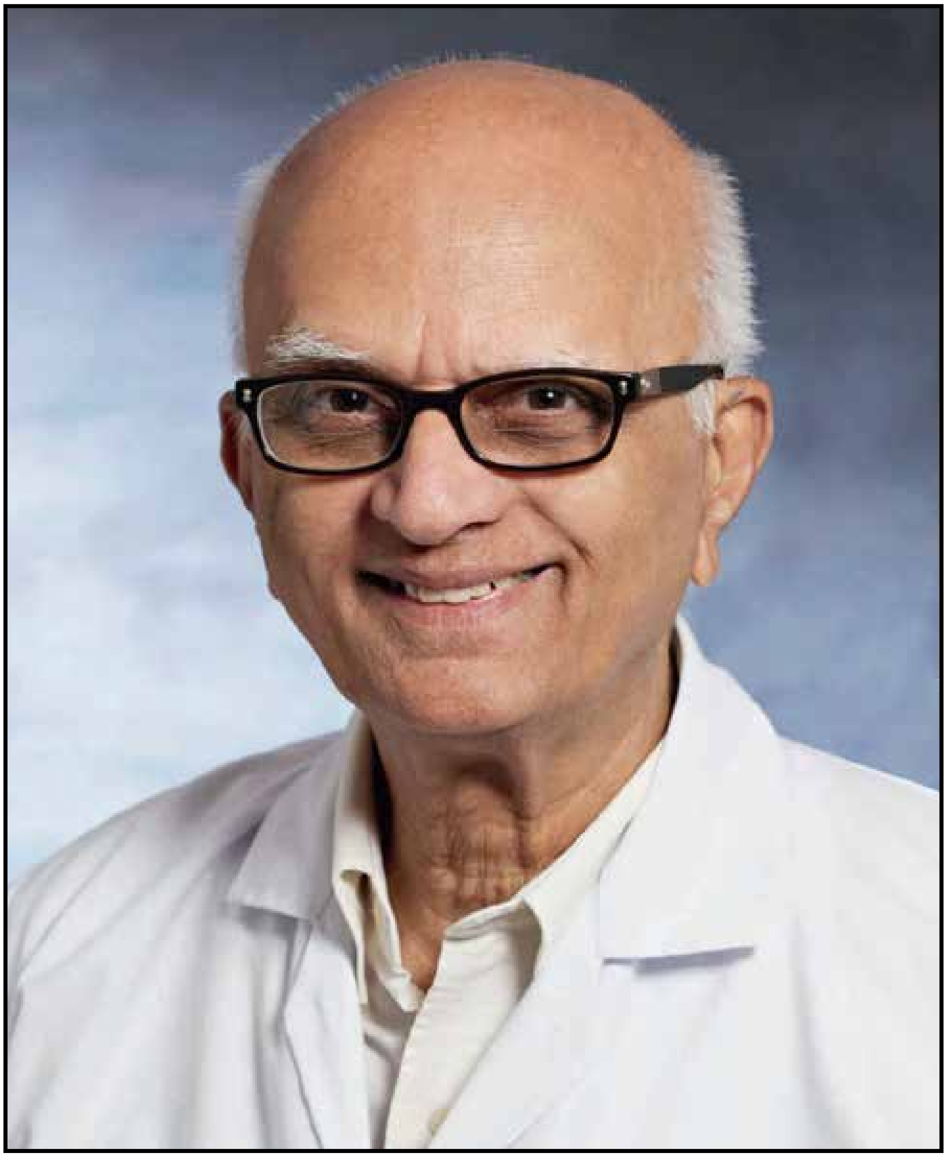
(January 2025)

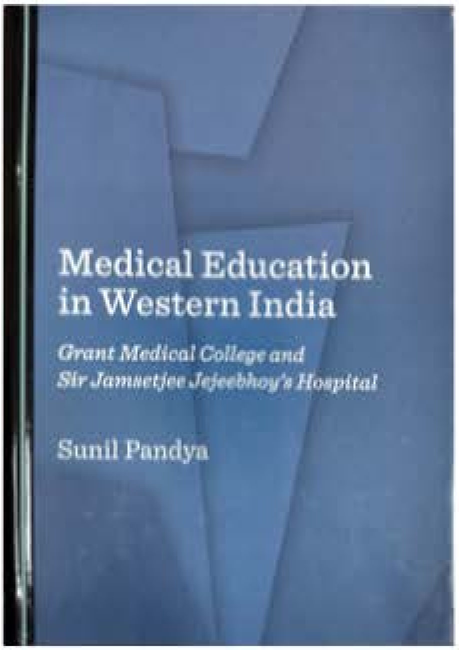
Celebrating our Founder Editor and his dedication to ethical medical care and research

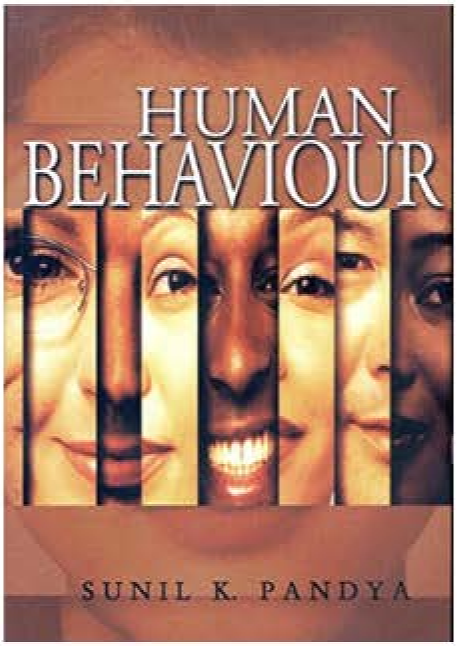


DR SUNIL K PANDYA

(February 11, 1940 to December 17, 2024)

The many facets of a Renaissance man:
Images and books by SKP





CONTENTS

Note: *The titles of Dr Pandya's writings are hyperlinked to their original HTML versions*

INTRODUCTION

Dr Sunil K Pandya: a meaningful and richly productive life

What makes a person who is an established neurosurgeon, a respected professor and ethical practitioner, feel the need to enter the additional and unknown arena of activism? The urge to create awareness of the need for ethical practice, the readiness to accept challenges and speak truth to power in the increasingly commercial environment of the 1990s are what set Dr Sunil K Pandya (SKP) apart from other honest and ethical doctors of the time. In his own words, "I do not wish to exist without a meaningful and productive life."

Not only did SKP and a small group of colleagues throw themselves into engaging with their students and co-workers, they challenged the medical associations and the top regulatory bodies such as ICMR, MCI, analysing through an ethics lens every policy and document that emerged from these authorities. SKP was the Founder Editor of the *Indian Journal of Medical Ethics (IJME),* in all its avatars, and stayed an enthusiastic and organic part of the journal over the next thirty-two years. In the early years, he and Anil Pilgaonkar spent hours after work inviting authors to write, typing up articles, coordinating with the typesetter, dealing with the printer, and often paying for the printing themselves. Yet no issue was ever delayed or skipped, as noted by Sanjay Nagral in an Obituary in *The Hindustan Times.* In this, they were ably supported by Satish Kulkarni, who did the typesetting for free, and others.

SKP chose to step down as Editor of *IJME* in 1999, and stuck to a policy of non-interference in its day-to-day functioning and policies, even when he had misgivings. This is, in itself, a rare quality among founders. He continued to take up activities related to ethics in medicine, and encourage others to do so. SKP wrote frequently in this journal and others. We were fortunate to have him write the Editorial commemorating the 30th anniversary year of *IJME's* existence, perhaps a milestone no one would have imagined possible in those early days. Quite recently, he congratulated FMES on the 40th issue of its fortnightly newsletter, on doing a "marvelous job" of keeping interested readers informed.

Very much a "people person", SKP was happy to meet anyone interested in the cause of ethics, welcoming all of us who joined *IJME* in any capacity, and taking great delight in people's unusual hobbies or interests. As a close friend has said, "he was humble, and interested in everything and everyone". Literature, especially the English and European classics, the Medical Humanities, the History of Medicine, and Gandhian principles, all fascinated him.

SKP's deep interest in the history of medicine led him to research and write a book titled *Medical Education in Western India: Grant Medical College and Sir Jamsetjee Jejeebhoy's Hospital,* described by MK Mani in *The Hindu* (of March 11, 2019), as "a gripping account of how these administrators, doctors and philanthropists united to develop a great institution, sometimes having to overcome prejudice and resistance from other officials of the East India Company."

SKP also gave lectures on the history of Grant Medical College, at the college.

His vigorous commitment to medicine and to the furthering of knowledge led him to donate his body for research to the Anatomy Department of the GS Medical College, Mumbai. The decision had been made years ago, but he was anxious that it should be implemented by his family. And so, he went "gentle into that good night", on December 17, 2024, with dignity and generosity, right till the end.

In this tribute, we present the personal reminiscences of close colleagues about the man himself, his felicitation by *IJME* in 2010, and a selection of his writings in the journal, arranged chronologically, in the original format. Readers can see the changing appearance of *IJME* through three decades. However, the issues covered in SKP's writing, from the doctor-patient relationship to the functioning of regulatory bodies, from the need for second opinions to that for revamping medical education, are all live issues even today, and the points he makes remain very relevant. Some debates, such as those on determination of brain death and testing every patient for AIDS, hotly debated at the time, are still evolving.

Through this online volume, we honour SKP, our Founder Editor and moving spirit for over a quarter century. He will be sorely missed by his family, friends and former students, and his extended family at *IJME,* the Forum for Medical Ethics Society (FMES), Research and Humanities in Medical Education *(RHiME),* and St John's Medical College. But his contributions to ethical medical care and to building the fledgling discipline of medical ethics and bioethics in India will survive well into the future.

Meenakshi D'Cruz.

Indian Journal of Medical Ethics Vol VIII No. 1 January-March 2011

Dr Sunil Krishnalal Pandya

On the occasion of the Third National Bioethics Conference of the *Indian Journal of Medical Ethics,* the editors of the journal and the coordinators and collaborators of the conference are privileged to honour Dr Sunil Krishnalal Pandya for his contribution to ethical medical practice, for increasing the public's awareness of bioethics, and for his untiring advocacy to bring ethics to the centre stage of health care and into the conduct of health professionals.

Born in 1940, Sunil Krishnalal Pandya studied medicine at the Grant Medical College and the Sir JJ Group of Hospitals in Mumbai. After obtaining his postgraduate degree in general surgery in 1965, he trained in neurosurgery under Dr Gajendra Sinh. He completed his further studies under Prof Valentine Logue at the Institute of Neurology, Queen's Square, London. In 1975, he joined the Department of Neurosurgery at Seth G S Medical College and KEM Hospital in Mumbai. After 23 years of service at this public hospital and prestigious medical college, he retired in 1998 as Professor and Head, Department of Neurosurgery. Since then, he has worked as a neurosurgeon at the Jaslok Hospital and Research Centre in Mumbai.

His contribution to the discipline of neurosurgery, through his research and writings in leading national and international medical journals, testifies to his status as a leading neurosurgeon as well as an exceptional contributor to the further development of the discipline. But he is taller than other great clinicians and scientists because of three additional virtues in his character, and his contribution flowing from these virtues is no less than his contribution to neurosurgery:

First and foremost is his commitment to ethical medical practice. He does not like to preach what he does not practise. He believes that students are intelligent, and that they soon see through our pious verbal outpourings if we talk about ethics but do not put these principles into practice. Many health activists have struggled to impress upon doctors that they must communicate with their patients, and also give them access to their medical records. Dr Pandya began by making the time to talk to his patient at length - drawing diagrams on blackboards and on paper if needed. He always made a carbon copy of the patient's medical record and handed this over at the end of the consultation; this was not an easy task in the busy public hospital where he served. He continues the same practice even today at the private trust hospital where he works.

The second characteristic that sets him apart from his colleagues is his constant effort to look beyond the narrow discipline of clinical medicine to the fields of medical history and bioethics. This interest led him to document the history of his alma mater, the Grant Medical College, to trace the development of hospitals and medical services in Mumbai, to write the history of medical ethics from ancient times to today in India, and so on.

The third characteristic that has earned him accolades as well as disapproval from the medical profession is that he says what he considers is right; he is never afraid of how he will be received or perceived by the audience. He always uses simple language and comes to the point quickly His comments on trends in the medical profession and services, in medical journals, in the *IJME* and in lay publications, have provided sensitive medical professionals food for thought, and pushed them to do something to change the situation. He tried to keep away from the limelight and refused to give priority to activism over being a role model in his practice. But on the urging of friends, he did come forward to fight the Maharashtra Medical Council elections in the year 1992, on the platform of the Forum for Medical Ethics. This was a turning point for the process of reforms in the elections to the medical council in Maharashtra. It also eventually led to the birth of a journal that is now the *Indian Journal of Medical Ethics.* He has continued to write with exceptional candour on the Medical Council of India; this includes a long piece indicting Dr Ketan Desai, at a time he was a revered and feared personality in the profession, and long before his arrest and the dissolution of the Council.

Over and above everything that he has done as a person, a medical professional and a reformer of medical practice and services, Dr Pandya's contribution has been in laying the foundation of a medical ethics journal. From 1991 to 1998, his office in the Department of Neurosurgery at the KEM Hospital in Mumbai was also a hub of bioethics activities. Every Wednesday, from 5 pm onwards, week after week, month after month and year after year, he hosted a meeting for anyone and everyone interested in bioethics. In each meeting he would generate discussion on an issue in bioethics. He would bring literature for everybody to read, he would get bioethics films to view and discuss, he would invite bioethicists passing through the city to speak. These weekly meetings also inculcated the spirit of collective functioning in those involved in the journal's publication. Though Dr Pandya had the most responsibility as editor, he never avoided the back-breaking manual work of bringing out the journal. He also ensured that he provided space to all others who were involved, to contribute. Above all, he consulted them and ensured that he carried the group with him. He made everyone commit to ensuring the timely publication of the journal, a tradition that has been upheld by all editors after him and one that has helped make the journal a success. He taught us to be inclusive and tolerant of other people's viewpoints, and to make the journal a genuine platform for interaction to learn and enrich bioethics.

He is a very humble human being. He attributes everything good that he is doing to what he learnt from his teachers, who are his role models. He is shy of taking credit for what the *IJME* is today, and will only say: "I started a small newsletter. People more talented than I made it an internationally recognised journal."

Indeed, a humble beginning with a solid foundation is always more enduring. The *IJME* completes 18 years of uninterrupted and regular publication today. In last five years, it has attracted a large number of institutions and individuals to ally with it in organising three national bioethics conferences. This inclusiveness, openness, and capacity to provide a platform to all who care for high ethical standards for health professionals and practices, will endure thanks to the solid foundation laid by some remarkably humble people. We express our gratitude for Dr Sunil Pandya's contribution and are proud to know that he is always with us and helping us in taking this work ahead.

Amar Jesani

Memories of SKP

I met Sunil Pandya only twice in my life: in 2014, at a meeting on medical education in Karamsad, Gujarat, and in 2017, when he came to Mangalore to deliver a talk on our forgotten heritage in medical ethics at an Ethics Conference. Of course, I was his admirer, having read his "Letters from Mumbai" and knowing about his key role in founding and running the *Indian Journal of Medical Ethics,* which is now a journal and institution we can be proud of. He was an exemplar in how, in a public hospital, he ran a surgical service focused on the patient and high quality.

I was privileged to have had a lively email correspondence with him over the past 15 months, which I will always treasure. Sunil made me drop the prefix Dr in our first email. He inspired me to write the column "Letter from Mangalore" in the *National Medical Journal of India*. I was surprised to find him respond with words of genuine appreciation the very day a piece on lack of clinical skills appeared. He signed off with the sentence, "I look forward to learning from many more such letters - and by other means as well." I have never received such a letter from a person 25 years my senior and without a trace of affectation. I realised that we shared a love of books, of the history of the profession, and the men of medicine- the writings of William Osler and Harvey Cushing, Lewis Thomas, Jacob Bronowski, Kenneth Clark, and the lives of Indian stalwarts like Jivraj Mehta, and CG Pandit. It was my privilege to source some books for him that he wanted to read. He requested a soft copy of the book *Intoxicated by My Illness: And Other Writings on Life and Death* by Anatole Broyard, a profoundly reflective book written in the terminal phase of the author's illness.

I was unaware of his illness till at the end of October. In a prompt but brief email response, he mentioned almost parenthetically at the end, "I am seriously ill." I was stunned, and his response was stoic: "As they say, life has its peculiar turns and twists," and he ended this final note with best wishes to me. The reason he wanted to read the book by Broyard now dawned on me. I wanted to meet him during a visit to Mumbai but couldn't. I learned about many other facets of his personality and his influence on so many people after his death. Sunil was a great man, a good man, of uncommon simplicity, authenticity, and humility. He was a man of courage who lived and died according to his principles, of which he was a living embodiment. I have a deep sense of personal loss at his passing, but I am very grateful that, as for countless others of his patients, colleagues, and friends, his life touched mine.

--Anurag Bhargava, *Professor of Medicine, and Head, Centre for Nutrition Studies, Yenepoya Medical College, Yenepoya (deemed) University, Mangalore.*

I am writing this on behalf of my colleagues at the Division of Health and Humanities and the Department of the History of Medicine at St. John's Medical College, Bangalore, although I know that they have messages of their own.

I knew of Dr. Sunil Pandya before I actually met him. I had read his fascinating historical account of the Medical School in Goa. I knew that the number of doctors who were interested in the History of Medicine was relatively small and I wondered what it would be to meet him in person. This happened much sooner than I expected, when he visited us to review the archives that we had. I can still picture him in a light blue shirt, the boxes of the Major General SL Bhatia collection all open in front of – his water bottle close at hand. He would rise occasionally to take a photograph on his tiny digital camera. I recall his complete immersion in the archives. I did not know that this would all lead to a tome on the history of western medical education in Mumbai and in Grant Medical College in particular. But I was delighted to write a review on the book for *Current Science.* We shared a common passion for the History of Medicine – his was a more scholarly pursuit while I attempted to popularise the history of medicine through the Maj Gen SL Bhatia Museum of the History of Medicine.

I remember him for his generosity and kindness and his unstinting efforts to facilitate others. He introduced Dr Manjulika Vaz and me to the Tata Memorial Hospital in Mumbai. And, over the years we have had a wonderful learning experience, thanks to him, interacting with Dr Badwe, the then Director, and Ms Nishu Goel, the Lead on the Patient-Navigator Programme.

I remember him for his insatiable curiosity. On one occasion he indicated an interest in visiting Dr Olinda Timms because he had read about her eclectic collection of bells from various countries and across India. We had a wonderful evening – but, the abiding thought is that there is wonder and learning in everything we encounter.

We did not know Sunil Pandya enough – but, we feel close to him. His gift of a large number of papers, clippings and books curated by my colleague Ms. Radhika Hegde, form the Sunil Pandya Collection at the archives at St. John's Research Institute. These are a constant reminder to us of the breadth of his interests and his scholarship but most importantly, of the man he was.

--- Mario Vaz, *Former Head, Department of History of Medicine; Division of Health and Humanities, St. John's Medical College, Bangalore*

I was jokering (facilitating) a Theatre of the Oppressed workshop at the University of Chicago Center in Delhi, in November 2016, when I noticed a stranger sitting at a distance and keenly watching the proceedings. As is my practice, I walked over to him and invited him to participate in the theatre games and exercises with the other participants. I explained that a theatre workshop does not favour mere observation, and that everyone is encouraged to participate. He explained that although he would have loved to join, he was constrained to sit out because of a medical condition.

During the ensuing lunch break, we sought each other out and were soon engaged in conversation about the games and exercises. I was surprised by his understanding and depth of knowledge about the Medical (now Health) Humanities and about Theatre of the Oppressed, which I had until then assumed was a rather obscure form of theatre for most people. At a later session, he was introduced as a speaker, and I kicked myself when I discovered that I had unknowingly been talking to Dr Sunil Pandya, founder editor of the *Indian Journal of Medical Ethics*. This is a journal that is the epitome of ethics just like its founding editor was. He later wrote : "What were my impressions as an observer? I was astonished at the ease with which the Theatre broke down barriers–hierarchical, social and personal."

That single chance encounter remains a lasting memory of the man, as unassuming and humble as anyone can be, whom I wish I had met much sooner and more often. Seldom has a single meeting left such a memorable impression on my mind. As we pay tribute to Dr Pandya today, I am reminded of the frailty of our existence, and of the fleeting serendipitous events that make living worthwhile.

--- Navjeevan Singh, *former Director-Professor of Pathology, University College of Medical Sciences, University of Delhi, Delhi*

I will miss him very much as he walked the talk in ethical clinical practice. They don't make many of his kind anymore.

And, I remember those days, 31 years ago, sitting in Dr Pandya's office. *IJME* started as *Medical Ethics,* and was nothing more than a newsletter.

And it survived, had highs and lows needing many cardio pulmonary resuscitations. Most of the times, Dr. Pandya would just pull out money from his own meagre KEM public hospital salary to bring out "just one more" issue.

----Nobhojit Roy, *Chair of the Center for Leadership in Global Health, Kigali, Rwanda*

My encounter with Dr Sunil Pandya occurred recently, after his retirement, on his visit to the Division of Health and Humanities at St John's Research Institute. He was here to explore Maj. Gen. Bhatia's archives for his book on the History of Medical Education in Western India. He was courteous and engaging, and I was attracted by the delight and enthusiasm he expressed at our work in the young Humanities Division and our plans for its growth.

I was a bit in awe, as his contributions, by this time, to both medicine and medical ethics were legendary. Further, he had just reviewed my recently published book *Biomedical Ethics,* in the *Indian Journal of Medical Ethics,* in glowing terms. He may have sensed my diffidence because, though usually reserved, he spontaneously agreed to join us at my home for high tea.

He was the perfect guest, charming and appreciative. But it was my bell collection that caught his attention. He listened to the stories of their provenance and peculiarities, and insisted that I should publish an illustrated book on these "tiny wonders"!

I did not realise how serious he was until I began to receive regular e-mails from him with anecdotes and curated stories on the world's oldest bells, bells of World War II, ancient bell foundries, bell metals, bells in religious history and unique bell shapes. All these are now in a folder, awaiting their rightful place in a publication he believed in more than I did.

These last few years, we exchanged e-mails on bells and general topics, including his health, which taught me a lot about the man behind the legend; his eclectic taste and openness, committed to people and beautiful ideas, encouraging both with equal zeal. He took his role of mentor and guide seriously, and the outpouring of affection and loss at his death is unsurprising. In a world of diminishing medical role models of the widely-read, honourable professional genre, he will be greatly missed.

--- Olinda Timms, *Adjunct Professor, Department of Health and Humanities at St. Johns Research Institute, Bengaluru*

Dr. Sunil Pandya's presence at the SL Bhatia History of Medicine Museum was always special. When he walked into the archives, he brought with him not just his quiet, unassuming energy but also his boundless passion for the history of medicine. He would sit with the books and manuscripts for hours together, gently flipping through pages as though greeting old friends. For him, history wasn't just about events or dates—it was about the people, the ideas, and the legacies they left behind.

In December 2018 and again in 2022, boxes of meticulously covered books arrived from Mumbai, each book wrapped with care. This collection stands as a testament to Dr Pandya's interdisciplinary engagement with the medical sciences, history, and ethics, deeply rooted in his reflective practice of medicine. The catalogued collection now comprises approximately 350 rare classical books.

The collection is a treasure trove spanning various domains:

- the History of Medicine: Including rare works from the 18th and 19th centuries.
- Medical Education and Ethics: Offering insights into the evolving principles of care and instruction.
- Indian History, Neurosurgery, and Ephemera: Highlighting his diverse intellectual pursuits.

Among the highlights are salvaged books from the Bombay Branch of the Royal Asiatic Society, which Dr. Pandya rescued in the 1980s from a massive discard by the library of the Seth G. S. Medical College. These works, some gifted by British professors from the Grant Medical College or British Physicians in private medical practice in Bombay, were later passed on to Seth G S Medical College in 1925. Additionally, his personal Osler collection, journals from the Escola Medica in Goa containing rare historical accounts, and manuscripts related to this institution enrich the holdings. Dr. Pandya's collection also features ephemera and rare magazines such as Sandoz, Abbot, *Pulse,* and *Housecalls,* which blend medical history with superb historical essays and photographic archives. The discontinuation of *Housecalls,* he once remarked, left a gap in documenting the narratives of Indian medical colleges and eminent personalities—a void partially filled by his curated donations, which are now available for reference.

Reflecting on his collection at the Bhatia Museum and Archives, Dr Pandya wrote, "I am grateful that you will provide an admirable home for these old friends—loved and cherished over decades. In your library, they will be of use to many, many people." But for us, as curators, we are the ones who feel truly grateful—grateful for his trust, his remarkable generosity, and the unwavering passion he shared, which has greatly inspired us. Dr Pandya embraced the interconnectedness of disciplines. His collection embodies this ethos, offering a lens into how history, ethics, and the humanities shape the practice of medicine. For Dr. Pandya, the history of medicine was not merely an academic pursuit but a way to enrich his reflections on the art and science of healing.

A frequent visitor to the museum archives, Dr Pandya saw the Archives at St John's as aligned with his vision—a space where history and medicine coalesce to inspire inquiry and understanding. His enduring contributions continue to guide and influence the study of health, ethics, and humanistic medicine, reminding us of the profound impact of interdisciplinary thinking in shaping both individual practice and collective memory. These books can be accessed only in-person, as of today, from the SL Bhatia History of Medicine Museum, Library and Archives in St John's Medical College on request.

***-- Radhika Hegde,** Curator, SL Bhatia History of Medicine Museum, Library and Archives; and **Manjulika Vaz,** Assistant Professor at the Division of Health and Humanities; St John's National Academy of Health Sciences.*

I got to know Dr Sunil Pandya when I was at the Foundation for Research in Community Health (FRCH), doing research on health systems and financing. He was quite fascinated by my analysis of budgets and would call me to his chamber in KEM Hospital to discuss health financing-related issues; and during such discussions I learnt from him about his interest in the history of medicine.

I too was interested in the history of medicine and specifically the history of Bombay's health care system. We exchanged documents and literature on this, a good bit of archival material, including on KEM hospital. I learnt from him a lot through his personal insights.

These informal discussions and moments spent with him were indeed fascinating. I wish I had collaborated on this formally with him. But that was not to be, as both of us were busy in our own work commitments.

I also got to know him as a physician as he advised and treated my partner, Satjot, for her chronic back pain. His approach was very humane and friendly and, of course, ethical. He was the fountainhead of medical ethics and we all know his contribution to this through FMES and the IJME journal. We will miss him and remember him through these remarkable contributions he has made. Let us celebrate this.

***-- Ravi Duggal,** Independent Sociologist and Public Health Researcher, Mumbai*

I first met Dr Sunil Pandya in 1975, at the age of 15, when a neurologist suspected my migraines were actually seizures due to a lesion in my brain. For many years, "SKP" would call me the "girl with the hole in her head". It did not strike me then that, by teasing, he was actually helping me shed the stigma of epilepsy.

Over the years I called upon SKP many times, as a journalist, an editor, a patient, and on behalf of family and friends. He was always accessible, he made complex ideas clear, he never talked down to me, and he spoke his mind without hesitation. And when a copyeditor chopped his interview into an incoherent paragraph, he could have given me a blasting – but simply said "Don't worry about it." SKP did not see himself as more important than the message.

Decades later when I joined *IJME* as executive editor, SKP had one bit of advice – bring the issue out on the first day of the month of publication – a practice we have tried to maintain by and large. As long as he was editor, he would read through the proofs and pick up errors that I had missed. Within a couple of days of the new issue being published, I'd receive a copy with his detailed comments. He respected editorial decisions and in my 14 years as executive editor, I do not remember a single complaint or appeal on behalf of someone. After he stepped down as editor, he was always there to give his opinion, but only when asked for it.

The memories that stay with me the most are of SKP the physician. He would take a minimum of one hour over each consultation, reading the reports, asking detailed questions, conducting a most thorough examination, and writing up meticulous notes which he would give you for your records. If you went back to him 10 years later, he would pull out his notes in a jiffy. What was even more striking was his respect and care for his patients.

Many years ago, I went to him with my father-in-law who had been advised surgery. As we left the consultation room, my father-in-law turned to SKP with tears in his eyes. Exhausted by endless tests and medical consultations over the years, he said: "You are the first doctor who examined me. You spoke *to me,* and in Hindi. You asked me what was wrong." That was the essence of SKP.

-- Sandhya Srinivasan, *Independent Researcher and Consulting Editor, IJME*

The sun may set on a life well-lived, but its warmth lingers in the hearts of those who remember.

Dr. Pandya was my first teacher in the history of medicine. When I had a question about the first Indian woman doctor, he quickly shared evidence from biographical sources. In our "Reviving Humanities in Medical Education" workshops, case studies from the history of medicine became an integral part of my teaching. He also showed me how American women like Ida Scudder and Elizabeth Lundy (later Kamala V Nimbkar) made significant contributions to healthcare and disability education in India at Christian Medical College (CMC) Vellore, and in starting the first school of occupational therapy in Mumbai, respectively.

When my contributions to disability activism were recognised, not in India but in New York, through the Henry Viscardi Award, Dr Pandya was among the first to congratulate me. More importantly, he educated me about the award's significance and the work of Dr Viscardi, which I had been unaware of. His dedication to historical accuracy and detail was unmatched. For instance, he meticulously compiled high-resolution images of Dr Viscardi's materials and even unearthed issues of *NASEOH* News to share with me. National Society for Equal Opportunities for the Handicapped (NASEOH) was founded by two industrialists - Vijay Merchant (the famous cricketer) and FA Fazalbhoy.

I cherish a personal memory of him at Marine Drive in Mumbai, where I often retreat to enjoy the ocean when visiting the city. One morning, as I watched the waves crashing against the rocks, I felt a gentle tap on my shoulder. I turned to see Dr Pandya with his characteristic smile. He told me he lived nearby and enjoyed morning walks there. Like this memory, his encouragement and advice will always stay with me.

Rest in peace, Dr Pandya. You will forever remain our teacher, mentor, and guide.

--- Satendra Singh, *Director-Professor of Physiology, University College of Medical Sciences, University of Delhi, and Co-Chair: International Council for Disability Inclusion in Medical Education, India*

Dr. Pandya was more than just a skilled surgeon. He was a teacher, a reader, a public health advocate, an ethicist, a historian, and a writer who spoke with clarity and honesty.

I met him only twice. The first time was in 2000, at a workshop on Ethics in Medicine in Nagpur. He was the main speaker, discussing medical ethics openly, not as a moral authority but with the honesty of someone who truly believed in what he said. The second time was in 2018, at the KEM Hospital in Mumbai. His honesty struck me again—he spoke his mind and never sought approval from anyone. He often said that his honesty and humility came from his mother.

Though I met him only twice, I closely followed his work. I read his essays and editorials in the I*ndian Journal of Medical Ethics* and the *National Medical Journal of India.* I would share these with my residents, telling them that Dr Pandya's writing was not only clear and honest but also challenged the way we think about medicine. His work, especially his "Letters from Bombay," introduced new perspectives on medical ethics and the challenges we face in our profession.

Dr Pandya's influence would often find its way into unexpected places—journal clubs, bedside discussions, and postgraduate sessions. Through his writings, my residents learned that medicine is not just about tests, surgeries, and treatments. It's about the relationship between doctor and patient, about public hospitals providing affordable care, and about practising ethics in our daily work.

I also watched his YouTube videos on the history of the Grant Medical College and KEM Hospital. Later, I learned from colleagues in Mumbai about his love for history and the meticulous research he did. His respect for his alma mater and teachers was clear. He always spoke proudly of them, knowing they had shaped his life and work. His writing reflected not just his intellect but also his deep love for the profession.

Dr Pandya lived a life marked by dedication, altruism, and purpose. He strongly believed in dying with dignity and embraced the unknown in peace. Like his colleague, Dr Manu Kothari, his views on life and death were unique. He often wrote about why we should not fear death, but rather welcome it when the time comes. As he would have wanted, we do not mourn his passing but celebrate a life that made a real difference. His values and contributions will continue to inspire doctors and teachers for years to come.

--SP Kalantri, *Department of Medicine, Mahatma Gandhi Institute of Medical Sciences, Sewagram, 442102, Maharashtra*

It was when we were launching our health humanities journal, *RHiME,* in 2014, that I first heard of Dr Sunil Pandya. When a call for submissions went out, he was amongst the first to respond in the affirmative. His paper titled "Learning in medical colleges: Then and now" was published soon after and it embodied his support for our endeavour, which was to bring about a transformation in the way medical students thought about illness. He wrote, "Students are not exposed to the humanities for 'want of time' due to massive syllabi and this in turn leads to physicians who are trained with very little or no exposure to the discussion of human suffering that accompanies disease." It is no wonder, then, that we requested him to join our editorial board, and he did so much to our delight. His support meant a lot to us, *RHiME* being, at the time, a fledgling journal trying something new and having no idea how it would be received. I was profoundly touched when, upon my premature, voluntary retirement from the University College of Medical Sciences, Delhi, he wrote something that cemented his place in my life as a mentor par excellence: "I, for one, am grateful for the brief but memorable opportunity I had of meeting you and listening to you."

Deeply reciprocated, Dr Pandya, deeply reciprocated. You will be missed.

--- Upreet Dhaliwal, *Former Director-Professor of Ophthalmology, University College of Medical Sciences, University of Delhi, Delhi*

On January 30, 2024, I got an email with the subject line "Salute from Mumbai". I did not recognise the sender's email ID. When I opened the email, the first sentence was, "I am Sunil Pandya, a retired neurosurgeon from Mumbai". It was early morning and that line woke me up more than the strong Chennai filter coffee in my hand. I knew Dr. Pandya well as I had read all his "Letters from Mumbai" series published in the *National Medical Journal of India.* I had met him personally just once before, during the National Bioethics Conference, but he was someone who was virtually present at all meetings of the *Indian Journal of Medical Ethics* editors, because of the deep impact he had – and continues to have – on the journal, and on medical ethics in India.

Dr Pandya had listened to an episode of my podcast titled "Clinician Introspects" and written to me expressing his admiration for the work and his sincere appreciation. He did not know me well, and there was no need for him to make the effort to write to me. But he did. My podcast was very crude and low profile. I recorded it on my phone and posted it on a free platform. It was no match for all the impressive podcasts on medical topics out there, produced and hosted professionally. It was a time when I was starting to get discouraged by the poor response and was contemplating discontinuing it.

It was at that point that Dr. Pandya's message came, and I cannot explain the elation that I felt when I read it. Such amazing words of appreciation from a man who stood for ethics and people - centred medical practice were all that I needed to keep going. If this was the impact he had on a random amateur like me, who had interacted with him just twice, I can imagine the nourishment, succour and motivation that his students, mentees and friends would have received from him. I will forever remember his e-mail and hold him in my mind as someone who has influenced the way I do my work.

----Vijayaprasad Gopichandran, *Rural Women's Social Education Centre, Chengalpet 603109, INDIA, and Working Editor, IJME.*

Should all patients be tested for AIDS (acquired immunodeficiency syndrome)?

Sunil K. Pandya

Some large hospitals in Bombay insist that every patient seeking investigation or treatment should undergo tests to check for Human Immunodeficiency Virus (HIV).

This is done on the following grounds: (1.) In view of the known spread of this disease, it is essential to test every one presenting at the hospital for the patient's own safety. If the test for HIV is positive, appropriate measures can be instituted in an attempt at preventing the development of AIDS. (2.) Hospital personnel must be protected against this disease which, at present, has no known therapy against it. This can only be done if each and every patient is tested. (3.) The data collected will facilitate epidemiological studies.

Problems posed by such insistence

1. All patients are forced to undergo a test, not performed gratis by the hospital, irrespective of their willingness to do so. There is, thus, an abrogation of the right of the patient to choose. The hospitals argue that an unwilling patient is free to seek investigation or therapy elsewhere. This, in effect, deprives the patient of his right to choose where he will seek advice and treatment.

2. No clear guideline exists on disclosure of the report when it is positive for HIV. The assumption that it will remain confidential is not borne out by the facts.

3. Should the test for HIV be positive, the patient and his family are ostracised by the hospital, doctors, nurses, other staff and society at large. In a recent instance in Bombay, a middle aged man, who tested positive for HIV, was accused by his own children of having indulged in promiscuous sexual intercourse out of wedlock. Untold agony followed till it was shown that he had probably contracted the disease from his wife who had been given contaminated blood as transfusions.

4. Should we, using the same principle, not test all patients for each of the variants of the hepatitis virus, the acid fast bacilli causing tuberculosis and leprosy, Treponema pallidum and other such infections?

A plea for sanity

Our collective behaviour at present resembles that in the recent past against persons with leprosy, tuberculosis and the venereal diseases. The almost hysterical attitudes adopted by individuals and groups who should know better against the person testing positive for HIV need immediate correction.

There can be no argument against taking reasonable precautions to prevent transmission of AIDS from the patient to anyone else - doctor, nurse, other attendant, relatives or society at large. Simple, common sense measures against contamination are adequate. The virus is easily killed by a number of methods of sterilisation. Such as autoclaving and the use of disinfectants.

There is, however, no excuse for treating the patient as a pariah. This is against the ethos of a doctor.

The oath of initiation (Caraka Samhita Vol. 1, pages 163-164)

....'Thou shalt behave and act without arrogance and with undistracted mind, humility and constant reflection ... thou shalt pray for the welfare of all creatures...'

'Day and night however thou mayest be engaged, thou shalt endeavour for the relief of patients with all thy heart and soul. Thou shalt not desert or injure thy patient even for the sake of thy life...'

Editorial correspondence:

Sunil K. Pandya
Department of Neurosurgery,
K.E.M. Hospital
Parel, Bombay 400 012

All other correspondence regarding the Forum:

Anil Pilgaokar
34-B N. Bharucha Road,
Bombay 400 007

ANNUAL SUBSCRIPTION FOR THE JOURNAL

	Individual
One year	Rs. 60.00
Two years	Rs. 100.00
Life	Rs. 1000.00

	Institution
One year	Rs. 100.00
Two years	Rs. 150.00
Life	Rs.2000.00

MEMBERS OF *Forum For Medical Ethics* DO NOT HAVE TO PAY SEPARATELY FOR THE JOURNAL

Editorial

The epidemics in Beed and Surat highlighted lapses on the part of medical professionals.

Was it truly the plague?

When newspapers splashed banner headlines proclaiming the infectious, pneumonic form of plague in Surat, no medical scientist asked this question.

The diagnosis of any bacterial infection is made when Koch’s postulates are satisfied. As we write this, we do not know whether the plague bacillus has been cultured. We learn from fragmentary reports in the newspapers that the organism has been identified by the National Institute for Communicable Diseases (NICD). Is it not the responsibility of NICD to provide details to the public at large and to the medical community?

Diagnosis has been based on the hemagglutination test, positive at titre of 1:8. We need positive results at much greater dilution or rising titres for making “a conclusive diagnosis.

If the NICD will not part with essential data should not the medical profession insist on its release? Is it not unscientific and unethical to treat patients for a disease without proof of its existence and permit panic and chaos which may have no basis?

Matters of prestige and priority?

Haffkine Institute asked scientists at the All India Institute of Medical Sciences (AIIMS) and at NICD to send tissue samples and bacteriological specimens collected by them for study. They have been rebuffed. News reports suggest that, there is infighting between workers at AIIMS and NICD.

When the lives of large segments of the population are at stake, our economy has been dealt crippling blows and the reputation of the country has taken a battering, is it correct for medical personnel to stand on prestige or the lure of being the first to report and publish data?

Unconcern or incompetence?

Senior research workers at the Haffkine Institute were refused permission to travel to Surat at the height of the epidemic to collect samples of tissue from the victims for study.

What was the basis’ for such refusal? Is it not the concern of the centre which for the first time ever provided the vaccine against plague to work on the new outbreak?

Assuming it is the plague, what is the remedy against it?

For several days after it hit the headlines no one pointed out that the plague germ is easily vanquished by modern antibiotics.

The astonishing publicity given to tetracycline as the answer against Yersinia pestis led to panic-stricken hordes rushing to empty the shelves of this antibiotic. The fact that co-trimoxazole and several newer antibiotics are equally effective was either not mentioned at all or published in fine print.

No one pointed out that to prevent the disease, attendants of a patient with proven pneumonic plague should be vaccinated against it. Since’the vaccine takes ten days or so to produce immunity against the germ, the person should take any one of the several antibiotics effective against the plague germ for these ten days. Had this been widely publicised we might have been spared the insane rush for tetracycline.

Sunil K. Pandya

Doctor-patient relationship

Sunil K. Pandya

Introduction

In the correspondence section of this issue Dr. Thomas George contests our expressed view that it is unethical for a doctor to take over a patient already under the care of another doctor without a note of referral.

The basis for this view is the doctor-patient relationship which has, hitherto, been held inviolable. We review this concept and return to another point raised by Dr. George.

The relationship

"There is a common belief among the public that a medical practitioner is at the beck and call of anyone who chooses to send for him, but it must be remembered that there is no law to compel a medical practitioner to attend a patient except in a case where he has previously bound himself by contractual obligations or has already undertaken the treatment."[1]

A contractual doctor-patient relationship is established when the patient makes a request for medical examination, diagnosis, opinion, advice or treatment and the doctor undertakes to provide these. (There are situations when a request by the patient is not necessary. Treatment of an infant - where the parents make the request - or that of a comatose victim of an accident are examples.) The sanctity of such a relationship safeguards the interest of the patient, the doctor assuming all responsibility for providing health care.

The patient has every right to terminate a relationship with his doctor at any time and seek the help of another. A reciprocal right rests with the doctor. The formal relationship may be brought to an end when the patient gives notice of intent to terminate it or when the doctor withdraws his undertaking. In the latter event, the doctor is duty bound to continue to offer all possible help to the patient till the patient establishes a formal relationship with another doctor. The General Medical Council of Great Britain upholds the right of doctors to refuse to accept individual patients when a satisfactory relationship between the doctor and patient does not exist for want of committment on either side[2].

A doctor can, at any time, request the help of a colleague or specialist in the best interests of his patient. Such a request must be specific and made in writing, all relevant medical details being provided to the other doctor. In an emergency, the request may be made and details provided orally on the understanding that as soon as time permits, a written note will follow. This step precludes any misunderstanding of intention or fact by the consultant.

The consultant, in turn, is duty-bound to return the patient to the referring doctor with a note bearing details of facts elicited, diagnosis made and treatment advised.

Ethical norms have traditionally discouraged shopping for opinions or therapy. Such a practice destroys the doctor-patient relationship established with the primary physician.

Thus arose the practice of not seeing a patient already under the care of another doctor without a specific referral.

Second opinion

The patient, in doubt despite detailed explanation by his doctor of the nature of his illness and treatment advocated, can ask for a second medical' opinion.

Medical ethics demands acquiescence based on the patient's right to such counsel. The doctor is obliged to write a referral note and provide all relevant details. If the doctor disagrees with the patient's choice of consultant for second opinion he is justified in terminating his relationship with the patient after writing the note of referral.

Consequences of disregard for the relationship

The obvious consequence is a free-for-all among doctors, with no holds barred, in the struggle to gain more patients. If I can cheerfully take over the investigation and treatment of a patient known to be under the care of another neurosurgeon, it is only a matter of time before I extend my grappling hook in the form of a tout or agent who will divert to me patients intending to see another neurosurgeon. Subtler and more vicious forms include linkages with pathology laboratories, imaging centres and others where, for a consideration, my 'virtues' are extolled before patients needing neurosurgery and the reputation of the consultant already in charge tarnished.

Lest this appear fanciful, let me assure you that such practices are not rare in the metropolitan centres.

Another consequence is the already common practice of shopping for opinions. The well-to-do patient moves from doctor to doctor, clinic to hospital, amassing a stack of documents which, at times, contain conflicting views and suggestions. Often, the new consultant orders repetition of tests that have just been performed, at another specified centre, for

---

Dr. Sunil K. Pandya is a member of the editorial team of *Medical Ethics*. He is a neurosurgeon at the K.E.M. Hospital, Bombay.

non-scientific reasons. Patients are also deflected to practitioners of alternative systems of health care and even to charlatans and quacks. Patient and family end up in total confusion, unable to choose between the many options offered. By trusting no one, they have destroyed the basis of faith. It is not uncommon for the patient to spend huge sums without receiving any relevant or effective care and when the illness has worsened to a critical state, be sent off to a public teaching hospital ‘for further management’. Just as too many cooks spoil the broth, multiple medical opinions breed confusion and harm the patient’s interest.

Dissolution of the doctor-patient relationship also brings in its wake a major legal handicap. Since the patient is consulting more than one expert, each of whom is in ignorance of what the other is doing, no one will accept responsibility in the event of a mishap. The safety net provided by the official system of referral and transfer of medical information in writing in both directions between general practitioner and consultant or consultant and consultant is now missing.

Worst of all, disregard for the relationship destroys the traditional bond of affection between family and general practitioner. The general practitioner is considered a member of the family by many. His counsel and advice are sought on all matters pertaining to health and sickness. The services of a consultant are sought on his recommendation and further treatment is based on the advice offered jointly by him and the consultant. The linkages provided by the system of referral gives the patient a fixed source of trusted counsel - the family doctor.

What if a doctor refuses to refer the patient?

Dr. George rightly asks, ‘How many doctors, either in the private or public sector, will actually refer patients to another in their own specialty?’ Given the prevalent atmosphere, the reluctance to part with a patient who represents a source of considerable income is not surprising.

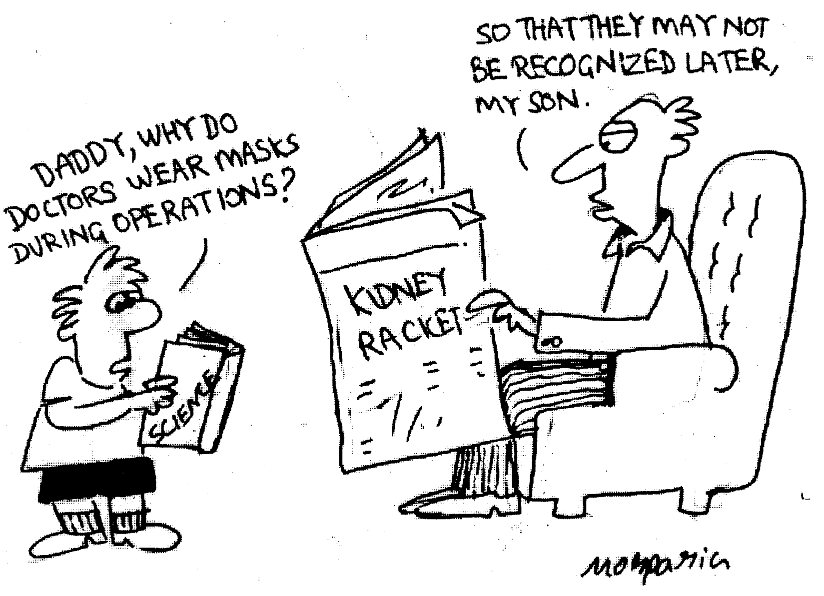
The solution has been long established. The patient is free to break his relationship with the doctor concerned and establish a relationship with another. ‘In doing so, he will cut off all connections with the former.

The situation gets somewhat complex when the patient has already undergone major surgery at the hands of a consultant who now refuses to refer him to another for a second opinion. Terminating the relationship may deprive the patient of all data pertaining to the earlier operation. (Few surgeons provide their patients a copy of the detailed operation note. Many surgeons retain vital reports, xray and scan films.)

Under such circumstances, when I am approached by a patient to provide a second opinion, I write to the earlier surgeon explaining the circumstances under which our opinion was sought. I request permission to see the patient, a copy of the patient’s operation notes and other relevant data. In almost all cases, these have been readily provided.

Reference

1. Modi JP: *Medical jurisprudence and toxicology N.* M. Tripathi Ltd., Bombay. 1947.
2. Anonymous: Refusal to accept patients of other doctors. *The GMC News Review* July 1993, Issue No. 3, page 1.



Doctors abetting artful dodgers

Introduction

Medical ethics require doctors to attend to their patients with sincerity, honesty, diligence and care. It does not, by any stretch of imagination, include aiding and abetting the wrongdoer. Of late we are witness to a series of examples wherein medical doctors stoop to fraud to help prominent, powerful and rich clients avoid the hardships of imprisonment ordered by the courts of law. Doctors, especially those professing to be experts on diseases of the cardiovascular system, have hastened to admit such prisoners to intensive care units where the latter have rested in air-conditioned comfort not just for a day or two but for weeks on end. All tests carried out during such prolonged stay fail to confirm the presence of any serious illness.

On occasion such prisoners have ensured that they do not spend a single clay in the prison. Once they obtain bail, the symptoms that prompted admission magically disappear and they leave the hospital to resume full activity.

The case of Mr. Adhi Rajaram [1,2]

On 17 October 1995, Mr. Rajaram, Secretary of the South Madras unit of the All India Anna Dravida Munnetra Kazagham, was arrested and brought before Justice C. Shivappa on charges of instigating assault on an advocate. The judge refused to grant bail as 'there was every possibility of (the accused) eliminating evidence with the free use of money and power.' On 31 August 1995, Mr. Rajaram had got himself admitted to the Government General Hospital, Madras, for 'post-operative complications' after he was interrogated by the Central Bureau of Investigation. On 27 September he got himself discharged against medical advice, met a politically powerful figure and got himself readmitted to the General Hospital a few hours later. On 17 October, after he was denied bail by Justice Shivappa, he got himself discharged from hospital against medical advice again, travelled on the pillion of a motorcycle and later surrendered to a magistrate and submitted that he needed urgent medical attention for chest pain. Mr. Rajaram was admitted to the Coronary Care Unit (CCU) of the same hospital from which he had got himself discharged against medical advice, for 'unstable angina' which disallowed him from attending court.

The case of Mr. T. T. V. Bhaskaran

Cardiologists at the General Hospital, Madras had also helped Mr. Bhaskaran, Managing Director of J. Jay TV who was arrested on charges of violating the Foreign Exchange Regulation Act. Mr. Bhaskaran also happens to be the nephew of Ms. Sasikala, principal aide to the Chief Minister of Tamil Nadu. Mr. Bhaskaran complained of pain in the chest and was admitted to the General Hospital within a few hours of being remanded to police custody on 22 September 1995. The Enforcement Directorate found the 'alacrity with which the petitioner developed a heart ailment intriguing' and commented that his subsequent conduct raised doubts about his actual medical condition. The accused was noted to run his own office from the hospital using a cellular phone. He was in the special ward and in the intensive care unit of the hospital for almost a month.[3,4] On 29 October, two days after he was granted bail by the court, Mr. Bhaskaran was reported to have the left the hospital with a spring in his walk.'

