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THEME - ETHICAL AND LEGAL CHALLENGES OF VACCINES AND VACCINATION

New National Health Policy 2017

Use of pellet guns for crowd control

Sectarian organ donation in Israel

Bias in medicine in the context of the film *Aligarh*

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The not-so-slight pain of vaccination

Vaccination, often taken for granted as those simple pricks of the needle which caused momentary pain to howling infants, has assumed a more sinister aspect of late. This theme issue of IJME throws light on the bulldozing strategies of big pharma, the distorted priorities of policy makers, and the breach of human rights and ethics to the detriment of the common citizen. The issue of compensation for vaccine- related injuries and the need to make immunisation policy more people –centred are also explored.

Another emotive subject – of whether a state should use pellet guns against its civilian populace; and even whether this should be a subject within the purview of a bioethics journal – has set off a debate appearing on these pages. Nursing error, sectarian organ donation, a student's response to the ground-breaking film *Aligarh*, and the negative fallout of otherwise progressive laws are other stimulating subjects covered in the issue. Last, but definitely not least, an editorial analyses the welcome aspects of the new National Health Policy, while advising caution towards potential grey areas.

The *Indian Journal of Medical Ethics* (formerly *Issues in Medical Ethics*) is a platform for discussion on healthcare ethics, with special reference to the problems of developing countries such as India. It hopes to involve all cadres of, and beneficiaries from, this system, and strengthen the hands of those with ethical values and concern for the underprivileged.

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Contributions to the journal, in the form of original papers, research findings, experiences in the field, case studies, debates, news and views on medical ethics, are welcome. All submissions must be in English and are subject to editorial review.

Contributors are requested to refer to the detailed guidelines for submission available on the journal website, www.ijme.in

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EDITORIALS

National Health Policy 2017: a cautious welcome

T SUNDARARAMAN

On March 15, 2017 the union cabinet approved the new National Health Policy. The next day a 28-page policy text (1) and an accompanying 13-page situational analysis (2) were placed in Parliament and in the public domain. To have, at all times, a health policy in place that shows a road map on how a nation would show "progressive realization" of health as a basic human right is an obligation under the International Covenant on Economic, Social and Cultural Rights. This is an international treaty adopted in 1976, to which India became a signatory in 1979, and this was one of the catalysts for the adoption of the first National Health Policy in 1983 (3). The immediate political backdrop to the articulation of a *National Health Policy 2017* (*NHP 2017*), replacing the 2002 policy, is that a new health policy and a national health assurance plan were both part of the BJP's electoral manifesto. It has taken close to 34 months after the government took office, and some 26 months after the draft was circulated for public discussion, to finally approve the policy. This is reflective of the considerable contestation and contradictory pressures, often almost evenly matched, that went into finalising this policy.

There is much that is positive in the 2017 policy. The articulation of goals, key policy principles and objectives is in tune with India's commitment towards Universal Health Coverage (UHC). The suggested architecture for achieving UHC (as articulated in para 3.3) is "Free primary care provision by the public sector, supplemented by strategic purchase of secondary care hospitalization and tertiary care services from both public and from non-government sector to fill critical gaps would be the main strategy of assuring healthcare services." It further clarifies that this "strategic purchase" is a short term measure; in the long term, even in secondary and tertiary care, the public sector would predominate. When it comes to strategic purchase it repeatedly sets out the order to be followed: "public sector hospitals followed by not-for-profit private sector and then commercial private sector in underserved areas" (1:para 3.3). The policy also calls for retaining a certain excess capacity in the public sector to meet the needs of health security and in times of crisis.

The document describes seven key policy shifts that it sees as mandatory for organising healthcare services to meet the needs of universal health coverage. The first and the third of these shifts directly reverse two important prescriptions of the structural adjustment-driven health sector reforms of the 1990s -- the introduction of selective primary healthcare, and of user fees for cost recovery. *NHP 2017*, in contrast, assures a policy shift "In primary care -- from selective care to assured comprehensive care with linkages to referral hospitals" and "In public hospitals – from user fees & cost recovery to assured free drugs, diagnostic and emergency services to all"(1: para 3.3).

There are other ideas in this policy that have considerable potential for change if implemented imaginatively. One such idea is the articulation of inter-sectoral preventive and promotive action packaged into seven priority areas adding up to a social movement of health - what it calls the *Swasth Nagrik Abhiyan* or Health in All.

Another fresh articulation in *NHP 2017* is of "health and wellness centers"- a term used to denote transforming the current sub-centre and PHC from its current and very limited package of services to a much larger coverage of non-communicable diseases. There is available in the form of a Ministry document published in 2015 an elaboration of this concept (4), which clearly recognises the importance of and the barriers to achieving such a transformation of primary healthcare. The mention of this commitment to upgrade primary healthcare facilities into 1.5 lakh "health and wellness centers" in the finance minister's budget speech, a month before the policy was announced, also provides grounds for optimism.

Also, the policy needs to be hailed for a large number of policy formulations related to national programmes for noncommunicable diseases and mental illness(1: paras 4.6,4.7), retention of doctors and specialists in remote areas in public

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services (1: para 11.3), creation of a multi-disciplinary public health management cadre (1: para 11.8),access, pricing, regulation and manufacture of technologies (1: paras 14.3 to 21); the crisp definition of the scope and needs of health technology assessment (1: para 22) and several new ideas and institutions proposed under research and development (1: paras 24 and 25). There are many in a democratic society who would have hoped for more. For example, a firm commitment to make use of the provisions of the Doha Declaration would have been welcome. The Doha Declaration is meant to ensure affordable access of nations to essential medicines even if they are on patent through compulsory licensing and other such remedies. Implementation of this declaration is now included as Target 11 under Goal 3 of the Sustainable Development Goals. But given the overall economic policies of the government, this would be all that could be reasonably expected. Even if a part of all these commitments were to be implemented, there would be much to celebrate.

However, celebration could be premature. There are many grounds for caution. Thus, though the use of numerical targets in three categories-- in terms of health status, health sector performance and health systems strengthening -- is a welcome step forward in systems level thinking, many of these targets have been set very low or pushed back, both in comparison to equally placed South Asian nations, and in comparison to our own previous targets. For example, an achievement of life expectancy of 70 or a total fertility rate (TFR) of 2.1 by 2025 could be anticipated with extrapolation of existing trends-- even without further efforts. A public health expenditure target of 2.5% of GDP was to have been achieved by 2018 in the 2015 draft (5), but has now been shifted back to 2025. Such a low expansion of investment is unlikely to match the funds needed to meet commitments like health and wellness centres, or free drugs and diagnostics in all public hospitals.

There are also major silences or inadequacies that are worrying since many key objectives are unattainable without the necessary policy corollaries. In urban health while the categories of urban vulnerability have been listed, the commitment to undertake affirmative action going beyond free care, that is required to meet these needs, has gone missing. In malnutrition the policy limits itself to micronutrients, perhaps on the grounds that the ministry's remit is limited -- but it should be clear that without addressing India's malnutrition burden the achievement of targets on child mortality are seriously compromised.

