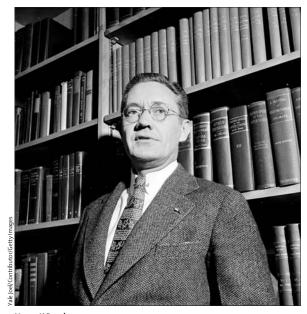
The art of medicine

The unintended ethics of Henry K Beecher

In the summer of 1966, the medical profession was hit with a bombshell. Henry K Beecher published "Ethics and Clinical Research", a landmark article, often called "Beecher's bombshell", which described 22 examples of clinical research he deemed ethically questionable. Beecher hit his mark. Describing the aftershock in the pages of this journal, one writer explained, "His article aroused controversy among American research-workers and highlighted a problem which had grown insidiously and almost unnoticed by the generality of American doctors". For onlookers beyond US borders, Beecher seemed to have attacked a distinctly American problem. But the outcome—regulations for nearly all American-funded research with human subjects—rippled across the globe.

In 1974, the US Government passed the National Research Act, which set rules that required "institutional review" of studies at home and abroad—rules that have remained embattled ever since and were contrary to Beecher's plan. Published 50 years ago this month, Beecher's article fundamentally changed the practice of clinical research ethics after World War 2, but did so in ways that Beecher neither expected nor supported. By dropping his bomb on his own profession, Beecher inadvertently created the very circumstances he had hoped to avoid.

The article was hugely controversial, and so was Beecher. When his piece appeared in 1966 in *The New England Journal of Medicine*, Beecher was the esteemed chief of anaesthesiology at Massachusetts General Hospital in Boston, a post he had held for more than two decades



Henry K Beecher

after a bootstrap climb to medical prominence. Raised in rural Kansas during World War 1, he changed his German surname to the Anglophone Beecher in the 1920s, and travelled east to take his medical degree at Harvard. During World War 2, he did influential pain research that thrust the problem of placebos to the centre of debates over how properly to design clinical trials. Never shy of a good fight, in 1968 he would lead the Harvard Committee to Examine the Definition of Brain Death, which set influential, controversial standards that allowed doctors to remove patients from life support. Beecher was ambitious, he was contentious, and he adored the limelight. One reason Beecher is widely remembered today is that he refused to let people forget him.

By publishing "Ethics and Clinical Research", he aimed to rock the profession out of moral complacency. But Beecher pointed out the ethical failings of the medical profession in a characteristically public way. 1 year earlier, Beecher had given a lecture at an elite conference well attended by science journalists, where he discussed cases of unethical research. Perhaps unsurprisingly, Beecher's report of doctors who used humans as quineapigs for their research appeared in news stories around the country, including in The New York Times and The Wall Street Journal. When Beecher returned from the lecture, his colleagues rebutted his claims with a press conference of their own. Galvanised, Beecher used the text of his conference talk as the kernel of "Ethics and Clinical Research". He sent the paper to The Journal of the American Medical Association, but the journal rejected it with no option to revisesome speculate because of a desire to avoid the scrum around Beecher. (To be fair, this early draft of the piece was also an organisational nightmare.) Beecher then sent the article to The New England Journal of Medicine, which agreed to publish it with careful editorial input. A week before the piece appeared in June, 1966, Beecher braced the Director of Massachusetts General Hospital: "unhappily, it may produce a considerable amount of controversy", Beecher wrote in a letter now archived at Harvard's Countway Center for the History of Medicine, "and you may be approached by members of the press for comment". Signalling a reputation for melodrama, he assured his boss that "I have not exaggerated the material", explaining how editors had worked to keep "the public protected from exaggeration on my part" so that the piece is "as unexaggerated as possible". Beecher's article added to friction within the medical profession about the ethics of research, to be sure. But it also, importantly, added to strife about the propriety of exposing weaknesses of the medical fraternity to those outside the profession.

