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The Underlying Question of Health Reform

The origins of the current acrimonious Health Reform debate of 2009 can be understood in the context of a comparison between two biblical brothers: Kayin and Yosef. As Jews and as human beings, we are expected to work for Tikkun Olam-to heal the world. We are provided with the means to do so: mitzvoth (commandments and acts of kindness) and tsedakah (acts of charity). Modern science has provided many tools to support these efforts, including epidemiology, which is the basic science of public health and health-care planning. Two inter-related issues that have not received adequate attention during the debates around health-care reform relate to public health and preventive medicine, and the underlying assumptions about whether health care is a universal right or a commodity purchasable in proportion to one's financial means.

This essay will explore some of the contributions to this discussion of epidemiology, and will seek insights from examples drawn from Torah and Ketubim. In particular, we will examine the different attitudes of Kayin and Yosef toward their brothers. This contrast can be best seen by examining Kayin's immortalized response, "Am I my brother's keeper?" to God's question, "Where is your brother, Hevel?" I believe that this is the fundamental question underlying the Health Reform debate, and unless we reveal and resolve these competing

visions of health care-as a right and responsibility-or as a commodity-we will be unable to resolve this dilemma.

Kayin, who was described as an "oved adama," a servant of the land, refused to take care of his brother, and his actions were directly responsible for Hevel's death. In contrast, Yosef proposed and implemented food, land and crop management, and tax policies that took care of his brothers, their families, his adopted nation and all the nations of the world. Thus, Yosef serves as a model for public-health leadership and an exemplar of universal access to care and responsible environmental management. We need to look more closely at the two narratives [emphasis added]:

Kayin and Yosef: Two Models of Public-Health Leadership?

Kayin:
And God said to Kayin, ‘Why are you angry, and why has your countenance fallen? Is it not so that if you improve, it will be forgiven you? If you do not improve, however, at the entrance, sin is lying, and to you is its longing, but you can rule over it.' (Genesis 4:6-7).
And God said to Kayin: 'Where is your brother, Hevel?' And [Kayin] said: 'I don't know; am I my brother's keeper?' And God said: 'What have you done? The voice of your brother's blood cries unto Me from the ground. (Genesis 4:9-11)

Yosef:
And [Yisrael] said to [Yosef]: Go now, look after your brothers' welfare, and the well-being of the flock; and bring me back word. (Genesis 37:14)

Let Pharaoh do this, and let him appoint overseers over the land, and take up the fifth part of the land of Egypt in the seven years of plenty. And let them gather all the food of these good years that come, and lay up corn under the hand of Pharaoh for food in the cities, and let them keep it. And the food shall be for a store to the land against the seven years of famine, which shall be in the land of Egypt; that the land perish not through the famine." (Genesis 41:34-36)
And Yosef went out from the presence of Pharaoh, and went throughout all the land of Egypt. And in the seven years of plenty the earth brought forth in heaps. And he gathered up all the food of the seven years which were in the land of Egypt, and laid up the food in the cities; the food of the field, which was round about every city, laid he up in the same. And Yosef laid up corn as the sand of the sea, very much, until they left off numbering; for it was without number. (Genesis 41:46-49)
And the famine was over all the face of the earth; and Yosef opened all the

storehouses, and sold unto the Egyptians; and the famine was sore in the land of Egypt. And all countries came into Egypt to Yosef to buy corn; because the famine was sore in all the earth. (Genesis 41:56-57)
And it shall come to pass at the ingatherings, that you shall give a fifth unto Pharaoh, and four parts shall be your own, for seed of the field, and for your food, and for them of your households, and for food for your little ones.' And they said: 'You have saved our lives.' (Genesis 49:24-25)

And now be not grieved, nor angry with yourselves, that you sold me; for God did send me [to Egypt] before you to preserve life. For these two years there has been famine in the land; and there are still five years, in which there shall be neither plowing nor harvest. And God sent me before you to give you a remnant on the earth, and to save you alive for a great deliverance. So now it was not you that sent me hither, but God. (Genesis 45:5-8)
And Yosef sustained his father, and his brothers, and all his father's household with bread, according to the want of their little ones. (Genesis 47:12)
And Yosef said unto them: 'Do not be afraid for am I in the place of God? And as for you, you did mean evil against me; but God meant it for good, to bring to pass, as it is this day, to save much people alive. Now therefore do not be afraid; I will sustain you, and your little ones.' And he comforted them, and spoke kindly unto them. (Genesis 50:19-21)

