

# Extending the boundaries of the Declaration of Helsinki: a case study of an unethical experiment in a non-medical setting

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## Abstract

*To examine the ethical issues involved in governmental decisions with potential health risks, we review the history of the decision to raise the interurban speed limit in Israel in light of its impact on road death and injury. In 1993, the Israeli Ministry of Transportation initiated an “experiment” to raise the interurban speed limit from 90 to 100 kph. The “experiment” did not include a protocol and did not specify cut-off points for early termination in the case of adverse results. After the raise in the speed limit, the death toll on interurban roads rose as a result of a sudden increase in speeds and case fatality rates. The committee’s decision is a case study in unfettered human experimentation and public health risks when the setting is non-medical and lacks a defined ethical framework. The case study states the case for extending Helsinki type safeguards to experimentation in non-medical settings.*

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**Keywords:** Declaration of Helsinki; human experimentation; speed limit

## Introduction

Medical ethics deals with, among other things, safeguarding the decision making process to do with matters of life and death. Social ethics deals with resolving the conflicts from use and abuse of resources, goods, services and products that sometimes produce pleasure for many, but pain and suffering for some. We present a case study of an episode at the interface between medical and social ethics: the “experiment” by the Israel Ministry of Transportation to raise speed limits on selected high-speed roads, in November 1993. The case study calls attention to the need for extending Declaration of Helsinki type safeguards, now standard in medical experiments, to decisions made outside conventional medical settings, but which may have an impact on public health.<sup>1</sup>

## The case study

### THE RECOMMENDATION

In 1993, a commission appointed by the Minister of Transportation of the government of Israel recommended raising the speed limit on selected

high-speed interurban roads from 90 to 110 kph (56 to 64 mph), for all vehicles, including trucks.<sup>2</sup> The commission also recommended lowering the speed limit in highly crowded urban areas to 30 kph. The stated justifications for raising the speed limit were (1) to bring road speed limits in Israel into line with European Union (EU) speed limits; (2) to set the legal thresholds above observed rises in actual travel speeds on high-speed roads; (3) and to gain the economic benefits of time-saving from interurban travel at higher speeds. The commission summarised much of the epidemiological literature on the risks for increases in deaths from raised speed limits. It noted data from Sweden showing that speeds just below 90 kph provide an optimum cost-benefit relationship for society at large, and that the European Union (EU) retained lower speed limits for trucks (70 kph for double trailers, 80 kph for single trailers, and 90 kph for lighter weights, respectively). It predicted that even though there would be zero to two more deaths per year on the high-speed road, death tolls overall would drop by some eight to ten, as traffic would be diverted from higher risk low-speed roads to lower risk high-speed roads. It concluded that environmental measures to remove hazards at designated black spots would cancel the well recognised effect of increased speeds increasing injury severity.

The report published by the commission included dissenting statements. These warned against ignoring the large number of studies showing that raised speed limits were followed by raised death tolls; that raised speed limits themselves induced even higher travel speeds; and that the spillover effect of speed addiction would create special risks from crashes with trucks and vehicles driven by young drivers.<sup>3–13</sup> The dissenters predicted there would be a rise of 40–60 extra deaths, mainly from the spillover effect of a 110 kph speed limit.<sup>1–13</sup> The commission’s report ignored objections from the Israel Defense Forces’ (IDF) road accident safety research division. The IDF warned that a 100 kph speed limit would increase death and injuries from crashes involving military drivers and soldiers, both on- and off-duty.

The most important point that the dissenters raised was that the government’s decision to carry

out the “experiment”—the term used by the then director of the Road Safety Authority—did not include a protocol with objectives, a study design, methods, a timetable, and measurable outcome variables serving as end points for evaluation, and did not specify cut off points for early termination in the case of adverse results, as is required for medical trials of new therapeutic procedures.<sup>14</sup> The dissenters characterised the decision as an unethical exercise in human experimentation.

### What happened

November 1993, the first month of enactment of 100 kph, was the worst ever for road death tolls over the past decade. Sixty-one (61) persons were killed, with a marked rise in case fatality, an index of severity of crash.