But the three under-stated policy corollaries that are major areas of concern relate to human resource adequacy, private sector regulation and governance. The "health and wellness centers" which form the core primary healthcare strategy cannot be operationalised without substantial investment in a regular, well-trained and motivated public provider workforce. Mere optimal use of existing human resources, while necessary, is a very far cry from being adequate. A very wishful, fanciful call for private sector volunteering pro-bono to close this gap (1: para 2.3.1 A), or a partnership with the private sector where a fee would be charged for the middle class to join in (1: 13.6.3 pg 20), are based neither on evidence nor on experience, and are completely contradictory to the meaning and scope of strategic purchasing in the rest of the text. The reluctance to invest in a well-managed public workforce is one vestige of the structural adjustment years that has not been overturned by this policy draft.

Secondly any large-scale private sector involvement requires a major effort at reform of the professional councils and regulation of clinical establishments. But when it comes to regulation of the private sector, all that *NHP 2017* has to offer is a weak call for "advocacy with the other states … for adoption of the Act", and this some seven years after the Act was passed. The Clinical Establishments Act requires each state to independently pass a resolution in their state assemblies adopting the Act- or else adopt a state level act for this purpose. Very few states have done so. When the accompanying situational analysis report itself indicates that existing purchasing of secondary healthcare has been seriously compromised by unethical practices and inappropriate care (2:para 2.12), adoption of the Clinical Establishments Act should have been projected as a necessary corollary to the expansion of purchasing. What is equally worrying is a new section (1: para 13), where strategic purchasing has (implicitly) a different purpose from that articulated earlier. This paragraph proposes an across-the-board engagement with the commercial private sector and seems more concerned about identifying and enhancing business opportunities for the commercial private sector and in routing part of public expenditure on healthcare through it. The meaning of strategic purchase in this section shifts from securing health outcomes to providing an economic stimulus to the healthcare industry. And this despite the clear statement in the situational analysis (2: para 2.13) of the multiple ways in which the government is already contributing to the booming profit-hungry private healthcare industry.

Similarly, while the assertions for restoring trust in public health systems, re-orienting public hospitals and providing free care in public hospitals are most welcome, the weak articulation on governance and accountability is worrying (1: para 26.1 to 26.3). Community monitoring and involvement of local bodies, though welcome measures, are inadequate with respect to the main sources of mis-governance. The 2015 draft had identified four main pathways of corruption in public health systems – weak procurement and logistic systems, transfers and postings, appointment of the chief district health officer and the selection of partners for partnership. There are well known best practices from amongst the states which show how each of these pathways could be effectively blocked. Unfortunately, that formulation (5: para 11.5) did not survive–and an opportunity was lost. One is thankful that one particular solution to the problems of governance did not succeed: viz: the creation of an over-arching body called a National Health Authority which would combine in itself the roles of setting standards, regulation and

purchasing care, possibly abridging the roles of states and central ministries, with little accountability of its own, and quite open to professional or corporate capture. But there is a need for creating many new institutions as correctly identified in this policy (eg National Healthcare Standards Organization (1: para 10), National Digital Health Authority (1: para23, also see paras 14.1, 14.5, 22, 25.1), and there is a need to strengthen the functioning of many existing ones. A policy statement on how institutional governance and coordination would be achieved would have been desirable. The earlier draft had called for specifying clear institutional governance policies and minimum standards of governance that would apply to all these institutions. That was dropped, perhaps for lack of clarity, but it is a direction worth pursuing.

Finally, one area of silence is the role and remit of the states as compared to the centre – not only in financing, but also in areas like setting standards, strategic purchasing and in the human resources strategies. Clearly a leave-it-to-the-states approach will not work, but nor will a single centralised set of standards or guidelines. At a time when taxation reforms reduce the fiscal space of states, specifying the share of public health expenditure that the centre would undertake was essential. Space for states to modify centrally set standards and guidelines but within specified timelines, and within frameworks defined on the basis of non-negotiable principles, was a desirable policy corollary.

What next? What the nation has now is a document with considerable strengths and clarity on many key issues and with some ideas that have great potential. But it is also a document with certain critical gaps that make one worry about the seriousness and ability of the government to implement this.

A policy does not necessarily translate into action on the ground. Between the policy and its implementation there occurs a process of selective amplification and attenuation of recommendations. Such amplification and attenuation is a combined result of the political environment, the influence of key stakeholders, the feasibility of different recommendations and the technical and administrative competence involved in implementation. The whole contestation over policy directions with respect to the terms and extent of private sector involvement has helped identify the key players and their positions. And though the corporate hand is strong, and its needs and thinking well supported by Niti Aayog and international aid agencies (a space now almost exclusively occupied by the Gates Foundation, with some support from USAID and the Bank), it is not a walkover for any side. For the community of health policy activists in civil society and in academics, as well as for the Ministry of Health, which by definition owns and is accountable for implementation of the policy in its final shape, the work is cut out. The challenge would be first to ensure that the government puts its money where its mouth is. We do not have enough indication of this happening. Budgets have been stagnant under the present government. Just two days after the policy was announced, *The Hindu* reported that major public hospitals are required to raise 30% of the funds required to meet the Seventh Pay Commission recommendations (6). This would mean that hospitals like JIPMER, which provides free high quality, comprehensive, tertiary care, and institutions like AIIMS which charge modest user fees, would have to raise the funds needed from their service users. But these are early days and one remains hopeful.

An equally important challenge is to make use of the budget as allocated to demonstrate and build the evidence required to support the strengths and big ideas of this health policy. Instead of expending time on producing another document called an implementation framework (as proposed in the policy document), it would be more useful to set up multi-stakeholder working groups or task forces for the many different policy proposals with their secretariats located in the concerned divisions of the ministry, so that implementation is fast-forwarded.

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Ethical and legal challenges of vaccines and vaccination: Reflections

AMAR JESANI, VEENA JOHARI

Vaccines and vaccination have emerged as key medical scientific tools for prevention of certain diseases. Documentation of the history of vaccination shows that the initial popular resistance to universal vaccination was based on false assumptions and eventually gave way to acceptance of vaccines and trust in their ability to save lives. The successes of the global eradication of smallpox, and now of polio, have only strengthened the premier position occupied by vaccines in disease prevention. However, the success of vaccines and public trust in their ability to eradicate disease are now under challenge, as increasing numbers of people refuse vaccination, questioning the effectiveness of vaccines and the need to vaccinate.

A few decades ago, a theme issue on the ethical and legal challenges in vaccination, particularly in the context of a developing country like India, would almost exclusively have focused on the measures needed for universal access to vaccination. Ensuring that children do not die of vaccine-preventable diseases is one of the core elements towards achieving equity and justice in public health. So much so, that it was normally argued that no amount of public investment in making vaccines universally available to children is too high. However, public health measures are often challenged by human rights norms. Today, individual rights to bodily integrity, to make choices, to have complete information on the vaccine, and other such rights are gaining more importance and need to be an integral part of public health programmes.

In any event, for a tool to remain scientific, it must be scrutinised for its scientific merit. Vaccines will retain their premier position in public health only if there is a continuous collection of evidence supporting them. Like any other scientific tools, they have benefits but also risks. The issue of risks is particularly pronounced in the use of vaccines, because they are used on otherwise healthy children for the future prevention of disease.

Besides, vaccines cannot be regarded as the sole intervention for disease control and improving the quality of people's lives. Disease prevention demands not just medical intervention but also attention to the social determinants of health such as nutrition, safe water, sanitation and so on. The choice of public health intervention must be made in a balanced way and not allow the medical model to subsume all others.