When Mr. Bhaskaran was advised coronary angiography, he refused permission for this test. Dr. Brahmanandam, Chief of Cardiology, General Hospital, Madras, when asked about this, said, 'If the patients refuse to undergo an investigation, what could be done? If Bhaskaran refused to undergo an angiogram, he had the right to do so.' When asked if such a patient can be kept in the CCU indefinitely, Dr. Brahmanandam replied, 'What can be done? I cannot discharge somebody who is sick either. I have to look after him.' It is of interest that this senior doctor also stated, 'As for my fellow medical professionals, what ethics is there amongst the medical community?' An un-named cardiologist in Madras who studied these cases commented, 'This is a case where both patients and doctors are cleverly using legal provisions to their advantage.' [1,2]

Union Ministers in office

Mr. H. K. L. Bhagat was recently arrested in connection with the murders of several Sikhs in 1984 in the aftermath of the assassination of Mrs. Indira Gandhi. The manner in which he, his family and lawyers manoevred his immediate transfer to hospital and ensured that he spent the bare minimum of time in Tihar jail has prompted public ridicule and has been lampooned by all our major cartoonists and satirists. (See page 50 of this issue for examples.) His daughter-in-law, Ms. Rita Bhagat, is reported to have been shocked when he was briefly sent from hospital to jail. 'How could they have sent him back to Tihar Jail despite such an aggravated prostate problem? He goes to the urinal at least 25 times a day,...' she said.[5]

Mr. Kalpnath Rai also complained of breathlessness and showed a rise in blood pressure soon after his arrest on 16 February 1996. In this instance, doctors at the G. B. Pant Hospital decided, after observing his progress over six and a half hours and carrying out several tests, to send him back to Tihar jail.[6]

The dangers of such abettment

By his act of felony, the doctor favoring a prisoner sets into operation a chain of damaging events.

The first and foremost danger - that of crying 'Wolf!' - has already been encountered. Greatly disturbed by the manner in which rich and powerful prisoners manoeuver themselves into the comforts of plush hospitals, a judge disallowed industrialist Rajan Pillai to transfer from Tihar Jail into a hospital. His physical state worsened in the jail and by the time it was decided to shift him to hospital, he was in extremis. His death is currently under judicial investigation. Crying 'Wolf!', then, can prove disastrous to those in genuine need. The doctor helping a person not in need of medical care by admitting him to hospital is at least as guilty as the prisoner pretending to be ill.

Admitting a fraudulent public figure to a ward, especially if this be one offering intensive care, harms genuinely sick patients. The already hard-to-get bed is blocked by the VIP, depriving the patient who really needs such care. It also ensures distraction of staff at all levels. Inevitably, they tend to fuss over the awe-inspiring figure with a relative neglect of the bona fide patients. With most weighty figures now carrying around them a gang of toughs wielding potent automatic weapons, the disturbance is complete in a ward where quiet and efficiency should prevail and where the seriously ill should be the focus of all attention.

The medical doctor is also to blame as admission of such prisoners to hospital is made on grounds that only another member of the profession can investigate and challenge. Where suspicion of malpractice is raised, another senior consultant in the field must spend time and energy to investigate and report on the findings. This, in turn, means that the treatment of his own patients must suffer for this duration. In the case of film star Mr. Sanjay Dutt, admitted to the intensive cardiac care unit at the Sir J.J. Group of Hospitals whilst in prison, the judge ordered three senior consultants to investigate the matter.

Fraudulently admitting a powerful but healthy prisoner to an intensive care ward when so many other genuinely ill prisoners in that and other prisons are deprived of all but the most elementary care is yet another kind of travesty of justice. The last, but not the least, danger is the abasement of the medical profession. What is one to make of the fact that when a three-member team of the Enforcement Directorate, armed with an order from the court, went to the General Hospital, Madras to interrogate Mr. Bhaskaran, they were told by the Dean and Dr. Brahmanandam, Chief of Cardiology, that they could not interrogate the prisoner for more than ten minutes. After a few monosyllabic replies were offered in response to their questions, the officers were made to leave.

Such instances are evidence of the growing tendency in doctors who attend to those in power to crawl as they pander to their base whims and desires. When, as often happens, such doctors happen to form the politically powerful segment of the profession, the danger is heightened as they serve as role models for highly impressionable and sometimes unthinking youngsters.

The extent of degradation that has already taken place is evident-from the fact that when the Central Bureau of Investigation attempted to put together an independent panel of specialists to ascertain the real health condition of Mr. Adhi Rajaram in Madras, they ran into a wall of polite refusals from some of the premier medical institutions of Tamil Nadu. Similar refusals in Mr. Bhaskaran's case led Dr. S. Ramadoss, founder of the PMK to exclaim against the lack of medical ethics that permitted the 'staging of such a drama' and demand a Central Government medical team to examine Mr. Bhaskaran.[3]

An obvious solution, overlooked on purpose?

Why don't the rich and famous - and doctors who are quick to rush to their help - work for the creation of facilities for medical services of the highest quality in our major prisons? Such facilities would ensure that there is never a repetition of the Rajan Pillai episode.

It would also ensure that the genuinely ill in prisons, unfortunate in that they lack monetary or political clout, will also get the medical attention they deserve. Sinde the prisoner, deprived of most of his rights by a court of law, is not allowed to choose his doctor and hospital, it is all the more important that he is provided medical care of the highest quality.

Sunil K. Pandya

References

1. Subramanian TS: Ducking the law. General Hospital, Madras as the ultimate refuge. Frontline 1 December 1995 p 112-l 14.
2. Shreedhar Jaya: Question of ethics. Frontline 29 December 1995 p 91-92.
3. Anonymous: Rhaskaran to be interrogated in hospital. The Hindu 13 October 1995 p 4.
4. Anonymous: Angina treatment brooks no delay. The Hindu 22 October 1995.
5. Anonymous: and back to Tihar jail... Times of India 17 February 1996 p9.
6. Anonymous: From jail to hospital... Times of India 17 February 1996 p9.

Hospital Ethics Committee

Sunil K. Pandya

Introduction

Most Indian hospitals have instituted such a committee principally for the purpose of checking whether proposals submitted for research meet established guidelines. Once this has been established, the researcher is permitted to.proceed with his work and the committee turns to subsequent proposals. This approach make a very limited usage of the personnel recruited on such a committee. Much more can be done to improve not only the quality of research undertaken by the institution but also the care of patients in the institution.

'Mission statement of the committee'

The committee must start with an open statement on its aims and objectives. These should be circulated throughout the institution and feedback sought on how this can be improved. It is also necessary to review this mission statement periodically and revise it when necessary.

The following could form the heads under which details can be entered:

- Care of the patient in this institution.
- Research.
- Education of the staff on biomedical ethics.

How should the committee function?

At the helm

There must be at least two senior persons complementing and supplementing each other. They should, preferably, belong to different disciplines.

Who should be a member?

The obvious answer is anyone with a deep commitment to medical ethics. It is important not to skew membership by having several persons from the same discipline. It is also essential to ensure representatives from:

- administration
- clinicians - medical, surgical, other disciplines
- basic sciences
- social worker
- nurse
- rehabilitation personnel
- priest/ philosopher
- lawyer
- statistician

Subcommittees?

If the ethics committee is charged with three principal goals: patient care, research and education of faculty and other personnel; it is logical to entrust each of these to a subcommittee. Monthly meetings of a large, single committee once a month over an hour and a half or two hours are unlikely to do justice to these goals.

Frequency of meetings

This will depend on the goals set for the committee. If the committee is only to restrict itself to processing applications for research, the number of such proposals will govern the dates on which meetings are to be held. Most ethics committees meet at least once a month in order to ensure that no research proposal is held up at the level of the committee.

Each member must attend at least 75% of all meetings.

Structure of each meeting

Silverman [2] suggests that no more than half an hour at the start of each meeting be devoted to 'business issues' : reading the minutes of the previous meeting, reports from subcommittees, new issues. The remaining time must be used to discuss and explore the different moral values within the institution. This is where free discussion on ethics is encouraged and decisions sought on this basis. He suggests that discussions on specific cases, their reports having been prepared and circulated in advance, are most likely to yield results. Such cases could be selected with a view to provoking discussions on informed consent, the means by which diagnosis is disclosed to the patient and relations, expenditure incurred by patients, the rationale and justification for expensive tests or therapies, relevance of research being undertaken within the institute...

He also recommends that time be spent at each meeting on reviewing relevant papers on medical ethics published in recent issues of journals, the focus being on how these can be used to improve standards in the institution.

Research

All research proposals must conform to standard scientific and ethical guidelines. These must be scrutinised by a designated member of the committee to ensure that there is no glaring deficiency. (In case of such a deficiency, the proposal should promptly be returned to the researcher with a note on what is needed.)

All proposals received before a stipulated date must be discussed at the next meeting.

The committee must pay special attention to:

- Will the study add substantially to existing knowledge?
- Is the study scientifically, statistically and ethically valid?
- Is it relevant?
- Are the results of this study likely to prove harmful? Pilgaokar[1] points out that we have a moral responsibility to desist from any inquiry as soon as it becomes clear that it is likely to endanger mankind.
- If experiments on animals form an essential component, are humane practices built into the project?
- If human subjects are involved, special attention must be paid to how truly informed consent is obtained, what measures have been provided in case of complications that may harm the subjects and how those defaulting from the study will be followed up if a drug or implant with medium or long term action is being used. Pilgaokar[1] has summed up the requirements of truly informed consent, listing the various kinds of information that must be conveyed to subjects.

Care of patients

Is the institution providing the best possible medical care? This could be considered under the following heads:

- The art of bedside medicine
- Relief of suffering
- Cure of disease
- Iatrogenic disease: incidence, trend over time
- Cost to patient: tests, drugs, other costs. Can these be lowered?
- Prompt attention to needs of the patient.
- Care of the seriously ill
- Dying patients
- The dead patient

Education of the staff within the institution‘

This could cover all aspects of patient care and research.

Other activities of an ethics committee

Silverman [2] also recommends that the committee:

- produces guidelines on a broad range of topics. Disclosure of diagnosis, diagnosis of brain death, requesting permission to harvest organs for transplantation, truly informed consent are some examples.
- sets up and ensures proper functioning of a forum for redressal of complaints from patients and families. This forum must receive complaints in writing, helping illiterate patients to prepare such documents. Complaints, proceedings of hearings on them, decisions and action taken must be kept on record.
- produces a document for the benefit of patients and their families informing them of services provided by the institution, rights of patients and relatives, their responsibilities, means by which they may seek redressal for any harm that may be done to them...
- surveys practices within the institution on a continuing basis: standards of patient care, unnecessary expenditure enforced on patients, obtaining truly informed consent. Patients and relatives could be polled on deficiencies/malpractice witnessed by them and their suggestions for improvement.
- obtains feedback from faculty, other staff on the functioning of the ethics committee; perceived deficiencies and Suggestions on how it might function more effectively. It may be necessary to permit anonymity of those making observations in order to safeguard them from victimisation and encourage free and frank observations.
- conducts seminars/workshops/mini-conferences on biomedical ethics, better research.. .

Why do some ethics committees fail?

Committee set up for the wrong reasons: Such reasons include a) an attempt at avoiding prosecution under the Consumers Protection Act; b) ensuring that research proposals made by members of the faculty sail smoothly through national and international agencies that offer grants and require clearance by a local ethics committee before they will take up the proposal for scrutiny; c) to form yet another ‘power group within the institution that can hold the rest of the faculty to ransom.

Goals that are too ambitious: Silverman [2] refers to the phase when ethics committees, like infants, ‘fail to thrive. When formed, there is much enthusiasm and activity by members of the committee. A little later, a feeling of frustration emerges as unrealistic goals set for the committee are not achieved. He refers to plans to educate the entire faculty and resident staff on medical ethics (including those in research) in a short while as an example of such a goal.

Lack of support by the institution: If *all* research protocols and matters of ethical concern are not placed before the committee and if the recommendations of the committee are flouted by the administration, demoralisation is inevitable.

The committee must also be provided adequate infrastructure for its deliberations, inquiries, follow up studies and maintenance, analysis of records. It will be necessary for the committee to enter into correspondence with other experts and groups, record proceedings of its meetings, circulate the minutes, interact with experts on other ethics committees, funding agencies and similar groups.

Funds and secretarial help are mandatory for the proper functioning of such a committee.

The entire institution must want and welcome the formation of such a committee, seeing it as a means for improving standards, providing better care to patients and carrying out research of the highest standards.

Poor selection of members on the committee: If these individuals are already short of time, it is unlikely that they will pay much attention to the tasks to be attended to on behalf of the committee. Cursory inspection of documents, little or no follow up action and frequent absences from meetings of the committee are expected consequences.

The members must possess a strong motivation for improving the conditions under which patients are treated and research practiced. They should have already devoted some time and energy in identifying current slip-ups and malpractice and the means to be employed in correcting them.

They must also be conversant with current trends in national and international biomedical ethics. Without continued self-education, they are likely to lapse into rigidity of approach and dogmatic decisions.

References

1. Pilgaokar, Anil: Ethics in biomedical research. Unpublished paper presented at annual meeting of the Medico Friend Circle, 1995.
2. Silverman Henry J: Revitalizing a hospital ethics committee. ***HEC Forum*** 1994;6: ***189-222.***

FROM OTHER JOURNALS

All's not well with clinical trials [1]

Research by US epidemiologist Kenneth Schulz and colleagues shows that a considerable number of doctors involved in clinical trials cheat by interfering with the randomness of clinical trials by ransacking private offices, cracking secret codes and probing contents of secret envelopes. Some may do so in order to ensure that their patients get the best treatment but, in attempting to fulfil their obligations to the patient, they vitiate their roles as medical researchers, skew results and invalidate the trial.

Doubt has been expressed by Samuel Hellman on whether a clinician can simultaneously fulfil the dual roles of doctor and researcher. The fundamental divergence between the clinician wishing to do his best for the individual patient and the researcher whose primary interest lies in collecting groups of patients suggests that Hellman's essay (pages 5- 10 of the special supplement in this issue) deserves study.

The interested reader will also find much of interest on pages 1-16 of the special supplement on Ethics Committees.

Voluntary euthanasia [2]

Independent legislator, Michael Moore, introduced his Medical Treatment (Amendment) Bill 1995 into the Legislative Assembly of the Australian Capital Territory, seeking to allow doctors to provide direct help in dying to terminally ill patients who requested it. The bill was defeated on 22 November with two rebel members of parliament crossing the floor to vote with the Liberal Party.

In the state of Victoria, doctors petitioned the government for a review of laws prohibiting voluntary euthanasia. This appeal was rejected.

In the Northern Territory it is expected that any day now the Rights of the terminally ill bill will be gazetted and become operational. Patients with severe pain from advanced cancer are already travelling from other states to see direct, immediate help in dying under this law. 70 year old Marta Alfonso-Bowes, who had reached Darwin and sought a lethal injection was dejected when she found that the law was not yet in operation. After a failed attempt at suicide, she succeeded in taking her own life on 24 September after taking an overdose of tablets.

The following news item in this journal describes how seven doctors have joined Dr. Jack Kevorkian in unveiling guidelines for medically assisted suicide in the USA. The group feels that patients and doctors and not politicians or courts should determine when incurable patients should be helped to die. The guidelines call for a written request from the patient, signed by a doctor and two adults with no financial interest in the case. A specialist in the patient's illness, one on the management of pain and a psychiatrist will have to verify in writing that the patient was mentally competent, suffered from an incurable disease and had uncontrollable suffering.

The journal also refers to a paper in the Journal of the American Medical Association (1995;274:1634- 1626) where a long term study costing twenty-eight million US dollars showed that many patients die under cold and painful circumstances. The study also shows that dying patients often fail to make their wishes known and when they do, encounter indifference by doctors to their request to be spared life-sustaining treatment.

Care of dying patients in hospital [3]

This paper describes a prospective study pf 50 dying patients in 13 wards in four large teaching hospitals in the west of Scotland. The opening sentence grabs attention. 'Though most terminally ill patients indicate a preference to die at home, . . . more than 60% of all death (over the past two decades) occurred in an institution.' The conclusion is equally riveting. 'Care of many of the dying patients observed in these hospitals was poor. We need to identify and implement practical steps to facilitate high quality care of the dying. Much can be learned from the hospice movement...'

References

1. Kuhse Helga: Clinical trials. Monash Bioethics Review 1996; 5:1-2
2. Anonymous: Voluntary euthanasia - Australia. News in brief. Monash Bioethics Review 1996;15:3-4
3. Mills Mina, Davies Huw TO, Macrae William A: Care of dying patients in hospital. Monash Bioethics Review 1996;15:11-19

EDITORIAL

A national disgrace

In the section entitled *Vox Populi* in this issue we have reproduced seven extracts from news items entitled ***The first** Indian porcine xenotransplant.* This episode raises vital issues.

Our understanding on the use of a pig's heart for transplant into a human being is that it is yet to pass trials in animals and has not been cleared by any authorised agency for use in man anywhere in the world, including India.The consideration of use of a pig's heart in man is justified only when the pig has been so bred that it carries genes identical to those in the patient in whom it is to be transplanted. Such a heart, it is proposed, is less likely to be rejected by its recipient. The entire operation of establishing genetic identity between the donor pig and recipient human, ensuring that the surgeon does not transfer infections (especially those by viruses hitherto unidentified) within the pig to the recipient in the process of transplantation; and other attendant problems have proved so formidable that to date no surgeon elsewhere in the world has dared to perform such a transplant. Indeed, the United Kingdon has banned any such transplant, pending further research.

And here we have a surgeon in poorly developed Assam, who has twice claimed to have carried out such a transplant without any enquiry into his credentials, experimental work, organisational facilities, laboratory expertise, peer review and official sanction! Were it not for its tragic aspects, such a claim would have verged on the ridiculous. The least that is expected of the regulatory agencies is an immediate halt to all of Baruah's activities. The Medical Council of India and that in Assam should have investigated all aspects of his activities **before** he started his transplantations. Instead, even **after** the events, we see no signs of any activity on their part.

The statement by the Health Minister of Assam, Kamla Kalita, to the Assam State Assembly — that the Government 'was examining all legal possibilities so that adequate action can be taken against him for trying to sensationalise the issue.' — is even more pathetic. This bureaucratese is easily translated: 'We have decided to do nothing for the present as regards the scientific aspects of Baruah's acts. At best we may administer a gentle tap on his knuckles for promoting himself.'

Baruah has compounded his felony by flouting all tenets of medical ethics. The news reports state that the patient, Purna Saikia, sought treatment from Baruah after reading advertisements inserted in local newspapers. Everything that Baruah does is shrouded in secrecy. The reports also suggest that truly informed consent was not obtained. There was no debate or discussion in any medical forum before undertaking this sensational surgery. No details on surgery and progress of the patient after surgery have been provided to the medical fraternity or the lay public. The only information available is that ferreted out by journalists and this has been horrifying. Heart, lungs, liver, pancreas were transplanted with abandon and even the pig's blood was transfused into the doomed Saikia. We are yet to learn the findings at autopsy.

To add insult to injury, the laws of the land have now permitted release of Baruah on bail. He has been directed not to perform any further transplant without permission of our national medical agencies. Presumably, he may continue other forms of surgical adventure.

No authority has, as yet, seen it fit to investigate Baruah's antigen-suppressing agent. Indeed, to the best' of our knowledge, no statutory body has investigated the earlier artificial valves designed by him though the four phases prescribed for any clinical trial appear not to be have been completed. The fact that the authorities in Hong Kong found the -use of these valves by Baruah and Ho a matter of questionable ethics and of grave concern should have awakened our own authorities. Certainly, this should have resulted in alarm bells ringing wildly when Baruah made his first announcement on the proposed transplant of a pig's heart into man.

Far from being repentent in any manner, Baruah now brazenly announces his plans for further such operations. In the same breath he speaks of an international conspiracy against him and plans for presenting his 'achievements' before experts in Barcelona and Sydney!

If, as some suspect, Baruah is a victim of psychosis, why is he allowed to roam the land, free to impose his deranged will on the hapless poor? Shouldn't he be behind bars in an asylum, kept out of harm's way? And if psychiatric assessment finds no evidence of insanity, shouldn't he be kept permanently behind a similar barred portal in gaol in the interest of public safety?

As pointed out by Dr. M. K. Mani in an earlier issue of this journal, our watchdogs continue to snore in bliss!'

Who will regulate when regulatory bodies have proved hopelessly incompetent?

When such problems are posed to those whose business it is to solve such conundrums — legislators and bureaucrats — one gets answers similar to those provided by the Health Minister of Assam. Catch-22 is very much in evidence. Here are three examples we have often encountered:

'There has been no complaint, so how can we investigate?'

And there cannot be a complaint, for those who should be registering it do everything possible to turn away the complainant.

'We are appointing a committee to look into this matter.' — the eternal refuge of the procrastinators! The committee report is never presented to the public and actions taken on it are shrouded in secrecy. Certainly this expensive exercise results in no punitive action against the rich, mighty and politically well-connected and no improvement is evident.

'Do what you like. If you wish, you can even go to court.' When multi-million-rupee corporations do all they can to avoid any appearance in the court of law, knowing of the delay not of months or years but of decades, how is the average citizen, with meagre funds, to fight against individuals or organisations (such as hospitals) with immense resources?

Well-meaning individuals have pleaded for society-at-large to take matters into its hands by forming power-groups. Thus far this has not borne fruit as the widely disparate groups that make up our society does not make such a coming together of dedicated minds easy.

The fundamental question

But all this bypasses the fundamental question that begs an answer.

Why do those in power — governments, bureaucrats, the judiciary — permit the continuation of regulatory agencies that do not deliver? Why are the functionaries in these statutory regulatory agencies never hauled up and severely penalised? Why are hopelessly inefficient and apathetic medical councils permitted to survive? Why are they not scrapped or recreated in such a manner that their existing failings are never allowed to prevail?

Instead, newer regulatory agencies are created. The National Human Rights Commission — in its role as regulator of health care malpractice — is an example. We are driven to the state where we draw consolation from the occasional dig the Commission has against the Medical Council of India. That the pinprick may not even penetrate epidermal layers protecting the Council members does not seem to worry anyone.

And, as you might expect, the government that does not feel it important to ensure that its original watchdogs do their duties efficiently, cannot be expected to nurture this new watchdog. Writing in *The* Hindu on 24 December 1996, senior journalist Kuldip Nayar referred to the deliberate neglect of the National Human Rights Commission by the Government of India and those in the States.

'The Centre and States have not taken human rights seriously.

'It has become a fashion to talk about human rights in drawing rooms. The elite probably consider them part of economic liberalisation, giving another edge to their entertaining life. Most functions held in Delhi on the Human Rights Day were at posh places, followed by sumptuous tea. Participants were in their- best attire. Foreigners and Indians mingled with one another, talking and laughing, as if it was a cocktail party hosted by an embassy, or an industrialist.

'The Centre believes that it has done its duty by setting up the National Human Rights Commission. So deliberate is its neglect that even the Commission members, who were carefully chosen for their pro- establishment record, have felt let down. None at the Centre has the time either for the Commission's protests or its recommendations. Most of its Commission members have not been able to meet even the Joint Secretary in the Home Ministry, not to speak of the Minister. The Commission, despite the fact that it is headed by a former Chief Justice of India, has been devalued like the Commission for the Scheduled Castes and the Scheduled Tribes or the Commission on the Linguistic Minorities. '

Kuldip Nayar goes on to comment on autopsies, especially those on individuals who die in police custody: 'It is an open secret that doctors bow to police pressure when writing the report. Often, there is a long time gap between the post-mortem and the report. Facilities in many mortuaries are rudimentary. A 'suggestion that the post-mortem examination be video-filmed has not been accepted by many States. They hate transparency.'

Sunil K. Pandya

Reference

1. Mani MK: Our watchdog sleeps and will not be awakened. Issues in *Medical Ethics* 1996;4:105- 107

The creatures outside looked from pig to man and from man to pig, and from pig to man again; but already it was impossible to say which was which.

George Orwell, *Animal farm New* York: Penguin Books. 1946.

Patients testing positive for HIV — ethical dilemmas in India

Sunil K. Pandya

Attitude of doctors towards such patients

Persons testing positive for infection by HIV or showing evidence of AIDS provoke revulsion and fear in medical doctors. These reactions stem from the general knowledge that the diagnosis of AIDS is akin to a death sentence and the belief that a positive HIV test is, inevitably, followed by the development of full blown AIDS. The fact that HIV is commonly contracted through sexual intercourse and anal penetration or addiction to drugs lends added reason for disgust.

There is a close parallel between the behaviour of the doctor faced with a patient showing evidence of AIDS and that, till very recently, towards a patient with leprosy.

This illogical fear has made doctors lose sight of some fundamental medical principles:

1. Contracting an infection from a patient is the doctor's occupational hazard. The logical step towards avoiding such infection is to take all the necessary precautions against transfer of infection. It is not logical to treat the patient as an untouchable.
2. HIV is a very fragile virus, vulnerable to all the commonly adopted measures for sterilisation and disinfection.
3 Transmission of HIV from patient to doctor in the course of medical examination and treatment is rare.
4. We are witness to individuals testing positive to HIV and continuing to lead normal lives without ever showing any trace of AIDS.
5. Tests for HIV are, at times, known to yield false positive results.

A new class of untouchables

For many patients, the ward of a public hospital is the last stopping place on a dismal journey of stigmatisation. Patients with AIDS are driven from their communities by fearful neighbours, pushed from one hospital to another by doctors and staff members reluctant to treat them and, finally, approaching death in the AIDS ward, left virtually to fend for themselves. AIDS patients have become India's new untouchables to spend their lives being shunned. Like caste untouchables, patients with AIDS are supposedly protected from discrimination by laws, but statutes have counted for little.

In 1994, a reporter for The *Statesman* chronicled the death of a 28 year old fruit seller, Deepak Biswas, in a Calcutta hospital ward. The *Statesman's* stories told how Biswas had been left for days on sheets stained with blood and how food had been pushed at him from a distance. After he died, weighing 60 pounds, attendants left his body untouched for eight hours in the tropical heat. Finally, the hospital superintendent helped a relative lift the body into a van to be taken to the cremation ground.

Later, neighbours pressed Biswas' family to leave their home, saying they might infect the area. Biswas, typical of many AIDS patients, had shuttled through four hospitals before arriving at the AIDS ward. At the School for Tropical Medicine, the main AIDS advisory centre for the government of West Bengal, doctors told Biswas' relatives there was, 'no seat' for him.[1]

They referred him to a doctor specialising in India's traditional herbal medicine, telling the family that in a case of incurable disease, 'we can use any drug or any measure'.

Other cases recounted by AIDS workers include that of a patient in Madras who was being treated for fever. His doctor informed his office that he had tested positive for HIV. When he returned to work, he was kept out by the elevator operator and a door attendant. He went home and took a near fatal drug overdose.

There are also the cases of pregnant women with HIV who' have gone from doctor to doctor seeking somebody to deliver their children. Here is a recent account of such practice. 'A number of obstetricians will not deliver a HIV patient who comes to their private nursing home. They are afraid that if everybody comes to know that this is an HIV infected patient, they will lose their practice. Secondly, they are afraid of infecting their operation theatre, labour ward and all their staff including themselves. So they would rather say `No', because they are going to get the same amount of money from her (as from other patients) and run the risk themselves. So also surgeons with private nursing homes.[2]

A Calcutta haematologist, Dr. Asha Rao, tells of a 27 year old who returned home with an HIV infection recently after years of working in Bombay. As soon as his condition became known he lost his job in a Calcutta tannery. His girlfriend left him, and his father forced him out of the family home.[1]

Making the diagnosis

We are witness to several unethical practices in checking for the presence of infection by HIV in our patients:

1. Doctors and medical institutions refuse to accept patients

---

Sunil K. Pandya, Department of Neurosurgery, Seth G. S. Medical College and K. E. M. Hospital, Parel, Mumbai 400012

for investigation of therapy unless they undergo tests for infection by HIV.

2. Tests ELISA, blot tests are ordered without the patient's informed consent and with no attempt at explaining to the patient or the family the implications of a positive result.

These steps are blatant violations of ethical norms. The General Medical Council of Great Britain has, for instance, made a specific ruling: 'The Council believes that the principle (of consent to investigation) should apply generally, but that it is particularly important in the case of testing for HIV infection, not because the condition is of a different kind from other infections but because of the possible serious social and financial consequences which may ensure for the patient from the mere fact of having been tested for the condition. Only in the most exceptional circumstances, where it is not possible for the prior consent of the patient to be obtained, can testing without explicit consent be justified.[3,4]

3. The patient showing a positive result on the test is peremptorily dismissed. If admitted to hospital, he is instantly discharged. In many instances, he is told that the reason for this dismissal is the positive HIV report.

4. No attempt is made to break the news gently.

5. No attempt is made to counsel the patient and family, confirm the diagnosis by blot tests or other sophisticated means, identify the route of infection and boost the patient's morale by telling him that come what may, the doctor is by his side to help as best as he can.

6. On the contrary, the doctor patient relationship is usually terminated abruptly on receipt of the positive report.

7. Citizens of Mumbai recall vividly the sixty year old patient at the Bombay Hospital who, when told that he had to leave the hospital as his test for HIV was positive, leaped to his death from its eighth floor?

Confidentiality

Respecting the patient's privacy

Once the diagnosis of HIV infection is made in a patient admitted to hospital or nursing home, it is rapidly broadcast to all staff members. The change in their attitude towards him is immediately obvious to the patient.

Some clinics plaster difficult to miss placards on the patient's bed informing all and sundry of the patient's HIV status. This is especially tragic when the placard remains in place during the hours when friends and relatives visit patients.

Other clinics print in bold letters the HIV status on the cover page of the patient's case notes, at times underlined in red.

When questioned, doctors and administrators offer the explanation that this measure is taken in order to ensure that everyone `takes the necessary precautions when handling the patient'.

Informing the spouse

Since the spouse may contract the disease from her infected husband, how is she to be informed of the very real danger she faces? A recent study makes the consideration of this issue of vital significance.

57% of individuals in rural South Africa would not tell their wives about their having contracted sexually transmitted disease. If infected by HIV, 66 would withhold information from their wives. 71% of men would not inform their casual partners about their HIV infection. The same study showed that a majority of women claimed a right to know if a man is infected6

There is every reason to believe that a comparable study in India would show similar results

How is this problem tackled in India? There are no clear guidelines on the subject issued by any authoritative agency. Most doctors do not consider this a matter warranting their interference. HIV infection has been diagnosed and the patient sent away. There, for most, the matter ends.

A few, concerned groups, notably at the National Institute of Mental Health and Neurological Sciences, have evolved a policy. They counsel each patient known to be infected by HIV, individually. At the end of the session where the diagnosis is conveyed and advice offered on available help and treatment; he is told of the possibility of passing on the infection to his spouse. He is strongly advised to inform the spouse about his HIV status and adopt the unfailing use of a condom during every sexual act. During the next interview he is asked whether the wife has been informed. If the answer is 'Yes', he is asked to bring the wife along during the next interview for joint counselling. If the answer is 'No', without any acceptable reason (such as the wife being out of station), he is once again asked to inform the wife. This time he is also told that should he fail to do so, the doctors at the centre will disclose the information to her.[7]

This practice has international sanction. As noted by Bayer and Gostin, 'What is crucial is the underlying ethical principle that confidentiality, while critical, is not the only ethical value. Indeed, when vulnerable unsuspecting persons are placed at risk it may be imperative to breach confidentiality? They refer to the case Tarasoff v. Regents of the University of California in America in 1976, where a central legal doctrine emerged. Under certain circumstances a clinician has an affirmative duty to warn or protect unsuspecting targets of his patient's violent intentions. Several judges in America have held it a duty of physicians to warn family members of the presence of infectious diseases in an individual. 'No case to date has criticised a physician's disclosure to make limited, appropriate disclosures of a patient's condition under circumstances in which the patient or others were reasonably at risk but for the disclosure. The legal system appears to encourage physicians to act responsibly by making more, rather then fewer, disclosures of patient confidences under the general public policy that the greater good is served despite intruding upon the patient's privacy.'[9]

The Centers for Disease Control and Prevention, Atlanta, Georgia, in its guidelines, is very specific. 'Patients who are HIV antibody positive should be instructed on how to inform their partners and to refer them for counselling and testing. If they are unwilling to notify their partners or if it cannot be assured that their partners will seek counselling, physicians or health department personnel should use confidential procedures to assure that the partners are notified.'[9]

Confidentiality in recording and reporting test results

Public health requirements make it necessary for laboratories to maintain records of positive HIV results. There is no difficulty as long as these records remain confidential documents. Where reporting (to public health authorities) is required by law, it is important to shield the identity of infected individuals from exposure.[8]

Law ***lags behind ethical requirements***

'There is no statutory provision regarding consent (in India) for testing. A combined application of the doctrine of unconscionable contracts, Article 14 (Equality Clause) and Article 21 of the Constitution (no person shall be deprived of his or her liberty except by procedure established by law) may help in developing the argument that consent has to be informed and supported by counselling services.

'There is no specific statute providing for confidentiality in India. Section 126 of the Evidence Act protects from disclosure, professional communications between lawyers and their clients. No such provision exists in the case of doctors.' [10]

Treatment of the patient testing positive for HIV

Several centres avoid all problems concerning the treatment of such patients by turning the patient away. 'Doctors in India have refused to treat HIV and AIDS patients in some institutions including the All India Institute of Medical Sciences, the premier public medical institute in India.'[9]

Describing the situation, at the largest public hospital in Madras, Chinai (1996) reports: Patients face discrimination at every level from ward boy right upto the doctors. Surgeries (on them) are constantly postponed. She cites the names of three patients, Kavita, Murugesha and Rajeshwari, who were left outside the hospital gate and transported by the (municipal) corporation lorry to the dumping ground. Having thrown patients out of the hospital, nurses would write that the patients are absconding, when they were not even fit to walk. 'We are told to take such patients away, but where do we take them?', asked the wife of one such patient. Poor patients, especially women coming from rural areas, are subject to the worst forms of humiliation and violation. We have gone to the police and the Tamil media but none are willing to do anything about it.' one member of the Positive Action Group said. [11]

Another report describes similar treatment in a hospital in Guwahati. Twenty one year old widow, Jahnabai Sharma and her daughter, Karishma, were seen at Guwahati Medical College after Jahnabai's husband died of AIDS. They were then sent to the infectious diseases hospital. Two weeks later they were discharged. The high court investigating this case was told that if HIV infection was suspected, the patients were subjected to tests and if found positive, were 'informally discharged'. In one case, a youth was discharged in haste with the saline drip attached to him. He died a few days later. An amount of Rs. 35,00,000 sanctioned by the Government of India to the hospital for treating patients with AIDS was lying unutilised.[12]

Where the patient is not turned away, he is made acutely conscious of the fact that he harbours an illness that is terrifying. Attendants do their best not to make any physical contact whatsoever. Sponging of the bed ridden patient is rarely carried out. When contact is inevitable, the attendant dons gloves, cap, mask and gown. We have witnessed doctors donning shielded goggles, plastic aprons and other paraphernalia such that they appear ready for a voyage in outer space.

Since doctors display fear and disgust, these percolate down the line to the humblest attendant who now tosses the patient's linen and hands his meal to him in such a manner that no contact is made. Snide remarks implying certain knowledge of the means by which the patient acquired the infection are made in the presence of the patient and his family.

The person handling the patient's bed pan and urinal does so almost under duress and with extreme disgust. When the patient needs suction of the larynx and trachea, these are done with the face averted to avoid infection by spray past the already formidable defences of goggles, mask, cap and gown. Whilst no one denies the need to take care when handling the patient's body fluids and when dealing with his person, should we rob the patient of his dignity in doing so?

I am often puzzled by those who are so diligent in avoiding being infected by the patient. Wearing cap, mask, gown and gloves they suck the patient's throat. They then stroll to the nurse's table and plonk themselves on the chair. With the same pair of gloves on, they wipe the sweat off their own foreheads, write notes on the case paper and then replace the pen in an inner pocket. They then move on to the next patient known to have a negative HIV test and minister unto him using the same gloves, cap, mask and gown!

It is important to recall the American Medical Association Code of 1847 - an assertion that is representative of prevailing international sentiment: 'And when pestilence prevails, it is their duty (the duty of doctors) to face the danger and to continue their labours for the alleviation of suffering, *even at the jeopardy of their own lives.*'[7] (emphasis added).

If contemporary confirmation is required, consider the words of physician philosopher, Edmund Pellegrino: 'To refuse to care for AIDS patients, even if the danger were greater than it is, is to abnegate what is essential to being a physician.'[13]

The General Medical Council of Great Britain is equally unambiguous: 'It is unethical for a registered medical practitioner to refuse treatment or investigation for which there are appropriate facilities, on the ground that the patient suffers, or may suffer, from a condition which could expose the doctor to a personal risk. It is equally unethical for a doctor to withhold treatment from any patient on the basis of a moral judgement that the patient's activities or lifestyle might have contributed to the condition for which treatment was being sought. Unethical behaviour of this kind might raise a question of serious professional misconduct.'[3,4]

Taking advantage of the diagnosis

I know of examples where the patient testing positive for HIV has been charged huge sums for therapy because everything that comes in contact with him during the performance of tests or treatment has to be destroyed. I know of patients who have been charged the full cost of metallic instruments used during surgery when the instruments were carefully cleansed, sterilised and re-used on other patients later.

Patients with AIDS, attending a workshop in Pune, expressed their agony over the dismal state of affairs in the public hospitals in Madras. The encountered corruption, callousness and denial of treatment in these institutions. Death certificates were not issued without the payment of Rs. 500 as a bribe at the largest public hospital in Madras? [1]

When registered doctors refuse to treat patients testing positive for HIV, quacks take advantage. A workshop in Pune in August 1996 exposed the hollow claims of Majid, a Kerala based mining engineer who made extravagant claims about an Ayurvedic potion he had concocted which was said to cure AIDS. A brochure distributed by Majid claims that his drug has the sanction of the Indian Council of Medical Research and the World Health Organisation. People are selling their houses and *mangalsutra* to pay for Majid's drug. Tests by the Indian Institute of Science, Bangalore showed that this drug contained corticosteroids. It is ironic that HIV patients had to warn the media against publishing advertisements of his drug and exposed his unfounded claims, the medical profession remaining blissfully unconcerned. [14]

Some frequently made arguments and rebuttals

1. I must know whether or not a patient has AIDS. If I know that his test for HIV is positive, I can take appropriate care to ensure that he does not pass his infection on to others.

   There can be no argument about the need for a doctor to know all he can about his patient provided such knowledge is obtained in the best interests of the patient. When information is sought merely for the protection of the doctor, or, worse, to the detriment of the interests of the patient (as when he is thrown out of the consulting room or hospital merely because his HIV test is positive), the search for information becomes perverse, unethical and immoral.

2. I have a life to lead and a family to look after. Why should I involve myself in treating a patient with a fatal, communicable disease?

   Such an attitude is born of ignorance and prejudice. HIV is a fragile virus that is easily destroyed. Ordinary precautions taken in the course of the management of any patient are more than sufficient to ensure that the treating physician does not get infected. Despite the hundreds of thousands of documented patients with HIV infection ,and AIDS the world over, there are hardly any proven cases of doctors being infected by the virus when the usual precautions were taken.

3. I have a right to refuse to treat any patient. What is wrong if I refuse to treat a patient with AIDS?

Refusal to treat on the basis of prejudice or fear is not expected of the good doctor. The law does permit any doctor to refuse to treat any patient provided such refusal is not likely to result in irreversible harm or death. By using this provision of the law, the doctor will be acting legally but it will be against all ethical and moral norms.

'There is no specific statute or rules or regulations obliging the doctors to treat HIV patients. However, all doctors and medical personnel have a common law duty to treat patients brought to them.'[10]

Some questions that are never answered by doctors

Since you demand that each of your patients gets himself tested for infection by HIV and shows you the result, is it not fair that you get yourself tested for HIV as well and announce the results to each of your patients?

What proof have you that patients can transmit HIV to you? Can you provide references in the medical literature to such transmission?

Since you insist on wearing cap, mask, goggles, gown and special protective shoes, could you provide references in the literature to prove that these are effective in preventing transmission of HIV?

When the literature shows that items used in the care of the patient who tests positive for HIV are easily sterilised by soaking them in bleach and then autoclaving them or sterilising them by glutaraldehyde or ethylene oxide, why do you destroy them?

Why do you charge patients testing positive for HIV more than you would other patients?

Where surgery is necessary, why do you charge a patient with HIV more than you do another with diabetic gangrene or peritonitis?

Public health strategy on AIDS

Prevention and treatment

Drugs effective against the AIDS virus (such as AZT or zidovudine) are not freely available to help those infected with HIV. Programs in India largely consist of advising people how AIDS is contracted, encouraging blood tests and handing out condoms. This is especially regrettable as India is a signatory to the Paris AIDS Summit Declaration (1 December 1994) which rightly states:

'Mindful that HIV/AIDS prevention and care and support strategies are inseparable, and hence must be an integral component of an effective and comprehensive approach to combating the pandemic, we declare our obligation to act with compassion for and in solidarity with those with HIV or at risk of becoming infected and undertake in our national policies to protect and promote the rights of individuals, in particular those living with or most vulnerable to HIV/AIDS through the legal and social environment.'[15]

Special care centres for AIDS sufferers, or hospices that might allow them to die with dignity, are virtually unknown. As a result, for many AIDS sufferers, the miseries of death are compounded.

The government's failure to set up effective AIDS programmes means that much of the burden falls on private efforts. Those attempting to stem the tide of infection by HIV battle against the taboos of a society that discourages sexual candour, against ancient superstitions that discourage the use of condom use and against indifference, sometimes even hostility, from local officials.

To take just one vulnerable group, the seriousness of the AIDS problem among Indian truckers can be gauged from discussions with them and their ride-along helpers. The drivers have an average of 150 to 200 sexual encounters a year with women and with girls.[16]

Sex *workers of foreign origin*

We have amidst us girls and young women who have been lured or kidnapped from neighbouring countries - Bangla Desh, Nepal, Myanmar. The manner in which we deal with them once we find that they are infected by HIV needs serious reconsideration.

Our current approach has elicited the following comment from a citizen of Nepal on the Internet: 'Acting on instructions from the Bombay High Court, police on 5 February 1996 raided some of the city's brothels. Four hundred and fifty six girls were rounded up, among them 218 Nepalese. Since there is no law against prostitution in India, it is customary to deal with the problem by sending the sex workers back to their home regions, once apprehended. This time, as a large number of Nepalese were also involved, the Maharashtra government notified the Centre, which in turn asked Nepal to take in the Nepalese girls. But Kathmandu has been in no hurry to comply and the impasse continues, even as two of the girls have died, presumably through AIDS complications.

'The Bombay High Court was well within its rights when it ordered the police action under the Suppression of Immoral Traffic of Women and Girls Act. But it was no moral indignation that motivated the justices. What spurred them was the disclosure by a daily paper that up to 65 percent of Mumbai's prostitutes may be HIV positive. Their solution was simple: send them back to where they came from. Case closed.

'Besides the questionable ethics of such a move, how could the learned jurists be oblivious of the wider danger of sending the hapless girls home? If the metropolis of Mumbai feels threatened by their presence, what would be the repercussions on the rural areas from where a great majority of these girls come? And how can it be proper that Mumbai (its men and economy) takes maximum advantage of poor women driven to prostitution, and then dumps them the moment they are seen as hazards? No one has bothered to ask that question, least of all the Nepalese government.'

Infected blood

A significant number of commercial blood donors test HIV positive. Although government policy requires hospitals and blood banks to test blood for HIV infection, surveys show that at least 30 percent of all blood used is not tested, and that this may account for as many as 12 percent of HIV infections.

The medical profession has failed to take action to prevent tainted blood from entering the blood banks. It was left to social organisations such as Common Cause and the Courts to compel the profession to act.

In an attempt to ensure safer blood supply and lessen malpractice, malfunctioning and corruption in our blood banking system, the Supreme Court told the government to create a National Council for Blood Transfusion. The judges advised the government to enact separate legislation for regulating the collection, processing, storage, distribution, and transportation of blood and the operation of blood banks. The order also called for all of India's blood banks to be licensed within a year. A quarter of them were unlicensed when the order was passed

Other provisions in the judicial order included the ending of professional sale of blood within 2 years, verifying that trained drug inspectors check the banks, and allowing 100 percent exemption on income tax to people donating money to the banks. The court's directive came in response to a petition filed by Common Cause.

The court ruled a long while ago. We have yet to see the ruling translated into practice.

Infected semen

At the seminar on medical ethics organised by Max Mueller Bhavan, New Delhi and All India Institute of Medical Sciences on 8 9 October 1995, a call for caution in the use of sperm supplied by private sperm banks, which have mushroomed in many cities, was sounded. Dr. Lalita Badhwar, a New Delhi gynaecologist, pointed out that most sperm banks did not test for HIV. Since semen is one of the most potent means for transmitting the virus, this lapse is blatant malpractice. During the discussion on this comment, Dr. Indira Hinduja of Mumbai clarified that her hospital had totally stopped artificial insemination because it was morally wrong to use untested donor sperm.

Grants for fighting AIDS how are they spent?

The Indian government has sent out conflicting messages. At times it has described AIDS as a national crisis and at others treating it as a menace that will go away. The government announced a $100 million five year AIDS programme in 1992, with $85 million of the money in the form of a loan from the World Bank. But as we near the end of the programme, only $35 million has been spent.

It is not just the authorities that are at fault. Those claiming to work on AIDS are not blameless.

According to Western experts, much of the money has gone on expensive conferences, planning sessions and reports. The sums spent on programs to improve blood screening, increase AIDS awareness, promote condom use and create clinics have been pitifully meagre.

Research on AIDS one unwelcome Indian example [14]

Desperation will lead people to do almost everything. This is a story about what happened to 10 people in Mumbai when an American veterinarian came calling with what he said was a miracle cure for AIDS.

These ten, all HIV positive, became guinea pigs in a secret test of an experimental vaccine whose effects, according to international health experts, are still largely unknown. The vaccine, based on Bovine Immunodeficiency Virus (BIV) has never been tested on animals and most scientists doubt whether it could offer any remedy to stricken humans.

But ten middle class, educated people in Bombay were persuaded BIV could save their lives. One of the patients who took part in the trials recalled the vet's pitch: 'He was saying the vaccine has come and you are very lucky people. He said we will become HIV negative - 100% HIV negative. That's what he told us.' After the trial was abandoned, the patients were left with no medical support.

Clandestine drug trials are unethical and against the law. But it can take years and hundreds of millions of pounds to carry out an authorised vaccine trial in the West and the American vet was in a hurry to exploit his patent application.

Bhairab Bhattacharya, aged 67, the Calcutta born inventor and naturalised American who says he has a Ph.D. in veterinary medicine, has spent several fruitless years trying to persuade the scientific community of the merits of BIV.

Bhattacharya was in correspondence with Dr. I. S. Gilada. Dr. Gilada and a social worker, Maya Gogte, assembled a list of trial participants. 'As such, our lives are useless,' said one participant. 'If something could come out for humanity, it is good. I have a scientific background and it sounded logical.'

Dr. Bhattacharya delivered a brief lecture in English about the properties of BIV. Participants were given no printed information about the vaccine and there was no translation for those who spoke only Hindi or Marathi. They signed consent forms, on which it was promised that the clinic would give them follow up medical support.

After they received the injection, Dr. Gilada handed each participant an envelope containing Rs. 1000. According to the sketchy notes taken by one of those who supervised the first injections, one of the participants was already in the terminal phases of AIDS, was suffering from diarrhoea and had a temperature of 104 degrees F. The man eventually died of AIDS-related ailments.

Dr. Bhattacharya made no attempt to secure official permission for his experiment. The central government and health authorities in Bombay and the state of Maharashtra say they were deliberately kept in the dark. Dr. Bhattacharya argues that the search for a cure for AIDS is too urgent for him to bother with formalities.

The trial was abandoned because of a dispute (between Bhattacharya and Gilada) over money. By the time the second or booster shot was administered on April 12, ***1994,*** the experiment was effectively over. A tenth man who could not be present at the clinic was so desperate to get his shot that he borrowed money for the train fare to New Delhi to track down Dr. Bhattacharya. He was shocked to find that they had not heard of him at the addresses Dr. Bhattacharya was supposed to be available. Dr. Bhattacharya travelled on to Calcutta where he says he injected four prostitutes who have HIV with the vaccine and distributed milk infected with BIV to several other women in the red light district.

Raju, a designer aged 38, who took part in the experiment said, 'They shouldn't have dumped us. They left us on the streets like stray dogs. It was completely inhuman.'

A draft code to be adopted by all doctors

We need to evolve a code of conduct which must be wholeheartedly subscribed to by all doctors. A draft code is offered. This could form the basis for the evolution of a definitive document.

We recognise the following truths:

1. The Human Immunodeficiency Virus (HIV) is a virus capable of infecting humans.
2. It is a fragile virus that is easily killed by the standard techniques for sterilisation.
3. It is commonly transmitted by one person to another through homosexual or heterosexual intercourse, transfusion of infected blood or blood products, or through unsterile hypodermic needles used for injection into a person already infected by HIV.
4. Such transmission of the virus can be avoided by the use

of. simple measures such as the use of a condom during sexual intercourse, screening of blood donors for HIV and the use of sterile hypodermic needles.

5. Infection by HIV produces a chronic, manageable illness.
6. We support the rights of infected patients to be treated without prejudice in their workplace, home, and health care.
7. Some individuals infected by HIV may go on to develop Acquired Immuno deficiency Syndrome (AIDS).
8. At present we have no cure for AIDS. The diagnosis of AIDS is, in most cases, tantamount to a death sentence.
9. Patients with AIDS may suffer a host of infectious diseases and suffer considerably before they die.
10. There is considerable prejudice in many minds against persons known to be infected by HIV or suffering from AIDS. This augments the agony of such individuals.

As aware and concerned physicians, we therefore resolve:

1. We are morally obliged and bound by duty to provide the best possible treatment to patients known to harbour HIV or suffer from AIDS, just as we would to any other patient entrusting himself or herself to our care.
2. Such care of patients known to harbour HIV or suffering from AIDS, will be provided under the umbrella of ethical principles, special care being taken to ensure confidentiality in view of the prevailing general prejudice against such individuals.
3. Patients will be offered counsel on the best course of action to prevent transmission of infection to spouses, other sexual partners and the population at large.
4. Where the patient is seen to act irresponsibly, we may find it necessary to intervene in the interest of the spouse or the public at large.
5. The function of the immune system improves with proper diet, exercise, healthy living and can be assisted by therapeutic means. We shall do all we can to reduce the possibility of inter current infection and maintain a state of health in such patients.
6. We shall discuss scientific knowledge on HIV and AIDS at every forum at our command so as to inform the public, empower it to take measures at preventing the spread of disease and ensure that those infected by HIV have free access to the best possible medical care.

Acknowledgements

I am obliged to Dr. Rakesh Tandon, Professor of Gastroenterology,' All India Institute of Medical Sciences, for re awakening interest in this subject and ensuring that I disciplined myself into preparing a formal document on it.

I am grateful to Dr. Gabriel Britto and Mr. S. K. Neelakanth of the National -Addiction Research Centre, Andheri, for providing many important references. They enabled me to consult these references in the comfort of my own office by transporting them to and fro.

I have benefited greatly from discussions with several workers in the field and with my colleagues in the Forum for Medical Ethics Society.

