COMMENT

Reflections on Gadchiroli

SADATH A SAYEED

Division of Medical Ethics, Harvard Medical School, 651 Huntington Avenue, 6th floor FXB, Boston, MA 02115 USA email:Sadath_Sayeed@hms.harvard.edu

"Medicine is a social science, and politics nothing but medicine on a grand scale."(1)

In 1993, the Society for Education, Action, and Research in Community Health (SEARCH) began conducting what it termed a "field trial of home-based neonatal care" in rural India. The centrepiece of this clinical, intervention-oriented study was the training of village women to evaluate babies around the time of their birth, teaching and delivering essential medical care to those in need during the first month of life. The published results of this community trial were remarkable: incidence of neonatal morbidity and mortality was dramatically reduced in the intervention villages over a three-year time frame. Nevertheless, the work of SEARCH has been the subject of criticism in a textbook on international biomedical research published in 2007 (2).

Using a standard paradigm regarding the protection of human research subjects, it might seem a straightforward task to sound alarms about the Gadchiroli field trial. The main complaints appear to be as follows: 1) no trial was needed because antibiotics for bacterial sepsis in newborns are known to work; 2) even if a trial was needed in order to show that trained healthcare workers could effectively diagnose and treat babies with antibiotics, the Declaration of Helsinki was violated because adjacent control villages were not provided the highest standard of care for the purposes of comparison. The ethical critique is captured by the following:

> It is wrong for them to exploit the situation by conducting research that they could not get away with in affluent populations. And it is a strange sort of justice that excuses it on the grounds that villages in the control group are no worse off than many other villages in rural India (2).

There is more than rhetorical force in this argument. It is a morally shameful thing that the poor and marginalised in India (and elsewhere) suffer an unfair and disproportionate share of preventable mortality and morbidity, and that their ability to access decent medical care seems perpetually frustrated by socially constructed forces largely beyond their control.

I admit at the outset that when I became aware that SEARCH's work had been criticised, I was surprised. SEARCH was, in part, created to discover effective ways to respond to a brutal, longstanding reality in India. My initial reaction was reflexive: how could someone question the actions of this conscientious, activist organisation whose grassroots approach has for decades, and in the face of much societal indifference, championed a programme of empowerment for Maharashtra's most marginalised people? Also, as a physician deeply troubled by human and health inequalities, I have felt personally challenged by the professional example set by SEARCH's founders - well educated doctors who have steadfastly forsaken self promotion and material wealth in order to live with the destitute poor in the hopes of gradually improving the quality of their lives and their relative social standing. In this short commentary, I argue that only with a fuller understanding of the social philosophy of SEARCH, can the ethical merits of the Gadchrioli field trial of home-based newborn care be genuinely appreciated.

India's neonatal mortality problem

Even today (a decade after SEARCH began to investigate the potential for home-based neonatal care), over a quarter of annual global newborn deaths (over 1 million per year) occur in India. Three babies are estimated to die every minute. The neonatal mortality rate (NMR) in India is 43/1000 live births, compared with 4.5 in the United States (3). In 2007, a national health profile of India reported that only 52% of pregnant women had at least three antenatal visits prior to delivery, only 41% of women had institutional deliveries, and that 52% delivered without formally recognised skilled assistance (4).

Depending on place and local tradition within India, family members often assist with home deliveries, as do traditional birth attendants. Their skills are extremely variable, and are predominantly oriented toward care of the pregnant woman rather than the newborn after birth(5). A recent community survey within a rural region in Uttar Pradesh describes the reality for many of the underserved in India:

> Among 200 [families], 70.5% reported home deliveries conducted by local untrained nurses or relatives, and most mothers initiated breastfeeding only on day three, (39.5%) of [parents] had seen a sick neonate in the family in the past 2 years, with 30.38% in whom illness manifested as continuous crying. Health care was sought for (23%) neonates (5).

In a 2002 observational study on care-seeking by families with ill neonates from a slum near New Delhi, private providers without formal medical training failed to refer 70% of neonates with conditions that ultimately led to their death, and even if referred, less than half of caregivers followed such

recommendations. 60% of all neonatal deaths occurred within 24 hours of illness recognition (6).