Public trust is fundamental to the success of vaccination programmes. But such trust, even if built on a relationship of decades, cannot be taken for granted. Medical professionals, once trusted as demigods, are now facing the wrath of people's disillusionment. Not only in India but elsewhere too, the misuse of vaccines and vaccination is being questioned. Coercion, and a contemptuous attitude toward people's need for simple but scientific information, further erodes people's trust. The only way to sustain the credibility of vaccines and people's trust in them is by regular reflection on their scientific and ethical use.

This theme issue on vaccines and vaccination raises certain critical questions so as to initiate corrective measures necessary to uphold the science and utility of vaccines as an important public health measure, with their ethical use.

The theme issue has six papers which discuss four aspects of the ethical and legal challenges in vaccination as a public health measure

1. Safety of vaccines

Vaccines are used on healthy people, particularly children. The first resistance to vaccines therefore normally emerges from people's personal experience of vaccination. Such experiences are contextual; they emanate not only from the harm caused by a vaccine, but also from the management of such safety issues by the system. Those who listen to these experiences then re-examine the vaccine itself in order to understand the source of the problem. This is becoming more pronounced, not in the traditional six vaccines used in India's immunisation programme, but in the introduction of new vaccines, and of old vaccines in combination with new ones.

The paper by Hirokuni Beppu and others, "Lessons learned in Japan from adverse reactions to the HPV vaccine: a medical ethics perspective", is a case study of the introduction of the HPV vaccine in Japan. Learning from people's experiences – and

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providing data on reports of safety concerns– the authors raise scientific issues concerning the safety and effectiveness of the HPV vaccine in Japan. They attribute the widespread use of this vaccine to three major factors with both structural and ethical import, namely, "(i) Aggressive promotion by the pharmaceutical industry, (ii) Trade negotiations by economic superpowers, and (iii) Contemporary medicine, which is characterised by overconfidence in technology and the lack of the humility to listen to patient complaints."

This paper, when read with a paper by Tom Jefferson and Lars Jorgensen published in the January 2017 issue of *IJME* (1), shows that it is essential for the companies that conducted research to make their raw data available for further scrutiny, in light of new safety concerns found for the HPV vaccine. It is astonishing that a regulatory agency like the European Medicine Agency (EMA) does not possess a copy of the raw data for reanalysis, and must revert to the companies – who have a conflict of interest–to get raw data re-examined. Invariably such exercises conclude that safety concerns were not related to the vaccine. Worryingly, the Indian drug regulator accorded marketing authorisation to this vaccine on the basis of approvals received by it from the EMA and the US FDA.

2. Human rights and law

It is very important for people to be convinced about the safety and effectiveness of vaccines. But how can this be done if the research data are protected as trade secrets of companies which carried out research on those vaccines? How would anybody believe that the companies, that privileged profit over public good over the years, are trustworthy? In such a situation, to what extent ought the state to assume a paternalistic role subsuming the individual's human rights?

Veena Johari's paper, "Identifying ethical issues in the development of vaccines and in vaccination", attempts to forge a unity of public health and human rights by arguing that when a preventive health intervention is introduced for the population at large, attention must be paid to the individual's autonomy and the risks s/he confronts. She notes that voluntariness for vaccination is not just morally correct preventive public health but also more efficacious as it makes for people's genuine participation for the improvement of their health. Similarly, she emphasises informed consent in vaccination, requiring public health programme to share critical information with people, enhance public engagement with communities, and to be accountable to people.

The article by Sarojini N and others, "An idea whose time has come: Compensation for vaccine related injuries and deaths in India", makes the case for instituting legal mechanisms to compensate for vaccine-related injuries and deaths in India. The authors provide information on compensation mechanisms in different parts of the world. They follow with a detailed analysis of Adverse Events Following Immunisation (AEFI) reported from various states in India to show that the AEFI reporting system is not uniformly robust and transparent. Thus, they build a solid argument for a separate compensation mechanism distinct from tort, and based on a no-fault system.

3. Trust and the prevention of distrust

As explained earlier, trust in vaccines and vaccination are important components of the success of preventive public health programmes. But there is increasing erosion of trust, not just because of people's misconceptions about such programmes, but also because of the way the system functions. Two recent events highlight this issue:

In January 2017, in Tamil Nadu and Karnataka, a rumour circulated through the social media on safety concerns regarding the measles-rubella vaccination campaign in schools and primary health centres. Subsequently, parents refused to send their children to school or simply refused vaccination. The first knee-jerk reaction of the health authority in Tamil Nadu, as reported in the media, was to issue threats of criminal cases and arrest against rumour mongers (2). Another media report, however, analysed the problem and discovered that the vaccination was being implemented after providing minimum information to the parents and the general public. This compounded the doubts in the minds of people, including many medical practitioners, about the need for mass vaccination for these diseases, more so in schools where facilities for managing AEFI were minimal (3).

While this public resistance to the measles-rubella vaccine was playing out, in January 20, 2017 at the 54th Annual Conference of the Indian Academy of Pediatrics (IAP) in Bengaluru, IAP member Vipin Vashishtha was manhandled and evicted by fellow doctors for raising issues related to the conflict of interest in the association's recommendation of vaccines for use in private practice (4). Dr Vashishtha had in December 2016 written a letter to members of the IAP on the subject and also written an editorial in Pediascene.com attacking the commercial interests of the industry and the collusion of doctors, government and funders (5).

These incidents show that people's trust cannot be taken for granted, and that it gets further eroded by evidence of financial conflicts of interest in the healthcare system. Vijayaprasad Gopichandran in his paper titled "Public trust in vaccination: an analytical framework", goes through the complex web of issues involved in gaining and retaining people's trust and preventing its erosion. He argues that both transparency of policies and close engagement with communities are ethical

imperatives for maintaining trust.

The second paper on this topic by Luke Juran and others, "Considering the 'public' in public health: Popular resistance to the Smallpox Eradication Programme in India", is a field study in Bihar and traces the history of how the programme was implemented from above without showing sensitivity to people's views and culture. The authors note, "The eradication of smallpox should be viewed as a milestone for biomedicine, public health, India, and the world. We have been freed from the shackles of a fatal virus and that is a commendable achievement. However, one has a moral duty to examine historic milestones in order to understand how they were achieved. Through this critical lens, we argue that it is rare, if not impossible, for an accomplishment of such magnitude to be realised without eliciting elements of distrust or outright resistance in the target population. The global eradication of smallpox was no exception." Thus, it highlights, once more, the fundamental role of public engagement, and teaches us that instead of getting carried away by success stories, we should reflect on the way that success was achieved.

4. Vaccination is not an end in itself

The last paper in this theme issue, by T Jacob John and others, "Vaccine delivery to disease control: a paradigm shift in health policy", observes that the Universal Immunisation Programme (UIP) in India is divorced from disease control. This separation is dangerous: it limits our capacity to measure the benefits of immunisation in disease control; it precludes assessment of the other measures, particularly the social determinants in disease control; and above all, it exposes the UIP to the unhealthy manoeuvres of commercial interests in including or excluding vaccines without well considered cost effectiveness. The paper argues for the integration of both programmes.

