News from here and there

Questions on ethical behaviour, citation farms cause retraction of research papers from renowned institutions

June and July 2023 were tumultuous months for academia with Harvard and Stanford universities announcing that investigations were being conducted on some of their most prominent faculty, and their widely cited papers. The people under scrutiny included Francesca Gino, a leading scholar of behavioural work at Harvard Business School, Boston, Massachusetts, USA and Marc Tessier-Lavigne, neuroscientific academician and President, Stanford University, Stanford, California, USA. Ms Gino, PhD in Economics and Management has been placed on administrative leave and Tessier-Lavigne's resignation would be effective from 31 August 2023 as per their respective institutes' official statements.

Multiple research papers from both as principal authors from as early as 2010 have had concerns raised about manipulation of data, incentivization of research environments for workers, tampering of results and deliberate publication of unreliable evidence which was subsequently not reproducible in other independent studies.

Francesca Gino's body of work includes dozens of papers on behavioural research dedicated to minimalistic interventions that can improve quality of life, such as optimal placement positions of healthy food items in buffets to ensure fruit get chosen first, and—ironically—at least one publication on how to elicit honest replies in tax return documents (a paper that has been cited 522 times so far). Doubts have been raised by separate groups of independent behavioural scientists on both the integrity and reliability of methods used in social science research by her group.

The investigations have also led to doubts of wider involvement of pharmaceutical and biotechnology companies in quality and quantity of results being published, in an effort to influence further research, marketing and treatment trends. Marc Tessier-Lavigne is expected to retract at least five papers which have had direct or indirect influences on further research on understanding of Alzheimer disease. He is a co-founder of Genentech, a biotech company which currently has drugs under trial for Alzheimer disease and is under the scanner for refusal of some of its employees to participate in an inquiry against Tessier-Lavigne. An investigator in the inquiry committee too subsequently had to step down for having a previously-undeclared US$18 million investment in Genentech.

Meanwhile, in India, Saveetha Dental College in Chennai, Tamil Nadu, has been identified by *Science* and *Retraction Watch*, for unethical use of self-citations to augment its citation score. (Joelving F. Did a 'nasty' publishing scheme help an Indian dental school win high rankings? *Science* [in collaboration with *Retraction Watch*]. 2023;380[6649]. Available at *www.science.org/content/article/did-nasty-publishing-scheme-help-indian-dental-school-win-high-rankings.*)

Many papers by researchers from the Saveetha Dental College include references to unrelated papers from the same institute. With increasingly elevated rankings on the National Institutional Ranking Framework, Saveetha Dental College was ranked as the apex dental college in India by the government's Ministry of Education in 2022 (Ministry of Education, Government of India. National Institutional Ranking Framework. India Rankings 2022: Dental. Available at *www.nirfindia.org/2022/DentalRanking.html*.)

Science is one of the world's top-rated science journals and is published by the American Association for the Advancement of Science. *Retraction Watch* is a database that lists retracted and/or corrected publications and publications which have an expression of concern. The use of such 'citation farms' to elevate positioning on ranking schemes is considered inappropriate and has also placed the dental college under examination by Elsevier (a large publication company with an extensive research database) and Clarivate Analytics, an analytics company that provides data and trends on citation patterns.

Internationally, only 4 of every 10 000 papers published are retracted. Guidelines from the non-profit Committee on Publication Ethics state the move is considered extreme and reserved for those publications where clear evidence of unreliability of findings is obtained.

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Non-stigmatizing and affirmative liver disease nomenclature announced

At the European Association for the Study of the Liver (EASL) Congress 2023 held between 21 and 24 June 2023, leaders of various multinational liver societies, including EASL, the American Association for the Study of Liver Diseases (AASLD), La Asociación Latinoamericana para el Estudio del Hígado (ALEH), the co-chairs of the Non-alcoholic Fatty Liver Disease (NAFLD) Nomenclature Initiative, and leading specialists, including hepatopathologists, hepatologists, gastroenterologists, endocrinologists, paediatricians, and public health and obesity experts, along with experts from industry, regulatory agencies, and patient advocacy groups, announced new terminologies for various liver diseases related to fat accumulation in the liver.

