True fighter for India

Aziz Haniffa profiles Amita Gupta, who is revolutionizing the understanding and treatment of a plethora of deadly diseases

Pr Amita Gupta may be less of a known name than her younger sister — trailblazing civil rights attorney Vanita Gupta — but her cutting-edge medical research at Johns Hopkins University and leading United States-India collaborations to fight diseases is the stuff of legend.

Amita is deputy director, Johns Hopkins University Center for Clinical Global Health Education, associate professor of medicine, Division of Infectious Diseases, and associate professor, International Health, Johns Hopkins Bloomberg School of Public Health. She grew up in the United States, England and France, and completed her undergraduate education at Massachusetts Institute of Technology, medical school at Harvard, and internal medi-

cine training at San Francisco General Hospital, University of California San Francisco.

Before she joined Johns Hopkins, Amita was an epidemic intelligence service officer focusing on global food-borne and diarrheal diseases epidemiology at the US Centers for Disease Control and Prevention. She worked on a cholera outbreak in Micronesia, typhoid fever detection in Vietnam, and salmonella outbreaks on almond farms in California and dairy farms in New England.

She then completed an infectious diseases fellowship and masters in health sciences in clinical investigation at Johns Hopkins.

Her career choice was greatly influenced by her childhood trips with parents Raj and Kamla Gupta.

"I first got interested in working in India and in infectious diseases when I visited my family in Aligarh, where animals roam freely and

sewage seeps in the open drains throughout the streets," Amita Gupta told *India Abroad*. "My sister developed shigella dysentery at age 4 and nearly died in the local hospital there. I was diagnosed with malaria at age 7 and remember shivering deliriously under numerous blankets on the rooftop cot I slept in. My older cousin contracted polio in Roorkee and was left with a limp and required lifelong use of a leg brace. Two other cousins and several other family members developed acute viral hepatitis over the years. My uncle while visiting us from India developed TB and we all had to get evaluated for TB exposure while we were living in England. These were just a few of the many infectious diseases that burdened my own family."

Dr Amita Gupta leads cutting-edge

diseases like AIDS and TB

United States-India collaborations to fight

She joined Johns Hopkins in 2002. At that time Dr Robert Bollinger — in collaboration with scientists from India's National AIDS Research Institute and Maharashtra's Byramji Jeejeebhoy Government Medical College in Pune — was starting India's first Phase III HIV-prevention trial to prevent transmission from mother to child. Over the next five years, she became a key member of this landmark trial, which was published in *Lancet* and which informed the World Health Organization's guide-



Hopkins-India collaboration site in Pune in 2012. Sebelius's visit was meant to highlight US-India medical research partnerships

lines on HIV prevention in women and children.

After that Gupta and Bollinger became a team, continuing to build and strengthen the US-India collaborations with the BJGMC, forging the Johns Hopkins University-BJMC HIV Clinical Trials Unit. The research is largely funded by the National Institutes of Health

but it also receives funding from the Indian Council of Medical Research, the Gilead Foundation, the Gates Foundation, and Ujala, the Gupta family foundation run by her parents and other private donors.

Amita leads a group of more than 60 dedicated clinical researchers — physicians, nurses, social scientists, epidemiologists, statisticians, computer scientists, etc — most of whom are in India. She and her colleagues focus on conducting clinical trials that address better ways of preventing and treatment of HIV and TB, especially in women and children in India. The trials are primarily conducted at the BJGMC's Sassoon Hospital, catering to the poorest populations of Pune and surrounding areas.

"India has presented me with the greatest opportunities and the greatest challenges," Amita said. "Doing clinical research in India is not for the fainthearted or the impatient. First you work hard to compete to get funding for the research; that can take one to two years to get a successful award... Then we often spend anywhere from two to five years conducting the study and then only may we find out if we have identified a strategy or not that can have a potential impact on public health in India and beyond. All the

while, our team spends much of our time ensuring compliance with the ever-increasing complex regulatory and bureaucratic environments of the US and of India to conduct human trials."