Need for more reflection

There is a tendency on the part of public health managers and experts to view all criticism of vaccines and vaccination as being anti-vaccine, anti-science or anti-public health. Critics are often branded as "anti-vaxxers". Science does not develop by gagging critics, for critical reflection is its hallmark. Without that neither the science of vaccines nor the public health of vaccination would be able to move forward and achieve their objective of improving the health of populations. The emerging discipline of public health ethics in India has an obligation to raise uncomfortable questions and propose non-conventional alternatives.

This theme issue was not intended to cover all the ethical and legal challenges in vaccines and vaccination. Many issues of critical importance are not covered in adequate detail. We hope that there will be more discussion on the issues raised here; and contributors will come forward and write on the subjects left out in this theme issue.

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ARTICLE

Nursing error: an integrated review of the literature

MOHADDESEH MOHSENPOUR, MOHAMMADALI HOSSEINI, ABBAS ABBASZADEH, FARAHNAZ MOHAMMADI SHAHBOULAGHI, HAMIDREZA KHANKEH

Abstract

Nursing errors are complex and take place frequently in the care of patients. However, despite their significance, they have not been properly defined or addressed in the literature. This integrative review of the literature explored the concept of nursing error, explained its definitions and described its attributes and measurements. The databases of Medline, CINAHL, Google Scholar and SID were searched using a number of keywords, including malpractice, adverse events and mistake, with and without the word nurse. The aim was to determine the definition of nursing error, regardless of the contextual aspects, in various scientific systems. After reviewing the relevant literature, content analysis (in MAXQDA) was applied to classify the definitions, attributes and measurements obtained on the basis of their similarities and differences. Ultimately, a definition was established for the concept of nursing error.

Introduction

The safety of the patient is a key component of the quality of care (1–3) and a critical concern in any healthcare system (4–6). Errors, on the other hand, are an integral part of human and professional life (6–7).Though medical and nursing errors are inevitable and common, they are serious and a major threat to the patient's safety (8–9). The incidence of errors is high in health systems worldwide (3,10–11) and they affect about one out of every 10 hospitalised patients (6,12–13). Moreover, nearly 7% of these errors are fatal (12). While there are no official statistics on the incidence of medical errors in Iran (9), descriptive studies have suggested similar rates in this country (14–15). Meanwhile, the increasing number of complaints filed about medical errors indicates the growing public awareness of the issue (9).

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The term "error" entails "deviation from correctness" and "taking the wrong path" (10). Lewis et al (2013) described nurses' involvement in errors as an ambiguous problem requiring explanation (16). Medical errors occur when care providers make the wrong decision or use the wrong procedure (8). Criminal law defines medical errors as the failure to meet diagnostic, therapeutic and care standards. In legal literature, failure is categorised as either negligence or violation of the rules (10). However, individuals studied by Sanagoo et al (2012) defined medical error as an act endangering the patient's life or causing any kind of harm to the patient (17). This is drastically different from the legal definition. Nursing aims to help vulnerable people. Caring is thus an entirely moral action (18). An incorrect act will cause additional harm to a vulnerable person. Since detrimental actions create turmoil in the minds of nurses, they try to avoid such actions (18–19).

While various scientific, ethical and legal references have described error (sometimes using complex and vague definitions), nursing error, in its professional sense, has not been well defined. Therefore, our study aimed to shed light on this concept. Since we aimed to focus on various definitions, attributes and consequences of nursing errors rather than the effects of an intervention or the frequency and incidence of a particular concept, we conducted an integrative review as a concept analysis method (20), which is a specific method for summarising the evidence available and clarifying a health issue or phenomenon (20–21).

Objective:

Concept analysis of nursing error by integrative review

Methods:

Our study adopted the integrative review method: a systematic rigorous method of concept analysis to review scientific literature using diverse methodologies with specific aims. The integrative review process generally involves concept identification and a research question, a search of the literature, evaluation of data, data analysis, and the presentation of results (20–21).

Concept identification and research question

This stage consists mainly of the identification and formulation of the problem and the objective of the review (21). As we

sought to develop a clear and scientific definition of the concept of nursing error, we stated the research question as: "how nursing errors can be defined, irrespective of the contextual aspects of various scientific systems".

Search of the literature

During the second stage of an integrative review, a well-defined method is used to make a broad systematic interdisciplinary search of the literature available on the basis of the research question (21). In our study, the Google search engine was used to search Persian websites. For references on topics related to medical ethics, law and jurisprudence, we manually searched the whole series of the *Iranian Journal of Medical Law* and the *Quarterly Journal of Medical Figh,* available at the Medical Ethics and Law Research Centre of Shahid Beheshti University of Medical Sciences, Tehran, Iran.

Several databases, including Medline, CINAHL (PubMed) and Google Scholar, were searched, using the keywords "errors", "malpractice", "adverse events" and "mistakes", with and without the word "nurse". We also searched the Scientific Information Database (a comprehensive data bank in Iran), using the keywords "error", "mistake" and "negligence", with and without the word "nurse", between 1990 till 2015.In addition, the titles, abstracts and keywords of articles were searched for the keywords. The same procedure was followed when the researchers came across a new synonym for "error" in the literature. The search procedure finally yielded 1924 articles (Fig. 1).

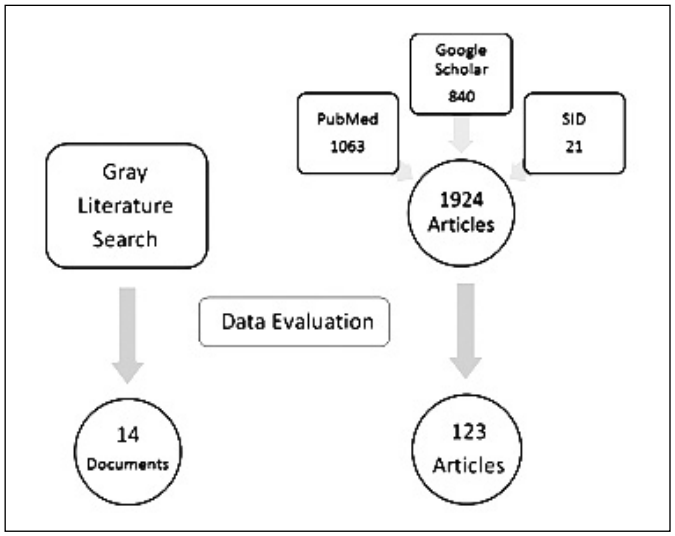

Figure1. Literature search process

Evaluation of data

The relevance of the extracted articles to the study question was evaluated by the assessment of their abstracts. In case of any ambiguity, however, the full text of the article concerned was reviewed. Articles containing appropriate answers to the research question (eg implicit or explicit definitions, antecedents, consequences, attributes, or measurements of nursing or other healthcare team errors) were identified and entered in MAXQDA (VERBI, Berlin, Germany) as the unit of analysis. Books and articles without an existing computer file were analysed manually. In total, 137 documents, including 123 full text articles, 2 theses, 3 reports, 7 books, one Internet page (MeSH term), and the Islamic Penal Code (notified in April 2013), were analysed.

Data analysis

Content analysis was used to analyse the literature. A number of meaning units, including the implicit and explicit definitions of nursing error, and the attributes, antecedents, consequences and measurement of the concept, were identified as codes in the article texts. These codes were then categorised on the basis of similarities and contrasts. Accordingly, the categories were grouped into themes. The attributes, antecedents and consequences of nursing error were presented as follows.