References

1. Burns John F: Virus begets wretched new class of untouchables. New *York Times 22* September 1996
2. Merchant Rashid: , A matter of life and strength. *Humanscape* 1996;3(13):21 *23*
3. General Medical Council: *Statement on HIV infection and AIDS the ethical considerations*. May 1993.
4. General Medical Council, Great Britain. Reproduced as Annexure E in Jayasuriya DC. (Editor) *HIV Law, ethics and human rights*. UNDP Regional Project on HIV and Development, New Delhi. 1995 p.420.
5. Pandya Sunil K: The patient with AIDS. *Medical Ethics* 1994;1(3):13.
6. Seidel G, Ntuli N: HIV, confidentiality, gender and support in rural South Africa [letter]. *The Lancet* 1996;347:469.
7. Ravi V: Personal communication. 1995
8. Bayer Ronald, Gostin Lawrence 0: AIDS and ethics. In Jayasuriya DC. (Editor) *HIV. Law, ethics* ***and*** *human rights*. UNDP Regional Project on HIV and Development, New Delhi. 1995 p.420.
9. Labowitz Kenneth E: Beyond Tarasoff :*AIDS and the obligation to breach confidentiality*. Saint Louis University Public Law Review 1990;9:495 515.
10. Grover Anand: HIV/AIDS related law in India. In Glick Robert A (Editor): *Law, ethics and HIV*. Proceedings of the UNDP intercountry consultation. 3-6 Cebu, Phillipines: United Nations Development Programme, Regional project on HIV/AIDS, New Delhi. 1993. P. *246*.
11. Chinai Rupa: Workshop on AIDS hit warns against Kerala based quack. *The Times of India 15* August 1996 p. 9.
12. Anonymous: HC summons officials for ill treating HIV patients. *Indian Express 26* August 1996 p. 5.
13. Pellegrino E: Altruism, self interest and medical ethics. *Journal of the American Medical Association* 1987;258: *1939* 1940.
14. Goldenberg Suzanne: Focus/Indian AIDS Scandal : Doctor who preyed on desperation. *The Guardian 9* December 1995, p 15
15. Paris Aids Summit Declaration 1994: Annexure A in Jayasuriya DC. (Editor) *HIV Law, ethics and human rights*. UNDP Regional Project on HIV and Development, New Delhi. 1995 p.420.
16. Burns John F: Denial and taboo blind India to horror of its AIDS scourge. New *York Times 22* September 1996

On the following pages we reproduce the revised South African code of ethics in HIV and AIDS. It provides a powerful example of how the national medical association of a country can instruct and guide its members and other personnel in the health services. We desperately need such guidelines in our own country. — Editor

The medical profession and the media

Members of the medical profession possess expert knowledge that can benefit society. They are, thus, duty-bound to do all they can to educate the general public on matters pertaining to health and the prevention and treatment of disease.

The role of the doctor as educator is especially important when the public imagination is fired by rumour on epidemic disease or when there is a real threat to public health as by toxins, pollution or microbes. The lay press, radio and television offer excellent means for reaching all segments of society.

Both the medical profession and the media have betrayed public expectation.

Some doctors are known to approach the media to propel themselves into the limelight. They tout their medical or surgical prowess, their proximity to politically powerful individuals and do their best to get themselves projected favourably. Journalists may be forced to write such stories because of the political clout exercised.

It is also well known that in most instances, damaging tales on doctors reach the press at the instigation of other doctors. While the motive can be whistle-blowing to safeguard the public, investigation often proves the story to be baseless. When such events occur periodically, the reputation of the medical profession also takes a beating.

Doctors' responsibilities

Doctors - even those in full-time service in our teaching hospitals - are reluctant to write for the lay press purely to educate the public.

Our professional associations too have failed in their duties to the public. Unlike the British Medical Association or the Americal Medical Association, which issue weekly statements on matters of public importance and, when necessary, detailed briefing papers and guidelines on matters of topical interest, the Indian Medical Association maintains an almost deafening silence. This deficiency is especially felt when there is a public health crisis such as an impending epidemic.

Worse, when the press approaches senior physicians for such information, they often encounter indifference, apathy and even lack of simple courtesy. Journalists are denied access to statistics and other data required to write a meaningful story. When the information pertains to hospital practices, the reporter usually encounters an iron curtain instead of being flooded with facts and figures explaining what is being done.

The faults are not all one-sided. The rights of the media to information, comments and analyses must be balanced by responsibilities. Yet these responsibilites are often ignored.

The media's failings

Over the past decade or so, our newspapers have undergone a sea change for the worse. Editors now function under the dictates of executives whose chief concerns are revenue and political balance.

Newspapers do not encourage specialisation by reporters. A senior reporter may cover a breaking political story today, a financial scam tomorrow, a public health story the day after and then a gangland murder.

To complicate matters further, the reporter is told at 10 a.m. to cover a complex health story and submit her report by 5 p.m. The consequences are predictable. Most reporters lack the requisite background expertise. They also lack the time or the inclination to look up details on the topic in the library or archives. Meeting experts personally is out of the question. They thus content themselves with sitting by the telephone and trying to get as many experts as they can to provide their observations and comments within two to five minutes. The resultant story is often a hotch-potch of quotes interspersed with the reporter's own observations and the few facts gathered. Contrast this with a news report in the *New York Times* or *The Times of London* where the reader is provided detailed background information, incisive comments from national and international experts and the reporter's analysis, suggestions and recommendations.

Our newspapers feature, from time to time, reports that sustain an individual doctor's inflated - and, at times, fraudulent - claims in print. In almost all such instances, no senior expert in the field has been consulted and the 'facts' put forth by the claimant have been accepted without question. Such lapses may be because reporters do not have the necessary expertise, time, energy or inclination to investigate such claims. Some have also suggested a doctor-reporter nexus.

Further, editors do not issue retractions even when proof is offered of the inflation or fraud. Such news items do not speak highly of either the competence or the integrity of our national dailies.

What could be done

Requests to the editors of *The Times of India* and *Indian Express* to get a physician to serve as a consultant on all medical stories have thus far met with no success.

It is a sad commentary that the medical councils have never investigated patently false claims or taken action against those advertising their 'competence' thus.

Much needs to be done both by the medical profession and those in charge of the media to correct the present sorry state of affairs. It is especially important to check malpractice, misrepresentations and the projection of individual doctors at their request.

Sunil K Pandya

***Sunil K Pandya**, consultant neurosurgeon, Jaslok Hospital, Mumbai*

TAKING A SECOND LOOK

Some opinions on the second opinion

Twenty-eight physicians, ethicists and sociologists responded to a questionnaire on the role of the second opinion in medicine today. Their comments provide the basis for further discussion on this practice, the issues involved, and the ethical complexities in changing health-care scenario

Sunil K Pandya

When a physician agrees to attend to a patient, there is an unwritten contract between the two. The patient entrusts himself to the physician and the physician agrees to do his best, at all times; for the patient. This contract disallows the patient from seeing another medical expert for opinion or advice without a referral note from his physician. It also enjoins the physician to respect the autonomy of the patient so that if the patient so desires, he will refer the patient to another physician for a second opinion.

Traditionally, the concept of a second opinion is based on certain assumptions. First, that the physician has studied the patient's medical history and clinical findings; if he is the patient's family doctor, he has also over time acquired a fund of medical and socio-economic information on the patient and his family. Second, that the physician is knowledgeable about the various specialists in the town or city and their respective strengths and capabilities, and is thus qualified to advise on whom to consult for a second opinion, and provide that consultant relevant and often-crucial medical information on the patient. Were the patient to consult another physician on his own, these benefits would be lost.

However, second opinions are often not sought on these principles. Some patients move from doctor to doctor without the primary physician's knowledge. They obtain a variety of opinions, often conflicting. Without any one doctor in overall charge of their therapy, they may follow whatever advice they choose to accept. If a complication ensues, no particular doctor can be held responsible.

Patients who do ask their primary physicians for a note of referral to another doctor are no better off. Such requests are often taken as a personal insult and evidence of lack of faith or trust in the doctor. Some doctors react by withholding key information, such as detailed notes on surgical operations. The result is often a general breakdown in the harmonious relationship necessary for good patient care.

The problem is compounded by the absence of clear-cut guidelines on he use of the second opinion. In India, our medical councils have failed to contribute to the discussion, or to regulate the use of the second opinion in any way.

It is in this context that colleagues were asked their opinions on the need for, and use of, the second opinion. by recording the views of respected academicians and medical professionals, one hopes to lay the ground for further discussion on the question. The following essay is an attempt to extract, from the responses received, considered thoughts on some aspects of this issue. Excerpts from the responses have been included to illustrate various perspectives.

Is the doctor-patient relationship a contract or fiduciary relation?

While several medical colleagues agree that the doctor-patient relationship today is some sort of unwritten contract, there were many qualifying notes. Ruth Macklin raises a fundamental question: what kind of contract is it, anyway, if it is both unwritten and unstated? “A contract in which the provisions are not clearly spelled out is not really a contract at all. In a legal sense, it would be considered invalid. From an ethical point of view, how can all parties - physicians or patients - be fully aware of their obligations or, for that matter, their rights? Contracts in the strict sense of the term are (usually) written documents that spell out the provisions clearly, say what all parties are obligated to do, and also specify penalties or remedies for breach of contract. That sounds very different from the physician-patient relationship,- which is perhaps better described as a fiduciary relationship.”

Clearly, this question needs further discussion for any systematic understanding of the issue.

And in fact Thomas George holds that it makes little sense to talk of contracts and obligations in our health care system. He would support enforcing the doctor-patient contract, and expecting referral notes from every patient, if we had a structured health care system, “as,. for example, in the National Health Service (NHS) in the UK. Borrowing only one part of the system leads to a lot of problems for the patient. At present there is no system at all in India and the.patients are completely at sea as to whom they should consult.”

The American Medical Association

According to the American Medical Association's code of medical ethics, physicians should recommend a second opinion whenever they believe it would be helpful in the patient's care. When doing so, they should explain the reasons for their recommendation and inform their patients that they are free to choose a physician on their own or with their assistance. Patients are also free to seek second opinions on their own with or without their physician's knowledge.

With the patient's consent, the referring physician should provide any information that the second-opinion physician may need. The second-opinion physician should maintain the confidentiality of the evaluation and report to the first physician, if the patient has given consent. Second-opinion physicians should provide their patients with a clear understanding of the opinion, whether or not it agrees with the recommendations of the first physician.

Where a patient initiates a second opinion, it is inappropriate for the primary physician to terminate the patient-physician relationship solely because of the patient's decision to obtain a second opinion.

In general, second-opinion physicians are free to assume responsibility for the care of the patient. . . . By accepting second-opinion patients for treatment, physicians affirm the right of patients to free choice in the selection of their physicians.

There are situations in which physicians may choose not to treat patients for whom they provide second opinions. Physicians may decide not to treat the patient in order to avoid any perceived conflict of interest or loss of objectivity in rendering the requested second opinion.Physicians must decide independently of their colleagues whether to treat second-opinion patients. Physicians may not establish an agreement or understanding among themselves that they will refuse to treat each other's patients when asked to provide a second opinion. Such agreements compromise the ability of patients to receive care from the physicians of their choice and are therefore not only unethical but also unlawful.

Council on Ethical and Judicial Affairs: Code of *medical ethics.* Chicago: American Medical Association 1997. 191 pages.

Homi Dastur argues that patients would not accept the enforcement of such regulations. "Very few patients would be willing to observe, accept or even understand (the concept of an unwritten contract), as is evident from the frequency with which those who can afford (to pay the different consultants) will seek multiple opinions. Many patients will reveal that they are under the care of another doctor only after the consultation is over. Sometimes one becomes aware (of the earlier consultant) only after reviewing reports which mention the name of the referring doctor."

Likewise, Bela Blasszauer suggests that such a contract would work only in theory, for doctor-patient relationships rarely develop in the prescribed manner. "Physician-patient encounters may take many forms. I may bump into the physician. I may have no other choice. I may be shopping for a suitable one. And so on."

Many doctors oppose enforcing contracts because they perceive the doctor-patient relationship as unequal, and liable to be misused by unethical doctors. "I would like to spare the patient the trauma (of having to face a doctor unwilling to refer his patient for a second opinion)," writes George. Blasszauer suggests that such contracts can generally not be made binding on the patient, since the conditions under which he sought advice or treatment were heavily weighted against him.

Others perceive the relationship differently. Eugene Robin and Robert McCauley suggest that the physician-patient relationship is a partnership and not a contract. "Either (patient or doctor) is free to 'terminate the relationship without cause', with the doctor having the additional burden of informing the patient when this occurs, and remaining available for such time as is reasonable for the patient to find another doctor who will assume responsibility for delivering medical care." This is generally true in the urban US, they state.

Sociologist Rohit Barot suggests that the Indian situation resembles private sector health services in Britain. He has been a patient in the UK National Health Service, as also with private practitioners there, and comments that the doctor-patient contract and the rules of referral seem to apply only in the NHS.

A one-way obligation?

Does the patient have responsibilities as well as rights in this relationship? "The doctor's duties, ethics, standards are well-known in theory and lapses from accepted norms are recognised in practice," writes Farokh Udwadia. "It is equally important (to emphasise) the patient's duties, responsibilities and obligations...It is time for this aspect to be discussed and the discussion circulated, for it must never be forgotten that the doctor-patient relationship is not a one-way street ."

Again, this view is a matter of debate. Jagdish Chinappa and Lawrence White argue that the two groups are very different. "The patient is the consumer who has needs based on certain beliefs and attitudes. The doctor is a service provider. Patients, under the stress of their illnesses, should be expected to behave irrationally and inconsistently." Therefore, Chinappa goes so far as to say, "honest and ethical action is therefore dependent only on the doctor and has to be decided upon the merits of every case. Certainly, the emphasis on autonomy guarantees a patient the right to ignore a doctor's advice, and to seek whatever opinions are wished: (I believe that this, even though considered a nuisance and counter-productive regarding patient care, is nonetheless a good thing.)"

Likewise, White notes, "Just as it is not an equal relationship in terms of power distribution, vulnerability, etc, so it is unequal with respect to promises on either side.. . it is generally accepted that patients have the right to do whatever they wish, including shopping for alternative opinions, etc." This does not mean that many physicians like or accept (the practice). "However, to demand otherwise will reinforce the physician's position of power and elitist attitude, which I believe would be a regressive step."

Why doctors should want a second opinion

There are a number of reasons why a second opinion may be sought. Traditionally, general physicians and patients seek specialist opinion and advice with benefit, especially when the disease is uncommon or the patient's condition serious. The patient with a hole in the heart, a brain tumour or failing kidneys will do better in the hands of specialists.

In certain situations a second opinion is almost a 'must'. "Take for example a 'shadow' in the lung of undetermined aetiology," writes Farokh Udwadia. "Is it tubercle, pneumonia, cancer or a rare disease, for example, Wegener's granulomatosis? What is the patient to do about it? In fact, it would be ***advisable*** to take more than one opinion..."

Christopher de Souza adds that young consultants would welcome second opinions from respected seniors — provided they were sure the patient would return to them for definitive therapy — in order to validate the line of treatment they propose. The senior consultant's concurrence would protect the younger colleague against unjust accusations and boost the patient's confidence in him.

B N Colabawalla feels that a second opinion may benefit the primary physician in yet another way. "Patients are now increasingly conscious of their rights and it would be improper for any physician to deny the patient his autonomy and right to seek a second opinion. It would be in the interest of the primary physician to make the necessary reference for a second opinion."

Unfortunately, requests for a second opinion from other consultants are uncommon. "The practice of referral from primary to secondary to tertiary, or from general physician to specialist remains an ideal not realised," according to M S Valiathan. who has rarely had a primary consultant seeking a second opinion from a senior consultant, or referring a patient to him. In cardio-thoracic surgery, at any rate... a senior consultant usually enters the, picture only when the primary consultant fears medico-legal trouble in a given situation."

The emphasis on autonomy guarantees, a patient the right to ignore a doctor's advice

That is not to say that patients aren't asking for them. One reason why second opinons are relatively uncommon is the absence of any publicly available medical audit. "Patients approach several consultants simply because, at present, they have no way to get authentic information on the quality of services provided by a given consultant or institution," says Valiathan.

Outpatients come to Anil Desai because they are dissatisfied with the information their primary physician gave them, or with the treatment's progress. "I always request a referral from the family physician, but (find that) many families do not not have a family physician."

However, the hospitalised patient is unable to obtain a second opinion without permission from the admitting physician — and even discussing such permission can be a source of stress for the patient and his relatives.

Is the second opinion a right?

All doctors surveyed felt so, though they did not agree on whether there were any limiting condiions. Some, like Blasszauer held that patient autonomy required that it be unlimited: "The patient has a freedom of choice, and even the responsibility... to go to as many doctors as he wishes. It is his life or that of his loved one that is at stake!" This right becomes particularly important with the deteriorating physician-patient relations. "Since trust in the medical profession has been greatly eroded, it is small wonder that patients (and I, myself, too) try to find the person who is up to date in his profession and displays humane features as well. In an open market system, this is no real problem. Even where there is a national health care system it may be cheaper for the system as well, if I can find the solution."

Others would limit that right, mostly to when the physician ignores the patient's wishes. Udwadia feels that "the patient's right to consult another doctor (independently) is absolute

The General Medical Council, UK

The General Medical Council (GMC) recommends that patients should continue to see specialists only on referral from a general practitioner. The GMC has strongly defended the referral system as a proven feature of medicine in the UK. Specialists should not usually accept a patient without referral from a general practitioner. The referral system is seen as the best way of ensuring that patients see the right specialist.

General Medical Council News, **Spring 1997, pages 1-2.**

when the treating physician refuses to allow another opinion in spite of the patient's request; is clearly disinclined or procrastinates unduly in granting permission to seek a second or third opinion, more so when the patient's condition is not improving or is, in fact, deteriorating; when he reacts with anger or displeasure to a request for another opinion, and the patient feels that he now no longer receives the care he expects and needs.

"Also, when the problem ... is of serious, unsolved diagnostic import (the patient) has an absolute right to seek as many opinions as he wishes. However, the physician, should caution the patient that ... too many opinions would only confuse and harm the patient."

But there are limits to this right, according to Udwadia. "It would be unjustified, in bad taste and bad manners if he seeks fresh medical advice of his own accord when already under treatment for an ailment for a considerable length of time by his primary physician. He should not seek a consultation with a new practitioner without permission and a referring letter from the primary physician. If the patient is dissatisfied, for whatever reason, with the primary physician, he should have the gumption to tell him so and inform him that henceforth he proposes to get treated elsewhere. This ... absolves the primary physician from further care of the patient. It is not uncommon for many patients to surreptitiously see many doctors (as if to test the primary physician's management), and then quietly go back to the primary physician without the latter even being aware of this duplicity."

Why don't patients tell doctors that they're 'double checking'?

Why do patients behave 'duplicitously'? P. K. Sethi and Colabawalla see the reason in the behaviour of most doctors. "In practice this (request by a patient for a second opinion) seldom happens because the public has an apprehension that I may be annoyed. It is we, as a profession, who should work towards dispelling this impression. We have not done so," writes Sethi. He holds that patients are justified in breaking their contracts if physicians are rude at the mention of a second opinion. And it is "morally, ethically and possibly even legally unjustifiable" for medical professionals to withhold information and case history details, either from the patient or the second opinion physician.

How should it be done?

Under the UK's National Health Service, only the primary physician can refer a patient for a second opinion, writes Blasszauer. The physician must make the request in writing and provide all relevant medical details. In return, he obtains in writing the diagnosis made by the consultant and his advice on treatment.

> *"Hospitalised patients wanting second opinions from outside doctors must first get themselves discharged," writes Prakash Tandon*

But this is rarely done in India, writes Thomas George, pointing out that patients rarely go up the primary, seondary and tertiary levels of care. Samiran Nundy notes that most patients in India do not have a doctor they can call their primary physician.

V. R. Joshi points out that even the most punctilious of consultants would find it hard to enforce such a protocol. "Patients often travel long distances from other cities or states to reach you. It is only when they reach your office that they are made aware that a referral note is required."

"Having come after seeking an appointment, I cannot refuse to see them just because they have no referral note," writes P. K. Sethi. "If, however, I discover that the patient is admitted to a local hospital and has come to me without informing the treating doctor, I ask him to go back and bring a referral note. I feel this is in the interest of the patient and also conforms to the code of medical ethics... The advice is often not implemented."

But it is not always possible to get a letter from the first doctor, feels Arunachalam, giving the patient's side of the story. He may be unavailable, or the patient hesitates to inform him, afraid the request would spoil relations. In fact the second opinion is often most needed when the patient is in the hospital — and least able to take an opinion without the admitting doctor's cooperation. Desai has always helped patients under his care obtain a second opinion without his physical presence, giving them full access to his case notes and the help of his house physician. On the other hand, if they seek a joint consultation — something Desai may also sometimes find necessary — he reserves the option on which consultant should be called in. There are also times when he recommends a joint consultation with the patient and relatives.

This is not always the practice. "We do not permit second opinions from outsiders under any condition," writes Prakash N. Tandon, arguing that the second opinion can only be used ethically within a structured format. Patients wanting such opinions must first get themselves discharged from the hospital. "Every patient discharged from our ward, either by us or at his request, is given a discharge summary with full information on the various investigations carried out, a copy of the operation note, our final diagnosis and condition on discharge. The patient is at liberty to use this information for whatever purpose he wishes." Tandon's hospital does not provide the patient copies of X-ray films and other imaging tests, but sends them directly to the consultant if asked.

Tandon argues that the patient's interests are met through multiple internal opinions. "Every patient admitted to our wards has the benefit of the collective opinion of the whole team which includes several senior consultants. By tradition, every patient is jointly discussed on more than one occasion.

“Permitting a second opinion from outside would create administrative problems on the one hand and a difficult clinical situation.” For example, he asks, what if the second opinion was at variance from the first opinion? Who would implement it?

“As a corollary, we refuse to provide a second opinion on patients admitted to other hospitals unless it is formally sought by the person treating the patient and with the permission of his administration. For purely administrative reasons, this is limited to public hospitals. The opinion is given to the treating surgeon and not to the patient or the family. At times, a joint meeting held with the family is addressed by the treating surgeon and ourselves.”

White disagrees with such a practice. “If a doctor does this, it strikes me that there is a component of spite and petulance arising out of the doctor’s own needs. Patients, particularly if seriously ill, often feel the need to validate their doctors’ opinion; after all, it is their life in the balance. Further, there are often enormous pressures from friends and relatives to get ‘another opinion’.” In other words, the second opinion can be taken for many ‘ethical’ reasons.

Robin and McCauley add, “If the primary physician learns that the patient is following advice not consistent with his principles of treatment, the doctor should advise the patient of the difficulty/danger as best the doctor sees it...It is the patient’s choice how to proceed. The doctor can be held responsible only for his own errors, not those of others.”

“If the patient is already admitted to hospital under another consultant, I would under no condition see the patient unless specifically asked to do so by the treating consultant,” writes Udwadia. “This would apply even if the patient concerned has been previously under my care for several years. "

“In the initial stages, before starting on a course of treatment, a patient may seek multiple advice,” says Mr Harsh Sethi. “‘But once treatment has started, then a new doctor should not accept a patient without a note of referral from the first doctor (provided he knows that the patient has been under treatment). At the last, he should speak to the first doctor and seek concurrence.”

The unreferred approach

What does one do when a patient seeks a second opinion without obtaining a note of referral from his primary physician? Macklin does not see this as a dilemma. “If a patient approaches you, seeking a medical opinion (whether it is a first or a second opinion), the patient is in need of diagnostic or therapeutic attention. You can decline to form a relationship . . . or accept the patient in your care and thereby establish a new doctor-patient relationship.”

Most respondents feel that it is the duty of the second physician to see the patient even without a note of referral from the primary physician, though such a note is desirable.

S. H. Advani adopts a firm stand. “I am absolutely clear in my mind regarding the patient and doctor relationship. In this relationship, the patient has the major say. It is the patient who is going to receive the treatment and he has to make sure that he receives the best treatment. I give my frank opinion to the patient (whether or not he comes with a letter from the primary physician) because I strongly believe that the patient has the right to take a second opinion. I don’t want the letter from the primary physician to participate in the second opinion.”

Ashok Bhanage emphasises that the doctor must work at all times with the patient’s interests at heart. “If I realise that I am the second consultant, I write my notes in more detail and elaborate the reasons for my decision. The patient is at liberty to show this note to the first or a third consultant.”

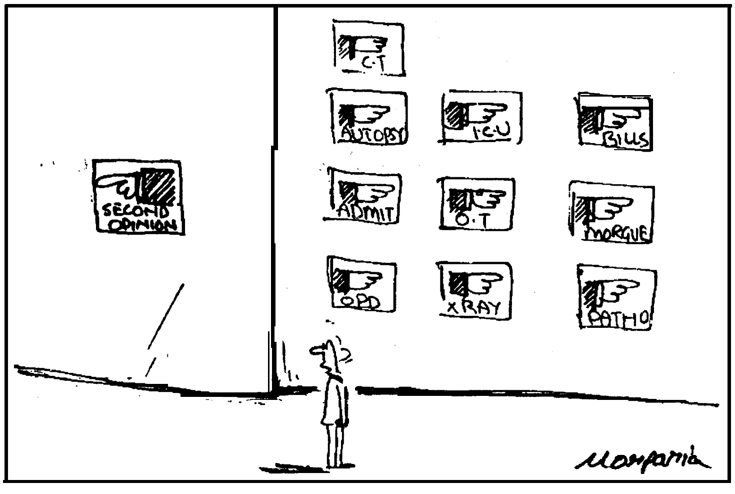
Aniruddha Malpani emphasises that the autonomy of the patient demands that a second opinion, should be provided. A letter from his primary physician is not necessary. “My relationship is with the patient and I am answerable to him, not to his primary doctor.”

Taking over the patient

Would you take over treatment of a patient already under the care of another consultant? This is one fear physicians have when referring their patients to their colleagues.

Some might argue that this is the patient’s prerogative. Arunachalam notes, “If I have changed doctors, I will certainly expect the second doctor to take full responsibility in treating me. If I consult more than one doctor (for getting opinions), I will retain the right to decide by whom I should ultimately be treated.”

Others are unequivocal: “If I find out that the patient is under the care of another consultant, I advise him to go back to that consultant,” writes Gajendra Sinh. “I do not take over treatment of these patients.”



On the principle that a patient has a right to autonomy over his decisions, most respondents see no difficulty in taking over the patient's management at his express request — provided such a step is in his interests.

However, Homi Dastur adds, "The suggestion to take over medical care would, at no time, come from me. It would have to be broached by the patient's general practitioner, if present, and the patient himself. Acceptsince would follow only **when** persuasion to return to the primary physician fails."

Advani differs. "The patient has the absolute right to be treated by the physician of his choice. If the patient decides to be treated by me, I would not normally hesitate to accept. I may inform the primary physician, though I don't consider this obligatory."

Blasszauer argues that the doctor must was incompetent, mistaken, negligent, or in some other way not acting in the best interest of the patient. Patients need physicians who seek to act in their best interest. Physicians owe more to the patient before them than they owe to other members of their profession. Even if 'physician etiquette' dictates that one doctor should not treat another doctor's patient, medical ethics demands that patients receive the best medical care. Notes of referral and reluctance to treat patients under the care of another doctor are elements of physician etiquette, not medical ethics as understood today."

Bypassed physicians may tell a seriously-ill patient that they do not wish to have anything further to do with their medical care

Barot feels that the second consultant is duty-bound to approach the primary physician for all relevant medical information on the patient.

Colabawalla outlines his approach: " If I am aware that the patient has been under the care of another colleague, I will offer my opinion and leave the choice to the patient. I would not 'take over' the case by ascribing to myself the arrogance that I know better! I **would then** try and persuade the patient to allow me to discuss the case with the primary physician.

"The difficulty arises when the patient unequivocally informs you that he does not wish to be treated by the primary physician, and requests you to take over the management. I would try to resolve that dilemma -- not that any dilemma can ever be resolved -- by accepting that the patient's autonomy and right to choose must be respected."

"If the patient is being looked after correctly I would persuade the patient to return to his consultant." writes Udwadia. "If the patient's problem has been wrongly diagnosed and if it is critical or life-threatening (e.g. a dissecting aneurysm of the aorta or an impending myocardial infarction), I would admit him to hospital under my care, inform the primary consultant and request him to see the patient in **hospital as** and when he wishes, so that we can jointly **look after** him."

The dangers of mixed therapy

Some patients will see several physicians to obtain a clutch of prescriptions, selectively following that advice which suits them. How can we help such patients avoid the complications that may follow?

Udwadia has seen patients who have gone through half a dozen or more physicians. "This is not uncommonly revealed to me at the end of the consultation! I ask that. the treatment advised be carried out under the supervision of any one doctor of the patient's choice, as I would be unable to follow-up on his problem as often as I would like to. I then write a letter to that doctor , outlining what I feel about the patient's problem and how, in my opinion, it should best be tackled. (Finally,) I tell the patient that if he wishes to see me again he will now have to get a letter from this doctor."

White agrees that selectively following advice offered by several physicians is courting trouble. "These are difficult situations, and in my opinion there is no one right answer. If I have a patient who is 'mixing and matching', I gently tell him he is receiving fragmented care, and that this is dangerous. Usually I tell the patient that I wouldn't continue management without a clear mandate. I feel strongly that patients have the right to several opinions, but that one doctor must quarterback the actual care. If he should suffer a complication, which of his medical attendants would be held responsible?'

And the state of the bypassed...

Many feel that the primary physician is justified in terminating his relationship with the patient. Valiathan sums up this sentiment: " The primary physician is not obliged to treat a patient who consults another physician or follows another line of treatment without his knowledge. When a doctor undertakes to take care of a patient he accepts a sacred contract with obligations on both sides. I do not agree that the doctor must take care of a patient 'under any circumstance'. Even Charaka, who imposed many strict conditions on the physician, **recognised** situations when a physician can terminate his sacred contract."

At times, the bypassed physician feels rejected and acts accordingly. Sometimes a seriously ill patient is told, "You have decided to consult X without informing me. I do not wish to have anything further to do with your medical care. Please go back to X."

All our experts frowned upon such behaviour. White writes: "Under these circumstances, the doctor's behaviour would be considered patient-abandonment. I would consider it a breach of ethical standards on grounds of beneficence, non-maleficence, fidelity to patient, and respect for patient's autonomy. What would be the physician's reasons for wanting to do this? The relationship starts out unequally, with the doctor having more power. This is counterbalanced, in my opinion, by the greater responsibility of the doctor, who needs to put his needs and wants aside and honour what is both a contract and a covenant. This is a critical issue - the physician's failure to put the patient's needs ahead of his own."

Colabawalla writes that the physician should "gracefully end the 'contract... in his own interest" if he feels that he has lost the patient's confidence "for whatever reason".

Barot strongly feels that the primary physician must pass information about the patient to the consultant or whoever else the patient may have chosen to deal with on health matters. The underlying ethic is that the primary physician should provide all necessary information as it concerns the patient's health (potentially a question of life and death).

Blasszauer agrees. "The primary physician should not shed his responsibility to the patient without clarifying his patient's motives," he writes. "The physician should . . . understand: he may have failed the patient; the patient may be out looking for hope, or proof that his doctor's diagnosis is right or that the recommended therapy is the only solution. If he cannot find the answer for his patient's motives, than he should sit down with the patient and have a frank discussion. If he sees that the patient had no ground whatsoever to abandon him, he may advise the patient to look for another physician, since without trust no such relationship could be beneficial. But until that moment, I believe, he does have some responsibility. The patient should not fall between two stools. The primary physician should be available till he -- on acceptable grounds -- terminates the relationship 'officially'. An insult to my vanity is not an acceptable ground."

Gajendra Sinh concurs with the need for reform within the profession. "Unless we put our own house in order it is difficult to see how we can restore the doctor-patient relationship."

Will a second opinion clinic work in India?

In Australia, a group of consultants from different disciplines offer counsel on the clear understanding that they will not takeover the patient's medical management. Would such a clinic work in India?

"It is fairly common in the U.S., in this connection, for a patient to be referred to a second physician for a decision about, say, the desirability of hysterectomy," write Robin and McCauley." The ground rules here are that the consultant will not be involved in the surgery; is not affiliated with (preferably doesn't even know) the treating doctor; and is paid the same, whatever his opinion. As you may imagine, this system has its own flaws and a long essay could be written about the good and bad aspects of this practice."

Several respondents fell that such a clinic has little chance of success. Chinappa holds that it could not work in "an unorganised health care facility like that in India. You need a high level of education in the patient and a high level of ethical and moral integrity in the medical profession for this system to work."

Teachers and colleagues who offered their views:

Dr. S HAdvani, chief, department of oncology, Tata Memorial Hospital, Mumbai

Dr. Subbiah Arunachalam, visiting professor, department of humanities and social sciences, Indian Institute ofTechnology, Chennai

Professor Rohit Barot PhD, department of sociology, University of Bristol, UK

Dr. Ashok Bhanage, consultant neurosurgeon Shivajinagar, Pune

Dr. Ravi Bhatia, consultant neurosurgeon Apollo Indraprastha Hospital, New Delhi

Dr. Bela Blasszauer, medical ethicist, Medical University of Pecs, Hungary

Dr. H B Chandalia, consultant endocrinologist, Jaslok Hospital, Mumbai

Dr. Jagdish Chinappa, consultant paediatrician, Manipal Hospital, Bangalore

Dr. B N Colabawalla, consultant urologist, Mumbai

Dr. Homi M Dastur, consultant neurosurgeon Jaslok Hospital, Mumbai

Dr. Anil D Desai, consultant neurologist, Jaslok Hospital, Mumbai

Dr. Christopher de Souza, consultant E.N.T. surgeon, Holy Family Hospital, Mumbai

Dr. Thomas George, consultant, Orthopaedic Hospital, Railway Hospital, Chennai

Dr. V R Joshi, consultant physician, Hinduja Hospital, Mumbai

Dr. Ruth Macklin, medical ethicist, Albert Einstein College of Medicine, New York, USA

Dr. Aniruddha Malpani, consultant in assisted fertility, Mumbai

Dr. Bashir Mamdani, professor of medicine, Cook County College of Medicine, Chicago, USA

Dr. Meenal Mamdani, professor of neurology, Chicago, USA

Drs. Eugene Robin and **Robert McCauley,** medical ethicists, USA

Dr. Samiran Nundy, consultant gastrointestinal surgeon Gangaram Hospital, New Delhi

Mr. Harsh Sethi, associate editor, *Seminar, New* Delhi

Dr. P K Sethi, consultant orthopaedic surgeon, Jaipur

Dr. Gajendra Sinh, consultant neurosurgeon Jaslok Hospital, Mumbai

Dr. Prakash N Tandon, professor emeritus of neurosurgery, All India Institute of Medical Sciences, New Delhi

Dr. Farokh E Udwadia, consultant physician, Breach Candy Hospital, Mumbai

Dr. Lawrence W White, medical ethicist, Berkeley, California, US A

Dr. M S Valiathan, vice-chancellor, Manipal Academy of Higher Education Manipal

Colabawalla adds that the idea is good, but “I doubt if it will ever be welcomed by most professional colleagues. There will always be the doubt that patients would be misappropriated.” Also, most medical professionals in India think they are too good to be challenged thus.

Udwadia agrees. “You require a general improvement in ethical standards for this to come about. When this does happen, specialist clinics for second opinions would be redundant.”

Bhanage expresses some hesitation: “It is virtually impossible to get a genuine second opinion in private practice where even the most senior doctors are very insecure and distrustful of their colleagues. A second opinion clinic will have to be manned by a senior doctor with a reputation for integrity.

White sees a similar problem in the US. “Medicine here has rapidly become a market commodity (unfortunately, in my opinion). A physician’s income often depends on ‘capturing market share’ from other physicians. Thus physicians and hospitals engage in extensive marketing and advertising, to ‘steal’ patients from others.”

Can a member of the clinic reject the patient’s request for treatment after he has attended the clinic?”

Hemraj Chandalia feels that if a patient insists he be followed up by the new consultant, “I will not deny the patient such an option.”

Bhanage cautions: “The medico-legal role of such a clinic will have to be defined. I feel it will be predominantly used by dissatisfied patients. Once it is seen by doctors as a forum used by patients to obtain evidence against them in a court of law, its role will shrink to this purpose only.”

My own comments:

My professors in medical ethics -- Drs. H. S. Mehta and H. I. Jhala -- taught me the procedure to be followed when referring a patient for a second opinion: a formal referral through a telephone call making the appointment and a confirmatory note also carrying a report on the patient’s medical history, findings and precise reason for referral. I believe it can only work in the patient’s best interests. This practice, was routine in Bombay some decades ago. It can function with the strengthening of the role of the family physician.

By providing certificates when its experts are convinced, the clinic can help patients as well as ethical doctors and testify on their behalf

I fully agree that the consultant must send the patient to the referring physician with a full report on diagnosis and advocated treatment. Taking the patient over when the referral was for an opinion is unfair, immoral and unethical. However, where surgery is indicated, the referring physician must always choose the surgeon based on the single criterion of competence.

I recognise the need for patients to obtain a second opinion, especially when a potentially hazardous form of treatment such as surgery is advocated. Towards this end, a second opinion clinic is to be welcomed, provided the clinicians categorically state that they will not take over the patient’s treatment.

Unlike Dr. Bhanage, I strongly support an additional medico-legal role for those working in this clinic. Current regulations require that the aggrieved patient seeking redressal from a court obtains two independent medical certificates on the validity of his claim, without which the case will not be admitted for hearing. Most doctors are reluctant to provide such certificates. By analysing the patient’s case dispassionately and providing such certificates when its experts are convinced that a valid case has been made, the clinic can help patients who have suffered from medical negligence or malpractice. It can also support and help doctors who practice ethically and conscientiously by testifying on their behalf, thus helping frustrate frivolous or malicious litigation and restore the fair name of the victimised physician.

I remain unsure on whether I should treat a patient who is under the care of another neurosurgeon in Bombay, without a referral being made to me. Whilst I recognise the autonomy of the patient, I am also concerned about the motives and outcomes of the current fashion for doctor-shopping. I often see patients obtain contradictory advice, experience delay in treatment, ending up confused and impoverished. I make every attempt at guiding the patient back to the original consultant.

Of late we have unreservedly accepted patients who have come to the K. E. M. Hospital because they cannot afford treatment in a private hospital. This seems to be an ethically valid ground for taking over even without a referral.

The clinician refusing to refer a patient elsewhere deserves censure. He would be well within his rights to terminate his relationship with the patient even as he writes a detailed note of referral. As has been stated effectively above, the interests of the patient must gain precedence over his own feelings.

I am sorry that the doctor-patient relationship - one that should be imbued with trust, friendship and an urge to help - has degenerated into mere commerce. I have had the good fortune of experiencing the ideal doctor-patient relationship during my childhood and youth and can only wish that we do all we can to restore it.

In the next issue we will carry responses to this discussion. Those interested can send their comments as early as possible.

improved skills but this should not be used as a excuse for brand promotion and for squeezing money from the poor.

Institutions like the Medical Council of India, the Indian Medical Association, the Indian Drug Manufacturers' Association, the Drug Controller of India and the judiciary should not only have suitable guidelines and laws but also monitor their application. They must have the power to enforce these rules. Unfortunately, they have neither nails to claw, nor teeth to bite, and not even a loud bark to warn.

Steps forward

The sky seems to be full of dark clouds but occasionally there is a silver lining. For example, some time around 1980, the general body of the Indian Academy of Paediatrics (IAP) took a donation for an oration made by an infant milk-substitute producer. In January 1997, the IAP resolved that "The IAP shall not accept the sponsorship in any form from any industry connected directly or indirectly with the products covered by the Infant Milk Substitutes, Feeding Bottles and Infant Food Act, 1992."

The current dependence of the medical profession on commercial sponsorship is a result of the failure of end-organ: the doctor. If doctors are convinced and committed to their ethical responsibility, they will not yield to the unscrupulous pressures of the industry. They must learn to say 'No' to gifts, subsidies and hospitality; to aid with strings attached; to brand promotion; and to prescribing irrational drugs and formulations.

Arun Phatak

Consultant paediatrician, editor of the Society for Rational Therapy and chairman for the Committee for the Protection of the Child Consumer of the Indian Academy of Paediatrics.

Based on the presentation made at the International Conference on Ethical Values in Health Care at Panchgani, January 2-4, 1998.

Neurosurgery and medical ethics

The Ninth Convention of Academia Eurasiana Neurochirurgica Houthem-St. Gerlach, The Netherlands July 29 - August 1, 1998.

Th Academia Eurasiana Neurochirurgica was founded in 1985 by Professors H. W. Pia (Giessen, Germany) and Keiji Sano (Japan) to foster exchanges between European and Asian neurosurgeons. This year, the theme was medical ethics.

Oriental views on ethics

H. Handa (Japan) reviewed traditional ethical ideas on life and organ transplantation in Japan and explained the Japanese reluctance to embrace the concept of brain death. The belief that the soul resided in every part of the human body disallowed the removal and transplant of a body part. Why, then, do the Japanese accept transplants from live organ donors? "It is difficult to explain," said Dr. Handa. One senses that Japanese society is in the process of coming to terms with the concept. Dr. Tomasz Trojanowski (Poland) commented that Polish law presumes the donor's willingness; persons not willing to donate organs must register their objection on admission to hospital. While persmission for organ removal is sought from the families of brain-dead patients, the law does not require this consent.

Dr. Iftekhar Ali Raja (Pakistan) discussed Islam and medical ethics. Starting off with a quotation from Einstein ("Religion without science is lame; science without religion is blind."), among the issues Dr. Raja discussed was euthanasia. He quoted Prophet Mohammed's last address: all killing (except that prescribed by the courts as punishment for certain well-defined crimes) is prohibited. "There is no mercy in such killing," Dr Raja said.

Dr Sunil Pandya (India) showed how the ancient Indian principles of medical ethics were at considerable variance with current realities. Dr. Fahlbusch (Germany) posed an ethical dilemma: what if a person dying ont the banks of the Ganges was found to have an eminently treatable illness like a blood clot? Would it be justified to enforce treatment on someone who had prepared to die and gain salvation?

Dr. A. Van Bommel, a convert to Islam who held the post of Imam, pointed out that the sanctity of life from the Muslim perspective demands every effort at preserving life. The ventilator would not be switched off as long as the heart was still beating and was evidence of life. Dr. Harry Rappaport (Israel) said cessation of respiration is central to the Jewish diagnosis of death. The rabbinical criteria for death include cessation of respiration and the diagnosis of irreversible brainstem damage. The Jewish doctor may not shorten life in order to improve the quality of survival.

Discussions on medical ethics often concentrate on dramatic issues such as euthanasia, neglecting the physician's positive duties: relieving pain, consoling and making the patient comfortable as the end approaches

Dr. Graham Teasdale (Glasgow, Ireland) felt that the attempt to solve ethical dilemmas on the basis of traditional religious beliefs implied an excessive reliance on authority, and could be antithetical to a modern, scientific approach to ethics. An ideal distillate of traditional wisdom and modern concepts would be possible through cross-cultural dialogues .

Christian thought

The first session on Christian thought noted that physicians are expected to have compassion -- which different

Dr Sunil K Pandya, *Flat 11, fifth floor, Shanti Kutir, Marine Drive, Mumbai 400 020*

from pity — for their patients. Since man has no right to interfere with life, the participant stated that euthanasia and assisted suicide were unacceptable. At the same time, the prolongation of useless life implied refusal to accept God's tenderness and mercy. Extraordinary means of preserving life which had lost all meaning were forbidden.

Professor W. J. Eijk (Netherlands) pointed out that discussions on medical ethics often concentrate on dramatic issues such as euthanasia. and neglect the physician's positive duties — relieving pain, consoling the individual and generally making the patient comfortable as the end approaches.

Dr. E. O. Backlund highlighted some anomalous situations following from current definitions of brain death: dead and living patients are treated side by side whilst formalities for organ donation are completed; the physician diagnosing brain death chooses the time of the patient's death — which can have judicial consequences; a baby can be born after the death of its mother.

On death with dignity, Dr. M. Nagai (Japan) felt that all acts that bring the patient closer to natural death are justified. The patient must be helped to die like a human being. Dr. Backlund commented on the perspective which views death as something to be fought tooth and nail. On the other hand, euthanasia is often taking the easy way out when counselling and good palliative care would have have been appropriate. Dr. Rappaport expressed doubts on the current trend in which life-and-death decisions are made by committees of hospital managers, lawyers and clergymen. While taking away doctors' powers to make decisions, will society absolve them of their responsibilities?

Dr. Graham Teasdale discussed ethics in research. An important argument made was that the insistence on fully informed consent can cause needless cruelty to patients and their relatives. Explanations of everything that can go wrong is not in the interests of the patient's peace of mind.

Dr. R. Dillman, Secretary of Medical Affairs, Royal Dutch Medical Association, presented details on the Netherlands experience with euthanasia. Doctors had been divided on the public demand for euthanasia. It was permitted after a national debate, and under specific conditions, to ensure transparency and accountablity. The law does not permit euthanasia, but no legal action is taken if the conditions are followed. Six thousand of 9,000 requests for euthanasia were turned down because the suffering was not unbearable, it could be palliated, available treatment had not been completed or there was evidence of treatable depression. The Netherlands Parliament will now consider legal modifications to make euthanasia legal.

The lessons from the Dutch experience: an euthanasia programme should not be embarked upon without an adequate legal framework that ensures transparency and accountability; patients must have free access to high quality medical care before such a step can be considered; there must be a full professional review of each case, and euthanasia is not an alternative to palliative care but is possibility when all else has failed to afford relief.

Dr. E. Schroten (Netherlands) discussed professional integrity in teaching medical ethics. The subject was best introduced with case studies, not ethical theories, with a phased analysis consisting of questions such as: What is the moral question? What are the options at first sight? What other information must be obtained? Who must be involved? What are relevant arguments?

The meeting was unusual in that it focussed on ethics in neurosurgery from a variety of viewpoints and contrasted traditional, religious and historical concepts with those based on modern scientific thought.

Sunil K. Pandya

Hardships of medical teachers

INCREASING pressures on medical teachers
Often talked and addressed among themselves
Due to limitations in their work
Patient care, teaching, administrative and research works

Impedence of their abilities and work
Though asking for expansion and new ones
Finally adjust with available ones
Due to financial constraints

Increasing workload every day
Lead to frustration and despondency
Representations are made on every other day
Hoping for improvement, on one of these days

Examinership,considered as prestigious
Some get it always,
Others get it at times
Needs influence and pulls

Internal examinership gets recognition
Also avoids leave and dislocation
But subjects one to local pressures
And to satisfy many people

External examinership too has difficulties
Tedious travel experiences
Followed by reimbursement policies
When money comes, subject to I.T. returns

More responsibilities including legal works
The threat of transfer— for service persons
And out-of-turn promotion — the hanging swords
Also no vacation as in for other teachers

P Thirumalaikolundasubramanian
Gizan, Saudi Arabia

COMPENSATION BY STATE

Eliminating Legislation Against Doctors.

Sunil K. Pandya[2]

Basics of such a scheme

Patients sue their doctors principally to gain sums of money as compensation for damage done to them. The victims of such litigation suffer considerably when they are innocent. One consequence of this sorry state of affairs has been the practice of 'defensive medicine', which, in turn, imposes worsening burdens in terms of escalating costs of investigation and therapy on the patients themselves,

Another important consequence: patients who suffer damage for whom no one can be held liable (as when the harm follows medical accident rather than negligence) have no recourse to compensation at present.

Some countries are experimenting with a system of 'liability without fault'. Here **compensation is sought and granted on the basis of extent of damage irrespective of its cause** and is related to the need of the patient. At one stroke this relieves doctors and courts of litigation and ensures that the majority suffering the consequences of medical accident also receive help. Instead of having to prove malpractice by an individual, evidence of harm would suffice. 'Inevitably, if the state has to pay, the current trend towards massive compensation awards would be reversed' (McClean 1989).

Such a system necessitates the setting up of a fund for this specific purpose using contributions by the state, the medical profession, insurance agencies, philanthropic institutions and the community at large.

Why should the medical profession contribute? The system outlined above would bar all civil proceedings which relate to damages arising from personal injury and death by accident: misadventure and negligence. The benefits to doctors in the form of peace of mind, ability to concentrate on treatment of the patient and savings in settlements provide sufficient reasons.

Some caveats

The Accident Compensation Scheme of New Zealand restricted such compensation to personal injury by accident including medical, surgical, dental or first aid misadventures but excluded damage caused by sickness, disease or the ageing process.

This has been disputed. Since the aim is to help all those in need, to exclude those handicapped as a natural consequence seems unfair. On the other hand, the funds needed to help all those handicapped by accident or ill health will be enormous and may be beyond available resources.

The individual patient will gain less money from such a system. The more equitable distribution of money to all those in need, based on the extent of need should, however, be generally welcome.

A review of decisions in New Zealand under the Accident Compensation Scheme shows that patients suffering harm from to failure to diagnose or treat accurately, risks known to the doctor but not to the patient and failure by the doctor to provide sufficient information to permit the patient to make an autonomous decision were not compensated. Thus, in practice, some forms of medical negligence were not covered, lending themselves to action in courts of law. Here, the principle (based on common sense and natural justice) that *where an injury is caused which should never*

---

1. Dr. Sunil K. Pandya is a neurosurgeon at the K. E. M. Hospital in Bombay.

have been caused, compensation should be paid by the person causing such harm has been applied.

Is such a system feasible in India?

The answer depends on the extent to which society and the medical profession are willing to bear the financial burden.

The medical and legal professions, social service agencies and the population at large would do well to ponder this alternative to the present system that sows the seeds of distrust and antagonism between patient and doctor.

Refererice

McLean Sheila AM: A patient's right to know. Information disclosure, the doctor and the law. Medico Legal Series, Dartmouth Publishing Co., Hants, England. 1989. Chapter 8, pages 140-161.

MOTHER vs FETUS

The front page of the *Indian. **Express*** on Sunday, 20 June 1993 featured a story on a pregnant woman, seriously ill with tetanus, admitted to the Sir J. J. Group of Hospitals in Bombay_ The patient and fetus were being monitored in the medical intensive care unit and appropriate care was being administered. Despite this, on the day before the mother died, she had cardiac and respiratory (arrests. She was revived briefly. Attempts at resuscitation continued but to no avail. Once death was confirmed, an emergency Caesarian section was carried out and the fetus delivered .

The news report states that the fetus is in a precarious condition and may have suffered brain damage when the mother had cardiac and respiratory arrest. The doctors in charge of the patient were asked why the Caesarian section was not done earlier. They replied that they worked on the principle that the life of the mother gains precedence over that of the fetus. Since the mother's life was in grave danger and a Caesarian section might have resulted in her death, they felt it wiser to do all they could for her.

It has been asked why the Caesarian section was not done once it was apparent that the mother was unlikely to survive. The obstetrician has a valid argument in favour of his stand: if he had operated whilst the patient had any chance of survival whatsoever, the trauma of surgery in her critical state would certainly have tipped the balance against her survival. He could, then, have been accused of having caused her death.