To conduct high quality, ethically sound clinical trials, Gupta and her colleagues in India had to work for years to establish an institutional review board qualified enough to review the research and prevent exploitation of poor patients in India. This involved building medical records and data collection systems that did not exist at the hospital. Building a laboratory capable of performing quality-assured clinical investigations and research tests also took more than a decade.

None of that could stymie Amita's passion. She was recently awarded a five-year grant of \$2.5 million as part of a bilateral cooperative funding initiative from the NIH, India's Department of Biotechnology and the Indian Council of Medical Research.

Amita and her Indian co-principal investigator, Dr Soumya Swaminathan, one of India's eminent TB researchers, are putting together a team of scientists from both countries to understand the social, environmental, clinical and biological factors associated with TB transmission and disease progression in India.

"India has the world's largest burden of disease according to the latest WHO statistics," Amita said. "And much of that continues to be preventable and treatable infectious diseases. India is number one in total number of TB cases — one in four people on the planet is an Indian with tuberculosis. It ranks number three in HIV in total number of

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cases. It has the largest number of undernourished children. With that it comes among the largest number of pneumonia deaths and diarrheal deaths in young children. India also has a complex health-care system where a myriad of care practices both good and bad — occur side by side."

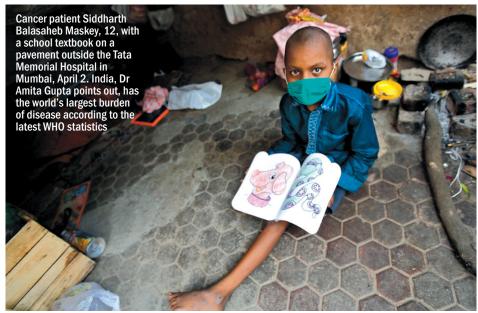
She continued, "I have found that the intersection between infectious diseases, the environment, and the social conditions human beings live in to be immensely interesting. An infectious diseases expert always has interesting histories to take from patients and populations, like: What did you eat, where did you travel, what animals or pets are you in contact with? What are your hobbies, who have you had sex with, etc. Never a dull moment!"

Despite gargantuan challenges, why is she virtually obsessed with trying to make a difference in India?

"India is where my family is from and where I have felt most connected to the people — to the public health needs," she replied. "India is such a complex and dynamic place where almost every infectious disease in the textbooks exists, so there is so much to learn and so much to be done. It also is a place where there are smart people and opportunities to build infrastructure to study these infectious diseases. There is a clear, compelling public health need. And if solutions can be sought for India that are scalable and cost-effective there, they have great relevance to the rest of the world."

She lamented: "Clinical research in India is still in its infancy. Medical schools and education systems in India have not fully materialized their potential nor have they created enough of a culture to drive high quality clinical research... Until recently, only a few Indian medical schools have had the resources and the faculty dedicated to clinical research to produce quality studies."

This, she continued, "is both a challenge and an opportunity. Building research capacity and investing in the study of public health priorities of importance to India and to the rest of the world takes time, perseverance, and a long-term vision. Dr Bollinger and I have focused on finding the right group of people to work with, who care about working in difficult and challenging environments like Indian public hospitals where there is overcrowding, frequent electricity outages, lack of basic necessities like gloves and sinks to wash your hands, limited resources to diagnose patients properly, but where there is real disease and need for good care. We have spent more than a decade building the right team... One of the most rewarding things for me has been watching the empowerment of many of our team members from India who now are leaders in international research networks. For example our outreach coordinator, Savita, chairs the international AIDS Clinical Trials Group Outreach and Retention committee,



IVEK PRAKASH/REUTERS

'Hopkins and India are fortunate to have people like Dr Gupta'

AZIZ HANIFFA

r Robert Bollinger, Dr Amita Gupta's mentor and now colleague, says he was blown away by her brilliance from the moment he met

""It was in rural Bihar in 1979," Bollinger, professor of medicine, public health and nursing, Johns Hopkins University, told *India Abroad*, "that I was given an opportunity to start my career in global health working with a leprosy control program in the Dhanbad district. That experience, working with the dedicated staff and very marginalized, stigmatized leprosy patients, shaped my career and established India as my second home."