Results

The results were comprehensively expressed and appropriate explanations were provided to facilitate a general understanding of them (21). To clarify the concept of nursing error, the data were reduced to seven themes, including nursing error as a concept based on outcome (with three sub-themes, namely definitions based on adverse events, legal definitions and goal-based definitions), on process, on cognitive reasoning, and on ethics, and nursing error characteristics, antecedents, and consequences.

Attributes of nursing errors

Several important attributes of nursing errors are mentioned in the literature. In brief, nursing errors are a "preventable" yet "unavoidable" challenge (13,22–23). They are preventable since their incidence should not be attributed to chance. On the other hand, nursing errors are unavoidable because appropriate and targeted measures can merely reduce their incidence, and not negate the probability of their occurrence (24). In fact, the only way to avert nursing errors is to avoid tasks, which is not possible in nursing.

The inadvertent nature of nursing errors was also emphasised in all definitions (22,25). More precisely speaking, an error occurs when a nurse aims to benefit the patient, ie acts of malice, malevolence and profiteering are not considered nursing errors (22,26). It is, however, important to mention that errors may occur either consciously or unconsciously, and deliberate errors are not categorised as nursing errors. For instance, while a nurse may know that inserting an intravenous line for a patient with dementia requires the informed consent of the latter's guardian, she/he may perform the task with the patient's consent considering the significance of drug timing. In this case, a conscious, benevolent error is committed without the intention to harm the patient.

Nursing error has negative connotations (16,24–25). In other words, a degree of deviation is involved in all nursing errors, no one benefits from or seeks errors, and errors have no direct favourable consequences.

The multiplicity of the terminologies related to nursing error and the several definitions of the term reflects the complexity of the concept (10,24). The situations in which nursing errors occur are very complicated and to analyse them, one must consider the cause of the error, environmental factors, theories of behaviour, the prevailing perceptions, anticipation of human error, and ethical theories. The best fitting definition of nursing error is clear in some situations, but this definition need not be as valid in other circumstances.

Nursing errors are human operations (24), iea human being, in this case a nurse, must be involved in their occurrence (16). Further, they have to be caused during the process of the provision of care and when the wrongdoer is in charge of such care. Finally, several (at least two) options must be available for a nursing error to take place, ie such errors are meaningless if a choice is not made.

Nursing error as an outcome-based concept

This theme emphasises unachieved outcomes ofcare or unintended outcomes caused by the omission or commission of acts of care (3,13,22,24–25,27). According to such definitions, nursing error can be defined as the commission of wrong care or the omission of care, both of which lead to unintended outcomes or are likely to lead to an unfavourable outcome(28–30). This category comprises two main subcategories, as follows.

- *Definitions based on adverse events*: According to these definitions, an error occurs when the medical management of a patient results in adverse consequences (3,22,24–25,27,31), eg harm, prolonged hospitalisation, measurable disability and death, or certain other conditions that can lead to such consequences. Outcome-based definitions, the first published definitions of medical errors, were put forward in a study of the side-effects of treatment by Moser in 1956(24) and a statement by the US Institute of Medicine, "To Err Is Human", issued in 1999(32). The definition by Medical Subject Headings was also one of the early definitions of medical error in this group.
- *Goal-based definitions*: In this group of definitions, the goal of care is seen as the only yardstick of the consequences of care and hence, error. Any deviation from achieving the intended goal is thus considered a nursing error (23,26). More precisely, this group of definitions assumes the goal of care to be authentic within a predetermined framework. Therefore, any deviation from this framework is regarded as a nursing error if it prevents the complete achievement of the goal (23). Unlike the definitions based on adverse effects, an action which leads to an outcome (even if not adverse) that is different from the intended goal is considered an error here.

Outcome-based definitions highlight costs, mortality and harm. They are of particular importance as they view nursing errors in relation to the patient's safety. However, there is controversy over their applicability. Some researchers argue that for an action to be deemed a nursing error on the basis of such definitions, one will have to wait until the end of the procedure. As a result, a proved nursing error cannot be corrected and should merely be compensated for (33). This category of definitions is not comprehensive. While these definitions narrow the scope of nursing errors to traumatic situations, the outcomes of care are determined under the best circumstances and cannot thus be generalised. Moreover, since these definitions disregard the limitations caused by the nature of diseases and the patient's response to treatment, they are too inclusive. Finally, it must also be noted that since the simultaneous occurrence of a number of abnormal operations and even other errors is required for a particular event to take place, a single error cannot be identified on the basis of this group of definitions.

Nursing error as a process-based concept

According to this group of definitions, errors are caused by faulty planning for the achievement of a goal or the misconduct of a well-designed plan (3,10,13,22,25,34–35). The definitions based on the action theory of Volpert (1992) and Hacker (1998) can be placed in this category (23). According to these definitions, any action comprises hierarchical and sequential components and can thus be expressed as a hierarchy of operations (23). Since any operation is considered to consist of several sub-goals, the failure to achieve one of these sub-goals or a disturbance in the hierarchy or sequence of operations and their sub-goals would lead to an error. This group of definitions emphasises standards as the indicators of performance. Therefore, actions that do not conform with the standards are identified as nursing errors (10,13,23). In other words, since what has been done is compared with what should have been done, a nursing error occurs when a nurse chooses the wrong procedure of care or performs the right procedure incorrectly (3). In contrast to outcome-based definitions, process-based definitions see such deviations as errors, regardless of the presence/absence of harm to the patient.

Not only human factors, but also environmental and organisational factors are involved in nursing errors. Since definitions based on these factors focus on the standards and quality of care, they are not comprehensive and exclusive, and intersect with context-based definitions. As a result, the definition of nursing errors will depend on that of standards and the failure to follow them. Some of these definitions describe the standard as the average actions that a normal nurse is assigned. Hence, actions that are below average or are irrelevant to the duties assigned are considered nursing errors. Some other definitions in this group mention the judgment of expert colleagues as a criterion for the standard. It is also essential to incorporate the factor of time into the definitions. In other words, due to the technological and scientific advances and theclinical facilities available, an action which may not be regarded as a nursing error at a particular time can be seen as one at another time.

Nursing error as a concept based on cognitive reasoning

In these definitions, nursing error is described in terms of an incorrect cognitive process of assessing a situation when achieving a goal (10,23,36–37). Since an error is considered the result of a disruption in cognitive reasoning, these definitions focus on "accuracy" and can thus link goal-based and process-based definitions (24,38–40). The proponents of this view believe that a behaviour takes place in a state of functioning that can be described as either the attentional mode or the automode. Since tasks are performed cautiously in the attentional mode, this state is slow and mental effort is required to use newly learnt skills. When the same task has been repeated often, the brain gradually switches to automode to prevent exhaustion. There is a chance of the occurrence of various errors during both states.

Apparently, these definitions consider not only goals, but also plans to achieve these goals. However, they concentrate only on human causes and ignore other possible causes.

Nursing error as an ethical concept

From the ethical standpoint, nursing error is a broad phenomenon which does not necessarily concern harm to the patient. Instead of defining an error as a deviation from the only existing correct way, ethics generally focuses on better or more fitting choices (10,26). In other words, when ethics is involved, there are no guidelines to violate. Since quality is an indefinite range, there is a better option for any particular choice. Hence, it is critical to know how fitting a specific choice has been under the circumstances in which it was made. Obviously, in contrast to the legal definition of nursing error, ethics judges an error on the basis of the individual's conscience rather than the extent of harm caused.