Competing Visions of Health Reform

Perhaps the most heated political debates surround the topic of "Health Reform," where the different sides of the often agitated discussions argue over various visions of improving access to health-care services, controlling costs, improving health-care quality, and eliminating disparities in clinical and public-health (population-health) outcomes. Competing visions of health-care reform range from universal access with a single-payer system, to a hybrid of private insurance companies, either with or without the so-called "public option," which may take the form of a government-run insurance program that competes with private insurers. The inclusion of a public option has been one of the more controversial aspects of the debate. Critics of the public option suggest that government-run health care "will offer the level of service of the Department of Motor Vehicles and the level of quality of the U.S. Post Office," or is a "step on the way to socialized medicine." Supporters of the public option argue that this is a necessary element to provide sufficient competitive pressure for the private insurers to keep premium costs affordable, or alternatively, to provide coverage in markets where no private insurers offer coverage. In a U.S. population of approximately 308

million, it is estimated that at least 50 million people-one in six-are currently uninsured, and a significant multiple of that figure are underinsured or one paycheck away from being uninsured, with over 80 million having been without insurance at some point in the previous year. Nevertheless, a significant proportion of U.S. citizens are already covered by some form of public option. If we consider the combined U.S. populations already served by Medicare (age 65+ or disabled), Medicaid (poor children and adults), Child Health Plus (low-income children), Veterans Administration (former military), TriCare (Department of Defense), Indian Health Service (Native Americans), Federal Employees Health Benefits Program (Congress and Federal Employees), Prison Health Services (incarcerated) and Federally Qualified Health Centers (low-income uninsured/working poor), an estimated 150 million Americans or nearly 50 percent of the U.S. population of over 307 million are currently covered entirely or part by a public
insurance program supported through taxes.

A second area of dissent surrounds the decisions about coverage of specific services, and the fear of "health-care rationing," as if rationing is not already taking place -either by income, ethnicity, age or geography. The emerging scientific discipline of "comparative effectiveness research" has been offered as the basis to be used for identifying which health-care services to cover-and is really a scientific basis for rationing health-care services. The evolving definition of comparative effectiveness research describes this as "... the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions ... to inform patients, providers, and decision-makers... about which interventions are most effective for which patients under specific circumstances" (Federal Coordinating Council for Comparative Effectiveness Research, U.S. Department of Health and Human Services). The methodological infrastructure of clinical effectiveness research is drawn from the science of epidemiology.

Epidemiology, Clinical Trials, Comparative Effectiveness Research and the Book of Daniel

Epidemiology is variously defined as the study of health and illness in populations, and is both a tool for understanding the etiology (causes) of disease, and a body of methods for evaluating differences in the health-care status of groups of people (referred to as population subgroups), as well as differences in outcomes for people who receive various health-care interventions. Epidemiologic research can be purely descriptive or observational, and it can also be experimental, such as in randomized clinical trials or randomized controlled trials

(RCTs). An important aspect of health reform draws upon epidemiologic methods in support of the evolving science of "comparative effective research," whereby experimental studies, in which people are assigned to two (or more) different treatments by the "flip of a coin" (randomization or random assignment), and then they are then followed up over time to one or more pre-determined clinical outcomes (for example, first heart attack, remission from cancer, disease-free survival, death, and so forth).
The key component of clinical trials is that they compare two or more treatments, usually a new, active treatment versus a comparison or control treatment, using structured observations following a formal and uniform schedule of observations and follow-up intervals. The differences in outcomes between the treatment groups are quantified and tested for statistical significance, and are described as the "effect size." The effect size is a comparative probabilistic statement, and is often reported as the "relative risk" (ratio of two risks) or "attributable risk" (difference between two risks). Relative risks that are significantly different from 1.0 and attributable risks that are significantly different from 0, and are clinically meaningful, are taken to be indicative of an association or even causality.

Randomization is necessary to reduce or eliminate the possibility of bias (or an alternative explanation) in selecting (or self-selecting) who receives which treatment, and is considered the "gold-standard" by which new treatments (drugs, devices, procedures, preventive services, bundles of services) are evaluated. RCTs are controlled human experiments based upon accumulated observational studies, and begin from the principle of "equipoise" which asserts that in order to conduct an ethical clinical trial, there must be insufficient existing evidence of either harm or benefit of one treatment over the other. Treatment is allocated purely by chance (randomization), rather than by the selection of either the physician or by patient, who has provided his/her "informed consent" to participate.