#### THE SUPREME COURT APPEAL

In January 1994, the Supreme Court rejected a petition from two community groups to cancel the Minister of Transportation’s decision.<sup>15</sup> The petition called attention to the fact that the government had a legally binding obligation to preserve and protect the life of its citizens. It contained a literature review of the effects of raised speed limits on speeds, spillover, and road deaths, and included a letter from Dr Allan Williams of the US Insurance Institute for Highway Safety. In the letter Dr Williams wrote: “It has been demonstrated conclusively that raising speed limits on major roads increases speeds and fatalities; lowering speed limits reduces speeds and fatalities . . . these findings hold worldwide. There is no reason that any country, including Israel, will have findings that differ from this common experience. . . .” The Supreme Court judges ruled that it was not within their purview to determine the scientific validity of the prediction of one group of experts over another. The government attorney’s brief included a promise to monitor the impact of the raised speed limit on travel speeds, but predicted that the death toll would drop with the rise in the speed limit. The brief stated that the government intended to raise the speed limit again to 110 kph, which in fact happened in 1995.

### Monitoring the trend in road deaths

After the rise in the speed limit, monthly death tolls continued to remain high compared to the same months in the previous four years.<sup>16, 17</sup> Subsequent trends indicated that increases in deaths on interurban roads and case fatality persisted for a five-year period, from 1993 through to 1998. (Richter E D, unpublished data) The findings indicated there was a spillover effect on all other major highways and feeder roads. The rise in the death toll was in all crash types (except cyclists and pedestrians), especially those involving trucks, motorcyclists, a single vehicle and soldiers.

### Public challenge, government response: from 100 to 110 to 120 kph

In July 1994, we sponsored an academic workshop on the findings from the first eight months of the

so-called experiment. At the meeting, two senior medical officers from the Ministry of Health compared the situation to the French scandal when officials remained silent about blood for haemophiliacs contaminated by HIV. In October 1994, the government convened a special meeting to assess the impact of the raised speed limit. In 1995 the commission was reconvened to determine if there was a direct cause-effect relationship between the 100 kph speed limit and the rise in the death toll. The commission’s report and research papers acknowledged a rise in the death toll, but concluded that the increase in the speed limit was not the explanation.<sup>18-20</sup> All these reports were critiqued for major methodologic flaws.<sup>21</sup> Nevertheless, the commission ruled against raising the posted limit to 110 kph, as it had originally recommended. It further recommended reducing the speed limit of trucks back down to 90 kph.

Later in 1995, the government raised the legal threshold for enforcement of the speed limit to 110 kph without changing the posted level of 100 kph. In late 1999, senior police officials proposed raising the speed limit to 120 kph for a new high-speed toll road. But the notion that the proposal was ethically problematic had by now penetrated the decision making process.<sup>22</sup> In 2000, the director of Israel’s Road Safety Authority himself described the new proposal to raise the speed limit again, to 120 kph, as an unethical exercise in human experimentation, using language identical to that which the dissenters used in 1993 to oppose 100 kph (statement by Shmuel Hershkowitz to Knesset economic committee, January 11 2000).

### 100 kph: an unethical non-medical experiment

The Ministry of Health saw the non-medical status of the decision making body as exempting the government commission’s review of data, analysis, and interpretation from the ethical criteria of medical institutional review boards, which in Israel are called Helsinki committees (after the Declaration of Helsinki). Even though the outcomes, which were of such concern, from the experiment were death, injury, and disability, the commission was not subject to the reviews and safeguards now mandatory for clinical trials and epidemiological research in the medical world.

We suggest that the commission’s lapses in evaluation and judgment directly resulted from its institutional framework and structure. No experts on trauma, epidemiology, ethics, or theology were included as voting members. There was no medical input into the commission’s decision making process despite the increased population-wide risks for death and injury from road trauma. The Ministry of Health remained silent on the issue, even though individual epidemiologists were opposed.

We surmise that what happened here has happened in many other settings as well. A government can make a decision that increases the risks for death and injury without specifying criteria for presence of

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Table 1 *A comparison of two experiments: Tuskegee and the 100 KPH experiment in Israel*