Nursing error as a contextual concept

As an abnormal behaviour, nursing error depends profoundly on how norm is defined. The definition of norm, however, varies in different contexts (3,13,24–25). Norm can be defined on the basis of religion, culture, beliefs and lifestyle. For example, due to differences in religious beliefs or world views, euthanasia is a norm in some countries and is objectionable in others. Most studies on medical errors in developing countries concentrated on adverse events (28–31, 37, 41). There is a lack of clarity regarding the concept of nursing error, which is not understood by healthcare systems in the developing countries in all its aspects. Various studies have tried to incorporate the effects of context into the definition of error. Some researchers have defined nursing error on the basis of the judgement of expert peers (26,42). They argue that when there is an absolute consensus on the occurrence of an error (eg if 20 out of 20 nurses agree that it is nursing error), an error has definitely occurred. Several other studies have established a link between contextual effects, perspectives on care, philosophy and theories (10,13). They claim that one's view of the world affects one's understanding of right and wrong. Determinists contend that all events are caused by nature, chance or destiny, rather than human action. They thus render the issue of nursing error meaningless. On the other hand, according to the post-modern view, events are definitely the result of human decisions and behaviours. Therefore, instead of chance or bad luck, care providers are to be blamed for unintended events in healthcare. According to Dekker, healthcare has both social and technical contexts (24). The context may be affected by differences in the characteristics of the professionals and nurses concerned. Nurses who have committed an error may have a different understanding of nursing error not only because of cultural differences, but also because of their training regarding error, workplace conditions and the amount of attention paid to errors in their organisation.

Some context-based definitions of nursing error also consider the effects of time. Thus, with changes in the accepted theories of care and the facilities available, something which may not be considered a nursing error at one time may come to be regarded as one at another time. For example, the guidelines for dressing methods are revised every year in a hospital. If a nurse follows the previous year's guidelines, he/she is committing a nursing error even though it was not an error a few days ago. The same goes for the replacement of instruments by the latest or best ones, or changes in theories or philosophies of care. According to the philosophy of the healthcare system, euthanasia may constitute an error but if this philosophy changes over time, it may become the norm.

The fact that the definition of nursing error depends on rules and standards of care emphasises its context-based nature (10,13,23,33). Since various organisations and countries formulate their own sets of rules and standards, it is apparently not feasible to develop a unique definition. The diversity of definitions makes the evaluation of the concept of nursing error a challenging task. Finally, patients' understanding of nursing error, which too is completely culture-dependent, can affect not only the nurses' perception, but also the general definition.

- *Legal definition of nursing error in Iran*: In legal terms (Islamic Panel Code of Iran), negligence in the provision of nursing care is categorised as irresponsibility and inattentiveness (43–45). Two components of these are incompetence and non-compliance with governmental provisions. Irresponsibility involves the omission of a technically and scientifically expected act (eg injection with a non-standard needle, leading to drug leakage and the need for surgery). Inattentiveness refers to actions which are not scientifically expected (eg intravenous injection of a drug that is not to be administered through the intravenous route and causes seizure or death). Incompetence refers to actions performed by inadequately experienced or skilled individuals (eg subcutaneous injection of fluids, resulting in necrosis or skin graft). Non-compliance with governmental provisions is described as the violation of nursing duties as declared by the Ministry of Health (eg failure to protect the patient's privacy, failure to take a decision under emergency conditions, and refusal to provide high-risk patients with the required care). Such

violations are evaluated by the board of magistrates and the Provincial Appeal Board, which then impose disciplinary measures, including a verbal/written reprimand and short- or long-term suspension, on the wrongdoer.

Since criminal law is concerned mainly with physical or mental harm, a nursing error is not regarded as a crime unless it has negative consequences, that is, negligence is proved only if a connection can be established between the nursing error and the harm (43). In other words, harm and negligence are interdependent; while negligence should have led to the damage, the damage should have resulted from the negligence. Nursing errors are evaluated only if there is either a public or private plaintiff.

Antecedents of nursing errors

Previous studies have adopted two main approaches to the identification of the causes of nursing errors (36,46–47). These approaches were presented by Reason (1990) who made a comprehensive classification of the antecedents of medical errors (48). The personal approach highlighted the personal factors (associated with the healthcare team and patients) related to nursing errors. The factors associated with the healthcare team included inexperience and young/old age of the nurse or doctor, the inability to give complicated or urgent care, poor communication (differences in language and medical terminology, lack of knowledge of the local language, incorrect reports and illegible handwriting. The factors related to patients that were viewed as nursing errors included the limitations faced by them and the presence of a relative to perform some of the tasks of care giving. In some cases, patient behaviours, eg patient falls, were also considered nursing errors.

The organisational approach, described by numerous studies (22,46), underscored the organisational (managerial) causes of nursing errors. This approach emphasised lack of coordination between teams, a crowded workplace, similarities in the names or appearance of medicines and poor equipment. There is greater interest in the organisational factors than the personal ones since they can be modified more easily and it is more practical to identify them. In addition, due to the negative connotation of nursing errors, the organisational factors are used to direct the blame from the wrongdoer towards the organisation.

Consequences of nursing errors

According to the review of the literature, the consequences of nursing care could be categorised as human, financial, organisational and professional (16,32,46). The human consequences have an impact not only on the patients and their families, but also on the nurses and other professionals involved in the error. As a result of nursing errors, patients may suffer from death or disability, or may have to prolong their stay in hospital. Further, nurses and other professionals may experience distress, feelings of guilt, anger, shame or inadequacy, depression, and a loss of self-esteem. In addition, they may develop personality defects, face stigma, or change their job or field of study (16,33,49–50). Research carried out earlier has indicated that patients and the medical team are the first and second victims, respectively, of nursing errors (49, 51–52). The human consequences of nursing errors are generally irreversible.

The financial fallouts of nursing errors affect patients and their family, responsible nurses and health organisations (25,47,53). Because of the need to prolong the hospital stay and changethe treatment plan, patients and their family have to pay additional costs (47,53). Responsible nurses also have to bear a financial burden because they have to take leave from work (due to the legal and emotional complications following the error) and the costs incurred (eg compensation for the cost of treatment). Finally, health and insurance organisations will be required to cover some of the costs arising from the nursing error.

Among the organisational consequences of nursing errors reported in the literature were damage to the system, loss of the hospital's reputation, legal disputes and an increase in costs. The professional consequences included temporary or permanent loss of professionals after the occurrence of the error and damage to the professional image.

Though researchers deem errors necessary (although very costly) for the dynamics of a system(24), it is to be noted that all the consequences of nursing errors are unpleasant. However, an appropriate defence mechanism against such unpleasant occurrences can produce positive effects. For example, learning from mistakes and reducing the frequency of nursing errors would be of some help. The unpleasant nature of nursing errors cannot prevent their recurrence, that is, in the absence of effective strategies, such errors would remain unreported and no lesson would have been learnt from them. According to previous studies, slight errors are unavoidable; but belief in the reversibility of errors and the relation between the level of shame and the degree of harm caused can contribute to reduction of the mentioned unpleasantness in preventing nursing errors.