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In "Ethics and Clinical Research", Beecher cited only five sources. One was Pope Pius XII. Another was himself. The remaining three citations, all salutary, were to British sources that Beecher held up as praiseworthy perspectives and profession-based solutions to the problem of research ethics. He cited "personal communication" with UK physician, Maurice Pappworth, who was seeking a publisher for a longer, like-minded manuscript on human-subjects research, "Human Guinea Pigs: Experimentation on Man". He also singled out a British Medical Research Council policy encouraging journals to make authors describe their ethics procedures as a condition of publishing their articles. None of the citations were to the 22 studies Beecher described in his piece. A friend in Harvard Law School had advised Beecher that citing the specific studies would open those researchers to liability, especially since Beecher claimed that although their wrongdoing was not wilful, it was the product of "thoughtlessness and carelessness" hardly any better—and that some "risked the health or the life of their subjects". Beecher wrote that his goal was to point out a broad pattern of "troubling practices", not to name and shame. Still, if he had to ask for advice, he had at least considered personal rebuke.

Beecher felt he knew what was needed, and it did not include regulation. He resisted formal rules because they imposed what he thought were impossible demands, such as consent. "All so-called codes are based on the bland assumption that meaningful or informed consent is available for the asking", Beecher wrote. He granted that consent was a useful ideal, but like Utopia, it was a state that existed only in theory and could never be achieved in practice. Even years later when it became necessary to observe regulations to win public grants, Beecher protested. He insisted, for example, that the Harvard ethics review committee he grudgingly chaired served not in a "policing" capacity but merely in an "advisory" role.

In his article, Beecher instead called for a retrenchment of the medical profession. "A far more dependable safeguard than consent is the presence of a truly *responsible* investigator", he wrote. He argued that the profession would create responsible researchers through medical journals—the enforcement of ethics by peers. "This implies editorial responsibility in addition to the investigator's", Beecher explained. Looking beyond the USA, Beecher found allies: "In the view of the British Medical Research Council it is not enough to ensure that all investigation is carried out in an ethical manner: it must be made unmistakably clear in the publications that the proprieties have been observed." He felt journals should refuse to publish even "valuable data" if the data had been "improperly obtained". Then, he reasoned, researchers would stop using unethical practices.

One mark of any profession is its ability to self-regulate—to agree to terms and mechanisms through which

members of the profession can police themselves. During the 1960s, the American medical profession was changing and so were its scruples. But Beecher did not think the profession needed outside regulation and called for better mechanisms for self-regulation. Beecher, after all, was an elitist: he wanted to maintain a privileged place for professional discretion and judgment among peers.

In publishing "Ethics and Clinical Research", Beecher had aimed to draw attention to a weakness in research ethics, and he succeeded. But he also inadvertently drew attention to a second weakness of the American medical profession, one that he had helped to create. As a prominent researcher and media darling, Beecher further fragmented a medical community already splitting over public exposures of its problems. By making his criticisms explosive, Beecher alerted public onlookers to cracks in the profession's veneer and simultaneously deepened those fractures.

A decade later, commentators would attribute the new US regulations on research involving human subjects in large part to Beecher's article. Yet Beecher had intended it otherwise. For him, the logical next step was not regulation, but reform from within the profession. The article, however, created circumstances in which members of the medical profession were at such odds with each other they were unable to solve problems for themselves. Ironically, Beecher's article showed policy makers and the reading public that the medical profession may not have deserved the autonomy it was traditionally afforded.

Beecher may have been a showman, but he was also an optimist. He was hopeful about the medical profession's ability to guide itself ethically, and it is a hopefulness that may well be warranted. The USA is working only now, after more than four decades of human-subjects regulation, to realign the law with changes in medical research. In 2015, the US Government proposed new rules to fix problems endemic to the National Research Act and to account for new research realities unimagined in the 1970s, such as the growth of privately funded clinical trials that are beyond the purview of federal regulation. In the meantime, medical journals have promoted some of the most effective and laudable shifts in research ethics, including public registries of clinical trials, by using the power of peers for the power of good. The history of Beecher's "Ethics and Clinical Research" shows how a particular context prompted current ethics systems—and also reveals how options from the past can invigorate creative, ethical research in the 21st century.

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Further Reading

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