	<i>Tuskegee experiment</i>	<i>The 100 kph experiment</i>
Pathogen	Treponema pallidum - spirochete	Kinetic energy
Source-mode of transmission	Person-to-person, sexual contact or placental transmission	Vehicle-person impact, first, second and third collision
Exposure voluntary-involuntary	Voluntary - sexual intercourse	Involuntary: most victims passively exposed
Addictive effects from exposure	No	Yes
Forewarning/prior consent to exposure to pathogen	Probably not	Sometimes yes, mostly no
Ethical issue	Withholding effective treatment and total cure from sick victims	Reduction of severity of exposure to population already at excess risk for death and injury from road crashes
Public health impact	Slow progression of disease in all victims; PYL <10 y (non-stochastic)	Stochastic for event: all or nothing; increase in risk in entire population
Degree of compulsion/power relationships	One powerless, voiceless subgroup: Black, poor, southern in 1950s, passive acquiescence of uninformed black community	Many powerless subgroups at excess risk: occupants of motor vehicles struck by trucks; pedestrians (aged, children, infirm); children in fast vehicles; soldiers; truck drivers working under incentive premiums
Role of "establishment", "power elites" (mandarins, consultants, academics, senior scientists)	Initiated "experiment"; no known falsification of data within study; withholding information from powerless subgroup	Encouraged and endorsed "experiment"; misinformation to entire society; repression of information on adverse effects, including high-risk subgroups
Scope	Restricted to one group; experiment terminated	Entire population; experiment expanded
Motivations	"Science", "knowledge", fame, prestige, bureaucratic inertia	"Cost-benefit", "rational policy", "EEC"; consultant contracts, new highways
Adequacy of current standards for best practice	Penicillin: good to excellent	"Best" standards: outcome criteria not explicitly defined
Attitude of public	Approval in early years; instant repudiation following exposure in 1970s	Polls: majority supports 100 kph; majority opposes when told it causes increased death and injury
Institutional safeguards	None at time (1945-1970)	None at time (1993-1999)

increased risk—or its absence—and without including representatives of the medical and ethical community in the decision making process

**100 kph: an Israeli Tuskegee experiment?**

"Do no harm" and "informed consent" are bedrock principles for evaluating proposals to carry out medical experiments in humans.<sup>1-23</sup> The entire decision making process of the commission raised troubling questions concerning its attention to these principles. Was the decision to continue with the "experiment" after the first high monthly death tolls similar to what happened in the infamous Tuskegee experiment, in which physicians deliberately withheld penicillin from poor black sharecroppers with tertiary syphilis?<sup>24</sup> The experiment to raise the speed limit differed from the Tuskegee experiment in two important respects (table 1). First, the raised speed limit did not require drivers to increase their speed. Second, the subjects were not a deprived minority, dependent on the doctors and nurses in a controlled medical setting, but an entire population of drivers. The fact that the potential subjects were the entire population of drivers and passengers begs the questions of ethical oversight of decisions with population-wide impacts.

**Speed addiction and voluntary and involuntary risks**

We contrast the commission's policies and actions, and the inaction of medical authorities to protect the general public, with the consensus that there is a

public health role for protecting non-smokers from the risks of environmental tobacco smoke. Are risks for injury and death increased not only for those who speed, but also for those road users—passengers and pedestrians—who are involuntarily exposed?

**Professional accountability**

We noted that the recommendations and risk assessments of the commission were contradicted by its own literature review. What is the case for the accountability of the professional members of the commission? Did the commission fail to satisfy criteria for meeting accepted standards for professional caution, judgment, prudence and accountability when making a decision concerning risk to the public? Did they consider evidence that the recommendations and risk scenarios represented the best possible interpretation of the available data? Is there an analogy here with the engineer who ignores his own or others' calculations of load tolerances and therefore is responsible by an error of omission if a bridge collapses or a ship sinks? Is there an analogy with a factory manager who knowingly exposes his or her workers to hazardous toxics?<sup>25</sup>

**The Benthamite dilemma: pleasure for most, pain for some**

The decision to increase the speed limit to 100 kph is an example of the clash between the absolutist ethical principle that life and its preservation is an

ultimate value and a Benthamite norm of the greatest good for the greatest number of people.<sup>26</sup> Decisions in land transport tend to be presented in terms of a paradigm that weighs the economic benefits of fast transport of persons and goods, against the costs of injury and death to the unlucky minority. In the USA, this “minority” consisted of some 41,345 dead and 3,200,000 injured in 1999, and speeding was estimated to account for 12,477 (30%) of the road death toll in 1998.<sup>27-28</sup> Death and injury are considered an unwelcome but necessary price to be paid by an unlucky minority for increasing happiness, pleasure and profit among the majority. In a medical setting, such a paradigm would be anathema.

### Conclusion

Our proposal to extend the boundaries of the Declaration of Helsinki from medical to social experiments goes against recent pressures to restrict the scope of informed consent within medical experimentation.<sup>29</sup> The commission’s decision is a case study of the possibilities of unfettered human experimentation and fatal medical risks where ethical guidelines and oversight are lacking. In the non-medical setting, the increased risks are not directly personal, but statistical and involuntary, and the general public is unaware of its participation in the experiment.

In conclusion, the story of the decision in Israel to increase the speed limit to 100 kph states the case for extending Helsinki-type safeguards to experimentation in non-medical settings with increased risk for death and injury.

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