The new terminologies are:

- Steatotic liver disease (SLD) will be the all-embracing term for all the aetiologies of steatosis.
- Steatohepatitis, being a key pathophysiological concept, will be retained.
- Metabolic dysfunction-associated steatotic liver disease (MASLD) will replace non-alcoholic fatty liver disease (NAFLD). MASLD will include patients with hepatic steatosis and at least one of five cardiometabolic risk factors.
- MetALD (pronounced as Met A-L-D), a new category outside of pure MASLD, will describe those with MASLD and who consume large amounts of alcohol weekly (women 140 g/week; men 210 g/week).

- Metabolic dysfunction-associated steatohepatitis (MASH) will replace non-alcoholic steatohepatitis (NASH).
- Cryptogenic SLD will refer to patients with no metabolic parameters and no known cause.

A transparent and collective Nomenclature Development Initiative process was begun in 2020. The aim was to determine the requirement for new nomenclature, and if needed, the best terms. The respective organizations nominated the stakeholders based on their discipline, professional expertise, geographical demonstration and demographics.

Over 225 global stakeholder panelists participated in one or more stages of the Nomenclature Development Initiative. Their goal was to ensure that better nomenclature be used globally to ensure better research and funding to save the lives of those suffering from liver diseases.

There were six stages in this transparent and collaborative Delphi process, including two in-person meetings and four online surveys. There was an average response rate of over 75% for the four rounds of data collection. The final response rate was 88%. Of these, 97% finally approved the recommendations. Also, over 60 key organizations, including global societies, patient and patient advocacy groups have endorsed the recommendations.

The change in terminology was a result of several reasons, including the need to reduce stigmatizing language such as 'fatty' and 'alcohol'.

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Catastrophic health spending and out-of-pocket expenditure on health in India

Since 2007, 29 June has been celebrated annually by the Government of India as 'Statistics Day', to commemorate the birth anniversary of late P.C. Mahalanobis. Mahalanobis is considered the Father of Indian Statistics and had established the Indian Statistical Institute in Calcutta (now Kolkata) in 1931. The theme selected for Statistics Day, 2023 was 'Alignment of State Indicator Framework with National Indicator Framework for monitoring Sustainable Development Goals'. The National Sample Survey Office (Field Operations Division) [NSSO (FOD)], Mumbai, Ministry of Statistics and Programme Implementation, celebrated the Statistics Day, 2023 in association with S.K. Somaiya College, Mumbai on 29 June 2023. On the occasion, 'The Sustainable Development Goals National indicator Framework Progress Report 2023' (*www.mospi. gov.in/sites/default/files/publication_reports/SDGs_NIF_Progress_Report_2023N_0.pdf*) was released by the Ministry of Statistics and Programme Implementation, National Statistical Office, Government of India.

The report documents important gains made by India in maternal and child health. The percentage of children (aged under 5 years) who are underweight had reduced from 35.7% in 2015–16 to 32.1% in 2019–21. The maternal mortality rate (per 100 000 live births) had reduced from 130 in 2014–15 to 97 in 2018–20. The under-5 mortality rate (per 100 000 live births) had reduced from 43 in 2015 to 32 in 2020.

The third of the United Nation's Sustainable Development Goals is to provide universal health coverage (UHC) and to improve financial protection and thereby prevent catastrophic spending. Over 90 million Indians live in households where spending on healthcare accounts for more than 10% of their household consumption expenditure (catastrophic health expenditure). Of these, 31 million live in families where the health spend is more than 25% of household expenditure.

In 2022–23, the highest proportion of people with large household expenditures on health as a share of total household expenditure of income >10% and >25% were in Kerala (16% and 6%, respectively), followed by Maharashtra (9% and 3%, respectively). Further, the highest out-of-pocket expenditure as a proportion of total health expenditure was highest in Uttar Pradesh (72%) followed by Kerala (68%) as per the National Health Accounts 2019–20. 'Large' in large household expenditure is defined as health expenditures exceeding 10% or 25% of total household expenditure or income (*www.who.int/data/gho/indicator-metadata-registry/imr-details/4844*).

Further, Niti Aayog had estimated that at least 30% of the population (nearly 400 million people) did not have any financial protection for health.