The reporter points to the added tragedy of this infant surviving with severe brain damage.

Here is a real life dilemma for the practicing doctor. Was it possible to determine with precision the point of no return as far as the mother was concerned? Should the criteria for the diagnosis of brain death have been used? What would you have done under the circumstances?

We welcome your responses and will analyse them in a forthcoming issue of this newsletter.

Should brain death be recognised as a clinical end point of care ?

Sunil K Pandya

The concept of brain death

In ancient times, before the realisation of the importance of the action of the heart and circulation of blood, a person was deemed to have died when he stopped breathing. The reflecting surface of a mirror was held before the face of the sick person. Death was diagnosed when the mirror was not fogged by water vapour present in the breath. Later, irreversible cessation of respiration and of the action of the heart were established as the criteria for the diagnosis of death.

In the middle of this century, attention was turned to the brain, which required much more energy than other organs. If its needs were not met for four minutes or more, irreversible damage to it followed. After a variable interval, the other organs failed and the person died. In the interim, there was a dead brain in a dying body.

The term 'brain death' was introduced in 1965 during a report of renal transplantation from a heart-beating, seemingly brain-dead donor. Following the path-breaking paper by the ad hoc committee of the Harvard Medical School and international debate on it, the concept of 'brain death' gained general acceptance.

The development of the science of organ transplantation and the availability of drugs that prevented rejection of transplanted organs by the recipient's body made the concept of brain death attractive. Given that once the brain is dead, death of the rest of the person within hours or days is inevitable, should we not use organs from this person to save other lives? International debates were followed by acceptance of this proposition. This has enabled transplant units save innumerable lives that would otherwise have been lost.

The law in India

Unlike the United States of America, India follows the British lead and has chosen irreversible damage of the brain-stem as being diagnostic of death. The Transplantation of Human Organs Act, 1994 (Central Act 42 of 1994), lays down the definition of death thus: 'Deceased person' means a person in whom permanent disappearance of all evidence of life occurs, by reason of brain-stem death or in a cardio-pulmonary sense at any time after live birth has taken place. It goes on to state that 'brain-stem death' means the stage at which all functions of the brain stem have permanently and irreversibly ceased.

Once brain-stem death has been diagnosed by an authorised committee using specified criteria, the dead person's organs can be removed for transplantation provided legally valid consent for this is available.

Stopping treatment after brain death

Traditionally, once there is permanent cessation of breathing and the action of the heart, all treatment is stopped. Under the Transplantation of Human Organs Act, 1994, it stands to reason that once brain death has been diagnosed, there is nothing to be gained by continuing any treatment. The only rational reason for continuing treatment after the diagnosis of brain death – use of the ventilator, drugs to prop up the blood pressure, antibiotics and intravenous fluids – is to provide time for the transplant teams to get their patients in and ready themselves for the operations to remove organs from the dead to the living.

However, as Mr Bumble observed in Dickens' *Oliver Twist*, at times 'the law is an ass, an idiot'.

Our present dilemma

Should we stop all care once the patient is brain dead?

As Lance Stell points out, to many laypersons (and to some medical professionals too, unfortunately), the term 'brain death' suggests that there is more than one kind of death ('brain death' and 'cardio-respiratory death'), or that there is more than one way to be dead (in a brain-sort-of-way and in a heart-sort-of-way), or that there are degrees of being dead ('brain-dead' and 'really dead' or 'dead-dead'), or that one might die more than once (first, when one's brain dies and again later when one's heart stops).

He narrates an experience that most of us have also encountered again and again. "Recently, I consulted on a case in which an ICU patient's attending physician, an experienced nephrologist, said the following to her patient's family: 'I am sorry to tell you that your daughter is *brain dead*. I will keep her on life-support for a while longer, I will even order her dialysed again, if you wish...at least until you decide what you want to do.' Not surprisingly, the patient's father asked, 'What are her chances of recovery, doctor?'

"Needless misunderstanding had complicated a tragedy. Since the patient had been diagnosed 'dead' by medically accepted neurological criteria, it was no longer appropriate to refer to the medical equipment attached to her as 'life support.' Nor should the attending physician have offered dialysis. After several hours, the confusion was resolved. All interventions were withdrawn. The patient was pronounced dead (when her heart stopped!)."

This dilemma prompted the organisers **of this conference** to put up the present topic for discussion. It stems from three deficiencies in the Transplantation of Human Organs Act:

Our legislators erroneously included the definition of brain death in an act intended to regulate organ transplantation.

Whilst defining brain death, they specified 'by reason of brain-stem death or in a cardio-pulmonary sense' thus leaving ambiguity in many minds.

It has not been specified that 'brain death' equals 'death'

***Dr Sunil K Pandya**, Jaslok Hospital and Research Centre, Dr G V Deshmukh Marg, Mumbai 400026. Email: shunil@vsnl.com.*

for all purposes.

As noted above, it stands to reason that if I can remove heart, lungs, liver and kidneys from a brain dead person for transplantation into other living individuals, I should also stop all medical care if such a person is not a candidate for the donation of organs for any reason whatsoever.

I find hospital administrators unwilling to permit such a step. They continue to hold fast to the old 'cardio-pulmonary' criterion for the diagnosis of death when the brain dead person is not a candidate for donating organs.

This has several harmful consequences. The agony of relations is prolonged for days, weeks or even up to six months till the heart finally comes to a permanent halt and the oscilloscope shows a continuous flat line instead of the P-Q-R-S-T squiggles. In many instances, the family undergoes the severely traumatic experience of seeking opinion after opinion from several consultants in the hope that someone will tell them that further treatment is likely to prove fruitful. The family continues to pay huge sums of money for 'intensive care' of a dead person. A bed in the intensive care unit is locked up by a dead person. Finally, doctors and nurses carry out the charade of caring for a person who is dead and spend time on the corpse that could be spent more fruitfully on other salvageable patients.

Some ways out under the present law

Dr M K Mani, senior nephrologist at the Apollo Hospital in Chennai, has a clearly laid down policy. Once a person is deemed to be brain dead, the relatives are called in and the diagnosis and its implications are clearly explained to them. After confirming that they have understood what has been told, they are asked to decide on the further course of action – donation of organs or stoppage of all treatment. Should they opt for the latter, the legal next-of-kin are requested to put this decision down on the case paper and sign the document. All treatment is now discontinued and the body is handed over to them. If, however, the family chooses to continue care in the intensive care unit till breathing and the action of the heart come to a permanent halt, this is honoured.

A senior consultant in Pune informed delegates attending the annual conference of this Society in that city some time ago that he proceeds along the same lines as Dr Mani but takes the additional step of asking the relatives to switch off the ventilator and stop the intravenous fluids.

These are unsatisfactory measures in that they do not have the clear sanction of the law. Mr. Bumble's observation and the law enunciated by U S Air Force Captain Edward A Murphy Jr ('If anything can go wrong, it will.') may yet lead to the prosecution of a doctor by misguided relatives of a brain dead person. We have been assured by senior judges sitting on the bench and senior lawyers practising at the Supreme Court that should such a case be brought before a court, it will, almost certainly, be dismissed. Even so, the dread of seeing one's name in bold headlines - 'Doctor ABC accused of killing patient' - haunts many minds. Courts are heavily burdened and judgements often delayed by years. The appearance of the line - 'Doctor ABC found not guilty of murder' – as a footnote at the bottom of an obscure column years after the event will prove small compensation for the agony suffered by the doctor and his family.

The permanent solution to this sorry situation

We need a separate Act specifying the new definition of death.

This Act should provide details of neurological criteria for death to be used in making the diagnosis. The Act must state clearly that this definition supersedes the older definition of death 'in a cardio-pulmonary sense'.

Once diagnosis of death is made under the new definition, the patient is, for all intents and purposes, dead.

This Society is ideally placed in bringing about this much-needed change in our law.

References:

Alexandre GPJ. From the early days of human kidney allo-transplantation to prospective xenotransplantation. In: Terashi PL, ed. *History of transplantation: twenty-five recollections*. UCLA Tissue Typing Laboratory, 1991. (Obtained from the internet)

Ad Hoc Committee of the Harvard Medical School: A definition of irreversible coma. Report of the ad hoc committee of the Harvard Medical School to examine the definition of brain-death. *Journal of the American Medical Association*, 1968; 205: 337-340,

Lofstedt S, von Reis G. Intracranial lesions with abolished passage of X-ray contrast throughout the internal carotid arteries. *Opuscula Medica* 1956; 8: 199-202. (Quoted by David J Powner, Medical diagnosis of death in adults: historical contributions to current controversies. *Lancet* Nov 2, 1996) (Obtained from the internet)

Spike, Jeffrey and Greenlaw, Jane. Ethics consultation: persistent brain death and religion: must a person believe in death to die? *Journal of Law, Medicine, and Ethics*, 1995; 23:291-94.

Stell Lance. Let's abolish "brain death". *Community Ethics* Volume 4, Number 1. (Obtained from the internet)

This paper was presented at a workshop on ethics in research at the Seventh National Critical Care Congress CCCON 2001 held in Bangalore from January 2 to 7, 2001.

Advertising remains unethical even in the digital age

Most codes on ethics in medicine prohibit advertising by doctors. There are good reasons for this prohibition. As professionals, it ill behoves us to publicly sing our own praises or solicit patients. We must await clients by referrals from colleagues or by word of mouth. Were physicians to advertise, patients run the risk of being lured to the one with the fanciest media coverage rather than to the most competent and experienced. This prohibition gains greater validity in a country such as India where ignorance and gullibility abound. This does not deprive the extraordinary physician of renown. Noteworthy contributions to medical theory or practice are legitimately published in medical journals after being subject to review by peers and can command admiration from colleagues.

Having known Dr. Aniruddha Malpani for several years and respected his abilities and expertise, I was unpleasantly surprised to run across his internet site www.drmalpani.com/pcss/index.htm.

The site advertises the Malpani clinic as ‘the best place to have a baby’. Clicking on ‘Read what the press has to say about our clinic and the services we offer’ takes one to a series of press reports featuring the clinic or statements made by Dr. and Dr. Mrs. Malpani. Here is an excerpt from this section:

“City doctor proclaims the end of male infertility …

“IS THERE any viable option for infertile male patients to father a child? Yes, says a city-based doctor, who attains the distinction of being the first medico in the country to treat such patients successfully. The new treatment is expected to illumine the lives of many unhappy couples.

“Dr Aniruddha Malpani, a well known specialist in infertility problems, has successfully impregnated a woman with testicular sperms for the first time in the country. Besides, he has also achieved fertilisation with precursor germ cells like spermatids , which is contrary to the known scientific wisdom that only matured and developed sperms can initiate pregnancy…Dr. Malpani’s clinical success shows that even the most sterile patient can now be successfully treated by testicular sperm injection.

“However, the treatment charges are quite expensive, ranging around Rs 90,000 for a single attempt.

“This cost, though cheap compared to that of the western countries, is beyond the reach of many in our country,” Dr. Malpani laminated (*sic*) adding that the charges would gate (*sic*) reduced as the treatment percolates down to a wider strata of the society.”

The site also features three reports filed in the *Times of India* on 5 and 6 November 2000. These suggest that ‘medical tourism’ to India could be yet another source of foreign exchange for this country. Since the cost of treatment here is a fraction of those in the West, Indian doctors can expect to attract patients frustrated by long waiting lists in their own countries. All three reports quote statements made by Dr. Malpani. Following on the heels of these reports was a letter by Dr. Malpani printed in the correspondence column of this newspaper, justifying advertising by Indian doctors on the web so as to attract such tourists and their lucre.

I remain unconvinced of the ‘benefits’ of advertising and am worried about its ill effects. For every Dr. Malpani who advertises one can expect scores of charlatans and quacks. Given the non-existent control on medical malpractice in India, and the example of ‘Dr. Majid’ who misled victims of AIDS for such a long time, advertising is more likely to worsen the plight of individuals who are already sick and desperate.

Given our circumstances, advertisement by doctors remains unethical even in the digital age.

Postscript: A section on the Malpani site offers Preimplantation Genetic Diagnosis - a technique used to rule out genetic disorders in the embryo- to select the sex of your baby. Since this technique enables identification of the sex of the test-tube embryo prior to implantation and the selective implantation of only those embryos that show up as male, Dr. Malpani’s clinic panders to families desiring baby boys. Presumably, embryos of the undesired sex are destroyed. Although Dr. Malpani concedes that this technique raises certain ‘worries and concerns’, his lengthy defence of such a practice suggests that he has convinced himself that no wrong is being done.

Sunil K Pandya

Note: the advertisement carried in this issue of the journal is *not* the same advertisement referred to in Dr Pandya’s comment. The advertisement printed in *IME* was circulated to the editorial board for approval before publication. A brief description of our advertisement policy is printed elsewhere in the journal.

***Sunil K Pandya**, Flat 11, fifth floor, Shanti Kutir, Marine Drive, Mumbai 400 020. Email: sunil@medicalethicsindia.org.*

Dr. Ketan Desai and the Medical Council of India: lessons yet to be learnt

Election to any position on the Medical Council of India - as, indeed, to any responsible position on any public service agency - ought to be on the basis of integrity, competence, proven service to fellow-citizens and an aptitude for the position.

As is common knowledge, elections to our national and state-level medical councils are fought with just one aim: to enrich oneself personally. Expenditure of huge sums; a total lack of scruples; political connections; a compulsive desire to grab power by any means, both fair and foul and finally, ruthless pursuit of the goal of personal enrichment are absolute necessities.

Given these conditions, it is not surprising that our medical councils are hopelessly corrupt, incompetent and disinterested in the common good. No wonder, the Delhi High Court in a recent judgement labeled the Medical Council of India as ‘a den of corruption’.

The reported sum spent by candidates for election as President of the Medical Council of India exceeds a crore of rupees. Were the actual figure even a tenth of this amount it is easy to see how no honest individual can ever aspire to serve in this position. It is also obvious that a person spending such a huge sum will have as his primary goal the recovery of his capital investment along with ‘adequate’ returns on it in the shortest possible period. The seeds of corruption have already been sown.

Two encouraging events.

Thanks to the crusading efforts of a handful of individuals, we are provided a glimmer of hope.

The setting aside of the fraudulent results of the elections to the Maharashtra Medical Council was the first of these events.

More important is the recent decision by the High Court in Delhi against Dr. Ketan Desai, President of the Medical Council of India. After the Court found him guilty of corruption he was forced to resign from the Selection Committee of the All India Institute of Medical Sciences.

Much remains to be done. The identification of wrongs in bodies such as the Medical Councils by our courts is a great step forward but cannot, by itself, bring about any permanent change.

Take the example in Maharashtra. Despite the passage of many months, nothing further has been done to restore normalcy to this body or eliminate the many inadequacies that permitted fraud over decades. The government rests, having followed the court directive to appoint an administrator. In all probability it will continue its siesta till the court is moved once again - against many odds and with the expenditure of much time, energy and money - and convinced to issue a fresh directive.

If events run true to form, a similar fate will befall the Medical Council of India.

Making malpractice difficult, if not impossible, requires major changes in the rules and regulations governing medical councils, their constitutions and their modes of operation. These changes must liberate these councils from control by the politicians and the bureaucrats both at the central or state levels.

At the moment even the members purporting to represent the state governments in the Medical Council of India are nominated by the Central Government. In addition, New Delhi appoints another eight members as government nominees. This results in automatic ‘election’ of a government-backed individual as President of the Medical Council. The President enjoys unfettered powers for five long years of his term. Since there is no bar on repeated re-elections of the same individual, a person can stay as President of MCI virtually for life! Such a long duration of control over the Council by one individual breeds vested interests and corruption. Besides younger entrants to the profession are denied the opportunity to bring new ideas. All these need to be changed.

The workings of these councils must be totally transparent both to members of the medical profession and to the public at large.

These goals, by themselves, pose formidable difficulties under present circumstances. Let us however, for a moment, imagine that they have, somehow, been achieved. We would still have a long way to go for there is yet another essential requirement for the restoration of normalcy - a change in the character of the medical professional.

Honest, dedicated and sincere doctors must be encouraged to stand as candidates to these councils. The rest of us must support such candidates and ensure their election. We must also guarantee the failure of any person demanding unmarked ballot papers or using other unfair means to frustrate the spirit of free and fair election.

We must also monitor the functioning of these councils, make our displeasure at fraudulent or unethical practice known and felt and, in general, serve as watchdogs to keep the councils on the straight and narrow path.

Should we prove capable of all this and more, we shall earn the gratitude of our fellow-citizens and of those who are yet to become doctors.

Sunil K. Pandya, Samiran Nundy

__Dr Sunil K. Pandya__, Neurosurgeon, Jaslok Hospital & Research Centre, Dr. G. V. Deshmukh Marg, Mumbai 400026. Email: sunil@medicalethicsindia.org. Dr Samiran Nundy, Surgeon, Gangaram Hospital, New Delhi.

VIEWPOINT

Medicine in India—a view from the West

SUNIL K PANDYA

Neurosurgeon, Jaslok Hospital and Research Centre, Dr G V Deshmukh Marg, Mumbai 400026. e-mail: shunil@vsnl.com

Dr Atul Gawande has rightly earned a formidable reputation at an early age with his first opus (1), written while he was still a resident doctor in an American hospital. He now commands our attention by a forthright and comprehensive review of current medical practices in India as witnessed by him. Published in the *New England Journal of Medicine,* the essay is assured wide readership. Alas! this Journal is not read by our ministers of health in New Delhi and various states or by the bureaucrats who man the ministries of health and education.

Dr Gawande's observations in and around Nanded are also true for most other parts of Maharshtra and indeed, India. Worse conditions that those noted by him can be witnessed in states such as Uttar Pradesh and Bihar. Newspapers in metropolitan Kolkata are full of tragic tales of medical misadventure and of the visits to clinics and hospitals by stray cats, dogs and even larger quadrupeds without let or hindrance.

Man's inhumanity to man

While writing for an American medical journal, it is but natural that Dr Gawande contrasts what he obtained in Nanded with his experiences in the state of Massachussetts. The shock for him and his western readers must be great. We, in India, are hardened by our own experiences and frustrations, consequent to failures in our attempts at improving practices. Those of us who have worked in large teaching hospitals in the private sector are all-too-familiar with the crowded outpatient clinics where scores of patients must be examined and advised in conditions that border on the inhuman and when time is always at a premium.

Despite our best intentions, we are, at times, abrupt with a poor person in pain, who has travelled hundreds of kilometres to seek help. Short cuts are a way of life in such hospitals, given the abject poverty of patients and unpardonable indifference of the powers-that-be to the needs of patients and public hospitals. As Dr Gawande points out, it is the inherent strength of our rural patients that often helps doctors remedy their illness despite perennial shortages and unsatisfactory working conditions in our government 'health centres'.

His account of the elite All India Institute of Medical Sciences in Delhi also provides matter for deep thought.

Delhi is a spacious city, almost rich by Indian standards —with broadband, ATMs, malls, and Hondas and Toyotas jostling with the cows and rickshaws on the six-lane asphalt roads. AIIMS (everyone just calls it 'Aims') is among the country's best-funded, best-staffed public hospitals. Yet even it has a waiting list for surgery.

One day, I accompanied the senior resident charged with supervising the list, kept in a hardbound 2003 appointment book. He hated the job. He had recorded in his book the names of 400 patients awaiting surgery by one of the three faculty surgeons on his team. He was scheduling operations for new patients as long as six months in the future. He tried to give patients with cancer the first priority, he told me, but people were constantly accosting him with letters from ministers, lawyers, and politicians insisting that he move their cases up in the schedule. By necessity, he accommodated them—and pushed the least connected ever further back in the queue.

A needless death

Even for hardened Indian doctors, it is difficult to control emotions when we read Dr Gawande's account of the 35-year-old man who died from a perfectly treatable collection of pus in the chest that squeezed the lungs and made it impossible for the patient to breathe even as his doctor and Dr Gawande tried to help him. The cause of the tragedy? Read the original account: '*Chest tubes were out of stock. So the resident handed the man's brother a prescription for one, and he ran out into the sweltering night to find a medical store that could supply it. Unbelievably, 10 minutes later, he came back with one in hand. Yet still, it was almost an hour before the procedure was done. The casualty ward was thought to be too crowded, and the patient waited to be moved to a procedure room. There, no one could locate a minor surgical set. The resident left to find a nurse. And by this time, I was doing chest compressions. The man was without a pulse or respiration for 15 minutes before the resident could* *finally put a knife between his ribs and let the pus shoot out. It made no difference. The man was dead by then.*

Such experiences are in contrast to ministerial and press accounts of how a particular Indian surgeon helped a child from Pakistan recover from complex illness in a well-equipped private hospital or of the much-touted prospects for India as a centre for 'medical tourism'. Dr Gawande's introspection after this and similar experiences brings him to the conclusion that most of us have also reached.

Where the fault lay is not quite apparent. Clearly, scarce resources were partly to blame. This was a hospital of 1000 beds, but it had no chest tubes, no pulse oximeters, no cardiac monitors, no ability to measure blood gases. Public hospitals are supposed to be free for patients, but because of inadequate supplies, patients are routinely asked to obtain their own drugs, tubes, tests, mesh for hernia repairs, staplers, suture material. In one rural hospital, I met a pale, 80-year-old man who'd come 20 miles by bus and on foot to see a doctor about rectal bleeding and a prolapsing anal mass, only to be sent right back out because the hospital had no gloves or lubricating gel. A prescription was written, and two hours later, the man hobbled back in, clutching both.

Corruption rules the roost

This reflects more than a lack of money, however. In the same hospital where I saw the man die—where basic equipment was lacking, the emergency ward had just two nurses, and filth was everywhere you stepped—there was a brand new spiral CT scanner and a gorgeous angiography facility that must have cost tens of thousands of dollars to build. More than one doctor told me that it was easier to get a new MRI machine for a government hospital than to maintain basic supplies and services. One reason is corruption: politicians are often happy to procure big-ticket items because they can take an under-the-table cut. More fundamental, though, is the mammoth difficulty of adapting the public system to its population's new and suddenly more complicated range of illnesses. Surgical care in particular requires rational, reliable organization almost more than it requires resources. In India, both are in short supply...The medical community in India has mostly resigned itself to current conditions. All the surgical residents I met planned to go into the private sector or abroad when they finished their training...Most attending surgeons were also plotting their escape. Many already see patients for cash on the side. Meanwhile, all doctors live with compromises in the care they give that they would never tolerate for their own families. And there lies the rub!

Dr Gawande holds a mirror up to each one of us who works in the field of health care. So much needs to be done ere we can hold our heads erect.

Reference

1. Gawande A. Dispatch from India. *N Engl J Med* 2003;**349:**2383–6.

EDITORIALS

Impact of life-prolonging technologies on end-of-life care in India

SUNIL K PANDYA

Consultant neurosurgeon, Jaslok Hospital, Mumbai. Address for correspondence: 5th floor, Shanti Kutir, Marine Drive, Mumbai 400 020 INDIA. email: shunil@vsnl.com

The debate on end-of-life care is just beginning in India but has been going on in developed countries for some decades. Since our conditions are markedly different from those obtaining in Europe or America, it is good that we are charting our own path.

This issue features three essays that will help further discussion. The most touching of these is the first person account by Dr. Rastogi. In his opening paragraph he highlights a fact that all of us must ponder. Advances in medical technology have now made it possible to keep the heart beating far longer that it would have in decades gone by. The crucial questions Dr Rastogi asks, and, indeed all doctors looking after seriously ill patients must ask are: At what cost are we keeping the patient's heart beating? Is the ultimate outcome likely to bring happiness or sorrow to the family?

I see, all too often, patients in our intensive care wards who are sarcastically but realistically referred to as cabbages. There they lie, in deep coma, oblivious to the world and likely to remain so. Relatives come, offer affection, encouragement and hope but the recipient of this outpouring of concern and love will never know of their attendance or their sentiments. The irreparably damaged brain has rendered the patient insensitive in all senses of the term.

Even when doctors are certain – from their tests and assessments – that the patient will never regain meaningful consciousness, they persevere in their ministrations. Deep coma and attendant paralysis renders the patient vulnerable to a variety of complications – infections, pressure sores on parts of the body bearing weight, clotting of blood in the veins of the lower limbs and danger of these clots suddenly breaking loose and invading the veins of the lungs. Often these patients cannot breathe and are therefore made to do so by a machine. All this care comes at a horrendous cost.

No relative would begrudge cost if the outcome is likely to bring happiness. Even the poorest of the poor at hospitals such as the KEM Hospital in Parel, Mumbai, will manage to gather the required funds, often by selling the small plot of land owned by the family or the mangalsutra adorning the mother's neck.

Decisions on whether or not to continue such expensive care should, rightly, be made by the relations. Unfortunately, faced with the prospective loss of a loved one, emotion overpowers reason. "Please do whatever you can to save his life, doctor" is the statement most doctors hear from the responsible relation.

It is only when days and weeks later, after paying huge sums that the family often can ill afford, when the family sees the patient in almost exactly the same condition that questions on efficacy of treatment emerge. When searching questions elicit information from the doctor to the effect that no one can predict whether or not the patient will improve beyond this stage, panic sets in. At this stage, the law will not allow termination of life and so the tragic drama must be played out till, eventually, infection or some other complication calls the finale.

Dr Jindal discusses some of the questions that we must consider in all strata of our society, now. Does an individual possess the right to refuse treatment? Who else can decide on treatment option? Who is to bear the costs of life prolonging treatment? To what extent is the medical team responsible for the terminal care?

India needs legally valid guidelines on these and other crucial issues. We need to know the conditions under which a person in full possession of his senses can dictate that doctors should not embark on dramatic, expensive measures to save his life when the prospect of meaningful existence is virtually non-existent. Such a person is in dread of being a 'living corpse' with tubes sticking out of every imaginable and unimaginable orifice in his body. He also wishes to spare his relations crippling costs and prolonged agony.

We also need legally valid guidelines on whether, under specified circumstances – such as the presence of wide-spread malignant cancer or a mercilessly progressive disease that paralyses the patient and will eventually render him unable to breathe or swallow so that he may choke to death – the doctor can be empowered to follow the patient's order to stop any further treatment. This is not termination of life. It is a decision to prevent tragic and soul-deadening prolongation of a life that has lost all meaning and, in any event, is soon to end.

Western countries have legally valid empowerment of the patient such that he can issue an 'Advance Directive', 'Living Will', 'Do not resuscitate' (DNR) order and 'Durable Power of Attorney for Health Care'. We desperately need such empowerment of our citizens.

Guidelines already laid down need to be widely disseminated and acted upon. The definition of brain death is now part of an Act passed by Parliament and yet we see so much misconception on it. Endless tragedy has followed the decision by hospital administrators to refuse clinicians in their institutions to take off all life-support systems once the diagnosis of brain death has been made.

Finally, we need to consider the dilemma posed by the death, some months ago, of 25 year old K Venkatesh from muscular dystrophy in Hyderabad. Aware that he would soon die no matter what his doctors did for him, he pleaded that they be allowed to harvest his organs for transplantation so that other lives would be saved. This heroic gesture was fully supported by his mother, K. Sujatha. Since there was a grave risk that Venkatesh, in his enfeebled state, would suffer widespread infection that would make transplantation of organs impossible, Venkatesh and Sujatha pleaded that his organs be harvested by terminating his life.

Venkatesh did not seek an escape from an ordeal or from suffering. He wished to perform a final act of service to his fellow beings before his inevitable and imminent death. As Sujatha put it, 'euthanasia' and 'mercy-killing' were mere terms that meant nothing for them. Alas! Venkatesh's wishes could not be respected. His organs could not be used to save other lives.

The crucial factor to be underlined is that all that needs to be done – some of which has been briefly referred to above – must be achieved by society at large and not by the medical profession. Rightly, doctors have been criticised for their paternalistic attitude towards patients and relatives. It is therefore fitting that the movement to bring the necessary changes in our law and practices into being must be made by society.

Who forms society? The masses, desperately concerned about their next meal, are unlikely to spearhead changes. The responsibility must, perforce, fall upon our intelligentsia – professors, scientists, lawyers, philosophers, social workers, media experts, civil servants and others – to arrive at a consensus on each of the various issues after honest, practical and soul-searching discussion and debate. The consensus decisions can then be discussed among widening circles before being incorporated in law.

We are already far behind the rest of the world in empowering our citizens to make their own decisions on the ending of their lives. It is high time we catch up.

ARTICLE

Medical Council of India : the rot within

SUNIL K PANDYA

Neurosurgeon, Jaslok Hospital and Research Centre, Dr G V Deshmukh Marg, Mumbai 400 020 INDIA email: shunil3@gmail.com

Abstract

The Medical Council of India is a statutory national agency charged with several responsibilities. Sadly, it is plagued by inefficiency, arbitrariness and lack of transparency.

It has been functioning for some years as the fiefdom of one person - Dr Ketan Desai. He has been re-elected president of the council despite strictures against him by the High Court of New Delhi.

This essay provides data that may help the reader identify the rot within the Council.

Permitted optimism, we may hope that this essay and similar observations by others will prompt a change for the better.

At present such optimism is not justified.

Introduction

The web page of the Medical Council of India provides the following information:

The Medical Council of India was set up in 1934 under the Indian Medical Council Act, 1933. This Act was repealed and a new Act, The Indian Medical Council Act, 1956, was enacted. This latter Act was further amended in 1964, 1993 and in 2001. The objectives of the Indian Medical Council, as per the Act, are as follows:

1. Maintenance of uniform standards of medical education, both undergraduate and postgraduate.
2. Recommendation for recognition/de-recognition of medical qualifications of medical institutions of India or foreign countries.
3. Permanent registration/provisional registration of doctors with recognised medical qualifications.
4. Reciprocity with foreign countries in the matter of mutual recognition of medical qualifications. (1)

The promotion of medical ethics; ensuring ethical medical practice and punishing wrong-doers; providing guidance to medical professionals on good medical practice, and advice on novel forms of treatment bristling with ethical implications (the use of embryos in medical research and the use of stem cells in clinical practice being just two recent examples) do not feature in the stated objectives.

In 2006, we learnt of a move to amend the Act. M R Madhavan and Ruchita Manghnani analysed the implications of the proposed amendments (2). They wrote:

"There are two major issues. First, the proportion of elected members in the MCI and its executive committee has been lowered. Second, the Bill gives the central government powers to override the decisions of the council, and even to dissolve the executive committee.

"The percentage of elected members of MCI will decline from 69% to 54%. If elections were not held on time for even 5 of the 49 elected seats, elected members would be in a minority.

"Elected members will be in a minority in the executive committee (excluding President and Vice President).

"The powers granted to the central government could lower the autonomy and independence of the MCI to function as a regulatory body.

"New provisions to improve accountability have been proposed without utilising provisions within the existing Act, such as the power of the central government to constitute a Commission of Enquiry."

Given these facts, an attempt is made here to analyse the functioning and efficacy of the Medical Council of India in the field of medical ethics.

The case of the irreplaceable Dr Ketan Desai

In December 2001, the *BMJ* reported on the dismissal of Ketan Desai, president of the MCI:

"The High Court in Delhi has ordered that Dr Ketan Desai, the president of the Medical Council of India, be removed from his post after it found him guilty of corrupt practices and abuse of power.

"Besides heading the council, which regulates the medical profession in India, Dr Desai also heads the Indian Medical Association, which represents India's doctors...

"A writ petition was filed last year by Harish Bhalla, a private practitioner, challenging the appointment of Dr Desai, providing evidence of his corrupt practices, his subversion of the council by usurping all key decision making roles and appointment powers, and seeking his removal.

"The petition accused Dr Desai of large scale bungling in medical admissions. Evidence was also presented on manipulation of inspection records of two medical colleges in

Pune and Ghaziabad for granting them recognition.

"Minutes of the council meetings showed that all critical decisions were concentrated in Dr Desai's hands. Dr Bhalla presented details from an income tax raid at Dr Desai's house last year, which showed unexplained receipt of 6.5 million rupees (£95,000; $136,000) via bank drafts in the names of his wife, daughters, and himself from several people in Delhi.

"The judges ruled that Dr Desai had misused his position as president of the Medical Council of India. 'We cannot allow an unscrupulous and corrupt person to function as the president of the MCI [Medical Council of India],' observed Justices Chopra and Kumar. 'Therefore we direct that Dr Ketan Desai shall cease to hold office of president of the MCI with immediate effect.'

"The judges also castigated the central government, whose officials had been accused of connivance in the affairs of the council, for not discharging its duties properly. Major General (Retired) S P Jhingon has now been appointed by the court to head the council as an interim administrator until the council is reconstituted." (3)

Neither the Medical Council of India nor Dr Ketan Desai challenged these statements published in the journal.

The judgement of the Delhi High Court notwithstanding, the list of members of the Medical Council of India, as shown on its website, included the following under "list of the executive committee members as on 9.01.2008": "Dr Ketan D Desai, B/h Rajpath Club, 7, Friends Avenue, Opp S G Highway, Bodakdev, Ahmedabad 380 059." (4)

Was this an accident? Were the Government and the Medical Council of India unaware of the decision of the Delhi High Court?

Reporting in *Frontline*, T K Rajalakshmi noted:

"...In an interim order issued on May 28, 2001, a single Judge of the High Court ordered the removal of Ketan Desai as MCI president until fresh elections were conducted.

"The Union of India and Ketan Desai filed appeals against the order.

"On June 4, a Division Bench of the High Court stayed the order and permitted the MCI to hold elections to the post of president and vice-president as scheduled.

"Harish Bhalla approached the Supreme Court. The apex court passed an order on June 18 substantially maintaining the Division Bench ruling. It directed the Delhi High Court to dispose of the appeals expeditiously. The petitioner filed an additional affidavit in the High Court. The final hearing began after all parties concerned filed their affidavits, rejoinders and counter-affidavits.

"The High Court had three aspects to deal with: the constitution of the MCI, the eligibility of Ketan Desai to hold the post of president and the alleged misuse of office by Ketan Desai. Under the Medical Council Act, the MCI has to be a representative body with people drawn from various sections of the medical community. It was found that the Council had only 77 members against the stipulated 123. Also, the number of nominated members was much larger than the number of elected members. Under the Act, the number of elected members must be more than twice the number of nominated members. But the Council had an equal number of members from each category. A two-member Bench of the High Court pulled up the Central government on this matter. It observed that the Centre had failed to perform its duty of constituting the Council under Section 3 of the Act and that it was owing to this failure that the Council had lost its representative character. The government, it noted, 'had not at all made bona fide efforts and not adopted effective measures to ensure that elected members are in place'.

"The order said that the fact that Ketan Desai had won the election to the post of president with an overwhelming majority proved that he sought to retain control over the Council by such manoeuvres.

"Despite the gravity of the charges against Ketan Desai, he was renominated to several committees at the AIIMS in August 2001. Union Health Minister C P Thakur is the president of the institute and the chairman of the governing body. The AIIMS Faculty Association's plea against Ketan Desai's continuance in the institute body went unheard...

"...Apart from levelling corruption charges against Ketan Desai, the petitioner questioned his membership of the Council. Ketan Desai was initially appointed against a vacancy and his term was to end on February 19, 2000. However, the Central government nominated him as a member on February 1, 2000. The date was later changed to February 14, 2000...

"...On February 18 and 20, 2000, the Income Tax Department raided the business and residential premises of Ketan Desai and bank drafts for Rs 65 lakhs were found to have been received by him and his family members. The Joint Director of Income Tax (Investigation), Ahmedabad, concluded that prima facie these drafts appeared to be arranged gifts and that further inquiry was needed in this matter. This conclusion was conveyed to the Income Tax Department in Delhi. Investigations by the Joint Directors of Income Tax in Ahmedabad and Delhi revealed that the gift entries were not in lieu of loans and records as claimed by Ketan Desai. The Joint Director of Income Tax (Investigation), Delhi, stated in a letter to his counterpart in Ahmedabad that 'these are accommodation transactions in the form of gifts and the alleged donors merely acted as conduits to channelise the unaccounted money of Dr Ketan Desai into his and his family members' bank accounts...'" (5)

Most damning of all was the final observation: "...It was not as if the Health Ministry was not aware of the state of affairs in the MCI. During a Rajya Sabha debate on August 6, C P Thakur agreed with the criticism by Y Radhakrishna Murthy of the Communist Party of India (Marxist) of the functioning of the MCI. The member's observations, the Minister said, were 'not far from the truth'. In this context, it is not clear why the government did not take any action to straighten out matters. In fact, it was only two days after the Rajya Sabha debate that Ketan Desai was renominated to the AIIMS committees..." (5)

The officials in the council itself also appeared to be oblivious of the ignominy consequent to the decision of the High Court in Delhi and of corruption within the council itself. During further discussion on the affidavit filed by the administrator in the Hon'ble Delhi High Court on June 7, 2002, in LPA No. 470/2002 - Dr K P Aggarwal vs Union of India & Others, when asked whether he had found any corruption in the council, the administrator replied that he was 100 per cent convinced that there had been corruption in the functioning of the council. Dr L S Chawla requested the administrator to apologise and withdraw the words as he could not make a sweeping statement of "100 per cent corruption" in the Council. At this juncture the administrator informed the court that he meant that there was no cooperation from the staff and everybody in detecting the corruption, which fact he had also conveyed to the solicitor general of India (6).

In 2005, the acting president of the Medical Council of India stated: "The charges were of corruption...

"I do not think there was any proven corruption charge. They were only allegations against which we have approached the Supreme Court. There was a CBI inquiry. I understand that the CBI inquiry has not proved any charges of corruption. They were only wild allegations. The Supreme Court has appointed me as the Acting President reposing full confidence in the Council." (7)

On September 16, 2005, *The Hindu* reported: "The Centre ... requested the Delhi High Court to quash the appointment of Lt Col (Rtd) A R N Setalvad as Medical Council of India Secretary terming the same as illegal.

"... allegation against (Setalvad) of embezzlement of Rs 8 crore from Bhavnagar Medical College, Gujarat and vigilance inquiry which is said to be pending, the appointment ..." the affidavit said.

"The Centre alleged that Setalvad was passing on files to former MCI president Dr Ketan Desai who was removed from the post in pursuance of orders passed by the Delhi High Court." (8)

It is of interest that even on June 8, 2009, Lt Col (Rtd) A R N Setalvad remains on the Council and holds the office of secretary.

Evidently, Dr Ketan Desai has kept a firm grip on the strings that moved the acting president and other functionaries at the council, and on who is who in the council.

In the minutes of the general body meeting held on March 1, 2009, the president (acting) "was also happy to share with the House" that the Interim Appeal which was preferred by him before the Hon'ble Supreme Court challenging the decision of the Hon'ble Delhi High Court of November 2001 before the Hon'ble Supreme Court "has been totally upheld vide order dated 05.02.2009". (9) As a result of this," not only the composition of the MCI with reference to its desired representative character stands testimonised, but also the decks have been cleared for the conduct of election of the office bearers of the Council, which has been itemized in the agenda. In a way, he can say with all humility at his disposal that the destiny has made the Council move a full circle back on to its path of committed responsibility, fair name and credibility."

These minutes go on to record elections to two key posts:

"6. Executive Committee - Election of members.

"6(i) President - Election of.

"Dr Rani Bhaskaran proposed the name of Dr Ketan Desai which was seconded by Dr Ved Prakash Mishra.

"As there were no other nomination received, the Scrutiny Committee submitted its report to the Returning Officer informing therein that they have received only one nomination for the post of President i.e. Dr Ketan Desai, which is in order.

"Accordingly, the Returning Officer Dr Indrajit Ray informed that Dr Ketan Desai was declared elected as President of the Medical Council of India for a term of 5 years...

"6(ii). Vice President - Election of.

"The election of Vice President of Medical Council of India was conducted u/s 3(2) of the IMC Act, 1956 as per the order of the Hon'ble Supreme Court dated 05.02.2009 in C.A. No. 599-600 of 2002 etc. - Dr P.C. Kesavankutty Nayar Vs. Harish Bhalla & Ors.

"The following name was proposed for the post of Vice-President. MCI:-

"Dr P C Kesavankutty Nayar - Proposed by Dr D J Borah Seconded by Dr B P Dubey

"As there were no other nomination proposed, Dr P C Kesavankutty Nayar was declared elected unanimously as Vice-President of the Medical council of India for a term of 5 years."

Predictably, the minutes of the meeting of the executive committee held on March 13, 2009 carry the following illuminating items right at the start.

"At the outset, the members of the Executive Committee congratulated Dr Ketan Desai, Professor & Head, Department of Urology, B J Medical College, Ahmedabad, on his assuming the office of the President, Medical Council of India and wished him a very best towards adding to the fair name and credibility of the Council.

"The President thanked Dr P C Kesavankutty Nayar, the then President (Acting) for handling the affairs of the Council diligently and effectively during the past 7 years. All the members congratulated Dr Nayar on his assuming the office of the Vice-President of the Council and wished him a very best."(10)

An impartial observer might be pardoned for voicing some nagging thoughts.

- How did the powers-that-be permit the council to function for seven years with the same individual as "president (acting)?"
- Did the august members of the council not find the functioning of "president (acting) for seven long years good enough to want him to function as president without the (acting)?
- Is there no one else in the country who can serve the Medical Council of India in the capacities of president and vice-president than these two worthies?
- What did the executive committee mean by Dr Ketan Desai "adding to the fair name and credibility of the Council"?

Decisions of the Medical Council of India on misconduct by doctors

I have studied decisions made prior to 2008 and provide my findings of some decisions that need clarification.

*The case of Dr ****

In response to a complaint that a doctor was present for an MCI inspection in a medical college other than the one in which he was employed, the MCI's ethics committee noted:

"The Ethics Committee feels that Dr *** was forced by the management of Basaveswara Medical College & Hospital, Chitragurga to attend the MCI inspection on 1.6.2005... It is very clear that the college has taken advantage of his inexperience and helplessness to force him to face MCI inspection ....

"...Such behaviour of the college towards medical teachers is highly objectionable and deserved to be condemned... Therefore, Ethics Committee decided to absolve him (Dr ***) from the charge of serving simultaneously in two medical colleges. The matter may be treated as closed." (11)

What action did the Medical Council of India take against the management of Basaveswara Medical College and Hospital, Chitragurga for behaviour that was "highly objectionable and deserved to be condemned"?

The case of Dr Tuli and VIMHANS

A complaint was filed against Dr S M Tuli (VIMHANS), New Delhi, stating that the histology report of a malignant tumour was not communicated to the patient and an oncology opinion not sought for three months. The patient died. Had the report been communicated in time and an oncology opinion sought, treatment may have provided a better outcome. The complaint was considered by the ethics and executive committees of the Medical Council of India - F.No. 292/2007. The ethics committee noted:

"1. The biopsy report of the patient was sent by the hospital for histopathology examinations on 12.09.2005 and the report of the said examination was received by the hospital on 16.09.2005.
"2. The operating surgeon Dr S M Tuli failed to inform the patient on the date of discharge on 16.09.2005 about the biopsy report which was highly malignant.
"3. On 27.09.2005 ... Dr S M Tuli failed to inform the patient about the serious diagnosis of malignancy and failed to advice him for the treatment.
"4. Three long months elapsed before the doctors of VIMHANS Hospital informed the patient regarding diagnosis of the disease and the case was referred to Oncologist on 27.12.2005.
"5. The Ethics Committee notice that there is fault on the part of treating doctor by not showing the report to the patient.

"The Ethics Committee further notice that there is failure on the part of VIMHANS Hospital, New Delhi also because they have failed to inform the patient about the biopsy report which has arrived at the hospital in time.

"The Ethics Committee has further noted the observations raised by the Delhi Medical Council on the lapses of the hospital in this regard and has therefore, decided to issue a strong censure to the concerned authorities of VIMHANS Hospital, New Delhi for this failure.

"This censure may also be communicated to the registering authority i.e. Directorate of Health Services, Govt. of NCT, New Delhi and also to the Secretary (Health) besides the hospital."

The conduct of the ethics committee thus far is impeccable. Having considered available evidence, the committee outlined appropriate corrective action. Subsequent events demand an explanation. According to the minutes, "The Executive Committee ... decided to refer back this case to the ethics committee for re-consideration." No reasons for this referral are noted. There is no reference to the ethics committee's recommendation that the hospital and its authorities be censured. Then, in an amazing and unexplained volte-face the ethics committee, after review, unanimously decided that the name of Dr S M Tuli should be removed from the Indian Medical Register for a period of four weeks instead of three months. "The matter may be sent to Executive Committee and the file may be treated as closed." As with the executive committee, so with the ethics committee, no explanation for this abrupt turnaround was deemed necessary. (12)

The case involving the Maharashtra Medical Council

Dealing with a complaint against Dr *** by Mr K K Abdul Azeez (F.No. 85/2008), the Medical Council of India decided: "... Dr *** is registered with Maharashtra Medical Council. Hence, the Ethics Committee decided that the matter may be referred to Maharashtra Medical Council for taking necessary action at their end .... The matter may be recorded in the referral register and the file may be treated as closed." (13)

The ethics committee of the Medical Council of India appeared unaware that when they made this dismissive decision, the Maharashtra Medical Council had no elected members. The earlier committee of members was disqualified by the Court. Its affairs were being dealt with by Mr R S Mhaskar, registrar.

When I made enquiries, I was unable to determine how the Maharashtra Medical Council dealt with cases referred to it by the Medical Council of India or complaints made to it by members of the public. I do not know what the Maharashtra Medical Council did in this particular case. The Medical Council of India is, of course, not interested as it has treated the file as closed.

Use of funds

Huge sums are collected periodically from every department in each medical college for inspection and certification of their facilities and the mandatory recognition by the Medical Council of India. Propriety demands accountability of the sums received and the manner in which they are spent. An attempt at studying the budget of the Medical Council of India using sources accessible to me yielded the following data (14):

33. MEDICAL COUNCIL OF INDIA

(Rupees in thousands)

	Actual Expenditure	Budget Estimates	Revised Estimates	Budget Estimates
	1997-98	1998-99	1998-99	1999-2000
Plan	25,00	85,00	65,00	73,00
Non-Plan	1,00,00	53,00	56,00	56,00

No further data can be obtained at this site. Did the Ministry of Health and Family Welfare wash its hands off the Medical Council of India in 2000?

The website of the council itself provides the following information on income or expenditure during the years 2006-2008 (15) (see below)

I am afraid I do not possess the expertise for analysing such statements but even so am puzzled by the sums spent under "establishment" (Rs 29,263,319.00) and "administration" (Rs 91,202,112.00). I note that these are in addition to sums spent from grants (Rs 44,893,188.00) and the sum set aside as depreciation (Rs 22,789,109.00). The total expenditure of the council during the year 2007-2008 was Rs 188,147,728.00.

My attempts at obtaining some information on expenditure from the meeting's minutes provided by the Medical Council of India yielded two interesting bits of information.

Dr Ketan Desai has been provided special facilities by the Council. In the minutes of the meeting of the Executive Committee held on April 27, 2009 (16) we learn that "The Executive Committee of the Council approved the recommendations of the Purchase Committee for installation of Video Conferencing system in the Council Office through the NCCF Limited as under:

Serial number	Particulars	Quantity	Rate (rupees)	Installation
1.	Sony Group Video Communication system Complete with installation PCP-1P	Two numbers	2,87,500/- each (VAT extra)	One each at President's Office at New Delhi and One at President's Office at Ahmedabad.

Income & Expenditure Account for the period ended 31.3.2008

INCOME	SCHEDULE	Current Year	Previous Year
		2007-08	**2006-07**
Income from Sales/Services	**12**	280,740.00	397,426.00
Grants/Subsidies	**13**	18,018,032.00	14,624,067.00
Fees/Subscriptions	**14**	178,185,225.00	139,464,725.00
Income from Investments (Income on Invest. from earmarked/endow Funds transferred to Funds)	**15**	0.00	0.00
Income from Royalty, Publication etc.	**16**	0.00	0.00
Interest Earned	**17**	30,382,010.00	6,034,431.00
Other Income	**18**	24,079,501.00	23,664,672.00
Increase / (decrease) in stock of Finished goods and works - in - progress	**19**	0.00	0.00
TOTAL (A)		**250,945,508.00**	**184,185,321.00**
EXPENDITURE			
Establishment Expenses	**20**	29,263,319.00	20,481,201.00
Administrative Expenses	**21**	91,202,112.00	68,577,452.00
Expenditure on Grants, Subsidies etc.	**22**	0.00	0.00
Interest	**23**	0.00	0.00
Expenditures from Grants	**24**	44,893,188.00	11,085,269.00
Depreciation (Net Total at the year end-corresponding to schedule 8)	**8**	22,789,109.00	23,541,868.00
Total (B)		**188,147,728.00**	**123,685,790.00**
Balancing being excess of Income Over Expenditure (A-B)		62,797,780.00	60,499,531.00
Transfer to Special Reserve (Specify each)	**2**	62,000,000.00	60,000,000.00
Transfer to General Reserve	**2**		
SURPLUS (DEFICIT) CARRIED TO CORPUS CAPITAL FUND	**1**	**797,780.00**	**499,531.00**

In an earlier meeting an equally weighty item had been considered:

"At the outset the members expressed a desire that a beautiful Guest House which has been constructed should be put to the optimal use by providing accommodation to the Members/Ex-Members/Ex-Officers and the medical college fraternity on their visit to New Delhi. After detailed deliberations, the House unanimously decided that the following schedule of charges be adopted for providing accommodation in the Guest House of the Council:

Charges

A. On Council's duty NIL (For attending meetings, inspections, transit stay, etc.)
B. On personal visit
(i) Members of the Council Rs 250/- per day
(ii) Ex-Members/Ex-Officers of the Council Rs 500/- per day
(iii) Any other member of the medical college Fraternity Rs 1,000/- per day" (17)

Tainted officials?

The dictionary defines the word thus:

taint (tnt)

v. taint·ed, taint·ing, taints

v. tr.

1. To affect with or as if with a disease.

2. To affect with decay or putrefaction; spoil. See Synonyms at contaminate.

3. To corrupt morally.

4. To affect with a tinge of something reprehensible. v. intr.

To become affected with decay or putrefaction; spoil. n.

1. A moral defect considered as a stain or spot. See Synonyms at stain.
2. An infecting touch, influence, or tinge.

Consider two recent news items. The first in *The Times of India* on June 6, 2009 carried the headline "MCI members on erring college board". In the text of the report, which investigated medical colleges in Chennai that charged capitation fees from students in violation of the law, the reporter noted:

"Even as questions swirl over the impunity with which private medical colleges are charging illegal donations despite an explicit Supreme Court ban, it now appears members of the apex regulatory body – the Medical Council of India (MCI) – themselves have strong links with the offending institutions.

"Two senior officials of MCI, the authority tasked with keeping a vigil on medical education, are currently board members of one of the colleges caught demanding capitation fees in the TOI-Times Now investigation. MCI president Ketan Desai and vice-president P C Kesavankutty Nayar are on the board of management of Sri Ramachandra University (SRU), which demanded Rs 40 lakh from students seeking MBBS admission."