Despite the general unreliability of the informal health service sector in India, it is estimated that less than 20% of the population utilises government-run outpatient services, and less than 45 % seeks inpatient care in public hospitals (7). The reasons for this are complex, but subsidised services are underutilised partly because the availability of such medical care offers no guarantee of quality. A 1999 Government of India Facility Survey indicated that about three-fourths of public community health centres did not have adequate equipment and only one-third of the primary health centres provided labour and delivery care (8). Six out of the seven available physicians per 10,000 persons in India work in urban areas within the more lucrative private sector (7). Accordingly, a large number of vacant posts remain unfilled in rural government health centres which offer healthcare to the poorest segments of population.

At the time SEARCH began its trial of home-based newborn care, all of these background conditions were locally amplified; in the early 1990s, India had yet to enjoy an economic boom spurred on by rapid development of the technical and service industries, and regardless, this growth never touched rural Maharashtra. In Gadchiroli district, less than half of the villages had an all-weather accessible road, less than a tenth of families had electricity, less than 40% had access to safe drinking water, and slightly over half of males over 7 years of age and less than 30% of females were literate. Over 50% of the population lived below the poverty line (9).

In 1993, SEARCH ascertained that the local NMR for the villages it served was around 60. They documented that 95% of deliveries occurred in the home, despite the relative proximity of public health care facilities. They also documented that available government health services were "plagued by staff absenteeism, poor motivation, and poor supervision". Through a household survey conducted in 1993, local villagers reported that over 50% of their newborns needed some kind of help, but less than 3% of these babies received professional medical attention. In order to better understand why so few neonates interfaced with the formal health sector, SEARCH catalogued familial attitudes exemplified by the following:

> Newborn babies are at God's mercy. They come with their destiny. If they have been sent for a short period, they go back. What can be done to save them?... It is futile to run around making efforts (9).

What is to be done?

It is difficult to overestimate the challenges facing anyone interested in meaningfully improving access to decent medical care for the neonates born in rural, impoverished India. Still, as one critic of SEARCH has done, it may be possible to conclude the following:

> Not every health intervention requires a clinical trial. Sometimes we understand quite enough to know that certain medical services are badly needed. What is required is not a clinical trial, but the political will and the resources to provide the care (2).

India has a serious neonatal mortality problem that is compounded by pervasive social inequalities that have existed for generations and often fall along caste and class lines. Perhaps a more enlightened and responsive Indian citizenry concerned about justice might be expected to prioritise expenditures from the public and private health sectors to constructively improve the situation for their most disadvantaged populations. Ideally, activist organisations ought to have reason to believe that, with raised awareness, sought-after resources for impoverished communities could be obtained (and this would not only include more medicines, doctors, and clinics, but also better roads, more electricity, clean water supplies, better education, stable economies of scale for villagers and farmers, and social security for families forced to tend to sick children).

Of course, this is not the situation that SEARCH found itself in when it began to consider how it might change the health care trajectory for neonates born in Gadchiroli. After years of experience of living among the rural poor, they instead had reason to believe that the available public and private health care delivery systems were incapable of providing quality newborn care. Further, they had reason to believe that even if the formal system of healthcare could be improved over time, the local rural population remained reluctant to access such care. Finally, they had reason to doubt whether, through advocacy alone, they might ever convince an increasingly urbanised society to be more responsive to the needs of the local population. In the meantime, they continued to bear intimate witness to an appalling high rate of neonatal death, parental sorrow, and a nagging communal feeling of helplessness.

Under such adverse circumstances, what did a commitment to justice demand of SEARCH? Let us now take a closer look at their approach to address the root problems of the rural poor in Gadchiroli. First, it is a caricature of SEARCH's dedicated efforts to suggest this case is primarily "a matter of researchers responding by doing what they know how (and are paid) to do."(2) It is also offensive to (even parenthetically) suggest that SEARCH's research was motivated by financial considerations. They did not look at background conditions of social injustice as problems that must be solved though conventional clinical research methodologies let alone modern political institutions. Rather, they viewed the plight of the rural poor as symptomatic of much deeper individual and social corrosion:

> [Some people] see things from a single point of view only. "What is there for me? What will I get from it?" This "I" can never be satisfied. It is a bottomless pit. This narrow, insular attitude only to think of self-interest makes the man lonely. He confines himself in this prison and becomes lonely from within. He yearns for liberation. The way to find liberation is to have contact with others. Gandhiji once said: "there is enough on this earth for everybody's need but not

> everybody's greed." Avarice can never be satisfied. To limit one's desires, to feel unhappy when others are unhappy and thus relate with others is one's duty. This is the way for liberation for both (10).