Informed consent is critical to any health-care treatment decision, including participation in a clinical trial, and the consent process (ideally) takes the form of an unpressured conversation, and presumes autonomy (the health-care provider needs to give the respect, time, and the opportunity for a potential participant to make an informed and non-coerced decision), beneficence (the health care provided should ensure the patient's well-being, do no harm, and should simultaneously maximize benefits and minimize risk of harm), and justice (ensure an equitable selection of participants-who is offered the opportunity to participate and who is not offered the opportunity to participate). The key element here requires the full disclosure of all risks and benefits of participation (including the

risk of not receiving treatment), and the ability of the patient to make an independent decision to participate.

RCTs are designed to determine the effect(s) of exposure to treatment on the clinical outcome(s) that are being studied, and RCTs provide the strongest, most direct evidence of cause and effect by eliminating potential confounding variables which are other factors which may be the true cause of observed differences in outcomes. The theory behind randomization asserts that the random assignment of treatments evenly distributes all known and unknown "factors" or "causes" to the treatment groups. Many studies have demonstrated that in the absence of randomization, differences in outcomes are often associated with selections of treatments that may reflect more complex lifestyle decisions that result in selecting a given treatment (for example, taking vitamins; going for screening tests, deciding to smoke or to quit smoking) rather than the treatment itself. Blinding of observers and participants is an important component of many (but not all) clinical trials, where often the participant is unaware as to which treatment he/she is receiving ("single-blinded"), or for an even stronger design, neither the health-care staff nor the patient know which treatment is being received ("double-blinded"). It is also important that the measurements are made by staff who are unaware of which treatment is actually being received by the patient ("blinded"). Blinding strategies are important for minimizing biases and subjective opinions about which treatment is better, and many RCTs compare a new drug either to an inert substance ("placebo-controlled studies") or to a standard, already approved medicine ("comparator"). However, blinding is not always feasible to implement in studies, particularly either where an invasive procedure is involved, or where a drug may have recognizable main effects or side effects (e.g., causing flushing, increased urination, fast or slow heart beat, etc.) that are easily identified by the patient and the staff. The designers of all clinical trials need to balance the need for methodological rigor with real-world considerations of safety and feasibility, and recognize that no perfect clinical trial exists. While experimental evidence is considered the most rigorous, there are ethical and practical situations that often require alternatives to randomization, all of which fall back on careful, well-structured observations and comparisons.

The Origin of Clinical Trials

Most medical historians attribute the first recorded clinical trial to Dr. James Lind of the British Royal Navy in 1753. Dr. Lind observed that scurvy "...killed thousands of people every year and had caused many more deaths in the Royal Navy than conflicts." So he selected twelve men from the ship, all of whom were

suffering from scurvy, and divided them into six pairs, giving each group different additions to their basic diet (cider; seawater; garlic; mustard and horseradish; spoonfuls of vinegar; two oranges and lemons). Dr. Lind observed that "[t]hose fed citrus fruits (oranges and lemons) experienced a remarkable recovery" and concluded that, while there was nothing new about his discovery as the benefits of lime juice had been known for centuries, citrus fruits were better than all other "remedies" for the treatment of scurvy (and also for the prevention of Vitamin C deficiency). Although the importance of Lind's findings on scurvy were recognized at the time, it was not until more than 40 years later that the British Admiralty ordered the routine supply of lemon juice to all Naval ships, virtually eliminating scurvy from the Royal Navy (www.JamesLindLibrary.org & BBC History). About a century later, in 1847, the Hungarian-born obstetrician, Dr. Ignaz Semmelweis, tested the effects of physicians' hand-washing after leaving the autopsy room and before entering the labor and delivery room on reducing fatal puerperal fever (also called "childbed fever"-a fatal blood-borne infection) among pregnant women in Vienna. Although the statistical results of this clinical trial were entirely conclusive, there was significant resistance to adopting this innovation (so much that it eventually drove Semmelweis to insanity and a premature death at age 47).