Asked whether it was appropriate for him to be a member of the board of management of an institution that he was supposed to monitor in his capacity of president of the Medical Council of India, Dr Ketan Desai replied: "I am the UGC nominee and my colleague, Nayar, is the MCI nominee. It's just like how the Dental Council of India members are on the board of several dental colleges. But I have never attended board meetings of SRU for at least three years now. We are there only as ex-officio members." (18)

Were it not for Dr Ketan Desai's formidable reputation, such a statement could have been attributed to naivety. The lie to his disclaimer was unwittingly provided by officials within the SRU. As the reporter pointed out, "Amazingly, the two medical colleges in Chennai are virtually unmindful of the peculiarity of the situation. An SRU official told this reporter, 'The top MCI officials are on our board. We will talk to them about the allegations (of illegal donations) and sort them out.'"

Dr Ketan Desai's expertise in "sorting matters out" will stand him and the SRU in good stead and to mutual benefit.

An independent report appeared on page 11 of the same issue of *The Times of India* as that on Dr Ketan Desai and Dr Nayar. Entitled "Trouble for UGC chief, CVC registers complaint against him on host of charges", it informed the reader that the Central Vigilance Commission had registered a complaint against the UGC chairman, S K Thorat. The allegations against him ranged from his involvement in pushing through a Rs 224 crore e-governance project, corruption in the grant of deemed university status and misusing UGC resources to run his own institute, Indian Institute of Dalit Studies. (19)

Isn't there an old English saying about birds of a feather?

"Herculean exercise"

In the minutes of the general body meeting held on March 1, 2009, we read an account of the presidential address delivered by Dr P C Kesavankutty Nayar, "president (acting)". Dr Nayar stated that "The 'intellectual informational inputs' that were received through this Herculean exercise were diligently compiled... in the commemorative Souvenir that was released today under the caption 'Tryst with Consensus'." (17)

In the context of Dr Nayar's reference to Hercules, those at the helm of affairs might consider the fifth of the Twelve Labours set to Hercules. King Augeas was best known for his stables, which housed the single greatest number of cattle in the country and had never been cleaned. Hercules was asked to perform the task of cleaning these stables in a day - deemed almost impossible since the livestock were divinely healthy and therefore produced an enormous quantity of dung.

In the context of cleaning up the Medical Council of India, where shall we find an Indian Hercules today?

References

1. Medical Council of India. Introduction. [Internet]. [cited 2009 Jun 25]. Available from: http://www.mciindia.org/know/mci/mci_intro.htm
2. Madhavan MR, Manghnani R. Indian Medical Council (Amendment) Bill. [Internet]. [cited 2009 Jun 25]. Available from: http://www.indiatogether.org/2006/mar/law-imcamend.htm
3. Sharma R. Head of the Medical Council of India removed for corruption. *BMJ* 2001 Dec 15; 323: 1385.
4. Medical Council of India. List of the executive committee members as on 03.03.2009 [Internet]. [cited 2009 Jun 25]. Available from http://www.mciindia.org/know/mci/mci_executive.htm on 26 August 2008)
5. Rajalakshmi TK. A cloud over the MCI. *Frontline.* 2001 Dec 22 - 2002 Jan 4; 18(26). [Internet]. [cited 2009 Jun 25]. Available from: http://www.hinduonnet.com/fline/fl1826/18261110.htm
6. Medical Council of India, general body, 121th session. Minutes of the meeting held on 2002 Aug 27. No. MCI-6(2)/2002-Med./
7. Ministry of health and family welfare. Department of health. EC No. 1420, Eighth Report, Estimates Committee [2004-2005], [Fourteenth Lok Sabha]. 2005 Apr 29.
8. Anonymous. MCI Secretary's appointment illegal: Centre. *The Hindu.* 2005 Sep 16. [Internet]. [cited 2009 Jun 25]. Available from: http://www.hindu.com/2005/09/16/stories/2005091612670400.htm
9. Medical Council of India, New Delhi, general body, 134th session. Minutes of the meeting. No. MCI-(2)/2008-Med./
10. Medical Council of India, executive committee. No. MCI-5(3)/2008-Med./
11. Medical Council of India, minutes of the meeting of the ethics committee. No. MCI-211(2)/2007-Ethics/
12. Medical Council of India, executive committee. Minutes of the meeting held on 2008 Jun 13-14.No.MCI-5(3)/2008-Med./
13. Medical Council of India, ethics committee. Minutes of the meeting held on 2008 Jun 30. NO. MCI-211(2)/2008-Ethics/
14. Report of the ministry of health and family welfare, government of India. [Internet]. [cited 2009 Jun 25]. Available from: ministrmohfw.nic.in/reports/1999-20Epb/PART%201-CHAPTER%204_33.pdf
15. Medical Council of India. Annual Report 2007-2008 (as approved by General Body). [Internet]. [cited 2009 Jun 25]. Available from: http://mciindia.org/tools/ann_reports/index.htm
16. Medical Council of India, executive committee. Minutes of the meeting. No. MCI-5(3)/2009-Med./
17. Medical Council of India, New Delhi. General body meeting, 134th session. Minutes of the meeting held on 2009 Mar 1. NO.MCI-(2)/2008-Med./
18. Narayan P. Times News Network. MCI members on erring college board. The *Times of India* 2009 Jun 6. [Internet]. [cited 2009 Jun 25]. Available from: http://timesofindia.indiatimes.com/articleshow/4623398.cms
19. Akshaya M. Trouble for UGC chief, CVC registers complaint against him on host of charges. The *Times of India* 2009 Jun 6. [Internet]. [cited 2009 Jun 25]. Available from: http://timesofindia.indiatimes.com/India/Trouble-for-UGC-chief-CVC-registers-complaint-against-him-on-host-of-charges/articleshow/4622468.cms

Opportunities for internships in ethics

Centre for Studies in Ethics and Rights (CSER) was set up in January 2005 by the Anusandhan Trust (AT) to undertake research in ethics and human rights.

CSER is engaged in research and training in ethics, rights and capacity building of voluntary organisations/NGOs. It organises training programmes in various fields, including bioethics, ethics in clinical trials and programme management. Our priority areas include professional ethics, research bioethics, public heath ethics, development ethics, law, human rights and ethics, comparative ethics, and exploring linkages between the discourses in ethics and rights in the Indian context.

CSER faculty members include social scientists, medical professionals, bioethicists and public health practitioners. These include Dr Amar Jesani, Dr Nobhojit Roy, Dr Padma Prakash, Ms Padma Deosthali, Ms Sandhya Srinivasan, Ms Pranoti Chirmuley and Ms Neha Madhiwalla.

CSER offers internships to graduate, postgraduate and doctoral students from the fields of medicine, law, social work and social sciences, and others who are interested in these areas of study. Faculty at CSER offers mentorship throughout the internship period and resources like libraries and documentations centres of CSER and CEHAT in Mumbai can be accessed by the intern. Interns will be expected to do a time-bound project or assignment to the satisfaction of CSER faculty. Certificates of experience will be provided to the students.

The internships are for a minimum of six weeks and can extend to six months. An intern from Mumbai and outstation who has an accommodation facility in Mumbai will get Rs. 8000/- as stipend. Any Intern from outstation who does not have any accommodation in Mumbai will get Rs.12, 000/- as stipend. CSER will offer partial support. CSER will cover the costs of any local travel and related expenses incurred by the intern while doing project-related work.

Interested applicants can email Mr Shinde [mahendra.cser@gmail.com or (call +91-22-2668 1568)] with updated resumes, areas of interest and contact details. A faculty member will follow up with the applicant. Interns will be selected based on their interests, skills, experience and the requirements of the centre.

Indian Journal of Medical Ethics Vol V No 1 January- March 2008

COMMENT

Stem cell transplantation in India: tall claims, questionable ethics

SUNIL K PANDYA

Department of neurosurgery, Jaslok Hospital and Research Centre, Mumbai 400 026 INDIA email: shunil3@gmail.com

Understandably, medical professionals and patients, the world over, are agog to see the effects of stem cell transplantation in the treatment of diseases where current remedies have failed.

In countries where effective regulation ensures that medical practices remain ethical and scientific, the use of stem cells in the treatment of diseases such as those of the heart, liver, brain and spinal cord has remained in the experimental stage. Trials in animals have shown unexpected complications - such as the formation of tumours by the transplanted stem cells - in some cases. Very carefully controlled clinical trials in humans have been permitted in a few instances. The results are being closely monitored by experts not involved in the trials as well as those conducting them.

The National Institutes of Health, USA, notes, on its website: "Adult stem cells, such as blood-forming stem cells in bone marrow ... are currently the only type of stem cell commonly used to treat human diseases. Doctors have been transferring [such cells] in bone marrow transplants for over 40 years... The clinical potential of adult stem cells has also been demonstrated in the treatment of other human diseases that include diabetes and advanced kidney cancer. *However, these newer uses have involved studies with a very limited number of patients."* [Emphasis added]. (1)

In India we see a marked contrast. Individuals and institutions offer stem cell therapy to all patients. Claims are made on successful use of stem cells in curing diseases of the heart, liver and other organs; spinal cords damaged by injury and even cancer.

Take the following example reproduced verbatim from the website of Life Line Hospital in Chennai:

"Spinal Cord Damage

"Stem cells have found use in Patients with Muscular or Bladder paralysis after Spinal Cord Injury. In patients with paraplegia. This therapy is of maximum use in patients 1-2 years after Spinal cord injury. It could also be potentially of use for patients with other neurological diseases of the spinal cord. In the future the therapy may be useful for patients with Brain Damage also. Stem cell Injected directly into the Spinal fluid or around the spinal cord, at the site of injury has been found to improve nerve function. The Injection procedure is done under local anesthesia and is painless." (2)

The following section at this website is equally dramatic:

"Cancer

"Natural Killer cells (NK cells) which can be purified from the peripheral blood is found to be beneficial even in late cases of cancers like - Melanoma, Liver, pancreatic, lung and Gastric cancers."

I requested Life Line Hospital to send me references to publications in indexed journals on these and other uses of stem cells by their doctors, describing their experimental studies, clinical trials and actual use in patients. I have received no response. The website also claims: "All Stemcell (sic) trials in Life Line Hospital are registered with NIH, USA and ICMR, India."

Dr Vasantha Muthuswamy, senior deputy director-general at the Indian Council for Medical Research (ICMR), informed me in a personal communication: "We have not given any approval to Lifeline Hospital." She elaborated: "ICMR has not given recognition to any centre for clinical applications. The only centres which we have cleared *for basic research on stem cell biology* [are] Manipal Acunova at Bangalore and Niche in stem cell research and regenerative medicine at Chennai." [Emphasis added]. I understand that Life Line Hospital obtains its stem cells from Niche. If this be so, both Life Line and Niche are guilty of unethical practices.

Here is another example:

"November 16, 2005: In the midst of controversy over the use of embryonic stem cells therapy for treatment, a private clinic on Wednesday claimed to have improved medical condition of 100 patients suffering from Alzheimer, paralysis and Parkinson's disease using the technique but government was cautious saying it would set up more operational guidelines for the area.

"The claim by Nu tech Mediworld, a registered in vitro Fertilisation and Genetic Centre in Delhi, was made in the presence of Union Health Secretary P K Hota." (3)

The clinic is headed by Dr Geeta Shroff.

On January 23, 2006, *The Hindu* reported a follow-up story from New Delhi: "The Government has ordered an inquiry into the activities of [this] clinic conducting embryonic stem cell therapy and warned of stringent action against those found violating the rules and guilty of playing with the health of unsuspecting patients, Health Minister Anbumani Ramadoss said.

"'We are conducting an inquiry into the claims of the clinic. Once the inquiry report comes, action will be taken against those responsible for violating the ethical norms and other issues,' Dr Anbumani said." (4)

My attempts at obtaining the findings of the inquiry and follow up action have failed. To the best of my knowledge, Dr Shroff sent scanty details on patients treated to the ICMR and did not turn up at a meeting of experts on spinal cord injury organised by it.

In August 2007, *Paraplegia* News reported: "Shroff has treated about 70 persons (including Mr Ajit Jogi, Chief Minister of Chattisgarh) for SCI (spinal cord injury). Although she believes that treatment would be optimal when started close to injury, most of her patients have been injured for at least a year. Basically, she decided not to treat the more acutely injured patients because critics would dismiss improvements as something that would have occurred anyway during a period in which functional gain is not uncommon." (5) It is noteworthy that all the treated paraplegic patients shown in this report, including Mr Jogi, are on chairs. None of them is shown standing or walking.

Worse, All India Institute of Medical Sciences (AIIMS), New Delhi, distributed information through the newspapers on success in treating cardiac disease in humans by using stem cell transplants. Attempts at obtaining information on the scientific basis for this therapy have not met with success. A search has failed to turn up publications on experimental studies, animal trials and phase 1 and 2 clinical trials in indexed medical journals trials prior to the newspaper reports. Since the proceedings of the ethics committee of this institution are unavailable to outsiders, we cannot learn of the discussions that preceded the clinical use of stem cells and the evidence of animal and other studies, if any, presented to the committee. Strangely enough, the director-general, ICMR, was quoted thus by *The Hindu* on April 5, 2005: "Dr N K Ganguly today said he stood by the authenticity of the work by the Institute (AIIMS)." (6) The basis for Dr Ganguly's certification is not available.

Dr Vasantha Muthuswamy, senior deputy director-general, has, however, courageously gone on record to state, with reference to these claims: "We are only a block away from AIIMS and we did not know this was happening there. If the nation's premier medical institute did not ask our permission for such therapy, how can we blame private clinics for what they do?" (7) She is understandably frustrated and voiced her feelings to the journal *Nature*, referring to the mushrooming of clinics offering stem cell therapy without any evidence that they were following basic ethical guidelines and scientific practice: "We want to promote stem-cell technology but not in this scandalous way." (8)

I was fortunate in being able to attend the session on stem cell therapy at the Second National Conference on Bioethics in Bangalore on December 8, 2007. The expert on the panel, Dr Bernard Lo, is professor of medicine and director of the programme on medical ethics at the University of California at San Francisco. He emphasised that whilst we have learned a lot on stem cells and their potential in medical practice, our knowledge on them is incomplete. He felt that we were not ready for the use of stem cells to cure disease or injury. He emphasised that unbridled usage could lead to complications (such as the formation of tumours) and bring stem cell therapy into disrepute. A member of the audience asked an important question. Pointing out that severe spinal cord injury causing paraplegia or quadriplegia was followed by a host of complications such as the formation of pressure ulcers, infections in the urinary system and lungs and an early death, he asked if it was wrong to use stem cells despite the current reservations. Dr Lo's reply was simple and to the point. He sympathised with the plight of the patient and the patient's family. He continued to have reservations on the clinical use of stem cells in spinal cord injury till we have more information. If, however, society in India felt that the use of stem cells in spinal cord injury was justified right away, the path to follow had to remain ethical and scientific. The carefully standardised treatment must remain confined to a few, carefully selected, major research hospitals and be strictly controlled and monitored. All the criteria used to process any clinical trial must be followed, detailed records maintained and the findings open to scrutiny. The patients and families must understand that the treatment is experimental and that unexpected complications may arise and jeopardise the well-being and even the lives of the patients. The patients must be followed up over a long period and findings - positive and negative - published in indexed medical journals.

Dr P M Bhargava, founding director of the Centre for Cellular and Molecular Biology, Hyderabad, was in the audience. His opinion was requested. He confirmed that stem cells were being used without authorisation or supervision in parts of the country and bemoaned the lack of a statutory agency that could act to prevent such usage.

His distress stems partly from statements such as that made by Health Secretary Prasanna Hota. He was the chief guest at a news conference held by fertility specialist Dr Geeta Shroff, who claimed in 2005 that she had treated over 100 patients with stem cell therapy. Hota said his presence should not be construed as an endorsement of the work but went on to say, "Sometimes, scientific knowledge cannot wait for bureaucratic apparatus." (9)

What is one to expect of institutions such as the ICMR where the director-general states: "We have no plan to legislate the guidelines that are in place for carrying out stem cell research... We will leave it to the medical profession to maintain a strict code of ethics." (6) Even on Christmas Day, 2007, the ICMR draft guidelines on the use of stem cells, cleared by the law ministry, await cabinet approval.

Why is it important that the guidelines be made mandatory by legislation? Failure of legislation permits blatant unethical practices. Consider the statement by Dorairajan Balasubramanian, research director at the LV Prasad Eye Institute in Hyderabad, himself involved in the use of stem cell to treat eye diseases. "Guidelines are only guidelines. Any violations cannot be punished." (9)

We are only too painfully aware of the fact that Dr Dhani Ram Baruah suffered nothing more than temporary inconvenience for his inhuman, unscientific and unethical act of transplanting the heart of a pig into a poor Assamese tribal with fatal consequences. In a manner later imitated by the AIIMS, Dr Baruah had claimed in the public media that medical science had taken a great leap forward with his operation. He too had no publications in indexed journals documenting his experimental and preclinical work (10).

Current practices suggest that we have a long way to go ere we can even approach the standards of scientific and ethical excellence that are the norm in many other countries. Our regulatory agencies are unwilling to act effectively when individuals or institutions flout required standards, especially when these are politically powerful.

If further proof of the ineptitude of our regulatory agencies is required we need look no further that the recent news items in our national dailies. Here is one such example pertaining to the trial in India of a vaccine against AIDS. This trial had been flagged off by Union Health Minister Anbumani Ramadoss and Union Science and Technology Minister Kapil Sibal at Pune's National AIDS Research Institute (NARI) and was a tripartite venture of the Indian Council of Medical Research (ICMR), the International AIDS Vaccine Initiative (IAVI), and the National AIDS Control Organization (NACO):

"On February 22, 2005 - 14 days into the trial in India - Targeted Genetics issued an official note on its European trial saying that 'the vaccine [AAV - tgAAC09] at the doses evaluated in this initial study did not elicit significant immune responses.'...The vaccine had failed in Europe even though it had been tested on 50 individuals in a Phase-I trial meant to evaluate safety.

"Ironically, to accommodate the trial, India departed from its established regulatory procedure. Until this genetically engineered AIDS vaccine was tested in 2005, the policy was that ... a molecule or a vaccine developed in a foreign country could never be tested in India for a Phase-I trial until the host country where the molecule was invented had undertaken a full fledged Phase-II trial.

"But this trial went ahead on the grounds that there was a health emergency and the need was to arrest the galloping epidemic of AIDS. Given the confidentiality clause of the trial, no independent verification has been possible on how the Indian volunteers fared physically and/or psychologically in the Pune trial.

"Commenting on this, Dr P M Bhargava stated: 'There was no justification for the trial. It was unethical and totally uncalled for. The volunteers can't be treated like guinea pigs, they should have been told that the vaccine being tested on them had failed (elsewhere).'" (11)

ICMR, the department of biotechnology and the department of science and technology are just three of several governmental agencies, each independently approving and financing clinical research. Given the difficulty in monitoring such research and detecting unethical practices in this country, how are these agencies to ensure that norms are followed and deviations from it and proven unethical practices detected and penalised? Would it not make sense to ensure that a single agency approves, funds and monitors all clinical research in the country and empower it to penalise defaulters?

References

1. National Institutes of Health resource for stem cell research. Stem Cell Information. [Cited 2007 Dec 24]. Available from: http://stemcells.nih.gov/info/health.asp
2. www.stemcellindia.com. Spinal Cord Damage. [Cited 2007 Dec 24]. Available from: http://www.stemcell-india.com/spinalcord-damage.htm
3. www.rediff.com. Clinic's embryonic stem cell therapy worries govt. 2005 Nov 16. [Cited 2007 Dec 24]. Available from: http://in.rediff.com/news/2005/nov/16stem.htm
4. UNI. Government to act against clinic using stem cell therapy. *The Hindu* 2006 Jan 23. [Cited 2007 Dec 24]. Available from: http://www.hindu.com/2006/01/23/stories/2006012300720900.htm
5. Johnston L. Embryonic stem-cell therapy. [Cited 2007 Dec 24]. Available from: http://www.healingtherapies.info/hESC.htm#Overview
6. Staff reporter. ICMR okays stem cell research by AIIMS. *The Hindu* 2005 Apr 5. [Cited 2007 Dec 24]. Available from: http://www.thehindu.com/2005/04/06/stories/2005040612771300.htm
7. Srinivasan S. Clinical Trials - part IV: Rogue research in the guise of stem cell therapy. Infochange features [Cited 2007 Dec 24]. Available from: http://www.infochangeindia.org/features326.jsp .
8. Jayaraman KS. Indian regulations fail to monitor growing stem-cell use in clinics. *Nature* 2005 Mar 17; 434 (259). [Cited 2007 Dec 24]. Available from:http://www.nature.com/nature/journal/v434/n7031/full/434259a.html
9. Mudur GS. Stem cell march, minus checks - Lack of research rules allows doctors to do as they like. *The Telegraph* 2005 16 Nov. [Cited 2007 Dec 24]. Available from: http://www.telegraphindia.com/1051117/asp/nation/story_5487047.asp
10. Vox populi. The first Indian porcine transplant. *Issues Med Ethics* 1997 Apr-Jun; 5 (2). [Cited 2007 Dec 24]. Available from: http://www.ijme.in/052mi062.html
11. Bagla P. Despite note that AIDS vaccine had failed, India changed rules and continued trials. *The Indian Express* 2007 Dec. [Cited 2007 Dec 31]. Available from: 23 http://www.indianexpress.com/sunday/story/253329.html

Indian Journal of Medical Ethics Vol IX No 3 July-September 2012

Tarnishing reputations: the downside of medical activism

Sunil K Pandya

Department of Neurosurgery, Jaslok Hospital, Dr G V Deshmukh Marg, Mumbai 400 026 INDIA e-mail: shunil3@gmail.com

When I started writing essays in favour of wronged patients in the late 1960s, I was warned of this possibility. Criticisms of that section of the medical profession that hurt patients or ill-treated them or cheated them inevitably drew censure of my action. While there was never any dispute about the facts laid down by me in my papers, the admonitions I received were against tarnishing the profession. I was upset at this as I have always taken great care to point out that the miscreants were only a proportion of the professionals. Even so, I was roundly criticised at a public meeting of doctors under the aegis of the Indian Medical Association for censuring any member of the profession.

While I continue to feel that errant doctors should be disciplined, I now have before me an example of an honest doctor whose reputation is being tarnished by a colleague. I have witnessed the agony of the wronged doctor and his family and write this essay to highlight the injustice done to them.

The facts as I understand them

Dr Apoorva Pauranik is a consultant neurophysician and Professor of Neurology at the Mahatma Gandhi Memorial Medical College and at the affiliated Maharaja Yeshwant Rao Hospital (MY Hospital) in Indore, Madhya Pradesh. I have known him for some decades and have always found him a sober, sincere, hard-working and straightforward person who has the best interests of his patients at heart. He is a keen votary of inclusion of the humanities in medical education and of ethical medical practice.

Imagine my surprise when I read a headline in a newspaper: "Indore docs flout clinical trial norms, earn lakhs" (1) and in the text "…Dr Apoorva Pauranik of neurology made Rs 42 lakh…" The same report quotes Dr Chandra M Gulhati, editor of *Monthly Index of Medical Specialities* (*MIMS*), as having repeated this allegation in volume 31, number 5, of his publication dated May 2011. Some reports even stated that Dr Pauranik had conducted a trial of a drug used in bronchial asthma and another for cardiac problems! (2)

The reports were sparked off after a campaign by Dr Anand Rai of the same hospital against Dr Pauranik and other senior teachers.

My enquiries show that Dr Pauranik's trials were conducted at the MY Hospital after obtaining the approval of the Drugs Controller General of India and the ethics committee of the hospital. The ethics committee has as its chairperson Prof Dr KD Bhargava and eminent members like retired High Court Justice P D Muley. Other lay members are Mr Govindan Kutty Menon, a social worker; Mr Jayantilal Bhandari, a social worker; and Mr Yogesh Mittal, an advocate. The agreement papers for the trials, including financial details, were scrutinised and signed by the dean of the hospital. The procedure for obtaining the consent of subjects was scrupulously followed.

All subjects who served as participants in the trials were paid travel expenses and sums to compensate the loss of wages on the day they attended the clinic, in accordance with guidelines laid down by the Indian Council of Medical Research.

The agreement papers permitted the scientific investigators to be remunerated for the time and effort spent in conducting the trial. The dean and the ethics committee knew this. This is common practice and as long as the accounts are transparent and audited, there is no objection to this practice. This income featured in the audited accounts of the trials and in the income tax returns of the investigators. Funds had also been spent by the sponsors of the trials for travel by the investigators to meetings where the trials were discussed.

The single death amongst patients included in the trials conducted by Dr Pauranik occurred 10 months after the 70-year old patient with Alzheimer's disease had last attended the clinic where follow-up evaluations were carried out. I cannot see how the death can be linked to the trial which she had discontinued 10 months earlier. Five adverse events noted in Dr Pauranik's trials were evaluated by an ethics and scientific review committee. The report of these discussions, signed by the chairperson, Dr KD Bhargava, Head, Department of Medicine, and two consultant neurologists from the CHL Apollo Hospital, Indore, in no way connected with the trials, pronounced these adverse effects unrelated to the trial.

Since the audit report is not in the public domain, it is difficult to comment on it.

A criticism was made of the use of donezepil hydrochloride in the dose of 23 mg in patients with Alzheimer's disease in Dr Pauranik's trial. This is surprising for the American Food and Drugs Administration has approved such usage since 2010. In any event, institutional ethics committees at 219 centres around the world and Indian regulatory authorities had approved of this dose for the trial and of the 1,467 patients enrolled for the trial around the world, only six were from Indore. There was no evidence of any adverse event related to the use of this dose of the drug at any centre. It is worth noting that other Indian centres participating in this trial included the Nizam's Institute of Medical Science, Hyderabad; Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram; PD Hinduja National Hospital and Research Centre, Mumbai; Kokilaben Dhirubhai Ambani Hospital, Mumbai; and St John's Medical College and Hospital, Bangalore.

Conclusion

Wherever clinical trials in India are conducted under substandard conditions, these must be uncovered and laid before public scrutiny; and if the facts speak against the investigator, suitable disciplinary action instituted. This does not mean that unfounded, misguided or vicious allegations be propagated by doctors and laypersons in the media. It is time that a mechanism was laid down for disciplining such vilifiers for slander and libel.

The lay public does not understand the intricacies of clinical trials in particular, and many medical matters in general. Editors of journals (especially those as prestigious as *MIMS*) and of the national dailies and TV networks carry a special responsibility when reporting on them. It is up to them to explain the pros and cons and double-check their statements. Few of them take the trouble to contact the individual they are about to place in the dock to obtain his version of the event(s) or scrutinise the relevant documents. In the event, they end up accusing innocent physicians and ruining their reputations.

The statement in an editorial in *The Lancet* (3) on cancer can be applied on a wider basis: "Many cancer patients are waiting for new drugs and media reports on clinical trials are increasing. The effect of mass media on the public is strong. In clinical trials, specialized knowledge and technology are required. The associated terms and skills differ from those of general medicine and are not familiar to the public and the media. If information on clinical trials is not properly shared among researchers, patients and media, it can result in chaos…"

Some suggestions on the conduct of clinical trials

Learning from the travails of Dr Pauranik, I offer the following suggestions:

a) A major problem highlighted in news reports is that Dr Pauranik profited to the tune of Rs 26,00,000. This is based on the fact that the sums sanctioned for the trials were paid directly into Dr Pauranik's personal bank account. The fact that all expenses incurred during the clinical trial were also met from this account has been ignored. Dr Pauranik maintained a separate ledger for trial-related income and expenses.

The practice followed in the few clinical trials in which I have participated has been to open a new bank account for each clinical trial. All deposits are made into it and expenses paid from it. At the conclusion of the trial, the account is closed and audited. The chartered accountant's statement will show the exact state of financial transactions and exonerate the innocent principal investigator of the charges of malfeasance.

b) It is best to appoint an investigating body that is totally independent of those conducting trials that have been questioned. In this case, the dean could have ensured that none of the principal investigators under investigation had anything to do with the analysis of their trials.

c) Travel to meetings of principal investigators of multi-centric trials is necessary for discussions, training on protocol and conduct of the study, analysis of interim results, analysis of adverse results and eventual collation and final analysis of findings. Dr Pauranik's travel to a meeting where, apart from the several Indian investigators, those from Austria, the Czech Republic, Hungary, Italy, Korea, the Philippines, Poland, Russia, Slovakia, Spain and the UK were also invited cannot be faulted on any count. The inclusion of the reports of such meetings in the closing report on the trial will enable readers to understand the necessity for travel.

d) One of the ways forward is for institutions to set up data safety monitoring boards for oversight within the institution. Setting up of clinical research secretariats and a society within the institution to accept and disburse grants from the pharmaceutical industry would also help.

Acknowledgements *I gladly acknowledge the help kindly and promptly given by Dr Arun Bhatt, President, Clininvent Research, that resulted in a more factual and improved essay. I also wish to thank the anonymous reviewer who offered constructive suggestions for improvement*.

References

1. Nagarajan R. Indore docs flout clinical trial norms, earn lakhs. *Times News Network* [Internet]. 2011Jun 3[cited 2012 Feb 15]. Available from: http://articles.timesofindia.indiatimes.com/2011-06-03/india/29616513_1_clinical-trials-quintiles-research-doctors
2. Dixit N. Indore psychiatrists admit to conducting drug trials on mentally Ill patients. *India Today* [Internet]. 2012 Jan 23 [cited 2012 Feb 15]. Available from: http://indiatoday.intoday.in/story/indore-psychiatrists-admit-to-conducting-drug-trials-on-mentally-ill-patients/1/170264.html
3. Yuji K, Narimatsu H, Tanimoto T, Komatsu T, Kami M. Sharing information on adverse events. *Lancet*. 2011 May 14;377(9778):1654.

Indian Journal of Medical Ethics Vol IX No 3 July-September 2012

My recent experiences as a patient

Sunil K Pandya

Department of Neurosurgery, Jaslok Hospital, 15, Deshmukh Marg, Mumbai 400 026 INDIA e-mail: shunil3@gmail.com

Abstract

As a neurosurgeon, it was a new experience for me to face the consequences of an accidental fall just before I underwent simple spinal surgery for relief from backache. This essay describes how I was affected by the unexpected operations that followed. The physical pain, the anxieties, small inconveniences and the relatively free use of drugs such as antibiotics, that I might have taken for granted in my patients undergoing surgery, now took on a new meaning for me. My perspective on my illness as patient, rather than as physician, and the special care given to me by medical, nursing, and paramedical colleagues were transforming experiences. Based on these occurrences, I offer suggestions on how we can improve our approach to patients.

It may sound ironic that a person who has performed several spinal operations needed to have three himself in rapid succession.

The beginning

Over June and July 2011, I developed pain travelling from the lower back down the left lower limb, with progressive reduction of the distance I could walk without pain. This was against a background of longstanding psoriasis with associated changes in the spinal column. My neurosurgery colleague examined me and decided that surgery was necessary to relieve pressure on a spinal nerve. I had expected such findings. As with any other patient, there was apprehension about the surgery, especially given my age (71 years). I prepared a document listing my advance directives for my colleague and handed it over to him. Briefly, it listed instructions in the event of complications from anaesthesia or surgery that left me severely brain damaged or permanently incapacitated. Such a document is not legally valid in India, but I was confident that he would implement my wishes.

The operation was scheduled for August 29, 2011. My colleague - to whom I had entrusted myself - sought the help of an expert in endoscopic spinal surgery, currently practising in Kolhapur. He kindly agreed to come to Mumbai and perform the operation in our hospital.

Unexpected twist

The next morning before leaving for the operation theatre I went to the toilet and emptied my urinary bladder. While emerging from the toilet, I slipped on the wet floor and fell flat on my back onto the floor. The central segment of the spinal column (dorsal spine) bore the brunt of the impact. As I lay on the floor, in considerable pain, I rapidly checked the movements and sensations of the limbs and found them unimpaired. This reassured me that there was no damage to the spinal cord or nerves.

On hearing the thud caused by my fall, my wife rushed into the toilet and found me unable to rise because of the pain. She helped me into the upright position and, after the pain had eased a little, on to my bed. The trolley arrived soon thereafter and took me to the theatre.

On reaching there, I informed my doctors about the fall and the pain. Clinical examination suggested injury to the muscles and ligaments. They advised proceeding with the surgery to which I readily consented, as I wanted to be rid of the pain down my left lower limb. The operation went off smoothly and I have experienced no ill consequences from it. The radiating pain appears to have been abolished. I was sent home the day after the operation.

The drugs prescribed were continued at home, paracetamol being taken orally at home in the same dose as was injected in the hospital. As I remained pain-free, on the fifth day I started reducing the dosage with a view to discontinuing it. However, the pain felt after the fall recurred. I raised the dosage of paracetamol, with some reduction but not abolition of the pain. The pain was worse when I lay down on my bed and when rising, and very troublesome even when I turned in bed, awakening me almost every hour or so.

A week after the operation, I was in misery and was readmitted to hospital. Computerised tomographic scan of the spine showed compression of a dorsal vertebra. It was deemed to be such that it would settle over time. A combination of physiotherapy and drugs helped control the pain. I was sent home a few days later.

Using the prescribed tablets I started attending my consulting room in the hospital and could see patients over two hours. Standing and walking were painful, and I stooped visibly when doing so.

As the pain worsened over time, I consulted our orthopaedic surgeon who suggested I see our spinal surgeon. After reviewing the new x-ray and scan films examinations, the surgeon recommended fusion of five vertebrae with the injured bone in the centre. Accordingly I was readmitted and the operation was carried out in two stages, 15 days apart.

Unwelcome side-effects

After each operation, the antibiotics prescribed caused a loss of appetite but this was worse after the last operation. For over 13 days, I was unable to consume food. I could manage three glasses of fresh fruit juice and water each day, and at best, a small bowl of yoghurt. Eating a spoonful of any solid food made me feel as if I had a huge ball of lead in my stomach. Even after the antibiotics were stopped, this difficulty in eating persisted for over a week.

The consequences were obvious. I lost a lot of weight and there was thinning and weakness of muscles. This was most marked in the muscles moving the hip and knee joints.

I also found myself choking with emotion with abnormal frequency. Gratitude at the unfailing courtesy shown by ward attendants, nurses and doctors; the thoughtfulness of visitors who brought books for me to read; the plight of a friend whose wife was being treated in a room two floors below mine for a serious illness that was eventually to carry her away – and other similar instances – brought me to the verge of tears and I often had to stop in mid-sentence, to avoid embarrassing myself and those around me. This persisted for some weeks, even after I returned home. I am not sure about the cause. I have witnessed it in patients undergoing serious operations, such as on the heart. I wonder whether, in my case, it followed a combination of prolonged pain and sleeplessness before surgery, helplessness in the hospital, the need to rely on others for help in simple tasks such as bathing, passing urine and stools, standing and walking. I was also witness to my wife taking leave from her research for weeks and spending all day by my side, attending to my needs.

When I was sent home on November 20, I was unable to climb or descend a single step. I was taken from my room to my friend's vehicle on a wheelchair and lifted manually on to the seat. On reaching home, I was helped to descend from the car, placed on a chair and carried on the chair to my bed. You can imagine my distress at the extent of my disability. Accustomed to striding effortlessly, climbing several floors and brisk action, I was reduced to a state where I needed help with the simplest movement!

Slow but steady recovery

At home there was slow and steady recovery of sleep and appetite. I continued the exercises prescribed in the hospital and could resume walking with the "walker". It was necessary for someone to be by my side as soon as I attempted to stand, to ensure that I did not fall. My physiotherapist at home assured me that I would improve gradually. This helped my morale.

As I took increasing quantities of food with high protein content and whey supplements, walking improved to the stage where I could discard the walker. This was a defining moment. I had grown dependent on it, fearing a fall without it. One evening a colleague visited me, seeing me sit on my bed, unaided and stand, pronounced that I did not need the walker any more. He asked me to start walking. I asked for the walker. "Why do you need the walker? I am here in case you need support but rest assured you will not need it." Even so, he offered me his hand. Holding it - more for moral than physical support - I was able to walk from my bedroom to the drawing room with just mild unsteadiness. There he helped me sit and forbade me from using the walker any more. Such was my diffidence that I had to steel myself to do so!

I now walk freely in my home, have progressively become able to climb three floors, walk around the circumference of our terrace and along the nearby sea face.

Fresh x-ray films of the operated area showed satisfactory repair of the broken bone. I should be able to return to work in two months.

How it feels to be a patient

I experienced a progressive loss of morale lying on the bed, being sponged instead of having my own bath and using the bedpan. When absolutely necessary, as in my case, this has to be endured and there was nothing my treating surgeons could do about it. Empathising with me did help, but true relief was only obtained when, at last, I was able to sit, stand and walk.

Like many before me, I bemoan the design and construction of the bedpan, which is especially painful to a person who has recently undergone spinal surgery. Bedpans are usually constructed of stainless steel and are cold, hard and uncomfortable. On the other hand, stainless steel is easy to clean and durable. The use of antiseptics renders them free from germs. Plastic has been shown to form a reservoir for microorganisms. Bedpan liners made of recycled pulp (moulded pulp) or biodegradable plastic, containing absorbent powder to eliminate splashing and spills do decrease infection but are expensive and not generally available in India.

As a member of the hospital staff, I was privileged. All those attending me, from the consultant to the persons helping me with urine and stools, were uniformly kind and courteous.

Many facilities offered to me are not easily available to most patients. I realise this is unfair to them. It is worth bringing this differential care to the notice of young staff members and medical students and helping them devise measures to reduce such differential care for the benefit of those not privileged. As you will see from the following paragraph, it may be practically difficult to treat all patients in the same manner as I was treated.

During the period when I could not take in any nutrition, our senior physiotherapist sent me fresh fruit juice from her home every day. Our dietician willingly offered to make whatever food I desired to my specifications and did so, unfortunately without any improvement in my being able to eat what was prepared so thoughtfully.

The consultants made regular visits and kept me informed of every step taken. I took great care in refraining from any interference in diagnostic tests or drug therapy. I know of the difficulties created when patients or their relations interfere in the treatment. If all consultants were considerate with their patients and explained the need for tests or the form of treatment being administered, this may eliminate interference by patient or relations, as their anxieties would have been addressed.

I found the resident doctors attending to me in some awe. Their examinations were often restricted to obtaining my opinion of the neurological findings and inspection of the wounds. They were careful to cause minimal pain. On the two occasions during the month I was in hospital for the second and third operations, when I had to request resident doctors to attend to me at night, their responses were swift.

In turn, I took care not to trouble them unless absolutely necessary. This is important as most resident doctors are very hard worked and under tremendous stress. Calls to them at odd hours of the night deprive them of much needed rest. I am fortunate in being a doctor, who can distinguish symptoms that can wait till the next day from those that cannot. Most patients have not been trained as I have been and may be unable to do so. As a result, nurses and doctors may show impatience with patients who make frequent calls on them. The nurses and doctors, in turn, must remain aware that such calls are being made out of distress and need to be dealt with serenely. In many instances, reassurance and good cheer may be all that is needed.

In relation to this, there is another very important point to be made. In many hospitals it is the practice for the resident doctor, when called at night by the nurse, to listen to the nurse's account of the patient's complaint and then prescribe over the telephone without going to the patient's bedside and examining the patient. The dangers of this approach cannot be overstated. The nurse does not have the expertise of the doctor. A symptom may arise from many causes, some of them with the potential to worsen the patient's condition. There is no substitute for examining the patient when called, even though it may turn out that it is for a trifling cause. I did not experience such behaviour during my stay in hospital, but have seen it during my rounds as a surgeon.

An interesting experience was the recording of blood pressure. A nurse would check my blood pressure and tell me that it was 140mm/80mm. Three hours or so later another would check it and find it 170/100 mm. A further three hours or so later, the third nurse would tell me it was 100/70. Such erratic readings can puzzle the clinician and even prompt prescription of a drug to lower blood pressure when it is not really needed.

Some suggestions

- Bathrooms and toilets, especially in hospitals and clinics, must have tiles with surfaces that are not smooth and reduce the chances of slipping and falling. The ill are especially prone to such injuries. It is also necessary to provide firmly anchored bars along the full lengths of the walls of toilets and bathrooms that can be used by patients to support themselves.
- The blood pressure instruments may need calibration. I also wonder if there should be periodic exercises when the blood pressure is recorded by different nurses, one after another, on the same person to check on consistency in results. With the urge to treat any finding deemed abnormal, this is essential to avoid unnecessary therapy that might even cause complications.
- A small rise in temperature – to 99.8 degrees – prompted our medical consultant to request white cell counts and when these showed a rise in total count from 90,00 to 11,000, to change antibiotics. At that time, there was painful swelling of a vein at the site of infusions. This was not considered as the cause for fever and mild increase in white cell count. I wonder whether it would have been in order to watch the temperature over the next day or two and obtain another white cell count before changing antibiotics.
- My complaints of loss of appetite usually inspired comments such as: "Consider food as medicine and take it slowly." "Take small quantities every hour or so." I had already tried these measures but the feeling of a huge load in the stomach rendered these ineffective. As a consultant later told me, many patients complain of loss of appetite on such antibiotics and we may need to take such complaints seriously. Often – especially when the patient is a lay person – several complaints are brushed aside with a statement such as "Don't worry about this. It will soon disappear." Spending a little time explaining the basis for the unwelcome side-effect, instituting measures to ameliorate the symptom(s) when possible and altering the principal therapy when the side-effect from it is causing damage will go a long way towards helping the patient.
- Suggestion boxes are usually maintained at central locations in hospitals, often on each floor. It is sad that most patients disregard them and do not voice their own observations of shortcomings and recommendations for improving the care of patients. Hospital authorities may also be at fault, as other priorities or problems make them neglect these important feed-back messages born of practical experiences.

Looking back

In summing up, I am, surprisingly, not unhappy at having undergone this experience. It has enriched me in many ways, most of all by emphasising to me the vast stores of affection and care available to me. These were lavished on me by my colleagues in hospital, my wife, my children, other relatives and friends. I am deeply humbled.

As a consequence of the severe loss of appetite during the last fortnight or so in the hospital, I have become lean – a welcome development – though I would not recommend this as a means for losing weight!

[Internet]. 2011 Sep 17[cited 2013 Jun 4]. Available from: http://www.gainesville.com/article/20110917/ZNYT04/109173020
20. Bhalla A. How they made the NRHM sick. *Tehelka.com* [Internet]. 2012 Mar 17[cited 2013 Jun 4];9(11). Available from: http://archive.tehelka.com/story_main52.asp?filename=Ne170312HOW.asp
21. Chatterjee P. How free healthcare became mired in corruption and murder in a key Indian state. *BMJ*. 2012 Feb 6;344:e453 doi: 10.1136/bmj.e453
22. Khetan A. Where did Rs 8,500 cr of UP's health funds go? *Tehelka.com* [Internet]. 2011 Aug 20[cited 2013 Jun 4];8(33). Available from: http://new.tehelka.com/story_main50.asp?filename=Ne200811COVERSTORY.asp
23. Shukla S. India probes corruption in flagship health programme. *Lancet*. 2012 Feb 25;379(9817):698.
24. Ambraseys N, Bilham R. Corruption kills. *Nature*. 2011Jan13;469(7329):153–5.
25. Holmberg S, Rothstein B. Dying of corruption. *Health Econ Policy Law*. 2011 Oct;6(4):529–47.
26. Hall MA, Camacho F, Dugan E, Balkrishnan R. Trust in the medical profession: conceptual and measurement issues. *Health Serv Res*. 2002 Oct; 37(5):1419–39.
27. Campbell AV. Can virtue prevail? Safeguarding integrity in medicine and science *Indian J Med Ethics*. 2013 Jan–Mar;10(1):11–13.

Indian Council of Medical Research: then and now

SUNIL K PANDYA

Department of Neurosurgery, Jaslok Hospital and Research Centre, Dr GV Deshmukh Marg, Mumbai 400 026 INDIA e-mail: shunil3@gmail.com

'O, what a fall was there, my countrymen!'
—*The tragedy of Julius Caesar,*
by William Shakespeare (Act 3, Scene 2)

Successor to the Indian Research Fund Association (IRFA), the Indian Council of Medical Research (ICMR) had Dr CG Pandit as its first director. He set high standards of probity and economy and was scrupulous in all his activities. He ensured ethical conduct in all activities of the council.

The contrast between the reputation of the council in its early days and that today is striking. I have chosen two heads of the council—Dr CG Pandit and Dr NK Ganguly—and have used illustrative examples from their tenures. I have also used an example from 1996, before Dr Ganguly was appointed director-general, to highlight the impotence of the council today when faced with a catastrophic breach of medical ethics.

A noticeable decline from Dr Pandit's standards was noted over the decades following his departure and reached a nadir when Dr NK Ganguly publicly praised Dr P Venugopal for his use of stem cells in the treatment of cardiac disease (1). The recent scandal in which Dr Ganguly has been implicated (2) adds nothing to his stature or that of the council.

Spartan values

Dr CG Pandit remains the gold standard against whom all succeeding heads of the council must be measured. His life and work have been recorded in his own words (3). I strongly recommend this work to all those having the best interests of medical research in India at heart.

Dr Pandit has described in this book the foundation and functions of IRFA and his appointment to IRFA as secretary in 1948 by Dr Jivraj Mehta. When IRFA was replaced by ICMR in 1950, Dr Pandit was appointed as its first director.

Let me provide some examples of his philosophy concerning the council.

A head clerk at the council told me in the 1970s that he had been with the ICMR since its beginning: "I remember the day when Dr Pandit moved into his room. It was spartan in its simplicity. It had a cupboard for his files and books, a table and two simple chairs—one for himself and the other for a visitor. A fan whirred overhead during the summer. . . Now there is wall-to-wall carpeting, air-conditioning, fancy lighting, a number of telephones, an array of other machines and an annexe where the personal assistant awaits summons from the director-general."

As an afterthought, he added: "And there are fancy flowerpots and other decorations."

The clerk also narrated a conversation with Dr Pandit's driver. "As director he was entitled to the use of an Ambassador car. On one occasion he had to attend a meeting with the minister and his secretary in the afternoon. As it progressed he realised that the meeting would go on beyond 5 pm. Excusing himself briefly from the meeting, he came to the driver and told him to return to the ICMR, as he would be delayed. 'What will you do about returning home?' asked the driver. 'Oh, I will manage. I cannot keep you and the car waiting beyond office hours,' he replied as he returned to the meeting."

On page 332 of Dr Pandit's book we learn that while he was at the helm, the yearly expenditure on the headquarters office of the council always remained around 7% of the total grant received by the council. About 4% of the grant was spent on laboratory animals, scientific reports, publications, library and stores, and other such activities; 89% of funds were spent on research and development activities including grants, pay and running expenses of scientific workers.

Critical self-analysis

When Dr Pandit neared the end of his stint at the ICMR, Dr S Sriramachari, additional director-general, suggested that he analyse the activities of the council from 1948 to 1965.

Dr Pandit in turn asked him to do the study impartially, documenting failures and achievements.

Dr Pandit was quick to point out that this was not the first time that such an assessment was made. "No organisation can continue to function effectively unless a periodic assessment is made of its working," he wrote (3: p 331–2).

The report by Dr Sriramachari, a document of over 150 pages, was produced and presented to the governing body. Dr Pandit joked that it was his last will and testament as far as the ICMR was concerned. It is difficult to recall a parallel situation in India, when a retiring chief, on the eve of his laying down office, placed an impartially drawn up balance sheet of the organisation on the table.

Need for another 'Sriramachari Report'

We await a similar analytical report as the council has completed 100 years. This is especially important as the budget allocated for the ICMR during the 12th Five-Year Plan is Rs 8,500 crore (4: p 315).

This report should also embody a cost–benefit analysis of the council, its several institutes scattered throughout the country and the research projects carried out from Delhi and at each of the institutes. The analysis of the council and of each of its institutes could be along the lines of the report by Dr Sriramachari referred to above.

I suggest the following points for inclusion in this analysis as regards each of the major, expensive projects:

1. Names, affiliations of principal researchers
2. Title of project
3. Time taken from submission of project proposal to decision on the proposal by the ICMR and actual start of work on the project
4. Summary of aims and objectives of the project
5. How many of these aims and objectives were achieved
6. Reasons why the rest were not achieved
7. Whether the research resulted in one or more patents
8. If patents were obtained, what was the subsequent fallout in terms of:
    a. Income to ICMR
    b. Income to researchers
    c. Commercial exploitation of the product in India thus far (give details)
    d. Commercial exploitation of the product abroad (give details)
9. Publications on the project with bibliographic references
10. Time frame under which the project was to be completed according to the initial project proposal
11. Time frame under which the project was actually completed
12. Reasons for overshooting time if delays had occurred
13. Cost of the project according to the initial project proposal
14. Actual cost of the completed project
15. Reasons for extra expenditure, if any
16. Feedback from the researchers on:
    a. Whether they encountered any difficulties in getting their project proposal approved
    b. Whether they encountered any difficulties in getting their funds each year at the start of the financial year
    c. Whether their communications to ICMR were promptly and efficiently dealt with
    d. Whether they encountered any difficulties in patenting
    e. Whether they encountered any difficulties in getting their patented product into commercial production through a third party on payment of royalties
    f. Whether they are satisfied with the returns from such commercial exploitation
    g. Any other observations they might like to make

In 2011, the IRFA/ICMR published a compendium of papers to celebrate its centenary (5). This is a step in the right direction but we also need a detailed analysis as outlined above.

The ICMR today

Naming the ICMR building

In 2002, when it was decided to name the building designed and set up by Dr Pandit, he was ignored in favour of Dr Ramalingaswami. While the latter scientist's claim to fame cannot be disputed, it is difficult to accept that his contributions to the development of the ICMR were greater than those of Dr Pandit. Dr NK Ganguly, director-general of ICMR, who should have known better, was a prominent participant in the dedication ceremony of this "historic event" (6).

No action against unethical research

The ICMR's responsibilities include ensuring that research in this country is conducted ethically, and "the Central Ethical Committee of ICMR on Human Research constituted under the Chairmanship of Hon'ble Justice (Retired) MN Venkatachaliah held its first meeting on September 10, 1996. Several subcommittees have been constituted to address specific topics, viz., epidemiological research; clinical evaluation of products to be used on humans; organ transplantation; human genetics, etc." (7).

In December 1997, Dhani Ram Baruah transplanted a pig's heart into Purna Saikia, an Assamese farmer (8), without preclinical studies, and without developing a means to overcome the certain rejection of the xenotransplant. Predictably, Saikia died soon after the operation.

I have failed to find a scientific paper published by Baruah on this operation, the studies that went into its planning and its sequel.

As late as February 2012, an editorial by Manji et al in the *Indian Journal of Medical Research*, published by ICMR, noted that even the limited use of heart valves of porcine origin, preserved in glutaraldehyde, should ideally be from "genetically-engineered" pigs (9). It is unlikely that any thought in this direction troubled Baruah six years earlier.

I have also been unable to lay my hands on any document published by the ICMR describing an inquiry undertaken by it into Baruah's unethical and fatal operation.

Far from being punished after due process of law, Baruah appears to be flourishing going by his several claims on his website, including the use of pig blood transfusions into humans and the "first successful clinical transplantation using pig as donor" (10).

ICMR and other national bodies created to further medical and scientific research appear to be indifferent to the operation in 1996 and the many other activities proudly referred to on Baruah's website.