Within this comment, we catch a glimpse of a complex moral dynamic animating all of the work of SEARCH in Gadchiroli. On the one hand, SEARCH was created by two physicians with master's level training in public health from Johns Hopkins University, and this education no doubt informed their understanding of how quality clinical research ought to be conducted. They clearly understood that to have the largest possible potential impact on India's tremendous neonatal mortality problem, to influence healthcare policy, some kind of empirical proof of the efficacy of their interventions would be needed. On the other hand, Abhay and Rani Bang did not come to Gadchiroli with a preset investigatory agenda or with specific sponsorship to conduct a clinical trial on newborn survival. Rather, they moved there to do as their guru Mahatma Gandhi had famously advised: "go to the villages of India."

> Our dream was simple. We wanted to change the conditions of our villages where the majority of our population lived. They were ailing and surrounded by death. We wanted to treat them and, along with health-service, bring social improvement (10).

As part of a calling and a means to their own self-liberation, this couple wanted to live in a rural setting, to listen and dialogue with their community about their problems, and to work to solve such problems in ways that empowered the community and avoided reliance on a historically unresponsive, increasingly urbanised, and materialistic Indian society.

It is telling that SEARCH's motto is "research, not on people, but with people", and, its vision a "realisation of 'Aarogya Swaraj', ie people's health in people's hands, by empowering individuals and communities to take charge of their own health, and thereby, help them achieve freedom from disease as well as dependence."(9) Such aspirations are hardly the typical goals of clinical investigators more familiar to many of us in academic medicine. Regarding the goals of research, Abhay Bang has said the following:

> How can a wheel of a bullock cart be made lighter, has anyone made any research for that? How to bring up the water-level of a well, or how can a running nose of child be cleaned so that it does not hurt – [is] any research being done on such subjects? If research regarding such small problems is done and reached rural people, their misery can be reduced (9).

The point of reflecting on the social philosophy of SEARCH and its approach to research is not to claim they possessed a superior understanding of the purpose and meaning of all human endeavour. However, any responsible accounting of SEARCH's work on newborn health in Gadchiroli ought to openly reckon with its unique and identity defining mission in attending to the problems of rural poor Indians.

It seems no small coincidence that the Bangs' inspiration, Mahatma Gandhi, regarded his adult life as a series of on-going personal experiments. I suspect that the Bangs' carried a similar attitude into Gadchiroli. This is part of the SEARCH narrative that appears entirely absent from recent textbook discussion about the ethics of the Gadchiroli home-based newborn studies. It is surely tempting and easier to narrowly bracket the published studies on newborn health as simply "clinical research on human subjects" and supply predictable analyses. However, in doing so, we gloss over SEARCH's radical communitarian perspective on core human values.

Sensing rudimentary, largely intractable, disconnections between rural people and systems of formal medical care, SEARCH concluded that a novel strategy was needed to pragmatically improve local health outcomes. If much of the rural population could not be convinced or incentivised to access available mostly free medical services, perhaps the best ethical compromise would be to bring the services to them in an expeditious, non-threatening, and respectful manner. This was a community-based experiment consistent with a rural empowerment social philosophy. SEARCH proposed to fundamentally alter the basic patient-provider transaction and the structure of routine health care encounters. They not only posited a horizontal approach to delivering quality health care, they also hypothesised that much of the machinery traditionally used to deliver good and satisfactory medical services (ostensibly in the form of a clinic and the personage of a highly trained and skilled, licensed physician) was unnecessary.