While these eighteenth- and nineteenth-century examples provide a glimpse into the origins of modern clinical trials (and also illustrate the delays associated with translating research into practice), an earlier nutritional clinical trial of following a Kosher diet compared to the local food was recorded in the Book of Daniel (Chapter 1:1-20). This Babylonian clinical trial was conducted and reported some 2,400 years earlier (605-562 BCE), by Daniel, another adept dream-interpreter who, as was the case for Yosef and Pharaoh in Egypt, also won favor from the king who ruled over the Jews then living in exile in Babylonia. Daniel's clinical trial contains many of the elements of modern clinical trials, with many of the associated modern challenges to causal inference. The text follows here with the corresponding clinical trials elements indicated [in brackets]:

Daniel's Nutritional Clinical Trial (1:3-20)

3. Then the king said to Ashpenaz, his chief officer, to bring from the Children of Israel, from the royal seed, and from the nobles [population subgroup; eligibility criteria].
4. Youths in whom there is no blemish, of handsome appearance, who understand all wisdom, erudite in knowledge, who understand how to express their thoughts, and who have strength to stand in the king's palace [inclusion/exclusion criteria],

and to teach them the script and the language of the Chaldeans.
5. The king allotted them a daily portion of the king's food and of the wine that he drank, and to train them for three years [trial duration], and at the end thereof, they would stand before the king [follow-up period; outcome evaluation].
8. Daniel resolved not to be defiled by the king's food or by the wine he drank; so he requested of the king's chief officer that he should not be defiled.
9. God granted Daniel kindness and mercy before the chief officer.
10. And the chief officer replied to Daniel, "I fear my lord the king, who allotted your food and your drink, for why should he see your [experimental group] faces troubled [clinical outcome] more than the youths like you [control group]? And you will forfeit my head to the king."
11. And Daniel answered the steward whom the chief officer had appointed for Daniel, Hananiah, Mishael, and Azariah.
12. "Now test [pre-specified comparison] your servants for ten days [trial duration], and let them give us some vegetables that we should eat, and water that we should drink [experimental intervention].
13. And let our [experimental group] appearance [clinical outcome], and the appearance [clinical outcome], of the youths who eat the king's food [control group], be seen [follow-up; outcome evaluation] by you [not blinded] and as you will see, so do with your servants."
14. He heeded them in this matter and tested [experimental intervention] them for ten days [trial duration].
15. And at the end of the ten days [trial duration], they [experimental group] looked handsomer and fatter [clinical outcomes] than all the youths who ate the king's food [control group].
16. And the steward would carry away their food and the wine they were to drink and give them vegetables [experimental intervention].
17. And to these youths, the four of them [sample size], God gave knowledge and understanding in every script and wisdom, and Daniel understood all visions and dreams.
18. And at the end of the days that the king ordered to bring them, the chief officer brought them before Nebuchadnezzar.
19. And the king spoke with them, and of all of them, no one was found to equal Daniel, Hananiah, Mishael, and Azariah [effect size or relative risk]; and they stood before the king.
20. And in every matter of the wisdom of understanding that the king requested of them, he found them ten times better [effect size or relative risk], than all the necromancers and astrologers in all his kingdom.

The Problem of Translating Research into Practice

Thus, Daniel was responsible for the first recorded clinical trial, suggesting that the methodological template for clinical trials is considerably older than usually ascribed. In fact, the reporting of Daniel's (non-randomized) clinical trial conforms to modern standards (the "CONSORT criteria"), and in some ways is even more thorough than many contemporary trials published in rigorously peer-reviewed journals (perhaps because Daniel had to "... answer to a Higher Authority"). What is supposed to happen with the results of clinical trials? Decisions by physicians as to whether to adopt innovations, by insurers as to whether to pay for services, and by patients as to whether to follow their physicians' advice, are increasingly being made based on the results of these clinical trials, and the burgeoning field of "translational research" seeks to understand how scientific discoveries are moved from the laboratory to the patient ("bench to bedside") and beyond to the community. I would argue that the true measure of the effectiveness of translation of research into practice is reflected not only in utilization of services and individual health status outcomes, but also in public health statistics such as disability, disease incidence, and survival/mortality. Both the principles of social justice and Tikkun Olam would require that everybody benefit equally from access to improved health-care services.

The average duration of time it takes for scientific innovations to travel from research to practice is frequently cited to be 17 years, with many examples, such as those above, demonstrating even longer durations-and differential access to research results across groups defined by economic, ethnic, gender, and other parameters. The recent addition of hand-washing reminder signs and widespread placement of antibacterial liquids in health care and other public settings is a stark reminder that the adoption of even a simple innovation such as hand-washing can take decades or centuries. Even today, the Centers for Disease Control and Prevention's (CDC) primary recommendation for preventing the transmission of influenza, including the much-feared H1N1 flu (and other communicable infections), is hand-washing.