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Johnson and Johnson stops manufacture of talc-based baby powder in India

Johnson & Johnson's (J&J) talc-based baby powder, one of its most recognizable brands across the globe, will no longer be manufactured in India from 22 June 2023, as per an application received by the Maharashtra Food and Drug Administration (FDA). However, the company will continue to distribute and sell this product till stocks last.

While the reason for this step has not been elucidated, it is presumably part of a global effort by the company to switch to a formulation based on cornstarch from the original talc-based product.

On 11 August 2022, the company had released a press statement that as part of a worldwide portfolio assessment, it had made the commercial decision to transition from a talc-based baby powder portfolio to an all cornstarch-based product. This decision follows the 2020 decision by J&J to stop selling its talc-based baby powder in the USA and Canada because of falling demand.

The move to stop manufacture and sales of the talc-based baby product in India by the company comes after a favourable January 2023 court verdict wherein the Bombay High Court squashed and set aside an order by the Maharashtra FDA. The FDA had restrained the company from manufacturing and selling its baby powder in India.

J&J had first started manufacturing its iconic talc-based baby powder in its plant in the suburb of Mulund in Bombay (now Mumbai) in 1965. Under a cosmetic licence, millions of batches of three different varieties of the baby powder have been manufactured and sold across the country.

In the USA, J&J is facing over 38 000 lawsuits from consumers and their survivors, who claim that the company's talc-based products are contaminated with asbestos, a known carcinogen. The company, however, has stated that its talc-based products are safe and free of asbestos, based on regulatory approvals and scientific testing over decades.

In October 2022, J&J created a subsidiary named LTL

Management and assigned all the talc lawsuits to it. It placed the subsidiary into bankruptcy and paused all pending lawsuits. J&J stated that this was to equitably compensate claimants, but the claimants stated that J&J should defend itself.

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Descendants of Henrietta Lacks, original provider of the immortal HeLa cell line, reach out-of-court settlement with Thermo Fisher Scientific

Seventy-three years after the demise of Henrietta Lacks, an African–American woman who worked in the tobacco fields of Clover, Virginia and who died from cervical cancer at the age of 31 years, in the 'coloured ward' of Johns Hopkins Hospital, Baltimore, Maryland, USA in 1951, her last-surviving son and family members were compensated for profits made off harvesting and multiplication of her cancer cell lines. The samples, which were collected from her tumour without her knowledge or consent by her then-attending gynaecologist during a routine biopsy, were given to Dr George Gey, medical researcher at the same facility. The resulting cell line has been named 'HeLa'. (Readers wishing to know more about the history of this unfortunate patient and her now famous cell line would do well to read Rebecca Skloot's book *The immortal life of Henrietta Lacks*.)

An official statement on Johns Hopkins website states that neither Dr Gey, who studied Ms Lacks' tissue, nor the parent institute profited off his research; however, an ethical responsibility regarding the samples has been accepted and states that Johns Hopkins continues to freely share cultures of the HeLa cell line for further research. Biotechnology companies and research laboratories that had acquired the cell lines have however, profited from the sale of HeLa cultures and from patents on tests on the same for more than half a century.

Thermo Fisher Scientific, Waltham, Massachusetts, USA is a world leader in diagnostics, biotechnology and pharmaceutical technology and related areas. The lawsuit against the company initially demanded US$9.9 million as compensation for profits generated from sale and patents of the HeLA cells, with disgorgement of the entirety of its profits obtained by commercializing the HeLa cell line to the Henrietta Lacks' estate. The rampant use of Henrietta Lacks cells without initial informed consent, and subsequent lack of information provided to her family and descendants has been attributed to racial and social inequalities against members of the Black community by the lawsuit. The exact terms of the settlement are unknown and the family's representative alluded to potential upcoming lawsuits against other companies marketing the HeLa cells as well.

HeLa cell line represents the first-ever successful harvesting of cells to thrive and multiply in an *in-vitro* laboratory setting. This indefinite, infinite cultivation of her cells makes Henrietta Lacks' cells into the first known immortalized human cell line. The case and its time-frame raises questions once again on codes of medical ethics, intellectual property rights on human tissue and subsequent distribution of profits/monetary compensation of profits made from the said genetic material.

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