How did SEARCH go about testing whether a well-trained literate village healthcare worker could perform these diagnostic and therapeutic tasks? It is true that they did not introduce the trained village health worker into all of the communities with whom they had previously established working relations. Some villages within SEARCH's total outreach program continued only to have vital statistical information on births and deaths collected every few months by a distinct and separate team of previously established male village health workers. This decision prompted the following criticism:

> The fact that poor villagers in India generally do not have access to good medical care does not mean that the same circumstances apply to clinical trials. In the SEARCH study, as in most clinical trials in underdeveloped areas of the world, the researchers could easily provide treatment [to the control group] (2).

For well over a decade, the global healthcare research and ethics community has engaged in a debate about how conditions might be controlled for under conditions of profound local resource scarcity where there exist obvious external constraints on individual liberty and upward social mobility (11). Some argue realistic assessment of contemporaneous conditions that constrain access to adequate healthcare for such populations potentially provides a sufficient reason to contextualise risks, harms, and benefits; thus, it can be justifiable to test a clinical intervention against the status quo on the ground. Others decry this manoeuvring and insist on universal standards for any and

all persons asked to participate in medical research – despite recognition that once the participants step back outside of the temporarily fabricated trial world they will almost certainly return to a state of affairs where inequitable access to basic healthcare services is the norm.

As is often the case in less-than-ideal situations that ask for a trade-off of closely held values, there are attractive moral intuitions on both sides of the debate. No doubt, impoverished people should not be subjected to inferior standards of care as research participants simply because they are poor and live involuntarily under adverse circumstances. Allowing double standards in medical research not only risks exploitation of these people, it has the potential to reinforce actual pre-existing social inequalities. There are further, insidious consequences. By giving in to the appalling conditions on the ground and contextualising harms and benefits, we seem to be excusing ourselves from doing more. It can be argued that we latently legitimate the acceptability of status quo gross human inequality.

On the other hand, bioethical discourse shouldn't only speak in a language of idealised abstraction if it seeks to be of service. We continue to live in a brutal, unjust world despite ubiquitous, millennia-old social awareness. Ethical principles only resonate in lived human experience. Thus, our perception of what it means to authentically demonstrate respect for persons, to act beneficently or justly often depends on the vantage from which we are perched. Where and how one finds real human, moral value might reasonably depend on whether one sits in an office some 12,000 miles away from the experienced problem versus whether one toils for years alongside persons suffering daily indignities under conditions of profound inequity.

Notably, SEARCH did not appear to have regarded the people within the "control" villages as research participants in a traditional sense. Community consent for the study was only sought in the intervention villages presumably because SEARCH did not propose to alter or remove any of its own prior existing or government-sponsored baseline services available in the other villages chosen for comparative monitoring. While some will continue to insist from afar that SEARCH was obligated to seek consent and offer the highest standard of medical care to the comparison villages, it remains (even to this day) a fantastical claim to think that high quality hospital equivalent neonatal services could "easily" be offered to babies born in the village huts of India.

Conclusion

Before anyone moves quickly to pass critical judgment on SEARCH's investigations into home-based newborn care, he or she ought to critically reflect on the full narrative of their lived experience actually serving the poor. Oftentimes, it is far easier to publish lip service homage to grand ethical declarations than it is to do the hard work of tangibly producing a modicum of justice for those who unfairly suffer early disease and death. It is no small irony that despite a claim by a critic of SEARCH that there is little researchers can do about the lack of treatment for most of the poor in India, their strategy of home-based newborn care (tested and proven to work in Gadchiroli) has been adopted by the Central Government of India in its most recent five-year national health plan to address rural neonatal mortality. This latest political fact does not excuse the government or the educated, affluent population from failing to do more for the poorest communities in India, but perhaps it can teach us to celebrate (with more humility) the conscientious dedication of decent people working alongside the destitute poor.

I believe SEARCH's regard for and use of research methodologies can only be understood in the context of their overall rural empowerment philosophy. SEARCH's sense of the need for human experimentation is informed by Gandhi's concern for the most marginalised, and is substantively different from modern, dominant Western tradition. In the end, SEARCH's work in Gadchiroli was and should remain controversial not so much because it violates formal bioethical declarations, but because it pushes the rest of us (much like Socrates) to more seriously evaluate what it means to live a good and meaningful human life.

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