Finally, according to all the aspects of the concept of nursing error mentioned above, nursing error may be defined as follows.

> *Nursing errors are complex, unintentional, preventable, yet unavoidable occurrences in which a nurse's choice regarding whether or not totake a particularaction for the patient's care has adverse human, financial, organisational and/or professional consequences. An inappropriate choice may be the result of personal or organisational factors and can be interpreted differentlyon the basis of time and context.*

We have attempted to arrive at this definition on the basis of all the aspects of nursing errors described in the literature but, as we mentioned, the concept of nursing error is also

viewed in the contextof time and culture. Any definition of this concept, however comprehensive, has its limitations. It would be useful to carry out other studies focusing on the contextual aspects of nursing errorto better understand this important clinical concept.

Conclusion

We have attempted to develop a comprehensive definition of nursing error by classifying and discussing the definitions available in the literature. The definitions of nursing error in the literature were classified into five main themes. Nursing errors were categorised on the basis of their outcomes, the care-providing process, the cognitive reasoning of nurses, and ethical and contextual aspects. The definition that we finally arrived at has its implications and limitations. The fact that "nursing errors" has been considered as an independent concept in this study is valuable.

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THEME - ETHICAL AND LEGAL CHALLENGES OF VACCINES AND VACCINATION

Lessons learnt in Japan from adverse reactions to the HPV vaccine: a medical ethics perspective

HIROKUNI BEPPU, MASUMI MINAGUCHI, KIYOSHI UCHIDE, KUNIHIKO KUMAMOTO, MASATO SEKIGUCHI, YUKARI YAJU

Abstract

The human papillomavirus (HPV) vaccine has been linked to a number of serious adverse reactions. The range of symptoms is diverse and they develop in a multi-layered manner over an extended period of time. The argument for the safety and effectiveness of the HPV vaccine overlooks the following flaws: (i) no consideration is given to the genetic basis of autoimmune diseases, and arguments that do not take this into account cannot assure the safety of the vaccine; (ii) the immune evasion mechanisms of HPV, which require the HPV vaccine to maintain an extraordinarily high antibody level for a long period of time for it to be effective, are disregarded; and (iii) the limitations of effectiveness of the vaccine. We also discuss various issues that came up in the course of developing, promoting and distributing the vaccine, as well as the pitfalls encountered in monitoring adverse events and epidemiological verification.

Introduction

In this paper, we review the adverse reactions following human papilloma virus (HPV) vaccination in Japan, and the measures taken by the Ministry of Health, Labour and Welfare (MHLW) (1) to withdraw active recommendation of the vaccine. These measures triggered domestic and international controversy. We also discuss various problems that occurred while developing, promoting and distributing the vaccine; the pitfalls encountered in monitoring adverse events and epidemiological verification; and the influence of big pharma on healthcare policy and research.

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I. Overview of the HPV vaccine issue in Japan

HPV vaccines were approved later in Japan than in the western countries (October 2009 for Cervarix, and July 2011 for Gardasil). The vaccination rate was initially low. However, after a campaign for the promotion of the vaccine, which led to government subsidisation of the cost of the vaccine in November 2010, the vaccination rate increased exponentially. This was followed by an unexpected increase in reports of adverse events (AEs). Importantly, these vaccines gave rise to a large number of serious AEs. Table 1 shows the number of reports of serious AEs/adverse drug reactions (ADRs), defined according to the ICH E2A guidelines (2), submitted with respect to HPV vaccines by vaccine manufacturers and medical professionals at the end of February 2016 (3). These numbers far exceed those for other vaccines, even if one allows for the probability that vigilance would be higher for a newly introduced vaccine than an older, time-tested one (4,5) (Fig. 1). As these data have been compiled from voluntary reports, the actual incidence of AEs may well be far higher (6,7).

Table 1
Reports of serious AEs/ADRs or HPV vaccines in Japan (3)

Vaccines	Total dose*	Total number of inoculated persons*	Serious AE/ADR reports	
			From MAH	From medical institutes
Cervarix	6,998,266	2,590,000	835	448
Gardasil	1,924,121	800,000	124	165

**Estimated from sales data*

***Note**: AE: adverse event; ADR: adverse drug reaction; MAH: marketing authorisation holder*

***Observation period**: December 2009–February 2016 (Cervarix), August 2011–February2016 (Gardasil)*

Other key features of the ADRs reported with HPV vaccines are the diversity of the symptoms and their development in a multi-layered manner over an extended period of time. The ADRs include complex, multi-system symptoms, such as seizures; disturbance of consciousness; systemic pain, including headache, myalgia, arthralgia, back pain and other pain; motor dysfunction, such as paralysis, muscular weakness, exhaustion and involuntary movements; numbness and sensory disturbances; autonomic symptoms, including dizziness, hypotension, tachycardia, nausea, vomiting and diarrhoea; respiratory dysfunction, including dyspnoea and

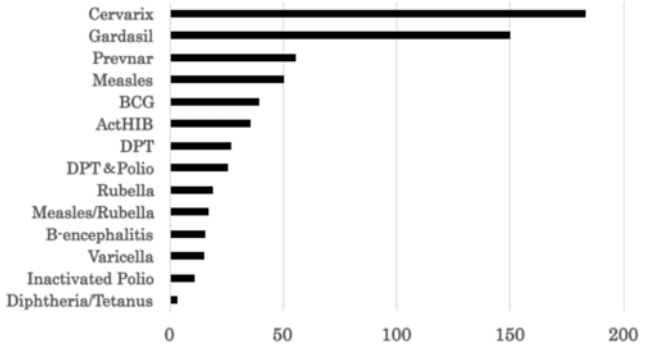

Fig. 1: Severe ADRs from HPV vaccines and other vaccines in Japan.
Data sourced from the national adverse events following immunisation (AEFI) registry in 2013–2016. (ADRs/10^6 inoculations)(4,5)
BCG: Bacillus Calmette–Guerin; DPT: diphtheria–pertussis–tetanus

asthma; endocrine disorders, such as menstrual disorder and hypermenorrhoea; hypersensitivity to light and sound; psychological symptoms, such as anxiety, frustration, hallucinations and overeating; higher brain dysfunction and cognitive impairments, including memory impairment, disorientation and loss of concentration; and sleep disorders, including hypersomnia and sudden sleep attacks. In some cases, these symptoms impair learning and result in extreme fatigue and decreased motivation, having a negative impact on everyday life (8–11). The situation in Japan is similar to that in other countries which have also reported a specific cluster of serious and complex symptoms that develop across multiple body systems over an extended period of time (12,13).

The reason why HPV vaccines cause these characteristic adverse effects remains to be studied in the future, but one of the most plausible explanations is that these vaccines are designed to maintain an extremely high antibody titre over a long period of time. Since prolonged inflammatory reactions associated with infection are known to cause autoimmune diseases and worsening of autoimmune reactions (14), long-time antigen stimulation with HPV vaccines might also induce complex autoimmune reactions via a mechanism similar to that seen with prolonged infection.