Dr NK Ganguly

Graduating in medicine from Calcutta, he obtained his MD in microbiology from the Postgraduate Institute of Medical Education and Research, Chandigarh. He served as director-general ICMR from 1998 to 2007.

As with my account on Dr Pandit, I include some incidents which have struck me as important. The first dates to his term in the ICMR.

The use of stem cells in cardiology at AIIMS

The ICMR has as its mandate the promotion of medical research of the highest standards throughout the country. To ensure this it must maintain an unfailing vigil for unethical practices anywhere and nip them in the bud, disciplining those guilty of such practices. Like charity, such vigil must begin at home and its environs. The All India Institute of Medical Sciences (AIIMS), a nationally reputed undergraduate and postgraduate institute, is the next-door neighbour of ICMR. The many links between ICMR and AIIMS should make it easy for ICMR to detect and correct unethical practices at the AIIMS.

In 2005, Dr P Venugopal, professor of cardiac surgery, AIIMS, and his colleagues published two papers on the injection of autologous stem cells into the coronary arteries in patients with cardiomyopathy and in those with ischemic heart disease (11, 12). Each paper occupied just one page and concluded that the pilot study indicated the safety of the use of bone marrow cells and showed clinical and echocardiographic improvements. It did not refer to any experimental studies on the use of stem cells in cardiac disease by this group or preclinical trials. We are not informed whether informed consent was obtained from these patients especially since we have no references to similar use of stem cells anywhere in medical journals and since marrow was obtained from iliac crests, coronary angiography and endomyocardial biopsies were carried out. There is no note to show that the research projects were approved by the ethics committee of the institute. There are no details that can help the reader to judge whether there was any significant improvement. We are expected to take statements made in the paper at face value.

Other authors from AIIMS proposed the use of stem cells as a therapeutic modality in the treatment of motor neurone disease and other neurodegenerative diseases (13) and in static encephalopathy including cerebral palsy (14) in the same supplement of the journal. In all cases there are no references to similar usage elsewhere in the world or of their own experimental studies.

In the same year, Devendra Gupta and Shilpa Sharma of AIIMS published a review paper (15). I quote a paragraph from their paper:

> *The All India Institute of Medical Sciences (AIIMS), New Delhi has taken the global lead in using the autologous stem cells obtained from bone marrow (sternum, tibia) and using them for various disorders (cardiomyopathies, diabetes, bony disorders, biliary atresia and choledochal cyst (cirrhotic livers), spina bifida, cerebral palsy and muscular dystrophy). This has been possible following an extensive background research that has gone for more than 2 years before using the stem cells on the human beings. At AIIMS, stem cells have been used in more than 150 patients, including neonates and infants for various disorders.*

While this paper does refer to ethical issues, these pertain to the storage of umbilical cord/blood and not to informed consent or sanction by the institute's ethics committee. We are provided no references to the "*extensive background research that has gone for more than 2 years before using the stem cells on the human beings*" although they list 31 other references.

My own search for references to the experimental work on stem cell work at the AIIMS leading to these papers has proved unrewarding. If, indeed, there be no preclinical study, phase I and phase II studies on the effects of the introduction of stem cells into human beings to cure disease, the scientific foundation of the claims made by Venugopal and others at the AIIMS lack validity and the experiments are patently unethical.

A study of pronouncements made by Venugopal to the press, in 2005, lead to greater consternation. A news item (16) claimed: "All India Institute of Medical Sciences is on the threshold of a medical breakthrough. The country's premier medical institute is preparing proof of efficacy of its stem cell therapy for the global medical fraternity. The institute has conducted tests on 33 heart patients over the last 18 months using the therapy and 'all of them are showing positive results,' says Dr P Venugopal, director, AIIMS."

Despite my efforts, I have been unable to secure a copy of the document offering ethics clearance for these tests. I have also failed to obtain papers detailing the techniques used in the treatment or objective assessments of the patients used in these trials by impartial experts before and after treatment. If one takes the news item at its face value, the AIIMS team was "preparing proof of efficacy of its stem cell therapy". If this was true, would it not have been proper to await scientific publication of the claims in a reputed, indexed medical journal after peer review before making the news public? It would be of interest to learn how many more stem cell transplants have been carried out at AIIMS from 2005 to date on the basis of claims and suggestions made in the papers published in 2005 and the improvements that followed in these patients.

As regards the statement that "no ethical issues are involved in the stem cell research using adult cells," there are considerable grounds for disagreement. Sharma (17) has pointed out:

> *A lot more basic information about stem cells and their behaviour are [sic] required before they can be used for treatment. Extensive basic research is required for standardization of methods for the isolation of embryonic and adult stem cells from various sources. Future prospects for embryonic stem cell research include the following: generation of therapeutic grade cell lines; identification of human embryonic stem cells (hESC) growth factors; controlled differentiation, i.e. generation of specific cell population; study of fundamental changes in cell cycle control that occurs during embryonic stem cells differentiation; maintenance of stem cell in undifferentiated stage; regulation of differentiation of ESC; pleuripotency and differentiation of established cell lines; standardization of animal free defined culture conditions; developmental potential of human versus mouse ESC; standardization in use of specific stem cells to specific organ systems, etc. In addition, ESC could also be used for toxicology tests and may be valuable tools for traditional drug discovery…*

Venugopal and his colleagues should have complied with the need for such studies before embarking on their clinical usages. I have failed to find evidence that they did.

I presume Dr Ganguly was privy to data not available to the rest of us for on April 5, 2005, *The Hindu* reported: "ICMR okays stem cell research by AIIMS" (1). The opening sentence of the report said: "Giving a thumbs-up sign to stem cell research work at the All-India Institute of Medical Sciences (AIIMS), the director-general of the Indian Council of Medical Research (ICMR), Dr NK Ganguly, today said he stood by the 'authenticity of the work by the Institute.' Dr Ganguly continued: "We have no plan to legislate the guidelines that are in place for carrying out stem cell research."

This rapid assessment by the head of ICMR of work that was just being reported is surprising, to say the least. One would have expected a careful study of the preclinical work, phase I and phase II clinical trials and observation of the results of treatment over years to identify ill-effects and confirmation of clinical improvement by impartial observers before making any comments.

Equally puzzling was the statement by Dr Vasantha Muthuswamy, deputy director-general, ICMR, and in charge of developing ethical guidelines for stem cell research and treatment: "We are only a block away from AIIMS and we did not know this (stem cell work) was happening there. If the nation's premier medical institute did not ask our permission for such therapy, how can we blame private clinics for what they do?" (18) Was the enthusiasm of Dr Ganguly for the claims of AIIMS based on non-scientific reasons?

I am also struck by the fact that despite the "research" in India, experts abroad are proceeding cautiously. Martin-Rendon and colleagues (19) concluded their systematic review of randomised controlled trials in the use of stem cells in acute myocardial infarction (AMI) thus: "Stem cell treatment for AMI still holds promise. Clinically, these data suggest that improvement over conventional therapy can be achieved. Further, adequately powered trials using optimal dosing, longer term outcome assessments, more reliable, and more patient-centred outcomes are required." Note that they recommend further, adequately powered trials and not unrestricted usage.

As noted above, despite the existence of guidelines for carrying out stem cell research, Dr Ganguly did not find it necessary to proceed to legislating them. Dr Dorairajan Balasubramanian, research director at the LV Prasad Eye Institute in Hyderabad, himself involved in the use of stem cell to treat eye diseases, had pointed out the need for legislation so that rogue researchers can be punished. "Guidelines are only guidelines. Any violations cannot be punished." (20). As I write this, the guidelines for stem cell research prepared by the ICMR and the Department of Biotechnology remain in draft form (21). The failure of ICMR and other national agencies to get the legislature to act on these guidelines have laid us open to international ridicule. Salter et al (22) referred to "a 2005 survey by ICMR [that] showed that in the absence of any powers of enforcement only a minority choose to do so… As stem cell science moves from the laboratory to the clinic and the experimental treatment of patients, it does so in a governance vacuum. As a result, scientists like Dr Geeta Shroff can publicise her treatment of 100 clinical cases of spinal injuries, paralysis, tuberculosis, neuro-muscular dystrophy and multiples sclerosis conducted without ICMR approval and receive simultaneous praise from the Indian health secretary and condemnation from Western stem cell scientists…"

Dr Ganguly and others implicated in ICMR land scandal

> *The arrests of several high-profile current and former officials of the Indian Council of Medical Research (ICMR) on corruption charges have sent shockwaves through the Indian medical establishment.*
>
> *The government-funded ICMR, headquartered in New Delhi, coordinates and promotes biomedical research in India and runs 28 research institutes across the country.*
>
> *Those arrested by the Special Fast Track Court of the Central Bureau of Investigation include Bela Shah, head of*

> *the ICMR's division of non-communicable diseases; Ashok Kumar Srivastava, its executive engineer; and Bhawani Thyagarajan, a retired joint secretary in the Ministry of Health, among several others. Following their arrests, Shah and Srivastava have been suspended by the ICMR while the investigation takes place.*
>
> *The case follows a comprehensive investigation run by the government's audit body, the Comptroller and Auditor General of India, which found that land procurement and irregular transfer for proposed building works by the ICMR between 2002 and 2008 were subject to large-scale irregularities, wasteful expenditure, cost overruns and inadequate oversight…*
>
> *Specific to recent arrests, the auditor found that land owned by the ICMR-affiliated Institute of Cytology and Preventive Oncology (ICPO) was illegally transferred to a private housing society of employees by the ICMR executive council at a fraction of its market price, causing massive losses to the government exchequer…*
>
> *Nirmal Kumar Ganguly, a former director-general of the ICMR and a leading Indian scientist, is also accused of the charges. He has an arrest warrant against him but has so far not presented himself in court. Ganguly is also chairman of the governing body of the Jawaharlal Institute of Postgraduate Medical Education and Research in Puducherry, and heads a medical ethics committee for the Medical Council of India… (2)*

The final 11 words emphasise the tragic state of affairs in Indian medicine.

References

1. Staff Reporter. ICMR okays stem cell research by AIIMS. *The Hindu* [Internet]. 2005 Apr 6 [cited 2013 Jun 1]. Available from: http://www.hindu.com/2005/04/06/stories/2005040612771300.htm
2. Kumar S. Indian medical officials charged in land deal case. *Nature / News* 8. 2013 March [cited 2013 Jun 1]. Available from: http://www.nature.com/news/indian-medical-officials-charged-in-land-deal-case-1.12554
3. Pandit CG. *My world of preventive medicine*. New Delhi: Indian Council of Medical Research; 1982:363.
4. Katoch VM. *XII plan document (2012–2017)* [Internet]. New Delhi: Department of Health Research; 2012:323. Available from:http://www.icmr.nic.in/Publications/plan/ICMR%20XIIth%20Plan%20(2012–2017).pdf
5. Katoch VM, Srivastava VK, Srivastava D. *Compendium of ICMR research papers (1919–2010)*. New Delhi: Indian Council of Medical Research; 2011[cited 2013 Jun 1]. Available from: http://www.icmr.nic.in/Publications/centenary_books/compendium/Final%20pdf/Compandium.pdf
6. Anonymous. *Dr CP Thakur dedicates ICMR building to professor V Ramalingaswami*. 2002. [cited 2013 Jun 1]. Available from: http://icmr.nic.in/press.htm
7. Anonymous. *History of ICMR*. Undated [cited 2013 Jun 2]. Available from: http://www.icmr.nic.in/history.htm
8. Anonymous. Vox populi: the first Indian porcine xenotransplant. *Issues Med Ethics*. 1997 Apr–Jun;5(2):62. Available from: http://www.issuesinmedicalethics.org/052mi062.html
9. Manji RA, Menkis AH, Ekser B, Cooper DKC. The future of bioprosthetic heart valves. *Indian J Med Res*. 2012;135:150–1.
10. Baruah DR. Dr Dhani Ram Baruah. Inventions [Internet]. Assam: 2010[cited 2013 Jun 12]. Available from: http://drdhanirambaruahnewinventionsinhumangenetics.com
11. Airan B, Bisoi AK, Mohanty S, Narang R, Patel CB, Bhargava B, Venugopal P. Cellular cardiomyoplasty—a clinical study. *Indian J Med Paed Oncol*. 2005;26 Suppl:1.
12. Seth S, Narang R, Bhargav B, Kothari SS, Venugopal P, Reddy KS, Kumar L, Mohanty S, Ray R, Naik N, Yadav R, Sharma S, Gulati G, Bisoi A, Airan B. Role of intra coronary injection of autologous mononuclear bone marrow stem cells in patients with chronic left ventricular dysfunction due to dilated cardiomyopathy or ischemic heart disease with open coronary arteries. *Indian J Med Paed Oncol*. 2005; 26 Suppl.:2.
13. Singh S. Stem cells as a therapeutic modality for motor neuron disease. *Indian J Med Paed Oncol*. 2005;26 Suppl.:20.
14. Srivastava MVP. Stem cell therapy in static encephalopathy including cerebral palsy. *Indian J Med Paed Oncol*. 2005;26 Suppl:16.
15. Gupta DK, Sharma S. Stem cell therapy—hope and scope in pediatric surgery. *J Indian Assoc Pediatr Surg*. 2005;10(3):138–141.
16. Anonymous. AIIMS claims cutting edge stem cell study. *The Times of India* [Internet]. 2005 Mar 23[cited 2013 Jun 12]. Available from: http://timesofindia.indiatimes.com/home/science/AIIMS-claims-cutting-edge-stem-cell-study/articleshow/1059744.cms?
17. Sharma A. Stem cell research in India: emerging scenario and policy concerns. *Asian Biotech Dev Review*. 2006;8(3):43–53.
18. Jayaraman KS. Indian regulations fail to monitor growing stem-cell use in clinics. *Nature*. 2005;434:259.
19. Martin-Rendon E, Brunskill SJ, Hyde CJ, Stanworth SJ, Mathur A, Wall SM. Autologous bone marrow stem cells to treat acute myocardial infarction: a systematic review. *Eur Heart J*. 2008;29;1807–18
20. Mudur G, Kidwai R. Stem cell march, minus checks—lack of research rules allows doctors to do as they like. *The Telegraph* [Internet]. 2005 Nov 16[cited 2013 Jun12]. Available from: http://www.telegraphindia.com/1051116/asp/frontpage/story_5482621.asp
21. Anonymous. *Guidelines for stem cell research (Draft)*. New Delhi: Indian Council of Medical Research, Department of Health Research and Department of Biotechnology. 2012. [cited 2013 Jun12]Available from: http://icmr.nic.in/stem_cell_guidelines.pdf
22. Salter B, Cooper M, Dickins A, Cardo V. *Stem cells in India: emerging economics and the politics of globalisation. Working paper no 16*[Internet]. Norwich: Global Biopolitics Research Group; 2006 Dec[cited 2013 Jun 12]. Available from: http://www.kcl.ac.uk/sspp/departments/politicaleconomy/research/biopolitics/publications/workingpapers/wp16.pdf

EDITORIALS

The Medical Council of India: need for a total overhaul

SUNIL K PANDYA

Department of Neurosurgery, Jaslok Hospital and Medical Centre, Dr GV Deshmukh Marg, Mumbai 400 026 INDIA e-mail: shunil3@gmail.com

> *O, what a fall was there, my countrymen!*
> *Then I, and you, and all of us fell down,*
> *Whilst bloody treason flourish'd over us.*
>
> Shakespeare: *The life and death of Julius Caesar*. Act 3, Scene 2

The Medical Council of India (MCI) is modelled on the General Medical Council of the United Kingdom. The latter agency is intended to subserve crucial functions (1):

- set the standards of good medical practice it expects of doctors throughout their working lives;
- assure the quality of undergraduate medical education in the country and co-ordinate all stages of medical education;
- administer systems for the registration and licensing of doctors to control their entry to, and continuation in, medical practice in the country;
- deal firmly and fairly with doctors whose fitness to practice is questioned.

In 2009, this journal carried an essay describing the rot within the MCI (2). At the close of the abstract of this essay were the following lines: "Permitted optimism, we may hope that this essay and similar observations by others will prompt a change for the better. At present such optimism is not justified."

To our great misfortune, matters have only worsened. The functions of the council are in disarray. Confusion is confounded by the day.

The role of the Government of India

The influence of the Government of India on the MCI has never been greater. Almost every aspect of its composition and functions are dictated by those at the helm of the central ministries concerned with health, family welfare and medical education.

In 2012, the Government of India proposed a move to merge the medical council, the dental council, the nursing council and others to form one body – National Commission for Human Resources for Health. Notwithstanding the fact that the functions of these councils vary widely, the move was widely publicised. The outcome of the deliberations of the Parliamentary Standing Committee and other agencies entrusted the task of deciding upon such a move remains enshrined within the dusty files that fill the cupboards of these agencies and have not been made public. To the best of my knowledge, there has been no informed public debate on the subject.

Arbitrarily and without any public debate on the issue, the government, by administrative fiat, announced a board of governors to run the affairs of the MCI after Dr Ketan Desai was debarred by the courts from presiding over it. We are not aware of any action taken by the Government of India against members of the council who aided and abetted Dr Desai in his activities or, indeed, against Dr Desai himself. The predicament in which Dr Desai finds himself at present has been dictated by the court of law despite the vacillations of the Central Bureau of Investigation (CBI); the latter said to be acting under the directives of the Government of India.

Having announced the first board of governors on the basis of undisclosed criteria, the Government of India saw it fit to summarily abolish the board, again on the basis of undisclosed criteria. In the democracy prevailing in our country, an elected government sees no reason to justify its actions to the public or even to the medical and academic communities.

The second board was also appointed without any justification of why particular individuals were selected as members. The careful nomination to this board by the Government of India of individuals from the private sector to the exclusion of reputed teachers in our national and state institutes of medical education and research in the public sector deserves scrutiny. It was almost as though the Government of India consciously and brazenly favours the private sector that has flourished as public sector medical colleges and hospitals decay for want of support and encouragement.

Recent steps emphasise the extent to which the government has compromised itself.

It is common knowledge that governors in various states are beholden to those occupying the highest positions in the Congress party and the Government of India. These governors, as chancellors of universities, have permitted the election and nomination of individuals whose credentials deserve close scrutiny (3–5). A glaring example is the "election" of Dr Ketan Desai as the representative of the University of Gujarat to the MCI. As was pointed out by Mr Julio Ribeiro, chairman of the Public Concern for Governance Trust in Mumbai, to the Governor of Gujarat on November 21, 2013, Dr Ketan Desai's licence to practise medicine was suspended on October 9, 2010 by the MCI (6). He was thus ineligible to enlist as a member of the council. In response to Mr Ribeiro's letter, Mr Amrut Parmar, section officer to the Governor of Gujarat blandly forwarded, on January 27, 2014, the explanation offered by the 'I/c Registrar' of the University of Gujarat. The University – and the Governor of Gujarat – appear satisfied by the reported opinion of Justice AM Ahmadi, former Chief Justice of India, that the MCI has no jurisdiction or authority to suspend the registration of any doctor registered with any state medical council. Neither Dr Ketan Desai nor the University of Gujarat has felt the need to challenge the MCI in a court of law. Instead, they take recourse to the opinion of a retired judge. Not being in possession of the full text of Justice Ahmadi's opinion, or of the grounds on which the Honourable Judge has drawn his conclusions, it is difficult to comment on the validity of his conclusions. It must be noted that to permit the election of a person under a cloud of suspicion to the MCI is contrary to the very raison d' être of the council.

The Times of India (7) describes the latest infamous act in the sordid saga: "The story of removal of Keshav Desiraju, a 1978 batch IAS officer… as health secretary and his transfer to the non-descript consumer affairs ministry is not only being seen as the influence of former MCI boss Ketan Desai but more importantly of Congress' courtier culture. In the process, Desiraju, considered one of the finest officers known for his work in education and health sectors, paid the price… Desiraju … played a key role in the cleaning up of the Medical Council of India that led to the ouster of Ketan Desai…"

A later report suggests the involvement of the Bharatiya Janata Party (BJP) and Samajwadi Party, in addition to the Congress, in restoring Dr Ketan Desai to the MCI. It also quotes from a note written by Mr Desiraju on January 7, 2014: "It is widely believed that all decisions within the Medical Council of India are being taken by the group led by Dr Ketan Desai.… There is every likelihood that we will be forced to approve and notify decisions regarding courses, new admissions etc which have been made on the grounds other than merit alone. This would be a very unfortunate position for the Government" (8).

A recent detrimental decision by the MCI

In its infinite wisdom, the MCI has recently suggested the exemption of medical associations of professionals from scrutiny by the council or its ethics committee.

In the recent past, the council itself has found some associations to be guilty of endorsing specific commercial products. In 2010, it suspended Goparaju Samaram, president, and Dharam Prakash, secretary of the Indian Medical Association (IMA) for such practices. The efficacy of this step was obvious. Devendra Shirole, national vice-president elect of IMA for the period 2011–12 stated, "There is no denying the fact that IMA endorsing food products is unethical. However, this is a hard fact that IMA as an association requires funds for carrying out various social and awareness related activities for the public. But the money should be raised ethically and not by indulging in commercial activities" (9). A similar salutary effect of the step by the council was seen in the editorial published in the *New Indian Journal of Pediatrics* in 2012 (10). Among other steps, the editorial advocated "… Restriction or banning of health claim advertisements in publications of scientific organisations. Such products or companies should not be promoted during their conferences…" This was especially welcome in view of the advertisement promoting a cereal preparation for babies in the *Indian Journal of Pediatrics* (10).

The new dispensation at the MCI apparently disagrees with those in the same council who had promoted medical ethics. By keeping associations and organisations of medical doctors outside the purview of the council, office-bearers and members of the MCI do a great dis-service. The question can be asked: "What provoked the council to take this disastrous step? Is it to curry favour with these associations and organisations so that they, in turn, continue to turn a blind eye to the goings on within the council? (see below). Or is there something even more sinister?"

Senior statesmen in the world of science and medicine

Elsewhere, eminent scientists such as presidents of and respected scientists in academic institutes, research centres and think tanks are quick to voice alarm when they diagnose disease in watchdog and policy-making agencies. Their commanding positions and membership of such exalted bodies as the US President's Council of Advisors on Science and Technology, the President's Science Advisory Committee, and the President's Commission for the Study of Bioethical Issues ensure attention to their observations and criticisms. Quick action on their recommendations follows.

Alas! In India we see no such reactions from those advising and guiding the Prime Minister of India or agencies such as the Planning Commission. Certainly, if any dismay is felt by these worthies, it is never made public and if made known in confidence to the powers-that-be, appears to make no impact.

Associations of medical doctors

As with the senior statesmen of science, so with the associations, societies and organisations of medical doctors such as the Association of Surgeons of India, the Association of Physicians of India, the Indian Medical Association and the specialty groups – the decay within the MCI elicits no response. Their presidents and office-bearers are oblivious to the destruction of the central agency in the country, which was once the watchdog of the medical profession and guarantor of ethical medical practice and education of the highest standards in our medical colleges and teaching hospitals. These appear to be matters of no import to the profession at large or to those who claim to be their leaders.

Marc Antony was able to state:

O, now you weep; and, I perceive, you feel
The dint of pity: these are gracious drops…

Shakespeare: *The life and death of Julius Caesar*. Act 3, Scene 2

Would that we could say something similar with regard to our peers!

What is to be done?

1. The conscience of our grey eminences in science, technology and medicine must be awakened. They must bring their collective intelligence to bear on the sorry state of the MCI and the state medical councils and use their considerable influence with the highest levels of government to stem the rot and set in place a system that is as near incorruptible as possible. Should the powers-that-be fail to heed their recommendations, they must withdraw their support, advice and labours from the advisory and other committees they have served so faithfully.

2. The medical profession at large and its leaders in associations and societies must bring pressure to bear on the government to effect change for the better. These associations are potent by reason of their numbers and the services they offer the nation and its sick VIPs. Were they to come together on a common platform they would form an irresistible force. Their widely read journals and platforms available at annual and other meetings, workshops and conferences could be used with great effect to alert their members on the consequences of the downward slide of the council.

3. Professionals – as individuals – also cannot shrug off their responsibilities. They wield the powerful weapon of the vote – to offices in their associations and to seats in the MCI. Used wisely, these can make a significant difference in the current state of affairs.

The public at large also needs to be made to understand that deteriorating standards of medical education and unethical medical practice is to the detriment of all citizens. The menace of worsening healthcare can only lead to medical disasters as poorly trained and unethical doctors emerging from substandard medical colleges and hospitals become teachers and administrators.

A concerted move must be made to bring about radical changes in the structure and functioning of the MCI:

- The appointment of members to the council must be made by a committee composed of medical, legal and lay experts of unimpeachable integrity. The creation of this committee must be open to public scrutiny. Office-bearers and members of the MCI must be appointed by this committee for a four-year term through a transparent process. Politicians and bureaucrats must have no say in the composition and operation of the council.
- The process of election has been proven to be riddled with corruption and malpractice. It must be abolished.
- The present mammoth council of 85 or so members must be trimmed severely. The General Medical Council of United Kingdom has 12 members. Why do we need any more? Why is it necessary for each university to nominate one member? The supervisory body referred to above can select three members of national and international eminence from our medical institutes and colleges for this purpose, at least one of them being a woman.
- The credentials of all office-bearers and members of the MCI must be impeccable and open to public scrutiny.
- All proceedings of the MCI must be open to public scrutiny. There is no place for secrecy or hidden dealings when the future of medical education and the health of the nation is at stake.

I strongly commend a close study of the structure and function of the General Medical Council of United Kingdom. There is much to be learnt from it (11).

References

1. General Medical Council, UK. Regulating doctors, ensuring good medical practice [Internet]. London: GMC; c2014 [cited 2014 Mar 11]. Available from: http://www.gmc-uk.org/concerns/complaints_and_role_of_the_gmc.asp (accessed on 25 February 2014)
2. Pandya SK. Medical Council of India: the rot within. *Indian J Med Ethics* 2009 Jul–Sep;6(3):125–31.
3. Pasha S. The spectre of Desai. *India Today* [Internet]. 2013 Dec 6 [cited 2014 Mar 10]. Available from: http://indiatoday.intoday.in/story/ketan-desai-medical-council-of-india-returns-to-haunt-regulatory-body/1/328211.htm
4. Rathee V. Govt urged to remove MCI vice-president for issuing false medical certificate. *India Medical Times* [Internet]. 2014 Jan 25 [cited 2014 Mar 10]. Available from: http://www.indiamedicaltimes.com/2014/01/25/health-ministry-urged-to-remove-mci-vice-president-for-issuing-false-medical-certificate/
5. Kumar P. Remove docs close to corrupt ex-chief from MCI, minister asked. *Governance Now* [Internet]. 2013 Nov 29 [cited 2014 Mar 10]. Available from: http://www.governancenow.com/news/regular-story/remove-docs-close-corrupt-ex-chief-mci-minister-asked
6. Prasannaraj P. Order of suspension of license of Dr Ketan Desai to practice medicine during the pendency of appeal before Ethics Committee of Board of Governors in supersession of Medical Council of India. Document No. MCI-211(2)/2010-Ethics/33317. New Delhi: Board of Governors in supersession of Medical Council of India; 2010 Oct 9 [cited 2014 Mar 11]. Available from: http://pbtindia.com/wp-content/uploads/2010/10/MCI-Decision-Desais-license-cancel-Oct.-9-2010-v2.0-1.pdf
7. Mukul A. Bureaucrat falls prey to Cong courtier culture. *The Times of India* [Internet]. 2014 Feb 14 [cited 2014 Mar 11]. Available from: http://timesofindia.indiatimes.com/india/Bureaucrat-falls-prey-to-Cong-courtier-culture/articleshow/30365195.cms
8. Anonymous. AAP accuses Azad, Narendra Modi, Mulayam Singh of trying to restore Dr Ketan Desai's clout in MCI. *India Medical Times* [Internet]. 2014 Feb 28 [cited 2014 Mar 11]. Available from: http://www.indiamedicaltimes.com/2014/02/28/aap-accuses-azad-narendra-modi-mulayam-singh-of-trying-to-restore-dr-ketan-desais-clout-in-mci/
9. Isalkar U. Unethical for doctors to endorse products: IMA members. *The Times of India*. 2010 Nov 24. Available from: http://timesofindia.indiatimes.com/city/pune/Unethical-for-doctors-to-endorse-products-IMA-members/articleshow/6978099.cms
10. Tiwari S, Borkar R, Agarwal RK. Editorial: Exaggerated health claims. *New Indian Journal of Pediatrics* 2012 Apr–Jun;1:41–4.
11. General Medical Council, UK. About us. London: GMC; c2014 [cited 2014 Mar 11]. Available from: http://www.gmc-uk.org/about/index.asp

---

The Prevention of Parent-to-child Transmission Programme: Is it fair to women?

SHYAMALA NATARAJ[1], MALA RAMANATHAN[2]

[1]Senior Scientist, Department of Humanities and Social Sciences, Indian Institute of Technology, Chennai, Tamil Nadu 600 036 INDIA [2]Additional Professor, Achutha Menon Centre for Health Science Studies Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala 695 011 INDIA. Author for correspondence: Shyamala Nataraj e-mail:nataraj.shyamala@gmail.com

In February 2014, the Government of India launched a multi-antiretroviral drug regimen to treat infected women and infants in efforts to reduce parent-to-child transmission (PTCT) of the human immunodeficiency virus (HIV) (1). The announcement has been long awaited because the multidrug regimen can reduce the risk of transmission during childbirth from 30%–35% to less than 2% with replacement feeding (2). Multidrug regimens to prevent PTCT have been used in high-income countries since the 1990s and in many low- and middle-income countries (LMICs) since 2010, when the World Health Organisation (WHO) removed the single-dose nevirapine (SdNVP) regimen from its list of recommended treatments. However, until now, India has been one of the few countries where infected pregnant women and their infants received the SdNVP, which reduces the risk of transmission to 16% in combination with breastfeeding, and to 11% in combination with replacement feeding. Meanwhile, new recommendations from the WHO suggest that for maximum efficiency, antiretroviral therapy (ART) should be given to all HIV-positive pregnant women irrespective of their CD4 counts (3). However, India will initiate the multidrug regimen among women with CD4 count ≤350 cells/mm^3 as per the recommendations of 2010 (4).

This delay in switching to a multidrug regimen has been ascribed to the need to strengthen infrastructural and human capacity to handle the clinical and monitoring requirements of CD4 counts and treatment adherence involved in this regimen for women and infants (5). Unlike the SdNVP regimen, the multidrug regimen is initiated in HIV-positive women 14 weeks after conception and is continued until after the woman has stopped breastfeeding. Infants are recommended the one daily dose of NVP for about six weeks after birth.

As effective as the multi-drug regimen is in preventing transmission from infected women to infants, the switch does not address the important aspect of preventing infection in women in the first place. This should be an integral component of the programme's design and is the most effective way to ensure zero risk to infants, while protecting the mothers as well. We examine the impact of the Prevention of Parent to Child Transmission programme on women in India, especially because it is the only initiative in the country that targets women outside sex work for HIV prevention and care. We locate our discussion in the wider context of the subjugation of women's autonomy and well-being in national health policies and practices related to population and reproductive health.

Women account for 39% of all infected people in India but the overwhelming majority – over 90% – have been infected after

COMMENT

Making medical care and research rational and affordable.

SUNIL K PANDYA

Abstract

Expenditure on insurance, consultations, the multitude of tests ordered by the doctor, and very expensive drugs make the treatment of illness a great burden. Should the patient need admission to a hospital and, worse, an intensive care unit, the load becomes almost unbearable. Medical research has moved from the domain of the single keen observer to that of highly qualified experts working in laboratories containing costly equipment. The budget for these projects now runs into lakhs or crores of rupees.

This essay questions current practices and suggests the need for a return to simplicity without any compromise on efficacy. Placing the patient at the centre of our attention and focusing on affording the best of care at least expense will result in the elimination of unnecessary tests, the use of rational, generic drugs and greater harmony between patients and their medical attendants. It will also help restore dignity to the patient and his family. They can hope for the return of health without a descent into poverty and debt.

Introduction

The escalating cost of medical care, unaccompanied by a corresponding increase in its efficacy, has become a subject of universal concern. In some instances, the efficacy of medical care decreases in inverse proportion to the rise in costs. An obvious example is the rise in the number of tests demanded by doctors and the lack of relevance of the findings of these tests to the care of the patient.

It is especially important for us to try to reach the ideal in cost-effective medical care as we have one-third of the world's poorest citizens. The plight of the sick in villages is, indeed, pitiable. Steps are necessary to ameliorate their predicament.

In private hospitals, the need to show increasing profits conflicts with the aims of humane and effective medical care.

The increasing use of medical insurance, rules devised by insurance companies, development of third party agencies that decide on whether or not insurance claims are genuine, and pressures on doctors and hospitals to maximise their incomes can lead to irrational practices and escalating costs. Keeping the patient in hospital for a minimum of twenty-four hours in order to validate his claim for reimbursement by the insurance company is an example. A patient who could have been sent home now occupies a bed merely to satisfy the requirements of the insurance company.

Medical research was earlier based on careful observation at the bedside. The progress of disease was recorded, leading to our understanding of the natural history of disease. The effects of a drug were similarly observed and recorded. A fine example is the work of Dr. William Withering on the use of the foxglove in the treatment of dropsy following poor function of the heart (1). The product derived from the study by this 18th century country doctor – digitalis – remains an important drug. Current medical research is much more complex, involving as it does detailed analyses and the use of expensive equipment and tests. Costs have rocketed as a consequence. There is need to ensure that expenses are kept to a minimum whilst safety and efficacy are maintained.

This essay attempts an analysis of some deleterious trends and suggests curative steps.

Definition

Webster's New World College Dictionary defines "cost-effective" as "producing good results for the amount of money spent; efficient or economical" (2). When applied to the care of patients, the definition must also include the satisfaction of the patient and family with the measures adopted.

Reduction of costs

Clinical examination of the patient and tests ordered by the doctor

Listening and talking to the patient

When the priority is seeing increasing numbers of patients in order to maximise income, the first casualty is the time spent with each patient. Most patients leave the doctor's consulting room with feelings such as, "The doctor never told me what I need to know. I could not ask him important questions and clear my doubts." If the doctor were to be questioned, his answer would be simple: "I have to see so many patients. I cannot afford to spare more than a few minutes for each patient."

Worse, the doctor attempts to compensate for his failure to obtain a detailed history and perform a careful examination

Author: **Sunil K Pandya** Kbtmpl Iptqjubm boe Sftfbsdi Dfousf, Dr GV Deshmukh Marg, Mumbai 400 026 INDIA - Sunil K Pandya (shunil3@gmail.com), Department of Neurosurgery.

To cite; Pandya SK. Making medical care and research rational and affordable. *Indian J Med Ethics*. 2015 Apr-Jun;12(2): 97-103.

by obtaining information through a battery of tests, many of them expensive. In doing so, the doctor violates the hallowed principles of clinical medicine laid down by the great masters. Here are two examples.

- Listen to your patient, he is telling you the diagnosis. – Sir William Osler, Regius Professor of Medicine, Oxford University (3)
- If you have 10 minutes to spend with a patient, spend nine on the history. – Dr Robert J Joynt (4), editor of *Archives of Neurology*, *Seminars in Neurology*, co-author of *Baker and Joynt's Clinical Neurology*, and founder of the department of neurology at the University of Rochester Medical Center)

Clinical assessment of the patient, when performed well, can help avoid unnecessary and expensive tests, with benefit to the patient. It also helps in building the basis for a good doctor–patient relationship.

Using expensive laboratory or imaging tests in preference to the use of clinical acumen in making a diagnosis has become all too evident. Attempts to understand the natural history of the patient's illness are giving way to rapid-fire investigations and gunshot therapy. In part, the use of expensive tests may also be gaining prominence because of the "incentives" offered by laboratories and scan centres. A portion of the fees paid by the patient to the centre is passed on to the clinician. This unethical conduct is camouflaged by the use of terms such as "fees for clinical assessment" or "provision of clinical details". Such sugarcoating appears to assuage the conscience of many colleagues.

Tests ordered

Clinical diagnosis must precede tests. Such a diagnosis is arrived at on the basis of the patient's history and the clinical findings. It is possible that this provisional conclusion may be overturned by the results of the relevant tests.

The test results must:

a) confirm the diagnosis or shift the focus to another diagnosis
b) help the clinician to establish the gravity of the illness
c) form the basis for the treatment or for a change in the treatment when the methods used thus far have failed to help
d) be used to assess the impact of the treatment and the need for long-term care.

Caution: Do not become "test-happy and technologically-powered". In the words of C. Yeh, "I am afraid that as a result, we may be training a new generation of practitioners to equate high-quality care with conducting a test. Instead of the test being used to discover new information about the patient, it is being used to define if one is even a patient" (5).

Jha points out another danger: "The diagnostic culture of *rule out* is kryptonite to clinical acumen" (6). Ruling out begets more ruling out, more tests and more uncertainty. Here is an example. The X-ray film shows a patch in the lung of a patient clinically suspected of having pneumonia. Hypothesis: This could be masking a tumour. Perform a CT scan. CT scan: "Doubtful abnormality along the arch of the aorta. Could this be an aneurysm? Perform an MRI scan." MRI scan: 'The aortic arch is merely atherosclerotic and unfolded. However, there is a suspicion of haemorrhage in the left adrenal…"

Beware also of the tendency to order tests merely because they are available.

Jha notes that students used to be praised by their teachers when they arrived at a diagnosis. Today, they are lauded for thinking of the atypical instead of the obvious and commonplace illnesses (6).

Tests that do not affect the diagnosis, therapy or prognosis are not worth carrying out.

Tests carried out merely to protect the clinician from medico-legal suits need careful consideration. Maintenance of medical records that clearly show the care bestowed on the patient and clinical findings at each stage of the illness often make such tests unnecessary. Inclusion in the patient's case records of the discussion of the pros and cons of particular tests (coronary artery angiography is an example) and why they were not done will show the care and concern of the clinician for the welfare of the patient.

Health insurance

A variety of health insurance policies are now available in India. The prudent will use one of them for each member of the family. The small investment, a part of which can be used to reduce income tax, will pay huge dividends in the unfortunate event of an illness.

When obtaining an insurance policy, it is incumbent on the applicant to be scrupulously honest, especially regarding illnesses that have been treated in the past and those for which he/she is under treatment. One of the commonest causes of conflict between the policy-holders/beneficiaries and insurance companies is the latter's claim that an honest disclosure was not made in the application.

Greed on the part of doctors, human ingenuity and the desire to be one up on insurance companies often result in the inflation of hospital bills by means of unnecessary tests; the prescription of expensive drugs, the use of which cannot be justified; exorbitant charges; and needlessly prolonged stays in the expensive intensive care unit and in the hospital in general. Such practices are unethical. The increased costs result in increased premiums.

Care of the poor patient in the village

Current deficiencies in the provision of health care to those living and toiling in villages have left them at a severe disadvantage. Poorly functioning primary health care centres make it difficult for them to obtain medical advice and treatment in their neighbourhood. Left to the mercies of ill-trained, poorly equipped self-proclaimed healers, their ailments worsen and they are compelled to seek treatment in towns and cities at desperate stages of their diseases.

Travel from their villages to urban medical centres entails enormous costs and a total disruption of their lives and work.

Many have cried themselves hoarse at the great need for well-staffed and equipped primary and secondary health care centres to cater to these patients. Till this need is met, the poor sick in rural areas will continue to bear their additional burden of illness under hopeless circumstances.

Care of the patient in the hospital

Intensive care units

There must be clear guidelines on who can be admitted to the intensive care unit and on when the patient must be shifted out of the unit.

Here are two examples of questionable admissions.

a) Patients with advanced cancer, widespread metastatic disease and a hopelessly poor prognosis are admitted to the intensive care unit either to tide over an immediate crisis (such as pneumonia and drop in blood pressure), or because the patient is very rich or politically powerful. Even after the crisis is over, they are retained in the intensive care unit for days or even weeks.

b) It is not uncommon to find patients in persistent vegetative states or severely handicapped patients who are clinically stable in intensive care units. Such patients are often retained in the intensive care unit for long periods on a variety of pretexts. An oft-used argument by doctors is the pressure exerted on them by the patient's family to ensure that the patient is retained in the intensive care unit. Similar pressures are also used to keep the patient in the hospital when care at home might be in the better interest of the patient. The motives of the family may vary from avoidance of taking responsibility for patients, even in their terminal stages, to the demonstration to their peers that they are doing their best and sparing no expenses. The wise physician will spend time discussing these issues with the family. Such discussions, may on more than one occasion, go a long way in resolving conflicts in the minds of relatives.

Such misuse of intensive care unit beds has two harmful consequences. First, life-saving beds are blocked to the detriment of those who need them. Second, the expenses incurred by patients unnecessarily retained in intensive care units continue to rise.

The use of antibiotics – the best of the latest syndrome

Another area to which we must pay careful attention is the use of antibiotics.

It is imperative for the treating physician to justify the use of such a drug on each occasion. The prescription of an antibiotic is unscientific when the illness is of viral origin. Further, microorganisms develop resistance to the antibiotic as a result of this practice, to say nothing of the added expenditure involved. There is wisdom in the wisecrack, "In 80% of ailments, cure follows in seven days if an antibiotic is used and a week if it is not used."

The urge to bring the patient's temperature into the normal range prompts the use of the latest antibiotic. This antibiotic is likely to be the most expensive drug in the market. It is also intended for the treatment of infection by organisms resistant to the commonly used antibiotics. As the fever persists, this antibiotic is jettisoned and substituted by another "very powerful" antibiotic. Such rapid change of antibiotics is certain to generate resistance to new drugs in microorganisms.

The rational use of antibiotics, based on proven sensitivity of the causal organism in the laboratory, is often ignored on the ground that the patient is in a critical state and the infection must be controlled at once. Were this so, it would make sense to use an antibiotic to which most of the common pathogens encountered in that intensive care unit over the past week have been shown to be vulnerable. Unfortunately, few intensive care units regularly keep themselves up to date with this important information.

Purchase of equipment, drugs and consumables

We have several chains of private hospitals. The success of the first hospital in the chain – judged by the income generated – prompts the promoter to set up another hospital. Further success follows and in a few years, hospitals are set up in other cities.

The establishment of the chain of hospitals necessitates the purchase of several computerised tomography and magnetic resonance units, cardiac catheter units, radio-isotope scanners, sonography units, heart–lung machines, dialysis units, monitors, operation theatre lights, operation theatre and laboratory microscopes, endoscopy and other instruments.

These hospitals also make recurrent purchases of a large number of expensive items, such as stents, heart valves, arterial and venous catheters, drugs and intravenous fluids.

The chain sets up a centralised purchase agency, wholly owned by the promoter. Given the massive bargaining power of such an agency, it obtains significant discounts on all purchases. It then sells the purchased goods with a mark-up to each of the hospitals. The hospitals, in turn, add their margin of profit when billing the patient. The consequent increase in the promoter's income is considerable.

Patients wishing to purchase expensive drugs and other items from the manufacturer or retailer in the open market are often denied this opportunity to cut their costs. Generic drugs are frowned upon.

The purchase of expensive machines results in an escalation of the costs incurred by the patient in other ways. The clinician who demands a particular machine is under pressure to generate revenues from the use of that machine so as to recover the cost and make a profit. There is evidence of such pressure leading to the illogical use of machines. The use of a gamma knife machine to treat cancer with multiple metastases is an example.

Some institutions, such as the Sanjay Gandhi Postgraduate Institute in Lucknow, have implemented measures to reduce the costs that patients have to bear. The institute obtains drugs and other consumables at a considerable discount on the maximum retail price (MRP) (7). The discount can be as high as 60%. The institute adds 5% of the cost to the discounted purchase price to cover its service changes and passes on the rest of the discount to the patient. This results in a saving of anywhere between 30% and 55% of the MRP. This and similar measures need to be implemented in all our hospitals.

Waste

Given the extent of poverty in our country, it appears illogical to exclusively use disposable items. Almost all our hospitals have forgotten the age-old practices of cleaning certain instruments and articles after each use, and sterilising and re-using them. This used to be done in the case of glass syringes, metal needles, latex gloves, endotracheal tubes and even arterial catheters for angiography, with proven efficacy and without complications.

The twin principles of convenience and reduction in labour have overthrown the consideration of thrift and cost-saving for the patient. In the process, we generate huge volumes of waste, which is not always dealt with scientifically. Willy-nilly, there are unscrupulous individuals and groups who bring many "disposable" items into re-use, without bothering about cleaning and sterilisation. This is to the detriment of patients.

Paperless and filmless facilities must be used extensively. Computer terminals in all operation theatres, intensive care units, wards and outpatient services display, on command, the complete case record of a given patient, the laboratory and imaging findings, drugs being prescribed and other relevant data. Inter-departmental and administrative correspondence, notices, announcements and memoranda are transmitted similarly. The savings from these measures are considerable.

Another example of waste is the manner in which medical conferences are organised. In the past, medical colleges were the preferred venues for these conferences and provided rich fare for the intellect. Whilst gastric needs were not ignored, they were accorded second place. Inexpensive and simple business lunches were the order of the day. Postgraduate students and junior teachers could easily afford the registration fees for the conferences. Those who attended the meetings did so to learn. A respected teacher inaugurated the conference. The presence of pharmaceutical companies and manufacturers of instruments was felt only in the exhibition hall, where they displayed their wares in modest stalls. They did not intrude into the conference.

Conferences are now held in starred hotels. Lavish meals are the rule rather than the exception. Delegates cannot escape the all-pervasive presence of companies manufacturing drugs and instruments. Slides that advertise products are projected between successive talks. We are constantly being told which company has sponsored breakfast, lunch and dinner. At one meeting, the biscuits served at tea were embossed with the brand name of the drug being sold by the company paying for them. Senior consultants and their families are flown in and housed in starred hotels by the companies. They have chauffeured cars at their disposal all the time. Small wonder, then, that whilst the dining halls are crowded all the time, the lecture halls become progressively less peopled as one proceeds from the inauguration of the conference to the last day.

The conference is inaugurated by a powerful politician and the inauguration is often delayed till this "dignitary" arrives. The display of sycophancy by the senior conference officials when he arrives would sicken any thinking observer. Since up-and-coming doctors attend these meetings, the effects of the current mores on them can only further demean the professed goals of such conferences. They are quick to learn that to rise in the hierarchy of officialdom of societies or associations, it is necessary to cultivate those in power, and that commerce must dominate over academic excellence. The humble researcher is consigned to oblivion. It is the flashy star performer on whom they model themselves.

Research

Research is distinctly different from re-search. The creation of a new chemical that eliminates a disease is much more important than merely confirming that a drug tried and tested abroad is effective in India as well.

The annual sums disbursed by governmental grant-giving agencies, such as the Department of Biotechnology, Department of Science and Technology and Indian Council of Medical Research (ICMR), are huge (8). The Plan outlay for medical research in the Expenditure Budget for 2014 –2015 is Rs 726 crore (Union Budget 2014–2015) (9).

Pleas for retrospective studies of the cost-effectiveness of the many research studies sponsored by them have fallen on deaf years.

If one analyses each research project sanctioned by these large funding agencies on the basis of the following questionnaire, it will perhaps yield information that will help weed out the chaff and result in research that is both relevant and meaningful.

1. Names and affiliations of the principal researchers
2. Title of the project
3. Time from submission of the project proposal to approval and actual start of work
4. Summary of the aims and objectives of the project
5. How many of these aims and objectives were achieved
6. Reasons why the rest were not achieved
7. Whether the research resulted in one or more patents

8. If patents were obtained, what was the subsequent fallout in terms of:
    a. income to the funding agency
    b. income to the researchers
    c. commercial exploitation of the product in India thus far (give details)
    d. commercial exploitation of the product abroad (give details)
9. Publications on the project, with bibliographic references
10. Time within which the project was to be completed
11. Time taken to actually complete the project
12. In case of delay, reasons for overshooting the time
13. Cost of the project according to the initial project proposal
14. Actual cost of the completed project
15. Reasons for extra expenditure, if any
16. Feedback from the researchers on:
    a) whether they encountered any difficulties in getting their project proposal approved
    b) whether they encountered any difficulties in getting their funds at the start of each financial year
    c) whether their communications to the ICMR were dealt with promptly and efficiently
    d) whether they encountered any difficulties in patenting
    e) whether they encountered any difficulty in getting their patented product into commercial production through a third party on the payment of royalties
    f) whether they are satisfied with the returns from such commercial exploitation
    g) any other observations they might like to make
17. Report of those monitoring the scientific and social aspects of the project from its commencement to its conclusion

Well-meaning but poor diktats

Owing to lack of monitoring and poor standards, a variety of practices were being followed earlier in the various hospitals and clinics. Many private hospitals and clinics made high investments in expensive equipment and gadgets, and then tried to recover their costs and make a profit at the expense of patients. In many instances, patients paid for unnecessary tests and treatments. In order to circumvent this, the Government of India decided on an accreditation policy and formed The National Accreditation Board for Hospitals and Healthcare Providers (NABH).

NABH issues dictats that must be complied with before it recognises a hospital. Private hospitals are especially keen on recognition by NABH so as to attract a larger number of patients.

The Board appears to have followed practices in vogue in western countries, regardless of their relevance in our country and overlooking our own experiences over the decades. One of the consequences of this is that some of the diktats are harmful. Let me give you two examples.

1. In the neurosurgery operation theatre at the King Edward Memorial Hospital in Mumbai, since 1957, preoperative scrubbing of the scalp and skin over the spine was being done using ether, tincture iodine and methylated spirit. Similar practices were being followed all over the country.

Ether was used principally to get rid of the greasy accumulation of sebum and particulate matter. It also took away the remnants of the dense rubber or polymer zinc paste left behind by elastic adhesive tape.

Tincture iodine was applied and allowed to dry, ensuring that there was adequate time for its antiseptic action to take place.

Spirit was used to wash away the iodine and leave behind unstained skin. The incidence of infection following such scrubbing was gratifyingly low.

These three cleansing agents have been abolished from the hospital at the instance of NABH (unpublished hospital rulings based on undeclared instructions from NABH). We are now expected to use "Betascrub" and "Betadine" for preoperative preparation of the skin. These are proprietary items and are expensive. The cost of scrubbing patients is now much higher than it was with our old and effective methods. When patients scrubbed with "Betascrub" and "Betadine" return to the ward, their relatives are alarmed by the dark brown stains on their pillowcases and bed sheets – a consequence of the iodine preparations not having been washed off. Those wishing to use methylated spirit are instead asked to use "Sterilium" or other handwash / handrub preparations, which are much more expensive.

2. A few decades ago, we were fortunate to have the eminent German neurosurgeon, Professor H.W. Pia, and his equally illustrious colleague, Dr Ernst Grote, visit neurosurgery centres in New Delhi, Kolkata and Mumbai to conduct workshops on microneurosurgery. The conventional practice was to cover the unsterile microscope with a sterile disposable plastic cover, which had a plain glass window to be placed over the objective lens. The disposable cover, which was not available in India at that time, was expensive The more important objection to its use was the fact that if it got torn accidentally during use, the microscope could not be used till another such cover was found to replace the damaged one. Finally, the cover restricted the mobility of the unencumbered microscope.