Epidemiologic methods are often criticized for failing to provide adequate (or any) mechanisms or explanations as to "why" differences are observed. However, effective policy can often be made merely based on the observation of differences, rather than on a true understanding of the underlying reasons (or causes) of those differences. The example most often cited was the removal of the Broad Street water pump handle by nineteenth-century British anesthesiologist/surgeon-turned-epidemiologist, Dr. John Snow, whose statistical analyses led him to conclude in 1854 that water played a significant role in the spread of cholera, and his direct actions resulted in controlling a severe cholera

outbreak in London.

Epidemiology has been particularly effective in studies of lifestyle and behavior, and numerous long-term community-based observational and experimental studies have demonstrated the significant contributions of a variety of behaviors, including diet composition (for example, calories; fat content; types of fat; salt/sodium content), physical activity, smoking, alcohol consumption, and even attendance at weekly religious services and prayer, to health and well-being. Although levels of biological evidence as to mechanisms are often lacking, and not all of these behaviors can be adequately studied in RCTs, these studies can still form the basis of informed government and health-care policies oriented toward improving public health.

Recent examples of such health and environmental policies in New York City include regulations to limit occupational and environmental exposures. These include increased tobacco taxes and bans on smoking in the workplace and other public settings. Other examples of current environmental public health legislation based on epidemiology include food labeling, which requires disclosure of food composition (calories, fat, salt/sodium content) at the point of sale in certain restaurants and for prepared foods, bans on trans-fats in food, and measures to reduce or eliminate the sale of soft drinks in public schools through bans and increased taxes.

One cannot help but be struck by these modern scientific analogues to the food labels of Kosher certification agencies or hekhsherim, and their designations of "meat" or "dairy (D)" or "pareve" and the parallels between the institutions of the mashgihim (Kosher food supervisors) and Food Inspectors of the U.S. Food and Drug Administration (FDA) and Department of Agriculture (USDA), as well as local municipal Health Department restaurant inspectors. Both sets of institutions are intended to ensure high levels of food purity and accurate disclosure of food contents, handling and preparation. Many other similar examples exist. While the health benefits of the primary covenantal sign of Jews, the berit milah or (male) circumcision, have been debated in Europe and the United States for over a century, two recent large randomized clinical trials conducted in Africa have demonstrated the effectiveness of male circumcision on reduction of HIV transmission to such a degree that thousands of African men have undergone voluntary adult circumcision (and mohelim, or ritual circumcisers, from Israel and elsewhere are in great demand now both to provide circumcisions and to train local community circumcisers in Africa).

Reason Beyond Reason

So how we can draw upon two sets of behavioral recommendations, one faith-based and one evidence-based, from the foregoing discussion, and bring together evidence-based medicine and ethical behavior? An important parallel exists between epidemiology and Torah in behavioral recommendations that take the form of behaviors to engage in and behaviors to avoid. In a sense, behavioral risk factors (and protective factors) can be seen to correspond to mitzvoth aseh ("positive commandments" to perform specific acts) and mitzvoth lo ta'aseh ("negative commandments" to abstain from certain acts), and reduced further to mishpatim ("judgments"), which have a rational (and potentially an epidemiologic) explanation and hukim ("decrees"), which transcend apparent reason, and include commandments about justice toward others and to the environment.

We have a mandate to "heal the world." Whether it is for reasons of enlightened self-interest, or for truly eleemosynary purposes, Kayin should have answered God's question differently: vayomer Kayin ‘keyn' (and Kayin said "yes"), as did Yosef. So our vision for effective public health and environmental leadership must combine the responsibility of Kayin to be an oved adama (a servant of the land), with the wisdom and compassion of Yosef, through whose command all people were nourished. Daniel demonstrated the health benefits of food and beverage, and provides epidemiologic methods as a valid tool to combine evidence and faith. However, it was Yosef who is the model public-health leader, who set aside his own self-interest, and took care of his brothers, their families, his (adopted) country and the whole world, also serving as an oved adama, perhaps in a more generalized sense, as a servant of man and a servant of the land. So in the face of this current debate over the transformation of the U.S. health-care system, we must answer God's question as Yosef did and as Kayin should have. Health care and a clean environment must be a right for all people in order for us to heal the world. We do have the means and resources to provide both a high standard of health care and a clean environment for all. But do we have the will do so?