Bollinger, also director, Center for Clinical Global Health Education, and associate director, Center for Global Health at Johns Hopkins University School of Medicine, continued: "In 1991, I began my collaboration with colleagues in Pune on some of the earliest studies of HIV in the country, and this initial project led to our establishment of the first and largest prospective study of HIV in India... After many years as the Hopkins principal investigator of this collaboration, I was very, very fortunate to be able to recruit Dr Amita Gupta to Hopkins from the CDC (*Centers for Disease Control*). It was very clear from when we met that she was a brilliant scientist, with the enthusiasm and leadership skills to ensure the

Dr Robert Bollinger

future of our US-India collaborations."

Bollinger said he was so impressed with Gupta's passion and brilliance that "I stepped down as the PI of the project a few years ago and she stepped up to lead our group at Hopkins, working with our colleagues in India. I am thankful to Amita that I remain involved in the collaboration as a co-investigator focused on helping the team in India and at Hopkins identify and apply for new grant opportunities, as well as help mentor the junior scientists in their grant and paper writing. We (Gupta and him) have complimentary skill-sets and experience. We also have a shared passion for this work and for India. I am so happy to see this project continue to thrive, grow and benefit the people of India and beyond under Amita's leadership. Hopkins and India are fortunate to have people like Dr Gupta."

overseeing scientific members from 26 countries and leading the agenda for how best to recruit patients into HIV and TB trials. Many of our India-based team members now have the confidence and skills to write grants and papers and take the initiative in developing new studies/improvements. Our study coordinator Nishi, for example, saw that many HIV-infected women continued to faced significant stigma even from the nurses at the hospital in Pune. So she worked with the nurses and developed a stigma reduction course for nurses. Now all nurses and nursing students at the BJGMC undergo this training."

She reiterated: "India, unfortunately, has a reputation for being a difficult place to work - particularly if one is good about actually following all the regulations that have been put into place, a requirement that NIH-funded research, for example, requires us to do. Here is an example of what it takes to conduct an NIH clinical trial in HIV or TB treatment: You work for 2-3 years and have a 10-15 percent chance of getting successful funding from the US NIH. You and your Indian collaborators then need to get ethical approvals from the Indian institution, have a competent institutional review board both in the US and in India... You then need to submit 30 copies of your application to the Indian government's Health Ministry Screening Committee, which only meets every three months, and await their review. Sometimes it can take 1-2 years to get a complete review and then you may get an answer stating, 'This project can be done without foreign funding, and therefore is being rejected.' If you do get good reviews, then you need to also submit to the Drug Controller General of India office and undergo their review. It has happened that the HMSC may approve but DCGI rejects the study because their technical reviewers feel it has insufficient merit. If they do approve it, then you may have to also apply to the Director General of Foreign Trade to obtain an import license for study drugs and materials needed for your study. Meanwhile, while you have been waiting for your approvals, the science has already been answered somewhere else like in South Africa, but since the study did not involve Indian patients India is not ready to adopt the new innovation or finding."

She has no regrets.

"Working in India is great," she said. "The patients are so appreciative, our staff are so committed and hardworking, our results can be really exciting. Our first clinical trial that we did — took seven years from inception to results — changed WHO guidelines and demonstrated that we can protect breastfed children from getting HIV by giving them a medicine called nevirapine, which is readily made by Indian generic companies. This was important because children were dying from diarrheal diseases when they were given unsafe water with formula."

She said Bollinger had "designed the study, and he trained me and taught me the ropes of how to have a successful US-India clinical research collaboration. I am now running the program and bringing many new American and Indian scientists to our team."