Drs Pia and Grote used relatively inexpensive formaldehyde tablets to sterilise the microscope. These were placed for 12 hours in a plastic bag that enveloped the entire microscope. Microbiology studies carried out following such sterilisation repeatedly showed that no organisms were present on the microscope. The plastic bag was removed carefully, such that no part of its outer surface touched the microscope. The bag was re-used. The sterile microscope could be used freely.

We are now told to discard the tablets and use the expensive disposable cover instead. While the tablets needed to sterilise the microscope cost less than Rs 10, the disposable cover costs around Rs 500!

By using such covers, we are raising costs, augmenting the quantity of plastic waste, using an inferior method of sterilisation, and handicapping the surgeon by making the instrument clumsy to use.

Jettisoning the principles of medical ethics

This is a major factor which has adversely affected the cost-effectiveness of medical care over the past few decades. You must have noted that the preceding pages contain several examples of practices that do not stand up to scrutiny if one considers the principles of medical ethics.

Had we been faithful to ethical principles, medical practice in India would have been truly beneficial to patients. Why have so many of us strayed from the straight and narrow path?

The teaching of medical ethics appears to have fallen by the wayside. When teaching courses on ethics at teaching institutes all over India, we are confronted by a common question: "Why is it that the topics discussed in this course have never featured during our entire undergraduate and postgraduate training?"

There are few teachers who can inspire impressionable medical students and young residents. Our youngsters are no fools. They are able to distinguish between the pious verbal outpourings of their seniors and the practices they follow to extract the last rupee from each patient and glorify themselves. Preaching the virtues of courtesy and holding discourses on the rights of patients are followed by rude and rough treatment of the poor patient, and fawning over the rich and powerful. The fact that there are teachers who force their juniors to include their names as the first author of papers for publication when they have done none of the work indicates that "positional" might is right. The influence of example is greater than that of precept.

The mushrooming of private, for-profit medical colleges and hospitals has worsened the situation.

Improving efficacy

The steps suggested so far will, in themselves, ease the burden on patients. Improving efficacy will help in other ways.

Here are some suggestions based on the existing practices in some of our institutions.

1. The late Mr Nani Palkhivala described Sankara Nethralaya in Chennai as "the best managed charitable organisation in India". Its practices are worthy of emulation by other institutions (10).

   Patients are attended to personally from the time of their arrival at the outpatient clinic. When it is necessary for the patient to move from one room to another for consultation, tests, minor procedures or the completion of formalities before admission to the hospital, the patient is personally guided by a staff member of the hospital. He/she need not fumble, search or ask for help. This facility is extended to the poorest patient and there is no cost involved.
2. The patient's level of comfort is enhanced in simple ways. For example, care is taken to reduce the noise level in all areas of the hospital. Maintaining a garden with flowers, shrubs and trees can be very effective in raising the patient's morale.
3. Some Indian hospitals have already started using computer-generated prescriptions, which have several advantages. The computer programme has a feature which ensures that the generic form of the drug is mentioned, the drug interactions are highlighted and the proper dosage has been prescribed. Directions on how and when each drug is to be taken are printed. Illegible handwriting is of no consequence now!
4. Another standard feature at some of our better hospitals is the provision of detailed, printed discharge summaries. These contain a brief description of the clinical features of the case, the results of the tests carried out, diagnosis, findings, procedure at surgery, postoperative recovery, and measures (including drug therapy) advised at discharge.
5. Transparency in all interactions between patients, doctors and the hospital administration (especially its accounts department) helps to raise the morale of the patient and keeps all the staff members in the hospital on their toes. There must be a similar transparency in all the financial dealings of the institution.
6. The establishment of a redressal forum in each hospital would increase the patients' and relatives' confidence in the hospital's staff. The forum must receive all complaints and grievances in writing. In the case of illiterate patients, a scribe may be engaged to first note down the grievances and then read aloud what he/she has recorded. Each complaint or grievance must be recorded in a register and deliberated upon by a committee consisting not only of hospital staff members and administrators, but also a social worker and reputed lay person (perhaps a retired editor or judge). The patient or a representative nominated by the patient must be invited to attend each hearing. The person against whom the complaint has been made and his immediate supervisor must be present at the hearing to answer queries that may be posed by the patient or committee members. The final judgment of the committee and corrective step(s), if any, must be conveyed to the patient in writing. A follow-up study on the implementation of the corrective step(s) must form part of the committee's records.

Closing thoughts

It is high time that corrective steps were taken to improve medical care and reduce costs. Focusing at all times on the welfare of the patient, and providing medical care that is humane, considerate and of the highest quality at the minimum cost, are ideals to cherish and strive for. Every

Indian has the right to be provided with the means for the maintenance of health and the treatment of disease. Universal access to healthcare has long been talked about in our country, but precious little has been done to make it a reality for the vast majority of our population.

A market-driven economy is best left in the market place. It has no place in the healing of the sick and the care of the ill. We must certainly not tolerate any move that smacks of profiteering.

The Mahatma's words, in a slightly modified form, can still serve as an excellent guide for us (11):

> *Recall the face of the poorest and the weakest patient whom you may have seen and ask yourself if the step you contemplate is going to be of any use to him.*

When we apply this test to modern medical care, pride is replaced by humility and a sense of dismay. There is so much to be done for the poorest and the weakest. Are our best minds and finest medical organisations equal to this task? Have they started work on it? Do they even consider this task worthy of them?

A paraphrased passage from the writing of the noted American author, Ms Ursula K Le Guin, is also relevant:

> *The profit motive is often in conflict with the aims of medicine.*
>
> *We live in an age of capitalism, its power seems inescapable - but then, so did the divine right of kings.*
>
> *Any human power can be resisted and changed by human beings* (12).

All that is needed is the will to change for the better.

Acknowledgements

I am grateful to Dr. Sanjay Mehendale, Director, ICMR National Institute of Epidemiology, Chennai, for his prompt response to my request for review of my essay and the many helpful suggestions he made for its improvement.

I am also obliged to the two anonymous reviewers who have helped me improve the paper. I have incorporated their valuable suggestions in my revised text.

References

1. Withering W: *An account of the foxglove and some of its medical uses: with practical remarks on dropsy and other diseases*. Birmingham, UK: M. Sweeny; 1785.
2. *Webster's New World College Dictionary*. Date unknown [cited 2015 Feb 24]. Available from: http://www.merriam-webster.com/dictionary/cost-effective
3. The Osler Symposia. About Sir William Osler and his inspirational words. Date unknown [cited 2015 Feb 24]. Available from: http://www.oslersymposia.org/about-Sir-William-Osler.html
4. Shoulson I. In memoriam: Robert J. Joynt, MD, PhD (1925–2012). *JAMA Neurology* [Internet]. 2012 Nov [cited 2015 Feb 24]:69 (11);:1518–9. doi:10.1001/archneurol.2012.2265. Available from: http://archneur.jamanetwork.com/article.aspx?articleid=1389840
5. Yeh C. 'Nothing is broken': for an injured doctor, quality-focused care misses the mark. *Health Aff (Millwood)*. 2014 Jun;33(6):1094–7. doi: 10.1377/hlthaff.2013.0855.
6. Jha S. Stop hunting for zebras in Texas: end the diagnostic culture of "rule out". *BMJ*. 2014 Apr 7;348:g2625. doi: 10.1136/bmj.g2625.
7. Pandya SK. Personal observation during visit to the Sanjay Gandhi Postgraduate Institute of Medical Sciences on December 14, 2014.
8. Department of Science and Technology, Government of India. *Annual Report 2013–14*. New Delhi: Ministry of Science and Technology, Government of India. Figure 1.2, p 217.
9. Union Budget, Government of India. *Expenditure Budget 2014–2015. Volume 1, Part III – Plan Outlay 2014–15*. p 39. Available from: http://indiabudget.nic.in/ub2014-15/eb/po.pdf
10. Sankara Nethralaya: a mission for vision. Sankara Nethralaya triggers interest in high places. 2012 Feb 14[cited 2015 Feb 24]. Available from: http://omlog.org/2012/02/sankara-nethralaya-triggers-interest-in-high-places.html
11. Gandhi International Institute for Peace. Essential quotes of Mahatma Gandhi [Internet] 2012[cited 2015 Feb 24]. Available from: http://www.gandhianpeace.com/quotes.html
12. Le Guin UK. Ursula K Le Guin's speech at National Book Awards: 'Books aren't just commodities' November 20, 2014[cited 2015 Feb 24]. Available from: http://www.theguardian.com/books/2014/nov/20/ursula-k-le-guin-national-book-awards-speech

World Association of Medical Editors (WAME) Conference

The World Association of Medical Editors (WAME, pronounced Whammy) came into existence 25 years ago. One of the key features of this organisation was its virtual nature with communication and interaction mainly by email. However, once in four years, the members attending the Peer Review Congress would participate in a WAME business meeting on the sidelines of the Congress. At the last WAME strategy meeting (the third since its inception), it was felt that the organisation having grown, an international conference for its members should be organised in 2015. This meeting will be held from October 2 to 4, 2015, at New Delhi. For further information please write to: india.editors@gmail.com or visit the website: http://www.wame.org/

EDITORIALS

The functioning of the Medical Council of India analysed by the Parliamentary Standing Committee of Health and Family Welfare

SUNIL K PANDYA

On March 8, 2016, the 92nd report on the functioning of the Medical Council of India (MCI) (1) was placed before both Houses of Parliament by Professor Ram Gopal Yadav, Chairman of the Parliamentary Standing Committee of Health and Family Welfare.

The committee examined the role and functioning of the MCI and obtained a background note on it from the Ministry of Health and Family Welfare, Government of India. The Ministry informed the Parliamentary Committee that it had set up a group of experts to study the Indian Medical Act of 1956, had obtained its report in February 2015 but that it "was under consideration of the Ministry". There is no explanation of why it took the Ministry over a year to complete its "consideration" and make changes for the better.

The committee noted that primary health care centres showed a worsening of vacant positions of doctors. Dr Devi Shetty, former member of the Board of Governors of the MCI stated, "I am not really that concerned about medical education but I am very concerned about the impact it has on the lives of common people…"(1:11) He did not find the effect of substandard medical education on these very common people important.

The representative of the Indian Medical Association made some astounding statements. Here is an example: "In India even a general practitioner sees 500-1000 patients daily."(1: p13) The unspoken assertion about the number of patients seen by individual specialists would then be truly mindboggling. Since an average doctor works for eight hours on each of six days, the available time is 2,880 minutes. Even at 500 patients, the time per patient is about 6 minutes. This time is barely adequate to obtain a cursory history, leave alone examine the patient!

The representative of the MCI could not tell the Parliamentary Committee the number of doctors registered with it who were actually practising in India and how many had emigrated. It merely stated that the process to collect such data had been undertaken. The Parliamentary Committee concluded in bold letters: "**the Indian Medical Register is not a live database and contains names of doctors who may have passed away or retired from active practice, by now, as well as those with a permanent address outside India and that there is no mechanism in place for filtering out such cases… the MCI has been unresponsive to health system needs** (of the country)… **"** (1: p 85)

The Parliamentary Committee noted that the MCI has 102 members of whom 35 are nominated and 67 elected and that central and state governments have nominated doctors from corporate private hospitals to represent themselves in the current MCI. Currently, there are 412 medical colleges in the country of which 217 (53%) are from the private sector. This is a damning statement in a country committed to "health for all" and in which the vast majority cannot afford private education and healthcare. The Parliamentary Committee recorded expert opinion that "MCI as presently elected has been mired in multiple controversies and corruption and what is of greater concern is it has failed to address the needs of the health system in the country. The MCI as presently constituted is not accountable or transparent in its functioning."

In its conclusions to this section of the report, the Parliamentary Committee once again notes in bold print: "…**The Medical Council of India, when tested on the above touchstone, has repeatedly been found short of fulfilling its mandated responsibilities…the MCI, as presently elected, neither represents professional excellence nor its ethos. The current composition of the Council reflects that more than half of the members are either from corporate hospitals or in private practice. The Committee is surprised to note that even doctors nominated under Sections 3(1) (a) and 3(1) (e) to represent the State Governments and the Central Government have been nominated from corporate private hospitals which are**

Author: Department of Neurosurgery, **Jaslok Hospital and Research Centre**, 15, Deshmukh Marg, Mumbai 400 026 INDIA – Sunil K Pandya (shunil3@gmail.com), Neurosurgeon.

To cite: Pandya SK. The functioning of the Medical Council of India analysed by the Parliamentary Standing Committee of Health and Family Welfare. *Indian J Med Ethics*. 2016 Apr-Jun; 1(2) NS: 68-71.

not only highly commercialised and provide care at exorbitant cost but have also been found to be violating value frameworks…the current composition of the MCI is biased against larger public health goals and public interest…**"**(1:p 87-8)

As regards the constitution of the MCI, the Parliamentary Committee made this recommendation: "**The Committee, accordingly, recommends that the regulatory framework of medical education and practice should be comprised of professionals of the highest standards of repute and integrity, appointed through a rigorous and independent selection process. This process must be transparent…Committee is of the considered view that the composition of the MCI is opaque and skewed and diversity needs to be brought into this because having only medical doctors in the Council is not an enabling factor for ensuring reforms in medical education and practice… "** (1: p 89)

The Parliamentary Committee advocated opening membership of the MCI to public health experts, social scientists, health economists, health NGOs, legal experts, quality assurance experts and patient advocacy groups. There is an urgent need to restructure the composition of MCI. The Parliamentary Committee agreed with the recommendation of the Roy Choudhary Committee that no member of the MCI can hold this office for more than two terms.

Among other topics, the Parliamentary Committee's report considered

Capitation fee and common entry examinations: It recommended a national common entrance test and a common exit test for all medical colleges, including those charging capitation fees to ensure that the quality and competence of every doctor is guaranteed and standardised.

Fees charged by private medical colleges: The Parliamentary Committee recommended uniformity of fees across the country among the public and private sector medical colleges, with strict enforcement of the fee structure.

Postgraduate medical education: "The present MCI system of oversight of PG medical education does not at any stage evaluate the teaching and learning process or have any benchmarks for quality… The Committee is, therefore, convinced that an overhaul of the whole system is required, and accordingly, recommends that the PG medical education system should be restructured in such a way that training is assessed by the quality of the product and not by the infrastructure and a robust system be put in place for evaluation of skills and competencies."

Merger of DNB and MD/MS programmes: Deploring the two parallel systems of postgraduate certification (University and NBE), the committee recommended that the current system of PG medical education should be restructured taking the best of both systems that is, all India common entrance exam for all seats and common exit evaluation for all candidates as practiced by DNB and the training and evaluation processes of the university based system into one national qualification. There should be only one regulatory body for postgraduate medical education and the training should be made more robust.

Chapter IX deals with regulation of professional conduct of doctors. I reproduce the Parliamentary Committee's recommendations in bold (as in the original document):

"The Committee observes that the oversight of professional conduct is the most important function of the MCI. However, the MCI has been completely passive on the ethics dimension which is evident from the fact that between 1963–2009, just 109 doctors have been blacklisted by the Ethics Committee of the MCI… Due to crass commercialization of the health sector, many unprincipled doctors and private sector hospitals have lost their moral compass and overcharge or subject their hapless patients to unnecessary surgeries and diagnostic procedures. The instance of unethical practice continues to grow due to which respect for the profession has dwindled and distrust replaced the high status the doctor once enjoyed in society. What is of greater concern to the Committee is that the medical profession has not been transparent in dealing with complaints. It is a matter of surprise that despite the worst kind of gross unethical practices happening by way of ghost faculty, fake patients and hired instruments and substantial amount of money (not white, of course) reportedly changing hands at the time of inspections, there is little proactive action on the part of the MCI to deal with this malady…" (1: p 102)

"The Committee notes that the Ethics Committee of the MCI presently consists entirely of medical doctors and is thus a self-regulatory body. But all over the world, it has now been realized that the medical profession (or any profession for that matter) tends to protect its own flock. The Committee, therefore, recommends that the new Board of Medical Ethics should also have non-doctor lay members from different fields…

"The Committee, therefore, recommends that the new Board of Medical Ethics should be mandated to develop standards and norms of professional conduct and codes of ethics for medical practice not only for individual doctors, but also for institutions of health service delivery, i.e., hospitals, clinics, nursing homes, rehabilitation centres, associations…" (1: p 103)

"The Committee is astonished to note that the MCI has notified on 1st February, 2016 an amendment to clause 6.8 of the Regulations, deleting the words 'and professional association of doctors' and exempt professional association of doctors from the ambit of MCI Code of Ethics Regulations, 2002. The Committee observes that exempting professional association of doctors from the ambit of Ethics Regulations is nothing short of legitimizing doctors' associations indulging in unethical and corrupt practices by way of receiving gifts in cash or kind under any pretext from the pharma industry or allied health industry. The Committee agrees with the view point of public health activists that 'an action that is ethically impermissible for an individual doctor cannot become permissible if a group of doctors carry out the same action in the name of an association.' The Committee could not uncover any rational reason as to why the MCI has taken such a retrograde decision. It seems that the MCI has become captive to private commercial interests, rather than its integrity in public interest…" (1: p104)

"The Committee also finds it intriguing that instead of intervening to thwart attempt of MCI at subverting the system, the Ministry has meekly surrendered to MCI…"(1: p105)

Chapter XII discusses corruption in the MCI. The Parliamentary Committee noted, "On being asked about the kinds of corruption that is happening in the MCI, <u>the President, MCI during evidence before the Committee admitted that corruption was there when there was sanctioning of medical colleges, or increasing or decreasing seats</u> (emphasis added). The Committee has also been informed that the private medical colleges arrange ghost faculty and patients during inspections by MCI and no action is taken for the irregularity. The Committee has also been given to understand that MCI is proactive in taking action on flimsy grounds against Government Medical Colleges which are 100% better…"(1: p 75)

"On being asked about the steps taken by the Ministry to tackle corruption in the MCI which has been there for the past 20–25 years, the Health Secretary during evidence submitted that the entire IMC act was under review. He also informed that the MCI Act as it exists today does not empower the Government to take action even in proven corruption charges. However, in the IMC (Amendment) Bill 2013, there is a provision that if there are proven charges then the Member can be removed. Such a provision was in the 2010 Ordinance also during the Board of Governor's time…"(1: p 75)

In its conclusions to this chapter, the Committee notes in bold print: "**The Committee is shocked to find that compromised individuals have been able to make it to the MCI, but the Ministry is not empowered to remove or sanction a Member of the Council even if he has been proved corrupt. In a day and age when the need for sturdy systems and enhanced transparency based regimes are being increasingly emphasized, such state of affairs indicate that the MCI has not evolved with the times. Such state of affairs are also symptomatic of the rot within and point to a deep systemic malice. Otherwise how could it happen that the MCI, which has laid down elaborate duties and responsibilities of the 'Physician' under the MCI Code of Ethics Regulations, 2002, could have at its very top a person who was arrested on charges of corruption in 2010. The former Union Health Minister, who must have an insider's view of the functioning of the MCI, making scathing comments about corruption in the MCI, speaks volumes of the decay in the MCI and is an eye-opener on the need for urgent reforms in the structure and functioning of MCI…"**(1: p 76)

Discussing the autonomy of the MCI and the government claim that it cannot remove a corrupt member, the Parliamentary Committee reiterated in bold print: "**The Committee is all for professional autonomy, but autonomy sans accountability tends to degenerate into autocracy and therefore cannot be acceptable. The MCI is funded by the Government and therefore the Government must have the leverage to enforce accountability in the MCI. Since the real cause of the problem is systemic and cannot be fixed without setting the system right, the Committee recommends that the Ministry should take expeditious action to amend the statute or enact a new legislation in a manner that it comprises within its ambit accountability provisions as well and empowers the Government with legal authority to intervene in matters of corruption…"** (1: p 77)

"The Committee takes note of the admission of the President of MCI that corruption is there when there is sanctioning of medical colleges or increasing or decreasing of medical seats. However, the Committee finds the inaction of the MCI enigmatic in this matter. If the MCI is aware of the fact that denial of recognition of a medical college or grant of seats and then its permission/enhancement or reduction leads to corruption, then the Committee wonders why it has failed to put in place a framework or system which can plug these loopholes…" (1: p 77)

"The Committee wonders to find that certain persons were appointed as Advisors to the President in transgression of law and the Joint Secretary in the Ministry of Health and Family Welfare vide his letter dated the 4th March, 2014 had to write to the President to cancel 'all such appointments which were not authorized by the Act.' The Committee takes serious note of such flouting of law and would like the matter to be thoroughly probed and an action taken report furnished to the Committee within three months from the presentation of this Report."(1: p 77-8)

In its summary the Parliamentary Committee finds fault with the government and the MCI.

"**Due to massive failures of the MCI and lack of initiatives on the part of the Government in unleashing reforms, there is total system failure due to which the medical education system is fast sliding downwards and quality has been hugely side-lined in the context of increasing commercialization of medical education and practice. The situation has gone far beyond the point where incremental tweaking of the existing system or piecemeal approach can give the contemplated dividends…"**(1: p 82)

The Parliamentary Committee has performed a difficult task commendably. Its recommendations are reasoned and rational. Their implementation should go a long way in cleaning the Augean stable that the MCI currently represents.

Is optimism justified?

Alas! I have my reservations. Recommendations of earlier committees, when found unpalatable by the government or when conflicting with vested interests of those in power have been rendered ineffective by the simple measures of either shelving them or, worse, referring them to yet another committee for study and recommendations.

A government that could transfer Mr Keshav Desiraju in order to facilitate Dr Ketan Desai's entry into the MCI through the backdoor of a recommendation by a pliant university in Ahmedabad, and which could accept the replacement of Dr Ketan Desai by someone else from the same state does not generate confidence.

I sincerely hope I am wrong and that these recommendations will be implemented *in toto*.

Reference

1. Department-related Parliamentary Standing Committee on Health and Family Welfare. 92nd report on the functioning of Medical Council of India. New Delhi: MoHFW; 2016 Mar 8 [cited 2016 April 8]. Available from: http://twofourinsight.com/wp-content/uploads/2016/03/20160308-RAJYA-SABH....

The Chennai floods of 2015 and the health system response

RAKHAL GAITONDE, VIJAYAPRASAD GOPICHANDRAN

Introduction

The Chennai floods of 2015 were a calamity of unexpected proportions(1).The impact on the lives of the poor has been immense. Thousands needed to abandon their already precarious dwellings on the banks of the Adyar River, and other low-lying areas for temporary shelters. The differential experience and impact of disasters on different segments of the population helps understand the dynamics of sociopolitical structures and supports.

The disaster was recognised as being largely manmade. It has been reported that one of the important water reservoirs of Chennai, the Chembarambakkam reservoir was opened up during incessant rains without adequate warning,which contributed to the massive deluge(2). Unplanned urban development, illegal constructions, and corrupt practices of permitting development projects without environmental impact assessment have all also contributed to the making of this disaster. There is an urgent need to envisage a role for the health system (as part of all other public systems) towards a more sustainable and resilient future.

This editorial focuses on the health system response to the Chennai floods. It takes anecdotes and experiences of the authors and others whom the authors have worked with during the floods and tries to analyse the successes and drawbacks of the health system response. It argues the case for an effective and responsive health system, which is highlighted in the face of disasters as an ethical imperative.

Ethical framework of analysis

Public health systems have an ethical obligation to protect and promote the health of populations and minimise health risks through equitable, transparent, responsive, proportional, accountable and sustainable actions. However, in the recent Chennai

Authors: **Centre for Technology and Policy, IIT-Madras**, No. 1, Kanagam Road,Taramani, Chennai, Tamil Nadu 600 113, INDIA–Rakhal Gaitonde (rakhal.gaitonde@gmail.com) Senior Scientist; **ESIC Medical College and PGIMSR,** KK Nagar, Chennai, Tamil Nadu 600 078, INDIA –Vijayaprasad Gopichandran(corresponding author –vijay.gopichandran@gmail.com) Assistant Professor, Department of Community Medicine.

To cite: Gaitonde R, Gopichandran V. The Chennai floods of 2015 and the health system response. *Indian J Med Ethics*. 2016 Apr-Jun;1(2) NS: 71-5.

indiatimes.com/life-style/health-fitness/health-news/Swine-flu-dengue-now-notifiable-diseases/articleshow/50768699.cms

4. Swine flu: Epidemic Disease Act invoked. *The Indian Express* [Internet]. 2009 Aug 12 [cited 2016 Feb 16]. Available from: http://archive.indianexpress.com/news/swine-flu-epidemic-disease-act-invoked/501041/
5. The Epidemic Disease Act of 1897. Act No 3 of 1897 [cited 2016 Feb 14]. Available from: http://mohfw.nic.in/showfile.php?lid=1835
6. Biswas AK. Swine flu and Indian strategy to combat the menace. *Mainstream Weekly.* 2009;XLVII (28). Available from: http://www.mainstreamweekly.net/article1477.html
7. Arnold D. Science, technology and medicine in colonial India. United Kingdom: Cambridge University Press; 2000: p143.
8. Echenberg M. Plague ports: the global urban impact of Bubonic plague, 1894–1901. London: New York University Press; 2007: p 58.
9. Government of India, Ministry of Health and Family Welfare. Order Notification of TB cases [Internet]. New Delhi: MoHFW; 2012 May 7[cited 2016 Feb 14]. Available from: http://www.tbcindia.nic.in/pdfs/TB%20Notification%20Govt%20%20Order%20dated%2007%2005%202012.pdf
10. Gawde NC. Do we need notification of tuberculosis? A public health perspective. *Indian J Med Ethics*. 2013;10(1):56–8 [cited 2016 Feb 19]. Available from: http://www.issuesinmedicalethics.org/index.php/ijme/article/view/80/2617
11. Integrated Disease Surveillance Project. New Delhi: Ministry of Health and Family Welfare, Government of India [cited 2016 Feb 16]. Available from: http://www.idsp.nic.in/
12. Rakesh PS. Public private partnership for communicable disease surveillance and control. Paper presented at AKGC 2015. Proceedings of the Fourth International Congress on Kerala studies, Thiruvananthapuram, India. Health; 2015 May 23 [cited 2016 May 16]. Available from: http://akgcentre.in/Districtseminar/sites/default/files/Attachment/14%20Dr%20Rakesh%20PS.pdf
13. John TJ, Samuel R, Balraj V, John R. Disease surveillance at district level: a model for developing countries. *Lancet*. 1998;352(9121):58–61.
14. John TJ, Rajappan K, Arjunan KK. Communicable diseases monitored by disease surveillance in Kottayam district, Kerala state, India. *Indian J Med Res.* 2004;120(2):86–93.
15. Kakkar M, Hazarika S, Zodpey S, Reddy KS. Influenza pandemic preparedness and response: a review of legal frameworks in India. *Indian J Public Health.* 2010;54(1):11–7. doi: 10.4103/0019-557X.70539.
16. Patro BK, Tripathy JP, Kashyap R. Epidemic diseases act 1897, India: whether sufficient to address the current challenges? *J Mahatma Gandhi Inst Med Sci.* 2013;18:109–11.
17. National Health Bill. Working draft. Version Jan 2009 [cited 2016 Feb 18]. Available from: http://www.prsindia.org/uploads/media/Draft_National_Bill.pdf
18. National Disaster Management Act 2005 [Internet][cited 2016 Feb 19]. Available from: http:// www.ndmindia.nic.in/acts-rules/DisasterManagementAct2005.pdf
19. New Mexico public health law handbook. Civil Proceedings Involving State Public Health Powers. Protections for a Person Isolated or Quarantined (Section 12-10A.-8.B., NMSA 1978) [cited 2016 May 16]. Available from: http://jec.unm.edu/manuals-resources/manuals/New Mexico Public Health Law Handbook.pdf
20. Telecom Regulatory Authority of India (homepage on Internet)] [cited 2016 Feb 19]. Available from: http://www.trai.gov.in/

Guidelines for stem cell science and clinical translation

SUNIL K PANDYA

The International Society for Stem Cell Research has released its updated guidelines for stem cell research in order to provide "assurance that stem cell research is conducted with scientific and ethical integrity and that new therapies are evidence-based." The guidelines were updated by a Guidelines Update Task Force consisting of twenty-five scientists, ethicists and experts in healthcare policy from nine countries. The chairpersons of this task force are Jonathan Kimmelman, George Daley and Insoo Hyun. There is no representative from India, the only person of Indian origin on it, Mahendra Rao, represents The New York Stem Cell Foundation.

A study of these guidelines shows us how unscientific and unsupervised the usage of stem cells in clinical practice is in India. We desperately need immediate corrective action with implementation of these or similar guidelines and strict and severe punishment of all those flouting them. The full force of government and judiciary must back the application of these guidelines.

Author: Department of Neurosurgery, **Jaslok Hospital and Research Centre,** 15, Deshmukh Marg, Mumbai 400 026 INDIA – Sunil K Pandya (shunil3@gmail.com), Neurosurgeon.

To cite: Pandya SK. Guidelines for stem cell science and clinical translation. *Indian J Med Ethics*. 2016 Jul-Sep:1(3)NS:160-1.

The lack of such guidelines is luring innumerable patients and their families to questionable, unscientific and unethical practices, usually at great cost and at times to their financial ruin, without any proven benefit.

The very first section of the guidelines deals with *Fundamental ethical principles*. It defines the primary goals of stem cell research as the advancement of scientific understanding and the generation of evidence for addressing unmet medical and public health needs. "**This research should be overseen by qualified investigators and coordinated in a manner that maintains public confidence…Key processes for maintaining the integrity of the research enterprise include those for independent peer review and oversight, replication and accountability at each stage of research."** (Emphasis added)(1: p 3).

This section also emphasises the primacy of patient welfare. "Physicians and physician-researchers owe their primary duty to the patient and/or research subject… Application of stem-cell based interventions outside of formal research settings should be evidence-based, subject to independent expert review and serve patients' best interests. It is a breach of professional medical ethics to market and provide stem cell-based interventions to a large patient population prior to rigorous and independent review of safety and efficacy."(1: p 4).

On transparency, the guidelines insist that researchers "should convey the scientific state of the art, including uncertainty about the safety, reliability or efficacy of potential applications."(1: p 4).

Discussing social justice, the guidelines emphasise that "costs of proving the safety and efficacy of a medical intervention be borne by entities that are expressly privileged to profit when such entities are marketed. Where cell-based interventions are introduced into clinical application, their use should be linked to robust evidence development."(1: p 4)

Section 2 deals with laboratory-based research including the use of tissues obtained from embryos.

Section 3, *Clinical translation of stem cells*, reiterates principles enunciated in Section 1. "In most countries and jurisdictions, the use of cellular products for medical therapy is regulated by governmental agencies to ensure the protection of patients…"(1: p 18). It emphasises the risks attending even minimal manipulation of cells outside the human body. Discussions on sourcing of stem cells, manufacture of cellular derivatives, preclinical studies precede general considerations. The need for rigorous demonstration of safety and efficacy in preclinical studies is emphasised. "More stringent design and reporting standards should be demanded where planned trials involve human research subjects with less advanced disease, when invasive delivery approaches are anticipated or, where the cell product presents greater risk and uncertainty."(1: p 23).

The need for assessing the risks for tumorigenicity, detailed and sensitive biodistribution studies of cells and addressing long-term risks is highlighted. Compelling preclinical evidence in well-designed studies must precede any clinical trial, small and large animals being used where necessary, the latter being preferred.

"**Sponsors, researchers and clinical investigators should publish preclinical studies in full and in ways that enable an independent observer to interpret the strength of the evidence supporting the conclusions…**" (1: p 28). **"All studies involving clinical application of stem-cell based interventions must be subject to prospective review, approval and ongoing monitoring by independent human subjects review committees"** (1: p 29). **"Researchers should promptly publish aggregate results regardless of whether they are positive, negative or inconclusive. Studies must be published in full and according to the international reporting guidelines."** (1: p 38) (Emphasis in original text).

The warning, reproduced in full below, is especially relevant to India:

"WARNING ON THE MARKETING OF UNPROVEN STEM CELL-BASED INTERVENTIONS: The ISSCR condemns the administration of unproven stem cell-based interventions outside of the context of clinical research or medical innovation compliant with the guidelines in this document and relevant laws, particularly when it is performed as a business activity. Scientists and clinicians should not participate in such activities as a matter of professional ethics. For the vast majority of medical conditions for which putative "stem cell therapies" are currently being marketed, there is insufficient evidence of safety and efficacy to justify routine or commercial use. Serious adverse events subsequent to such procedures have been reported and the long-term safety of most stem cell-based interventions remains undetermined. The premature commercialization of unproven stem cell treatments, and other cell-based interventions inaccurately marketed as containing or acting on stem cells, not only puts patients at risk but also represents one of the most serious threats to the stem cell research community, as it may jeopardize the reputation of the field and cause confusion about the actual state of scientific and clinical development. Government authorities and professional organizations are strongly encouraged to establish and strictly enforce regulations governing the introduction of stem cell-based medical interventions into commercial use." (1: p 39).

A study of the "research" on and clinical usage of stem cells at each of the many stem cell centres in India using the criteria laid down in these guidelines will yield very useful data, much of it eye-opening. We lack legal notification of our regulatory authorities for stem-cell research and clinical usage. Agencies currently monitoring and funding medical research in India lack the power and the ability to investigate wrong-doing, much less punish and discipline wrong-doers.

A detailed study of this important document by those in power in government, our research agencies and organisations and by every clinician likely to consider the use of stem cells in any form is mandatory.

Reference

1. ISSCR Guidelines Updates Task Force, International Society for Stem Cell Research. Guidelines for stem cell science and clinical translation. ISSCR; 2016 May 12 [cited 2016 May 21]. Available from: http://www.isscr.org/docs/default-source/guidelines/isscr-guidelines-for-stem-cell-science-and-clinical-translation.pdf?sfvrsn=2

Indian Journal of Medical Ethics Vol III No 1 January-March 2018

Henry Molaison's operation for epilepsy: a case study in medical ethics

SUNIL K PANDYA

Abstract

Dr William Beecher Scoville, an eminent American neurosurgeon of the 1940s, offered to treat Mr Molaison for his intractable epilepsy. During the operation, he removed large portions of both of Mr. Molaison's temporal lobes. Such an operation had never been performed earlier as the function of these parts of the brain was not clearly understood and neurosurgeons such as Dr. Wilder Penfield of Canada feared they could cause grave damage to the patient.

Mr Molaison developed severe loss of memory to the extent that a few minutes after meeting someone, he had no recollection of the meeting and he could not find his way to his own home.

Mr Dittrich, grandson of Dr. Scoville, has analysed the operation on Mr. Molaison's brain against the background of neurosurgery in the 1940s. This essay discusses the ethical aspects of Dr. Scoville's operation in the light of current understanding and practice.

Introduction

Mr Luke Dittrich, grandson of Dr Scoville, an eminent American neurosurgeon, has written a comprehensive book on the life of Mr Henry Molaison (1), Dr Scoville's most renowned patient. This account also portrays Dr Scoville, warts and all. Dittrich also tells us about Mrs Scoville's illness and her treatment by Dr Scoville.

Important lessons in the practice of medical ethics can be drawn from the interactions between the doctor, his two patients and events following Mr Molaison's death.

Except where indicated by reference numbers, all the following quotations are from Dittrich's book.

Henry Molaison

He was born in Manchester, Connecticut on February 26, 1926. As a child, Henry Molaison wanted to be a neurosurgeon. Instead, he suffered a major, life-long handicap at the hands of a neurosurgeon, which at once rendered him incapable of looking after himself and made him an object of innumerable medical research studies.

Author: **Sunil K. Pandya** (shunil3@gmail.com), Department of Neurosurgery, Jaslok Hospital and Research Centre, Dr GV Deshmukh Marg, Mumbai 400 026, INDIA.

To cite: Pandya SK. Henry Molaison's operation for epilepsy: a case study in medical ethics. *Indian J Med Ethics*. 2018 Jan-Mar;3(1) NS: 48-51. DOI: 10.20529/IJME.2017.087

Manuscript Editor: Sanjay A Pai

Blond, blue-eyed Henry, aged around eight years, was returning home along the backstreets. As he heard no vehicles, he stepped off the side-walk on to the road to cross it. A bicyclist coasting down a sloping road rounded a curve and unaware of Henry, crashed into him. Henry landed on the road, hurting the left side of his head, the scalp just above his eyebrow tearing on impact. As his head rebounded off the road three times, his brain was injured. He awakened five minutes or so after the fall. The wound was stitched and he carried a bandage above his left eyes for a few days. Seizures followed, mild to start with and more intense with the passage of time. By the age of 15 years, he was suffering generalised fits attended by loss of consciousness.

To supplement the meagre income of his father, who worked as an electrician, Henry took on part-time jobs – usher at a movie theatre, helping out with the stocks at a shoe-store and in a junkyard. He attempted apprenticeship as a motor-winder. Gradually, despite drugs to control fits, he found himself greatly handicapped by the severity and frequency of his epileptic attacks.

Dr Harvey Goddard, his physician, decided to consult neurosurgeon Dr William Beecher Scoville. Dr Scoville confirmed that drugs to control epilepsy failed even when a combination of four such drugs was given 2–5 times a day. Henry, aged 27, was confined to his home for fear of injury during fits which now came on several times each day. His future was dark. Dr Scoville talked to him and his parents about operations on the temporal lobes that had helped some similar patients.

Henry's operation was carried out on August 25, 1953. Dr Scoville could find no abnormality in the temporal lobes. Records of the electrical activity of these lobes also showed no abnormality. Certainly, there was no localised area from which epileptic discharges could be identified. Had there been visible disease or an identifiable source of fits, this part of the brain could have been removed to render Henry fit-free.

Most neurosurgeons would have shrugged their shoulders and closed up the wound. Dittrich points out that at this stage, even a surgeon of the eminence of Dr Wilder Penfield would have conceded defeat, as there was no hint of the origin of the seizures. He quotes Penfield, "The neurosurgeon must balance the chance of freeing his patients from seizures against the risks and functional losses that may be associated with ablation." This was particularly important in those days when the functions of the temporal lobes were not as well understood as they are today.

"My grandfather was not Wilder Penfield," says Dittrich. Dr Scoville decided to remove the medial temporal lobes on *both* sides.

Six weeks later, Dr Scoville sent his paper on temporal lobe surgery to the *Journal of Neurosurgery* for publication. In the paper he reiterated what he had stated at his earlier presentation to the Harvey Cushing Society and noted that surgery on the medical temporal lobes "resulted in no marked physiologic or behavioural changes, *with the one exception of a very grave, recent memory loss, so severe as to prevent the patient from remembering the locations of the rooms in which he lives, the names of his close associates or even the way to the toilet or urinal*" (italics by Dr Scoville).

As Dittrich pithily puts it, in this statement Dr Scoville announced the birth of patient HM and wrote the obituary of Henry Molaison.

In a later publication (2), Scoville and Milner provided greater details on Molaison's handicap.

> *After operation this young man could no longer recognize the hospital staff nor find his way to the bathroom, and he seemed to recall nothing of the day-to-day events of his hospital life. There was also a partial retrograde amnesia, inasmuch as he did not remember the death of a favourite uncle three years previously, nor anything of the period in hospital, yet could recall some trivial events that had occurred just before his admission to the hospital. His early memories were apparently vivid and intact.*
>
> *This patient's memory defect has persisted without improvement to the present time, and numerous illustrations of its severity could be given. Ten months ago the family moved from their old house to a new one a few blocks away on the same street; he still has not learned the new address, though remembering the old one perfectly, nor can he be trusted to find his way home alone. Moreover, he does not know where objects in continual use are kept; for example, his mother still has to tell him where to find the lawn mower, even though he may have been using it only the day before. She also states that he will do the same jigsaw puzzles day after day without showing any practice effect and that he will read the same magazines over and over again without finding their contents familiar.*
>
> *This patient has even eaten luncheon in front of one of us (B.M.) without being able to name, a mere half-hour later, a single item of food he had eaten; in fact, he could not remember having eaten luncheon at all. Yet to a casual observer this man seems like a relatively normal individual, since his understanding and reasoning are undiminished.*(2)

Molaison's extraordinary state, caused by removal of the medial parts of both temporal lobes, led to numerous research studies by those attempting to understand the functions of the temporal lobes. As these studies were carried out and reported in medical journals, Molaison's privacy was respected by never using his full name but labelling him just as "H.M". The full name was used again only after his death.

Access to him was restricted to those with academic credentials. One of the first to gain access was Dr Brenda Milner. She was deputed by Dr Wilder Penfield to study the consequences of this unprecedented operation. Later Dr Suzanne Corkin, a student of Dr Brenda Milner, took over the studies on Henry Molaison's brain functions and determined who could be allowed to see him. She was to continue to study him till he died and was then able to obtain Molaison's brain for study. Dittrich was never allowed to meet Molaison during his lifetime despite several pleas and attempts to do so.

In the 1940s, it was felt that memory was distributed across the entire cerebrum. It was not associated with any particular lobe of the brain. Ten years later, when Dr Milner studied two of Dr Penfield's patients whose left temporal lobes were removed as they contained epileptic foci, she noted that they suffered profound loss of memory. Many other patients, whose left temporal lobes had been removed, showed no such deficit.

Drs Penfield and Milner postulated that some unidentified disease in these two patients must have damaged the medial temporal lobes on both sides. Lacking the sophisticated tests available to us today, such as computerised tomography, magnetic resonance scanning and functional magnetic resonance imaging, this remained a hypothesis.

> *Were Penfield willing to test the theory by actually removing both hippocampi of a patient and seeing what happened, he and Milner might have been able to obtain what they needed.*

They would then have identified the seat of memory in the human brain.

> *But Penfield would never do that. He was too wary of causing unnecessary harm. Despite having revolutionized the field of epilepsy surgery, he was fundamentally a conservative, cautious doctor. He viewed all novelty with skepticism.*

Questionable ethics

Dittrich commented on his grandfather's decision to destroy the medial temporal lobes in Molaison:

> *This decision was the riskiest possible one for Henry. Whatever the functions of the medical temporal lobe structures were – and again, nobody at the time had any idea what they did – my grandfather would be eliminating them. The risks to Henry were as inarguable as they were unimaginable*.

Dr Scoville did this operation despite the experimental findings by Heinrich Klüver (1897–1979) and Paul Bucy (1904–1992) in 1939 (3, 4). Klüver and Bucy had built upon the description by Hughlings Jackson (1835–1911) of uncinate fits with the causal foci in the temporal lobes. They carried out experiments in Rhesus monkeys to study the effects of removal of the medial temporal lobes. They showed, especially in the aggressive female monkey named Aurora, that removal of both temporal lobes reduced previously aggressive animals into docile, "psychically blind" individuals. The term "psychically blind" was used to describe the inability of these monkeys to recognize objects by sight even when their vision was unimpaired. They concluded that damage to both temporal lobes "disrupted the processes by which the meaning of a sensory precept is appreciated". Their ability to understand what they perceived was abolished.

The unprecedented surgery on Molaison's brain, without any scientific backing for the infliction of such damage, left him amnesic. As he expressed it so well, "Every day is alone in itself. Whatever enjoyment I've had and whatever sorrow I've had." The next day, his slate had been wiped clean with no trace of bygone events.

As noted above, a more prudent surgeon such as Dr Wilder Penfield would have stopped once no abnormality was detected on inspection, and on a study of cortical electrical recordings. Not so Dr Scoville who proceeded with the destruction of the mechanisms for memory in Henry Molaison.

Were such an operation to be performed under modern circumstances, the neurosurgeon would find himself in deep trouble. At the least, Dr Scoville would have been accused of medical adventurism, acting outside accepted medical practice.

The permanent handicaps that Henry Molaison suffered would result in heavy damages imposed by a court of law.

Mrs Scoville

In the mid-1940s, Dr Scoville's wife displayed evidence of mental illness. After hospitalisation, she was subjected to hypothermia, fever therapy (her body temperature being elevated to 105–106 degrees Fahrenheit), electroconvulsive therapy and insulin shock therapy. The description of Mrs Scoville's descent into madness is wrenching, especially since before her illness she had been assessed as being markedly above the average in intelligence and a true lover of music.

Dr Scoville wrote to his parents, "I have been so happily married and am utterly heartbroken."

Her own assessment of the marriage was different, being influenced by Dr Scoville's infidelity and promiscuity. Dittrich describes a Thanksgiving dinner, "my grandfather holding court at the head of the table, his second wife to one side, my grandmother sitting mostly silent a few seats away." He had, by then, performed bilateral frontal lobotomies on her.

Dittrich, very fond of his grandmother, wrote:

> *Whatever they did to my grandmother at the asylums, however bad it got, whatever they took, whatever he took… What remained was strong… In 1957… my grandmother took a trip to Reno, Nevada. She walked into one of the local shops that specialized in quick no-contest divorces. She filled out each of the form they gave her…She left my grandfather, moved to New York City on her own… She started over…*

Questionable ethics

Given his infidelity and promiscuousness, Dr Scoville's destructive surgery on both her frontal lobes raises major ethical questions. He knew that such surgery would render an agitated person docile.

Decision on her treatment should have been made by an objective third party. Knowledge of the permanent consequences of the destructive operation would have hindered most surgeons, especially since prior to her illness she had been described as being markedly above the average in intelligence and a true lover of music.

Her behaviour almost two decades after the operation, her devotion in the late 1950s to the blind and her affection for her grandchildren show that the damage inflicted by Dr Scoville had not quelled her indomitable spirit.

Henry Molaison's brain

Towards the end of his life, Molaison was besieged with other illnesses – a recurrence of fits requiring large doses of anticonvulsants, a need for antidepressants and anxiolytics, brittle bones, fractures, and a stroke.

Dr Corkin brought in neuroanatomist Dr Jacopo Annese to see Molaison. The purpose was to ensure that a proper study of Molaison's brain would follow his death. Molaison never consented to an autopsy. He was deemed to suffer from dementia and consent was therefore given by a third cousin, Tom Mooney, who claimed he had looked after Molaison during his last days. The first cousins of Henry Molaison were not informed of the research being carried out on him or his death. Their consent was not sought.

Molaison died in 2008. Dr Corkin ensured that the body was kept refrigerated. Magnetic resonance scans of the dead brain were carried out at the Massachusetts General Hospital before the brain was removed for preservation and study. As Dr Corkin accompanied the brain to the airport for the flight to San Diego, the *New York Times* revealed HM's full name for the first time, describing him as "the most important patient in the history of brain science" (5). Dr Annese was at the airport to take charge of the precious organ. He took it with him to the Brain Observatory at the Institute for Brain and Society, which he had founded in San Diego.

Dr Annese studied the brain in detail and released a digitised 3-dimensional model of it that can be accessed by anyone. A disagreement between Dr Corkin and Dr Annese led to an ugly dispute over the custody of the brain and its slices. In April 2010, Dr Corkin asked Dr Annese to send her everything related to Henry Molaison's brain. By then Dr Annese had spent thousands of hours working on the brain and spent $750,000 in grant money over the studies. Bickering and meetings followed. Lawyers were brought in. Dr Corkin's stated reason for insisting on retaining the brain and its slices was that these precious resources should be in good custody so that future researchers could benefit from them.

Dittrich's descriptions of his meetings with Dr Corkin do no credit to her. When asked for her notes of fifty years of interviews with Molaison, she blandly told Dittrich that they had been destroyed (6). How then was Molaison's legacy in the form of data to be made permanently accessible by future researchers?

It is indeed a pity that even after death, Henry Molaison was short-changed.

***Note**: The author's review of Dittrich's book has been published in Neurology India (7).*

References

1. Dittrich L. *Patient H.M.: a story of memory, madness, and family secrets*. Hardcover. New York: Random House; 2016.
2. Scoville WB, Milner B. Loss of recent memory after bilateral hippocampal lesions. *J Neurol Neurosurg Psychiatry*. 1957 Feb;20(1):11–21.
3. Klüver H, Bucy PC. Psychic blindness and other symptoms following bilateral temporal lobectomy in rhesus monkeys. *Am J Physiol*. 1937;119:352–3.
4. Naham Frederick KD, Pribram Karl H, Heinrich K. In: *Biographical memoirs*. National Academy of Sciences. Volume 73. Washington, DC: National Academy of Sciences; 1998.
5. Carey B. H.M., an unforgettable amnesiac dies at 82. *NY Times*. 2008 Dec 4. Available from: http://www.nytimes.com/2008/12/05/us/05hm.html
6. Zhang S. The untold story of neuroscience's most famous brain. *Wired com*. 2008 Aug 9 [cited 2017 Jul 31]. Available from: https://www.wired com/2016/08/untold-story-neurosciences-famous-brain/
7. Pandya S. [book review] Dittrich Luke: Patient H.M.: a story of memory, madness, and family secrets. *Neurol India*. 2017 Mar–Apr;65(7 Suppl):S1:105–8. Available from: http://www.neurologyindia.com/article.asp?issn=0028-3886;year=2017;volume=65;issue=7;spage=105;epage=108;aulast=Pandya

---

Controlled human infection models for vaccine development: Zika virus debate

VIJAYAPRASAD GOPICHANDRAN

Abstract

An ethics panel, convened by the National Institute of Health and other research bodies in the USA, disallowed researchers from the Johns Hopkins University and University of Vermont from performing controlled human infection of healthy volunteers to develop a vaccine against Zika virus infection. The members published their ethical analysis and recommendations in February 2017. They have elaborated on the risks posed by human challenge with Zika virus to the volunteers and other uninvolved third parties and have systematically analysed the social value of such a human challenge experiment. They have also posited some mandatory ethical requirements which should be met before allowing the infection of healthy volunteers with the Zika virus. This commentary elaborates on the debate on the ethics of the human challenge model for the development of a Zika virus vaccine and the role of systematic ethical analysis in protecting the interests of research participants. It further analyses the importance of this debate to the development of a Zika vaccine in India.

Introduction

In December 2016, an ethics panel convened by the US National Institutes of Health (NIH), the National Institute of Allergy and Infectious Diseases (NIAID) and the Department of Defense Walter Reed Army Institute of Research (WRAIR) reviewed a proposal by researchers from the Johns Hopkins University and the University of Vermont College of Medicine in the USA to conduct controlled infection of healthy human volunteers with the Zika virus (ZIKV) to develop a vaccine against the virus. The panel published its recommendations in February 2017, halting the progress of any such experiments, as it deemed such research unethical in the current context of research on and development and understanding of the ZIKV (1). This evoked mixed opinions and led to vociferous debates between the proponents of the controlled human infection models (CHIM) for ZIKV vaccine development and the bioethicists, who view the risks to the participants and other uninvolved third parties as too high to allow the experiments (2,3).

Author: **Vijayaprasad Gopichandran** (vijay.gopichandran@gmail.com), Assistant Professor, Department of Community Medicine, ESIC Medical College and PGIMSR, KK Nagar, Chennai, Tamil Nadu, 600 078 INDIA.

