest he turn us over to *anasin*.

9. Rabbi Dr. Avraham Steinberg, HaRefuah KaHalachah VI 5:3:1
The community and the collective are not only a collection of individuals, but an independent entity, of its own nature and with its own rules and with the community's collective needs, sometimes even at the expense of the individual. And even though an individual is not nullified opposite the community, still, the community must make a special calculation of its own in different circumstances.

The Need for Informed Consent

10. Dr. Christopher Meyers, *Autonomy and Critical Care Decision-Making,* Bioethics 18:2 (2004) pp. 111-112
Beyond the obvious threats of immature age, mental illness and trauma-induced incapacitation, healthcare also brings reduced competency due to disease, fear, power asymmetries, physician bias, physician denial, family conflict, pressures related to economic or managed care considerations, the complexities of medical decisions, and the bureaucratic structures of medical institutions.

11. Dr. Christopher Meyers, *Autonomy and Critical Care Decision-Making,* Bioethics 18:2 (2004) pg. 110
In my experience, many clinicians see the assent standard as being sufficient for autonomous consent. So long as the patient has expressed a 'willingness to accept the proposed care', she has autonomously chosen. Surely, though, this is false. Assent requires merely that the patient *agree to* the recommendations of others, whereas autonomous consent requires a rich evaluation of information, of the full range of options, and of whether likely outcomes are consistent with life plans, along with the intentional selection of preferred alternatives. With assent, the patient *gives permission*; with consent, the patient *chooses*. With assent, the patient *accedes* to treatment; with consent, the patient *takes ownership* of or *identifies* with the choice made.

12. LSO Rules of Professional Conduct (2014), Rule 7.2-9
When a lawyer deals on a client's behalf with an unrepresented person, the lawyer shall: …
(b) take care to see that the unrepresented person is not proceeding under the impression that their interests will be protected by the lawyer; and
(c) take care to see that the unrepresented person understands that the lawyer is acting exclusively in the interests of the client and accordingly their comments may be partisan.

Vaccine Distribution

13. *Fair Allocation of Scarce Medical Resources in the Time of Covid-19*, New England Journal of Medicine
Emanuel, Persad, Upshur, Thome, Parker, Glickman, Zhang, Boyle, Smith, Phillips
https://www.nejm.org/doi/full/10.1056/NEJMsb2005114
Previous proposals for allocation of resources in pandemics and other settings of absolute scarcity, including our own prior research and analysis, converge on four fundamental values: maximizing the benefits produced by scarce resources, treating people equally, promoting and rewarding instrumental value, and giving priority to the worst off.

14. Rabbi Shlomo Wosner (21st century Israel), Shevet haLevi 10:167:1
In any case, it is obvious that if [two patients arrive simultaneously and] the situation of someone who is not of higher priority is worse and he is in great danger, we must treat him first, and this is obvious...

15. Rabbi Yisrael Meir Kagan (20th century Poland), Mishneh Berurah 334:68
One who can save either a healthy person or a dying person [from a fire] must save the healthier person.

16. Rabbi Moshe Feinstein (20th century USA), Igrot Moshe Choshen Mishpat 2:73:2
Regarding the case of two patients, one for whom doctors estimate that they can only provide short-term healing, extending life as much as possible, or perhaps removing pain, but he needs immediate treatment, and the second whom they estimate that they can heal, but they don't know whether he needs immediate care like that provided in the hospital's ER, and there is only one bed in the unit… It appears, in my humble opinion, that if both arrive simultaneously, meaning they have yet to bring either one in, they must first bring in the one whom the doctors on scene believe they can heal, if there is even a possibility that they would need to begin his treatment immediately.

17. Rabbi Asher Weiss (Agudath Israel of America Torah Projects Commission)
https://player.vimeo.com/video/404795764

Review Questions

1) What are four justifications for challenge trials?
2) What is the ethical difference between regular trials and challenge trials?
3) If Judaism permits risk-taking for profit, would Judaism permit society to skip lockdowns in order to support the economy?
4) What are three factors that undermine Informed Consent?
5) What three Jewish approaches to triage did we identify?