To cite: Gopichandran V. Controlled human infection models for vaccine development: Zika virus debate. *Indian J Med Ethics*. 2018 Jan-Mar;3(1) NS: 51-5. DOI: 10.20529/IJME.2017.093

Manuscript Editor: Mala Ramanathan

ZIKV is a mosquito-borne flavivirus, causing a febrile exanthematous (fever with rash) illness in humans. Though it was isolated and identified in 1947, the first major human outbreak was only in 2007 in the Island of Yap, in the Pacific (4). In July 2015, Brazil reported an association between ZIKV and Guillain-Barre syndrome (GBS – a severe form of nervous disorder due to immunological problems caused by the ZIKV); and in October of the same year, an association between ZIKV infection of pregnant women and microcephaly (small head) of new-borns with severe neurological damage (4). Most illness caused by ZIKV infection is mild and not apparent. However, its association with GBS and congenital Zika syndrome (CZS) are the major causes for concern. The virus is transmitted by the bite of the *Aedes* mosquito, as well as by sexual transmission and vertical transmission from the mother to the foetus (5). The virus rapidly spread to Mexico, Central America, the Caribbean, and all over South America. Given these concerns and the possibility of the spread of the virus to other tropical and subtropical areas, the World Health Organisation declared the disease a Public Health Emergency of International Concern in January 2016 (4). Since then, the ZIKV has been a dreaded emerging infectious disease, and laboratory research and animal experiments have been conducted to understand

Indian Journal of Medical Ethics Vol IV No 2 April-June 2019

Something is rotten in our medical colleges

SUNIL K PANDYA

Introduction

Marcellus' observation in Shakespeare's *Hamlet* (1) that "Something is rotten in the state of Denmark." (Act 1, Scene 4) could well be applied to medical education in India today. and could be followed up by repeating another statement earlier in the play, "and I am sick at heart" (Act 1, Scene 1).

I was fortunate to have studied medicine in Mumbai at a time when we were keen to learn not only the science of medicine but the art of practice from teachers of the calibre of Drs Minocher Mody, JG Parikh, Noshir Wadia, CG Saraiya, WD Sulakhe, NG Talwalkar, and Noshir H Antia at the Grant Medical College (GMC) and Rustom Jal Vakil, Rustom N Cooper, AV Baliga, Nathoobhai D Patel and PK Sen at the Seth GS Medical College (GSMC). We would move from one college to the other, eager to listen to them teach and demonstrate how a patient should be examined and a diagnosis made.

Our teachers deserved our respect and homage. Although termed 'Honoraries' and expected to work in the institutions for 4 hours each day, we saw them in the wards and laboratories from 8 am to 4 pm. daily. They taught us all they knew, sincerely and diligently. I recall approaching Professor P K Sen at GSMC, whilst I was a postgraduate student at the Grant Medical College, with some trepidation to request permission to attend his clinics for postgraduate students in surgery. He instantly and graciously granted permission with one proviso, "You can listen but do not interrupt." Likewise, Dr SD Bhandarkar, the eminent endocrinologist at GSMC, told me how he attended Dr Noshir Wadia's clinics regularly each week at GMC and benefited greatly from them.

When individuals such as Drs Sir Harold Gillies, Robert J Last, Michael de Bakey, Denton Cooley, Victor McKusick, A Earle Walker and MG Yasargil visited, we would take pains to find out when and where we could listen to them and ensure that we learned from them. We would even travel to arts and science colleges to learn from visiting atomic physicists, astronomers, botanists, and zoologists...

This was apart from attendance at the occasional readings of great works of literature at the British Council and the SIES. College and, when we could afford the cost, shows such as *The Tintookies* (aboriginal term meaning" little people from the sandhills") by the Australian group led by Peter Scriven; foreign actors and dramatists like Emlyn Williams; plays staged by the Indian National Theatre; groups featuring local stars such as Alyque Padamsee and Gerson da Cunha and classical dance and musical performances.

We borrowed books from the libraries of the British Council, American Center, the J N Petit Library and other repositories of wisdom and heritage.

Our teachers and these activities engendered in us a love for medicine and empathy with our patients. Equally important, we developed a breadth of vision and were on intimate terms with the humanities.

Contrast this with what obtains today.

Lessons learnt from a senior resident doctor

In a recent exchange of emails, saddening truths were brought home to me by my young correspondent – a final year resident in Cardiology in one of our public sector teaching hospitals. I reproduce the comments below:

- *Everyone knows the status of medical education in our country.*
- *The pattern of the entrance examination has systematically destroyed any urge to learn. It's an open secret!*
- *When will your generation wake up to save medical education and the future of healthcare in India? Why should our generation be victimised?*
- *Why do our teachers not take ward rounds and teach at the bedside of patients? We learn from our teachers that taking a history and conducting a detailed examination are unnecessary as they place all their faith in investigations.*

Author: **Sunil K Pandya** (shunil3@gmail.com), Department of Neurosurgery, Jaslok Hospital and Research Centre, Dr GV Deshmukh Marg, Mumbai 400 026, INDIA

To cite: Pandya SK. Something is rotten in our medical colleges. *Indian J Med Ethics*. 2019 Apr-Jun;4(2)NS: 92-4. DOI:10.20529/IJME.2019.021.

- *I wish to learn interventional cardiology but am frustrated by the fact that few life-saving procedures are carried out by teachers in my hospital, because they want to carry them out in private hospitals where they have been allowed to practise although they are full-time professors here.*
- *There is no accountability for medical teachers.*
- *There is no place where we can go and complain with certainty of redressal.*
- *Why is promotion in professorial cadres based on fake research articles and on quotas? What about merit? Why is feedback from the students they are teaching not considered at all?*
- *Do you know that our guides use our theses as weapons of attack and defense? I can assure you that 99.99% theses are based on manipulated results and are of no practical importance.*
- *I find it strange that medical graduates feel an overwhelming compulsion to attend coaching classes.*
- *Most of my teachers have placed their offspring in medical schools in US as they have realised that education in our medical colleges is worsening day by day.*

From my own enquiries I learn that this situation prevails in many departments in our teaching hospitals. Ward rounds and bedside clinics have almost disappeared from the teaching arena, as have autopsies and clinico-pathological correlation in weekly brain-cutting sessions or study of autopsied lungs, hearts and great vessels. No lessons are learnt from the dead on the natural history of disease, missed diagnoses and errors in medical and surgical therapy.

Lectures are often a bare recitation of facts, lacklustre and bereft of personal enthusiasm. No examples from studies by the lecturer and others in the department are provided to back up statements. Stimulation of thought, the spirit of enquiry and discussion are not encouraged. Having completed his spiel, the lecturer walks out. As noted by my correspondent above, no lecturer or department ever seeks or values feedback from students. Forced to attend such talks by mandatory roll calls, students are quick to tune out as the lecturer drones on. Presentations on the internet – as exemplified by those from the Khan Academy (https://www.khanacademy.org/science/health-and-medicine) – and tuitions are used to replace what should have been taught in the medical college and hospital.

Since Indian medical education is driven by diktats from governments – in Delhi and the states – and those issuing orders are not famed for their progressive or principled vision or action, there are few grounds for optimism about change.

Attempts at inculcating the humanities in medical students and postgraduates are few and amateurish. We lack professionally run, well-financed departments manned by respected, competent and highly motivated individuals. Administrators of medical colleges and hospitals do not see the need for them.

Some promising attempts at improving the present sorry situation

Despite these huge odds, efforts are being made by concerned individuals and groups at improving the situation. St John's National Academy of Health Sciences, Bengaluru, the University College of Medical Sciences and Guru Tegh Bahadur Hospital, Delhi, GSMC, Mumbai, and the Christian Medical College and Hospital, Vellore, are some examples of institutions striving to inculcate the humanities in their students. A variety of means are used to instil into students and residents the principles of medical ethics, the spirit of empathy, courtesy towards patients and their families and a love for the arts. Plays, The Theatre of the Oppressed, films and talks by the likes of Drs Farokh Udwadia, Prakash Amte, Abhay Bang, Mario Vaz, Satendra Singh and Himmat Bawaskar, are some of the means used.

There are some common handicaps faced at all these centres. The organisers, working in an honorary capacity, have to confront the crushing burden of lectures, laboratory sessions and tuitions on students and hospital workload on residents. They must beg heads of academic departments for slots when students can attend the programmes set up by them. They must hunt for funds for their activities. They must sustain interest and enthusiasm in the programmes in their own teams, and then in students and residents.

Needs for the future

In the great teaching centres of Europe, America and Australia, medical colleges are ranked not only on the basis of their scientific excellence but also on the achievements of their departments of humanities. We desperately need such a culture in India.

In order to enhance the importance of the humanities, our medical colleges must, first of all, improve their standards of teaching medicine and caring for patients. These are the foundations on which the humanities can be built.

Towards this end, we will need a major revamping of our educational system.

Our teachers must be selected and promoted on the basis of a single criterion: merit.

The selection of students to be admitted to our medical colleges must be based on vocational aptitude as much as on academic excellence. The system of evaluating the latter must change from numbers of marks to assessment at a systematic interview.

The large number of applicants cannot be used as an excuse for the perpetuation of the existing hopelessly inadequate system.

An intellectually stimulating and professionally challenging medical curriculum must include strict measures to enable each student to acquire clinical expertise at the bedside and in the autopsy room. These principles championed by Drs Herman Boerhaave in Leiden, Thomas Sydenham in London, Pierre Charles Alexandre Louis in Paris, Charles Morehead in Bombay and William Osler in Canada and America remain of paramount importance.

Creation of departments of the humanities must follow. Each department must be adequately staffed with a head, professors, assistant professors, lecturers and office staff. Each of them must possess impeccable qualifications, proven enthusiasm and sincerity in promoting the goals of the department. The department must have a significant presence in the institution's library, archives and museum.

A curriculum for the humanities must be laid out with care and aim at cultivating in students and residents a life-long interest in ethics, history, philosophy and the arts. Such a curriculum must, of necessity, be devoid of compulsion, learning by rote and stressful tests and examinations.

Some foreign medical colleges offer the following modules to their students:

- Classics
- Comparative literature
- Film studies
- History
- Liberal Arts
- Music
- Philosophy
- Theology and religious studies

In our country, we also need to lay strong emphasis on respect for and care of women and children, the differently-abled and the poor.

Conclusion

We are fortunate in having exemplary mentors who have made their departments reach, and at times, surpass international standards in every aspect of patient care, teaching and research. They awaken in their junior colleagues a passion for learning and hunger for knowledge; but such mentors are few. We need ALL our teachers to reach the heights they have scaled so successfully.

In a recent oration, Dr Nalini Shah, Emeritus Professor of Endocrinology at GSMC emphasised some neglected truths (2). Our students must be convinced that education is a continuing process that ends only when we breathe for the last time. The best teachers are perennial students at heart. Learning any new subject must start with an understanding of history, the works of pioneers and the means by which they overcame the many obstacles they faced. Our best teachers are our patients. Inspired and passionate residents and students are invaluable members of the clinical team. Research is an integral part of learning and leads to our making an addition, howsoever humble, to existing stores of knowledge.

If and when we can meet these needs, the young cardiology resident referred to above will rest content as will all the others aiming at "the practice of medicine as an art, not a trade; a calling, not a business; a calling in which your heart will be exercised equally with your head." (William Osler)(3).

References

1. Shakespeare W. *Hamlet, Prince of Denmark*. Open Source Shakespeare. Date unknown [cited 2019 Feb 7]. Available from: http://www.opensourceshakespeare.org/views/plays/play_view.php?WorkID=hamlet&Scope=entire&pleasewait=1&msg=pl
2. Shah N. *Dr Nalini Shah: A lifetime at KEM: learning the art and science of medicine*. Oracon 2019 [cited 2019 Feb 7].Available from:. https://www.youtube.com/watch?v=j5MA8CCNz3g (Accessed on 7 February 2019)
3. Osler W. The master-word in medicine. In: *Aequanimitas with other addresses to medical students, nurses and practitioners of medicine.* Philadelphia: F. Blakiston's Son & Co;1910. Pages 365-88.

Indian Journal of Medical Ethics Vol V No 4 October-December 2020

COMMENTS

Pernkopf's atlas: Should unethically obtained life-saving data be discarded?

SUNIL K. PANDYA

Abstract

Dr Pernkopf's Topographische anatomie des menschen (Topographical anatomy of man), in four volumes, was originally published in German. It had taken the author and his colleagues over twenty years to produce it, the first volume being published in 1937. It was translated into English in 1964. The atlas was received with uniform acclaim in Europe and America and praised for its accuracy and the quality of its illustrations.

A recent study compared its utility with that of Dr Frank Netter's Atlas of human anatomy, first published in 1989, with its 7th edition out in 2018. "The respondents (nerve surgeons) found Pernkopf 's atlas having both greater anatomical detail (range 79%-91%) and greater utility for surgery (range 66%- 82%) when compared with Netter's (P < .001) in all plate comparisons." (1)

Internationally renowned and respected neurosurgeon, Dr M Gazi Yasargil – not given to handing out praise lightly – said in 2004 of this atlas, "Pernkopf's work, in particular … Vol. 4 (800 pages, 218 figures) is of fantastic quality and is appreciated worldwide." (2)

Surgeons continue to use Dr. Pernkopf's atlas to plan their operations (3). A recent example is its use in the treatment of a 13-year-old Israeli schoolboy (4).

This essay discusses whether it is rational to refuse to use data and publications that are accurate and likely to help in treating patients. Since such information can save lives, should we spurn it because it was based on information obtained unethically?

Eduard Pernkopf

Pernkopf (1888-1955) was born in a small village in lower Austria, the son of a country doctor. He received his medical degree from the Vienna Medical School in 1912 and taught anatomy thereafter. He succeeded his teacher, Ferdinand Hochstetter (1861-1954) as director of the Second Anatomy Institute in Vienna from 1933 onwards.

The Viennese Anatomy Institute had been divided into two departments in 1870. Anatomy 1 was clinically-oriented and led by Jewish scientists. The chairmen of Anatomy 2 tended towards nationalism and anti-Semitism. During the 1920s and 1930s, there was much antagonism between students from the two departments. In 1938, Anatomy 1 and 2 were reunited under the chairmanship of Pernkopf.

Pernkopf was described as an obsessive worker and demanding supervisor. He developed his dissection and illustration techniques using skilled artists quite early in his career. His personal routine of 18-hour work days was, in his later years, focused completely on the atlas (5).

Pernkopf joined the National Socialist German Workers, or Nazi Party, in 1933. He joined the Storm Troopers, or Brown Shirts, a year later. One month after Nazi Germany invaded Austria in 1938, Pernkopf was made dean of the medical faculty in Vienna. From 1943 to 1945, he was *Rektor Magnificus* (president) of the University of Vienna.

From 1938 onwards, he was highly placed in the hierarchy of the Nazi party in Vienna. His speeches endorsed the Nazi emphasis on eliminating the unfit and "defective" from the population. Under his dispensation, all professors were required to swear an oath of loyalty to Hitler (6).

By the end of World War II, 38,000 doctors in Germany were members of the Nazi party and more than 7% of all physicians were members of the SS (*Schutzstaffel* or protection squadron). Serving the Nazi party advanced their academic careers, enabling them to carry out research and experiments and to write theses (7).

Pernkopf's deemed function under the Nazi regime was to lead the country to better *state and racial health*. The doctor was to be a servant of the nation and his greatest responsibility was not to the health of the individual patient, but to the health of the state.

Bruns and Chelouche (8) point out that a variant of medical ethics was very much a part of the medical curriculum under the Nazi regime (1939-1945). "The appointed lecturers were mostly … members of the Nazi Party and imparted Nazi political and moral values in their teaching. These values included the unequal worth of human beings, the moral imperative of preserving a pure Aryan people… and the priority of public health over individual-patient care."

Author: **Sunil K Pandya** (shunil3@gmail.com), Department of Neurosurgery, Jaslok Hospital & Medical Centre, Dr. G. V. Deshmukh Marg, Mumbai 400026.

To cite: Pandya SK. Pernkopf's Atlas: Should unethically obtained life-saving data be discarded? *Indian J Med Ethics.* 2020 Oct-Dec; 5(4) NS: 319-26. DOI: 10.20529/IJME.2020.088.

Manuscript Editor: Sanjay A Pai

Peer Reviewers: Ido Solt and an anonymous reviewer

The end of World War II resulted in several reverses for Pernkopf. He was dismissed as head of the Institute of Anatomy on May 10, 1945 (6). In August that year, he and his artist Batke were arrested by the American military. He was never charged with war crimes, but was sentenced to hard labour for three years in an American prison camp for war criminals near Salzburg. He continued to work on his atlas during imprisonment. On his release, Dr. Hans Hoff, a Jewish physician and Director of the Institute of Neurology in Vienna, allotted him two rooms for his work.

The atlas was all that kept him alive. Once again, he brought together his artists. In 1952, he published the section entitled *Der Hals* (The neck).

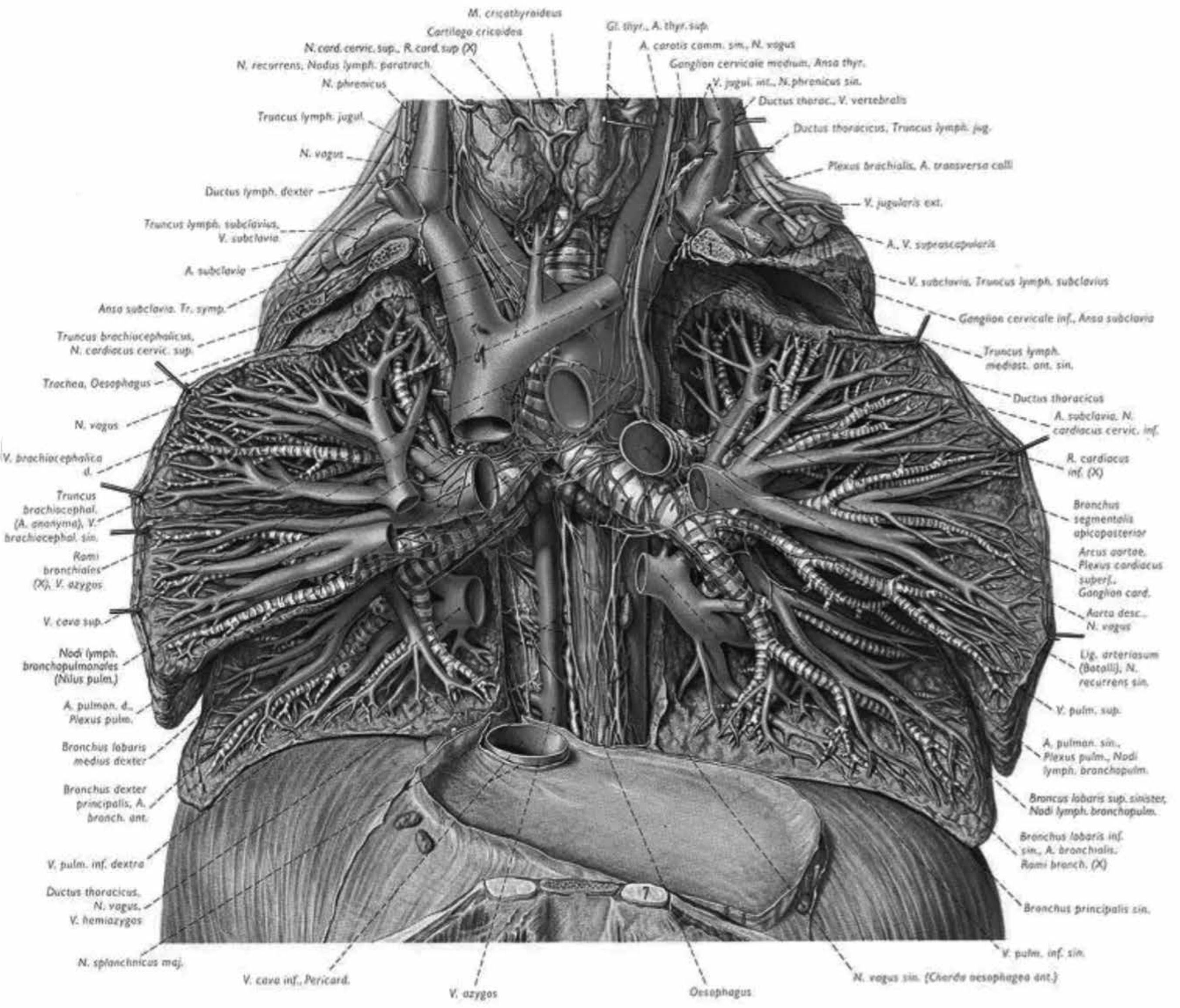
Pernkopf's student and post-war successor as Director of the Second Anatomy Institute – Hermann von Hayek – praised Pernkopf's love of music. He referred to his composition of an unpublished symphonic drama and called him a great teacher, researcher and human being (5).

Pernkopf died on April 17, 1955, from a haemorrhagic stroke whilst working on the fourth volume of his book. The last two volumes were brought out by Werner Platzer, regarded by many as his protégé.

> *Despite Pernkopf's long fall from grace, his burial turns out the entire faculty. He is celebrated by fellow professors as a perfectionist, a stirring teacher and the impresario of what many increasingly regard as the world's greatest anatomy book. (9)*

The Pernkopf atlas

The first edition of Volume 1 was published in 1937. Currently available volumes of the atlas are of the 2nd and subsequent revised editions (10).



Detailed illustration of the dissected lower neck and chest from Pernkopf's atlas. From CODEX 99 - under a Creative Commons *CC BY-NC-SA 4.0* license.

Paterniti (9), an American investigative writer, provides graphic descriptions of the creation of this atlas and of Pernkopf's work on it.

Needing a dissection guide for his anatomy students, Pernkopf started out with the creation of a laboratory manual. Studying other anatomy texts, he found them outdated or unsatisfactory. He upscaled his project to provide the definitive atlas on human anatomy. This *magnum opus*, in four volumes, contained 800 paintings by eleven carefully selected artists. The technique of four colour separation was refined for his purpose. (Full colour photographs are separated into components, corresponding to the four primary colours – cyan, magenta, yellow, and black. During printing, halftone dots of each of these four colours in varying densities are overprinted, the various combinations producing the wide range of reproducible colours. A different printing plate needs to be made of each colour and this, in turn, requires separate negatives or positives.)

Pernkopf wrote the text by hand. His wife typed it out. Assisting Pernkopf were the best graphic designers and artists in Vienna, among them Erich Lepier, Ludwig Schrott, Karl Endtresser and Frank Batke. About half of the original illustrations in the anatomical atlas were not created during the Nazi years. Some were made before 1937 and others after 1945. The dates of creation as well as the source of the bodies used as models for 350 paintings are unclear (5).

When dissections were performed for the illustrations to be included in the book, Pernkopf was "driven by ideas of accuracy and clarity". His publishers, Urban and Schwarzenberg, shared his dedication and vision.

Paterniti (9) also tells us of the search for Franz Batke – the last of Pernkopf's artists – by Professor David Williams who taught medical illustration at Purdue University. On meeting him, Williams wrote in his journal, "I am truly beginning to see this man as a genius." After studying art under Batke and reviewing Pernkopf's atlas, Williams praised it as "the standard by which all other illustrated anatomic works will be measured." Paterniti too appears to have been enthralled by the work:

> *The book is blindingly beautiful, an exaltation, a paean and a eulogy all at once. Page after page, the human body unfolds itself, and with each page the invisible becomes visible, some deeper secret reveals itself. (9)*
>
> *So who is Pernkopf? If he's taciturn with his painters, it is because he maintains the utmost professionalism. A dreamer, an intellect, a lover of music, he is in the workshop early in the morning and late at night: He is simply an overwhelming presence. The Book becomes both his great unwritten symphony and, slowly, his madness. (9)*

The supply of corpses for dissection in Vienna

Michael Atlas (11) provides details on the controversy regarding Pernkopf and his anatomical atlas:

> *The piece that really sparked the current controversy about the Pernkopf atlas was a letter to the editor of JAMA in November 1996 signed by a professor of dental surgery from Columbia University and a professor of family and community medicine from the University of Toronto… Most pointedly they said that the precise origins of the cadavers used in Pernkopf's work are unknown, but evidence suggested they may have been victims of political terror. It is known that the Anatomy Institute of the University of Vienna received the cadavers of prisoners executed at the Vienna District Court and of others put to death at Gestapo execution chambers in Linz, Munich, and Prague. (11)*

In 1998, the Jewish Holocaust Remembrance Authority requested an enquiry by the University of Vienna and that Pernkopf's history and a commemoration of the victims of the Nazis be included in future editions of the atlas.

> *The final report of the Pernkopf Commission of the Faculty Senate of the University of Vienna was issued on 1 October 1998. The investigation revealed that the Institute of Anatomy received at least 1,377 bodies of executed persons, including 8 victims of Jewish origin… On the basis of a general decree of February 18th, 1939, the bodies of persons executed were assigned to the Department of Anatomy of the nearest university for the purposes of research and teaching… No proof could be found that bodies had been brought to the Vienna Department of Anatomy from the Mauthausen (concentration) camp complex… The presumption and suspicions that some of the illustrations might be of prisoners of war or Jewish victims are based predominantly on impressions which strike the critical observer. In these cases, however, the investigation was able neither to prove nor to disprove the suspicions. Because of the systematic practice of making specimens anonymous, it seems likely that a final clarification of such suspicions will not now be possible. (11)*

It is relevant to study how bodies had been acquired for dissection in Vienna before Pernkopf's tenure. Buklijas provides an excellent historical review (12).

Vienna was the site of the earliest recorded anatomical dissection outside the Mediterranean, preceding cities in today's Germany and Switzerland by almost a century. Unclaimed bodies and those of executed criminals, those dying of suicide and duelists, were used for this purpose. In Vienna, anatomies were performed first sporadically, and from 1537 annually, by a faculty member in the Allgemeine Krankenhaus der Stadt Wien – Vienna's large teaching hospital – and in the presence of medical students, doctors, apothecaries, surgeons, and learned men from the faculty of arts.

The bodies of executed criminals and paupers formed the bulk of the corpses used for anatomical and pathological studies up to the 19th century. Around 1850, the Allgemeine Krankenhaus was itself supplying 2000 corpses annually to the medical faculty. (The mortality rate in the hospital was 13.4% in the 1850s.). The hospital accommodated thousands of the sick poor. Emperor Joseph II decreed that the use of the bodies of these patients for medical education was a fair repayment for the free medical care they had received in the hospital.

These corpses were treated with respect. In the 1850s, the society of St. Joseph of Arimathaea, named after the Biblical character who buried the body of Christ after crucifixion, organised and paid for the burial of dissected cadavers from the anatomical institute. "It replaced linen bags, in which the remains had traditionally been buried, with wooden coffins. Between 1857 and its dissolution in 1917, the Arimathaea became such an integral part of anatomy that anatomical cadavers became known as *Arimathaealeichen*" ('Arimathaea corpses'). This overcame the objection of the Roman Catholic church regarding the ultimate fate of the bodies."(12)

Nineteenth-century Vienna was renowned for its medical facilities. High standards of education and research, easy access to corpses for anatomical and pathological studies, and to patients with a variety of diseases attracted students from all over the western world.

For religious and political reasons, Jewish bodies were kept out of the reach of anatomists. Up to the 1920s, few Jewish bodies were subjected to dissection.

Pringle (13) provides details on the procedure under the Nazi dispensation. From 1938, anatomists at the University of Vienna made arrangements with local Nazi officials to receive the bodies of prisoners shot in the Gestapo rifle range or guillotined in Vienna's court building. If the medical school morgue was full, court officials postponed the executions (5).

> *Eduard Pernkopf's anatomical atlas, celebrated for its art but notorious for using the cadavers of victims of the fascist regime in the 1930s and 1940s, was the last in a tradition that went back to the nineteenth century.* (13)

Whilst working with the aged Batke, one of Pernkopf's artists, Williams asked whether death-camp cadavers were used in the book. The old man became enraged and denied it vehemently. Simon Wiesenthal, Holocaust survivor and founder of the Jewish Documentation Centre, examined the records and his conclusions confirmed Batke's statement (9).

Arguments for and against banning the atlas

Michael Atlas (11) and Paterniti (9) summarise these well.

Scott Norton, Chief of Dermatology at the Walter Reed Institute of Research (14, 15) was placed in a dilemma when he found two volumes of Pernkopf's atlas in his department.

Norton referred to two book reviews. The first was in the *New England Journal of Medicine* (1990): "The publication of this third edition of the Pernkopf Anatomy testifies to the success that this classic atlas has met with among anatomists throughout the world… This outstanding book should be of great value to anatomists and surgeons. It is in a class of its own and will continue to be valued as a reference work." The second was in the *Journal of the American Medical Association* (1990): "The majority of the illustrations in this atlas are truly works of art, demonstrating by their clarity and precision the best in collaboration between master medical artists and skillful anatomic prosectors."

Norton noted that outside the University of Vienna, the story of Pernkopf and his atlas was largely unknown until the mid-1990s, when several reports led to investigations of the university's wartime practices.

Norton went about his task systematically. He collected background information on the atlas, distributed it to all members of his department and held a meeting after they had studied it. He pointed out, "Just as Andreas Vesalius's *De humani corporis fabrica* and *Gray's Anatomy* blur the line between science and art, *Pernkopf's Anatomy* maps the human body in exquisite detail that has won praise from generations of medical illustrators." He did not hold back information on Pernkopf's Nazi links and the sources of bodies for anatomical dissections. He quoted Helmut Gruber (then the Viennese school's deputy dean) that it was 99% certain that Pernkopf's atlas did NOT contain any drawings of Jews or other victims of concentration camps. He also quoted Richard Panush who had stated in a letter to the *Journal of the American Medical Association* in 1996: "(We) decided to expunge it (the atlas) from our collection… I believe that our moral obligation to society, to victims and survivors of Nazism, and to posterity is to repudiate Pernkopf and all that he represented…"

Norton then asked his colleagues whether it was acceptable for them to use the atlas.

The consensus reached by the department was that the atlas should not be retained in the department library as it was tainted and the information in it was not unique. The volumes were therefore transferred to the special collection in Walter Reed's main library because of its place in medical education and ethics. Library users were to be permitted to use it as "fully expunging the book hearkens to Nazi-era book burnings."

Norton commented that this consensus "inserted an uncomfortable moral relativism. After all, anatomists historically have obtained their models from the gallows and graveyard. Would Pernkopf's atlas be less tainted if the cadavers were from executed hardened criminals, say, child murderers, rather than those whose crimes were political?" He also posed another question, "Can a scientific or an artistic achievement be separated from the manner by which it was attained?"(14, 15)

Bagatur (16) explains the rationale for the condemnation by the medical community of any use of knowledge derived from Nazi biomedical research. The use of such data corrupts the institution of medicine itself. He referred to the disfavour with which such eponyms as Reiter's syndrome, Hallervorden-Spatz syndrome and Asperger's disease are viewed today because of the Nazi associations of the persons after whom they are named.

Many of those who lost family members and friends in the Nazi concentration camps could not see the atlas as a repository of anatomical accuracy and beauty. For them, "the Book is nothing but a dirty crime scene, violated bodies that might include her brethren. The artists are no better than vultures over their carrion."(9)

Some, like Abraham Foxman, national director of the Anti-Defamation League, said that the research findings of heinous crimes or atrocities should not be used, even if it would do good, because it would retrospectively cleanse the atrocity and possibly justify similar acts in the future.

Kenneth Mellanby, then reader in medical entomology at the London School of Hygiene and Tropical Medicine, was appointed the *British Medical Journal*'s first ever foreign correspondent to cover the Nuremberg medical trials. Mellanby had induced and studied scabies on conscientious objectors who had volunteered to be human guinea pigs. His attitude to the victims of Nazi medical crimes was, "the victims were dead; if their sufferings could in any way add to medical knowledge and help others, surely this would be something they themselves would have preferred." (17)

The accuracy and superlative quality of illustrations in Pernkopf's atlas have been lauded by all reviewers.

Michael Atlas and others believe that the use of the atlas itself is the most fitting tribute to those who died for it. "It is ironic retribution for the Jewish cadavers (or whoever died for whatever beliefs) to be used to illustrate a Nazi's anatomic atlas and be immortalized by it. Using this atlas allows these cadavers to speak to us from half a century ago. They make us reexamine and again repudiate the Nazi beliefs that created a society that killed them."(11)

Edward B Hutton, Jr, president of Waverly, Inc, was the American publisher of the atlas. The stand taken by him is of interest. In a November 1996 letter to *JAMA*, Hutton said his company continued to publish the Pernkopf atlas because of its scientific merit and because, to date, no concrete evidence had been found to substantiate Pernkopf's use of cadavers originating from Nazi concentration camp victims. Hutton acknowledged that Pernkopf was an avowed Nazi and, that while Hutton and his company renounced Pernkopf's abhorrent views, they "separate Pernkopf, the man, from the work because of the lack of evidence as to the true origin of the cadavers used in the atlas."(11)

Garrett Riggs (18) echoed the feelings of many when he said, "Just as I can in no way condone the beliefs of Pernkopf and his Nazi cronies, neither can I deny the beauty, grace and precision of the images they produced."

Howard Israel (19) presented arguments, supported by many, that if some benefit could be derived from the use of the atlas today, to save a life or enable a surgeon to perform more skillfully, its use would honor those who suffered and sacrificed their lives. Such an argument might also maintain that not using tainted knowledge when it might help make better medical decisions might be actually unethical. Israel noted that there was no indication to the unsuspecting user that the book had any link to Nazi medicine, and he viewed suppression of the work as inappropriate and reminiscent of the book burnings that took place in Nazi Germany.

Paterniti (9) describes David Williams' visit to the repository in which the paintings used for the atlas are stored. Werner Platzer, who completed the last two volumes, showed Williams the nineteen binders stuffed with 800 original works of art.

> *But this time in their presence, he is not exactly euphoric. If he feels a deep sense of fulfillment in seeing these paintings one last time, he also feels a strange sadness. When it is over, when the sun dips below a building and a streetlight blinks on in the window, he is almost trembling. He pulls out a handkerchief, removes his glasses and wipes his face. His hair is slightly disheveled. He exhales, looks once at the oversize binders against the wall, presses his lips tightly together and then turns his back and leaves the room.*

It is also important to remain within the bounds of reason. What is one to make of the controversy regarding the United States National Library of Medicine's Visible Human Project? The person who became the male Visible Human was Joseph Paul Jernigan. Jernigan was a convicted murderer (11). On July 3, 1981, he stabbed and shot to death a seventy-five-year-old man, who surprised him during a robbery. He was executed on August 5, 1993. He had willed his body to the Texas Anatomy Board, but almost certainly did not know he was a candidate for the Visible Human Project at the time of his death. Only after the body had been selected and processed did the committee choosing the body realize that they had selected an executed prisoner convicted of murder. The use of this particular cadaver raises the question of whether the project glamorises a convicted murderer, making him appear more sympathetic by allowing him to perform a service to society through no effort of his own. The *Visible Human Male* is, after all, a rather heroic, perhaps even a noble figure. Neither the National Library of Medicine nor the Colorado team identified Jernigan as the Visible Human male. However, his date and cause of death, as well as his state of origin were public information. His identity has been widely known and reported.

The announcement that the subject was an executed prisoner brought an interesting response from, of all places, the University of Vienna, specifically a group from the Department of Emergency Medicine. These doctors maintained that the death penalty and medical participation in an execution were unethical and that informed consent by the executed person did not dispel the unethical basis of the material used in this project. They called for the immediate withdrawal of the anatomical images as morally necessary (11)

Nazis not alone in committing medical crimes

Among the more heinous medical crimes, one must include the Japanese Unit 731 operating in occupied China, during World War II. It went under the relatively innocuous title of Army Epidemic Prevention Research Laboratory. In fact, under Surgeon General Shiro Ishii, it experimented in chemical and biological weapons. Details on the activities can be found in Wikipedia and papers available on the internet. Suffice it to say that Chinese prisoners were vivisected after they had been infected with a variety of diseases. Experiments on amputation, removal and transplantation of organs and the breeding of plague-infested fleas were only some of their other activities. These experiments continued up to the end of World War II. It is important to note that General Douglas MacArthur, Supreme Commander of the Allied Powers, secretly granted immunity to the physicians of Unit 731 in exchange for providing America, *but not the other wartime allies*, with their research on biological warfare and data from human experimentation (20).

Lest we feel superior to researchers during World War II, let us not forget the secret laboratories in China, Russia, the USA, Britain and other countries which continue, even today, to invent, experiment on and build stockpiles of deadly poisons, viruses and other pathogens.

Would regulations and guidelines have averted the atrocities committed by the medical community in Nazi Germany?

This question is especially relevant when we consider Nazi Germany where following the rules was mandatory.

Intrepid researchers, among whom John Hunter (1728-1793) stands out, usually experimented first upon themselves. His celebrated experiment on the transmission on venereal disease is well known. Others, such as Philippe Ricord (1800-1889) experimented on patients. The concept of informed consent had not yet evolved.

Albert Neisser (1855-1916) of Breslau, a leading dermatologist and famed for his discovery of *Neisseria gonorrhoeae*, attempted prevention of syphilis in 1892. He injected serum from a syphilitic patient into girls aged 10 – 24 years, and into prostitutes. The liberal newspaper *Münchner Freie Presse* included information on Neisser's study in its ongoing discussion on human experimentation in hospitals. Debate in the Prussian parliament followed, where Rudolph Virchow (1821-1902) defended Neisser. The case was investigated by a court which ruled that Neisser should have sought the express consent of the patients. The Prussian government, after seeking expert opinion, issued path-breaking regulations on human experimentation in 1900 (21).

Moll and Krischel (21) quote from this report:

> *"... that medical interventions for purposes other than diagnosis, therapy, and immunization are absolutely prohibited, even if all other legal and ethical requirements for performing such interventions are fulfilled if: (1) the person in question is a minor or is not fully competent on other grounds; (2) the person concerned has not declared unequivocally that he consents to the intervention; (3) the declaration has not been made on the basis of a proper explanation of the adverse consequences that might result from the intervention…"*

They point out that under the Prussian culture "…it would be unthinkable that those ministerial directives would not have been treated with the utmost respect and introduced and obeyed in the most rigid way…" And yet, a few decades later, Nazi Germany wilfully flouted these laws that remained operational.

One more example will suffice to show that those in power will contravene regulations when it suits their convenience or purpose.

The Nuremberg code was drafted after detailed discussions on Nazi atrocities and its ten points delivered as a verdict by the judges on August 20, 1947. In 1999, Horner analysed subsequent medical research and concluded:

> *…when the Nuremberg Code was published after the trial it continued to be ignored by many doctors for some thirty years afterwards. Indeed its central principle of informed consent has itself been eroded by subsequent international agreements on the ethics of medical research… (22)*

America – in the forefront of the Nuremberg trials – had itself started the infamous infection of at least 5128 vulnerable Guatemalans with syphilis, gonorrhea and chancroid from 1946 and intentionally infected 1308 of these subjects between 1946 and 1948. The "research" was conducted by the Public Health Service and was funded by the National Institutes of Health. "The public had no knowledge of the experiments for more than half a century." (23) The Public Health Service of the U. S. Government had started the now notorious 'Tuskegee Study of Untreated Syphilis in the Negro Male' in 1932 *and continued the study for 40 years!*

Sadly, the promulgation of codes does not prevent unethical research.

Summing up responses to the arguments against Pernkopf

Appleyard (24), discussing the arts in general and writing on Christmas Eve, posed the question: Should we love the art if the artist is a monster?

He came to certain conclusions. Good or great art may be made by people who have done something horribly wrong. He quoted Roger Crisp, professor of moral philosophy at Oxford. "…Imagine if more and more revelations came out, so almost every great artist was morally tainted. Would we stop looking at art? I don't think so."

Appleyard asked, "What about Caravaggio, a murderer, a street hoodlum and one of the greatest artists of the Renaissance?" Waldemar Januszczak, art critic, felt that Caravaggio's art "has such enormous power and depth, carries so much religious conviction, that the darkness of its creator feels irrelevant." Appleyard also reminds us of Paul Gauguin – "a paedophile racist, running around with these 13-year-old girls who become his so-called wives. Many scholars think it completely compromises you when you look at those doe-eyed, brown bodies and how they were representative of a culture of racism and colonialism." Tamar Garb, professor of the history of art at University College, London, commented that the history of art would have been different if there had been no Gauguin just as the history of cinema would have been different without Roman Polanski. (Polanski's reputation on the basis of his films such as *Rosemary's baby, Pianist and Chinatown* was marred by the accusation that he had raped a 13-year-old girl in 1977.)

Perhaps we should follow the principle used by Roland Barthes "the most influential aesthetic thinker of the 1970s. For him, once a work of art is made, the creator vanishes, becoming an irrelevance."(24)

The controversy over Pernkopf's atlas has resulted in some good. It provoked a historical and ethical analysis of the study and teaching of anatomy in Austria and Germany during the Nazi era and prompted philosophical debate. Hildebrandt (5) discusses these aspects and points out that in the case of this atlas the dilemma was especially poignant as the volumes under discussion provided unparalleled anatomical illustrations that remain useful to surgeons and students alike. She refers to the more recent criticisms of another German anatomist, who had once served on the faculty of the University of Heidelberg – Gunther von Hagens, who has been accused of using bodies of executed criminals from China (25).

Hildebrandt's conclusions (5) are rational and thought-provoking. Pernkopf's atlas is:

> *…the product of the very human mind of an obsessive perfectionist who would have pursued his work under any political circumstances. Indeed, the first and the last parts of the atlas were not created during the time of the NS regime in Austria but before and after under very different political and material conditions… a ban could not atone the great evil committed by human beings on other human beings. Rather, it is up to a new human generation to glean good from this murky history by continuing to use Pernkopf's atlas in a rational, historically conscious manner."*

As she points out, the atlas can be used to teach not only anatomy but also history and ethics.

Yee and co-workers (26) discussed the continued use of the atlas with historians and religious authorities. Rabbi Joseph Polak, a Holocaust survivor and Chief Justice of the Massachusetts Rabbinical Court, was one of the experts consulted. The general conclusions were that the use of the atlas could be permitted under the Jewish principle of *Pikuach Nefesh* – the saving of human life (27).

I found the statements made by Dr Susan Mackinnon, who continues to use the atlas when performing complex operations on nerves, relevant:

> *I would think that as an ethical surgeon I would take it as a given that I should use whatever educational resource I thought would help me to maximise a successful outcome and that my patient would expect that of me. In my experience, it would set back detailed nerve surgery tremendously if these books are lost."(3)*

Conclusion

When scientific data is obtained unethically, the means can only be condemned. There can never be a justification for such practices as were used by the Nazi medical experimenters, that violated all ethical principles.

That said, what is to be done to the invaluable, life-saving data yielded by such unethical studies? The victims of unethical practices have already passed away. We do them no harm by using the data.

We have two options. Erase all such data from all our medical repositories in such a manner that they can never be used by anyone. We shall then have jettisoned life-saving information and practices. This step may result in the worsening of patients who could have been helped by such information or even result in the loss of their lives. How does this help humanity?

The second option is to use the life-saving data and practices whilst remaining fully aware of the means by which they were obtained. In teaching institutes in particular, whenever such data is used to help the patient, a tribute is paid to the victims from whom this beneficial information had been obtained. This will also impress ethical principles upon young minds.

In making such use, we are remembering and honouring the victims even as we ameliorate symptoms and save lives.

Acknowledgements

Dr Anantanarayanan Raman (Australia) carefully went through my final draft and made several improvements.

I am grateful to Drs Reeta Mani (Bengaluru) and Bindu Desai (USA) for obtaining the full texts of references beyond my reach.

The anonymous referee to whom this paper was sent for review made excellent suggestions. I have incorporated information based on them.

References

1. Yee A, Coombs DM, Hildebrandt S, Seidelman W E, Coert J H, Mackinnon S E. Nerve surgeons' assessment of the role of Eduard Pernkopf's Atlas of topographic and applied human anatomy in surgical practice. *Neurosurgery*. 2019 Feb1; 84(2):491-8.
2. Yasargil MG, Ture U, Yasargil DCH. Impact of temporal lobe surgery. (Editorial). *J Neurosurg.* 2004 Nov; 101(5):725-38.
3. Baker K. Eduard Pernkopf: the Nazi book of anatomy still used by surgeons. 19 August 19[cited 2020 Aug 15]. Available from https://www.bbc.com/news/health-49294861#:~:text=Eduard%20Pernkopf%3A%20The%20Nazi%20book%20of%20anatomy%20still%20used%20by%20surgeons,-By%20Keiligh%20Baker&text=When%20nerve%20surgeon%20Dr%20Susan,20th%20Century%20book%20of%20anatomy.
4. Kershner I. In Israel, modern medicine grapples with ghosts of the Third Reich. *The New York Times.* 2020 May 12[cited 2020 Aug 15]. Available from: https://www.nytimes.com/2020/05/12/world/middleeast/nazi-medical-text-israel.html
5. Hildebrandt S. How the Pernkopf controversy facilitated a historical and ethical analysis of the anatomical sciences in Austria and Germany: a recommendation for the continued use of the Pernkopf atlas. *Clin Anat*. 2006 Mar;19(2):91-100
6. Hubbard C. Eduard Pernkopf's *Atlas of Topographical and Applied Human Anatomy* the continuing ethical controversy. Anat Rec. 2001 Oct 15;265(5):207-11.
7. Silver JR. The decline of German medicine 1933-1945. *J R Coll Physicians Edinb.* 2003;33:54-66
8. Bruns F, Chelouche T. Lectures on inhumanity: teaching medical ethics in German medical schools under Nazism. *Ann Intern Med.* 2017; 166(8):

591-5.

9. Paterniti M. The most dangerous beauty. *GQ* 2002 Sep 28[cited 2020 Apr 18]. Available from: https://www.gq.com/story/pernkopfs-anatomy-nazi-history
10. Pernkopf E. ed, Ferner H, transl Monsen H. *Atlas of topographical and applied human anatomy.* Volume 1. Head and neck. 2nd revised ed. Baltimore-Munich: Urban & Schwarzenberg; 1980.
11. Atlas M C: Ethics and access to teaching materials in the medical library: the case of the Pernkopf atlas. *Bull Med Libr Assoc.* 2001 Jan;89(1):51-8
12. Buklijas T. Culture of death and politics of corpse supply: anatomy in Vienna. 1848-1914 *Bull Hist Med.* 2008 Fall; 82(3):570-607
13. Pringle H. Anatomy. Confronting Anatomy's Nazi past. *Science* 2010 Jul 16; 329(5989):274-6.
14. Norton SA: On first looking into Pernkopf's atlas. (Part 1). *Arch Dermatol*. 2001 May:137(5):549-51
15. Norton SA: On first looking into Pernkopf's atlas. (Part 2). *Arch Dermatol*. 2001 Jul:137(7): 867-8.
16. Bagatur E. Nazi medicine – Part 2: the downfall of a profession and Pernkopf's anatomy atlas. *Clin Orthop Relat Res*. 2018 Nov; 476(11):2123-7.
17. Weindling P. Human guinea pigs and the ethics of experimentation: the *BMJ*'s correspondent at the Nuremberg medical trial. *BMJ*. 1996 Dec 7; 313(7070):1467-70.
18. Riggs G. What should we do about Eduard Pernkopf's atlas? *Acad Med*. 1998 Apr; 73(4):380–6.
19. Israel HA: The Nazi origins of Eduard Pernkopf's *Topographische Anatomie des Menschen*: the biomedical ethical issues. Reference Librarian. 1998; 29(61/62):131-46. Epub
20. Vanderbrook AJ. *Imperial Japan's human experiments before and during World War Two.* University of Central Florida. *Electronic Theses and Dissertations,* 2004-2019. 2013[cited 2020 Aug 19]. p 55. Available from: https://stars.library.ucf.edu/etd/2589
21. Moll FH, Krischel M. Albert Neisser and the first Prussian directive on informed consent. In: Sakti Das MD, Ed.: *Skeletons in the closet: Indignities and injustices in medicine.* Linthicum, Maryland: The American Urological Association; 2012.
22. Horner JS. Retreat from Nuremberg? Can we prevent unethical medical research? *Public Health.* 1999; 113:205-10.
23. Rodriguez MA. First, do no harm: The US sexually transmitted experiments in Guatemala. *Am J Public Health.* 2013:103:2122-6.
24. Appleyard B. Should we love the art if the artist is a monster? *The Sunday Times*. 2017 Dec 24[cited 2020 Aug 15]. Available from: https://www.thetimes.co.uk/article/should-we-love-the-art-if-the-artist-is-a-monster-nvrdmg3hd
25. Harding L. Von Hagens forced to return controversial corpses to China. *The Guardian*. 2004 Jan 23[cited 2020 Aug 16]. Available from: https://www.theguardian.com/world/2004/jan/23/arts.china
26. Yee A, Hildebrandt S, Seidelman WE, Mackinnon SE. Letter to the editor: Nazi medicine – Part 2: The downfall of a profession and Pernkopf's anatomy atlas. *Clin Orthop Relat Res*. 2018; 476:2465-6.
27. Polak JA. Vienna protocol for when Jewish or possibly-Jewish human remains are discovered. In: Czech H, Drumi C, Weindling P, Eds. Medical ethics in the70 years after the Nuremberg Code, 1947 to the present. *Cent Eur J Med.* 2018 [cited 2020 Apr 14]; 130: S239-43. Available from: https://link.springer.com/content/pdf/10.1007/s00508-018-1343-y.pdf

---

Moving from clinical to pragmatic equipoise in health policy and systems research

VIJAYAPRASAD GOPICHANDRAN

Abstract

Health policy and systems research refers to the research conducted on the formulation, impact, organisation and functioning of health policies, and how to optimise the functioning of health systems and policies towards achieving health for all. There is emerging scholarship on the ethics of conducting such health policy and systems research. Ethics of health policy and systems research, though similar to the ethics of traditional clinical research in many ways, has several important distinctions. In traditional clinical research on human participants, where two treatments or interventions are compared, clinical equipoise is an important ethical consideration. This refers to the genuine uncertainty among professional peers on whether one of the interventions is better than the other. This uncertainty is in the biomedical efficacy of the intervention. Unless such equipoise exists, clinical research is said to be unethical from the benefit-risk balance and justice perspectives. In health policy and systems research, the question of clinical equipoise is often not relevant. This article will describe the condition of clinical equipoise in health policy and systems research, its applications and challenges.

***Key words**: clinical equipoise, health policy and systems research, pragmatic equipoise*

Author: **Vijayaprasad Gopichandran** (vijay.gopichandran@gmail.com), Assistant Professor, Department of Community Medicine, ESIC Medical College and PGIMSR, KK Nagar, Chennai 600 078 INDIA.

To cite: Gopichandran V. Moving from clinical to pragmatic equipoise in health policy and systems research. *Indian J Med Ethics*. 2020 Oct-Dec;5(4) NS: 326-9. DOI: 10.20529/IJME.2020.77.

Manuscript Editor: Sandhya Srinivasan, Veena Johari

Introduction

Health policy and systems research (HPSR) refers to all research that attempts to understand the way health systems function and methods to strengthen them (1,2). The important goals of HPSR are to understand the dynamics of functioning of a health system, to study how interventions impact the functioning and outputs of the system, to evaluate the influence of policies on health system functions and outcomes and to strengthen the health system through interventions and policies that are grounded in evidence. Therefore, HPSR is a multidisciplinary enterprise involving contributions from healthcare providers, public health experts, policy makers and