Individuals who experienced ADRs following HPV vaccination established a voluntary liaison organisation to facilitate communication with others who also experienced ADRs in Japan. When these ADRs were reported in the mass media, HPV vaccination became a major social issue. In response to the negative press surrounding HPV vaccination, the MHLW withdrew its active recommendation in June 2013 on the grounds of "an undeniable causal relationship between persistent pain and the vaccination"(1). As a result, the inoculation rate for the vaccine decreased rapidly [from 80% at its peak to less than 1% at present (15)]. In response to this change, proponents of the HPV vaccine initiated a push-back campaign and began actively lobbying the government.

On January 20, 2014, the expert advisory committee established by the MHLW (16) presented the view that the diverse pain and motor dysfunctions experienced by many individuals after HPV vaccination comprised psychosomatic reactions to anxiety or stimulatory pain caused by needle injection, and were not due to any components of the vaccine itself. However, doctors and researchers who examined patients with post-vaccination symptoms arrived at a completely different conclusion, highlighting both the characteristic symptoms and course, which are difficult to explain as psychosomatic reactions (9–11).

Thus, the safety of the HPV vaccine remains far from certain in Japan, justifying the public's strong distrust. Recognising the potentially negative influence of these events on public opinion in other countries, pharmaceutical companies initiated a counter-intervention strategy through public and private organisations, such as the World Health Organisation(WHO). The Global Advisory Committee on Vaccine Safety (GACVS), one of the WHO's advisory committees, claimed it had "not found any safety issue that would alter its recommendations for the use of the vaccine" and criticised the MHLW's decision to withdraw active recommendation (17).

Despite these obstacles, in July 2016, a victims' group filed a multi-plaintiff lawsuit in the district courts of Tokyo, Nagoya, Osaka and Fukuoka against the Japanese government and the two pharmaceutical companies that had produced these vaccines. Furthermore, in December of the same year, additional victims joined the multi-plaintiff lawsuit, bringing the total number of plaintiffs to 119 (18).

So far, we have reviewed the adverse reactions to HPV vaccines and the measures taken by the MHLW in Japan that provoked controversy both in Japan and abroad. In the next section, we discuss the safety and efficacy of the HPV vaccines promoted by the WHO and other organisations, and identify a flaw in the basis of their arguments in favour of the vaccines.

II. The problem with the HPV vaccine: refuting the GACVS statement (19)

a. Safety issues

Investigation by the MHLW

Regarding Japan, the GACVS statement (17) says that "review of clinical data by the national expert committee led to a conclusion that symptoms were not related to the vaccine". However, there are major problems with the expert committee's investigation (16).

The most serious problem is that very few members of the committee actually examined patients with post-vaccination symptoms. The committee's investigation focused exclusively on pain and motor dysfunction, and ignored many other diverse symptoms that have been observed. Further, cases in which adverse events occurred more than a month after vaccination were excluded from consideration on the ground that most adverse effects of vaccines occur within one month of vaccination. However, subsequent studies have clarified that symptoms commonly appear even after a considerable period of time has elapsed since vaccination (9–11).

The methods used for determining psychosomatic reactions to be the cause of symptoms are also open to question (16). The expert advisory committee proposed four hypotheses regarding the pathophysiology of post-vaccination symptoms: (i) neurological disorder, (ii) intoxication, (iii) immunological reaction, and (iv) psychosomatic reaction. Those cases which do not conform to the committee's criteria for (i)–(iii) were regarded as having no causal relationship with the HPV vaccine. However, since the definition of the psychosomatic response is ambiguous and the diagnosis is exclusively made by the subjective judgement of the doctor, many cases are diagnosed as psychosomatic reactions.

Support for the expert advisory committee's conclusion is far from universal. Doctors and researchers who actually examined patients with post-vaccination symptoms pointed out that it is difficult to explain all symptoms as psychosomatic reactions on the basis of the results of experiments and case reports (8–11, 20–22). Prior to investigating HPV vaccine-associated neuro-immunopathy (HANS), a new disease concept proposed by Nishioka (22),Yokota et al excluded from their survey all individuals who exhibited any physical/psychological abnormality before the vaccination (9). Thus, the survey design further strengthened the conclusion that the psychosomatic response could not account for the majority of the AEs of the HPV vaccine, as claimed by the committee.

Further, as 11 of the 15 members of the expert advisory committee have conflicts of interest with vaccine manufacturers, the public is justified in requesting that a more diverse range of scientists reviews the relevant data (23). Thus, the safety of the HPV vaccine remains far from certain in Japan, justifying the public's strong concerns. Outside Japan, Jefferson et al (24) and Gøtzsche et al (25) also expressed concern about the nature and quality of regulation of the HPV vaccine by the European Medicine Agency.

Criticism of the evidence for safety mentioned in the GACVS statement

Regarding the safety of the HPV vaccine, the GACVS claimed in its statement that it had not found any safety issues warranting an alteration in its recommendations for the use of the vaccine, and criticised Japan for stopping the active promotion of HPV vaccination (17). However, the studies (26–31) cited by the GACVS as evidence for the vaccine's safety raise the following fundamental questions.

i) Genetic basis of autoimmunity

Among the pathophysiological mechanisms related to adverse reactions after vaccination, the involvement of autoimmunity is one of the most probable. The various mechanisms suggested with regard to autoimmune diseases include: molecular mimicry (32), in which a foreign antigen shares structural similarities with self-antigen; the disruption of essential mechanisms in central and peripheral immune tolerance (33); and human endogenous retroviruses genes producing functional proteins or developing antibodies against the individual's own proteins (34).

Although the aetiology has not been fully elucidated, most autoimmune diseases are complex polygenic conditions, in which the affected individual inherits multiple genetic polymorphisms that contribute to disease susceptibility, and these genes interact with environmental factors to cause the disease. It is a well-known fact that some human leucocyte antigen alleles occur at a higher frequency in patients with certain autoimmune diseases than in the general population (35).

At present, what is claimed to be the primary evidence for the safety of the HPV vaccine is that there is no statistically significant difference in the incidence of autoimmune diseases among vaccinated females and unvaccinated females or the general population. However, since the proportion of genetically susceptible people in the general population is very small and limited, simple comparisons of the incidence of autoimmune diseases between those who have been vaccinated and a control (unvaccinated) group are likely to show no significant difference. Arguments that do not take this into account cannot assure the safety of the vaccine. The baseline prevalence of many autoimmune diseases is relatively low. Thus, careful large-scale post-marketing surveillance that takes into account the immunological characteristics of individual patients is required to scientifically verify the relationship between vaccination and autoimmune diseases (36).

ii) Coding and the loss of important information

In drug regulatory agencies and the pharmaceutical industry, all AEs in a patient's medical record are coded for computer processing and thus, details contained in the raw data are "lost". As a result, the clinical significance and extent of drug risk are masked(37,38). This process results in a kind of circular reasoning, in which post-vaccination symptoms are isolated and analysed retrospectively within the framework of the existing disease concepts, instead of being viewed comprehensively.

iii) Paradigm shift

HPV is equipped with various immune evasion mechanisms, which could cause the immune system to become more tolerant to the infection, creating a microenvironment susceptible to further infection and facilitating the progression of cervical intraepithelial neoplasia (CIN). To counteract these immune evasion mechanisms, the HPV vaccine is designed to maintain an extraordinarily high level of antibodies for more than a decade (39, 40). This moves the HPV vaccine out of the paradigm of "vaccine" as it is conventionally understood. These unique characteristics of the HPV vaccine make it essential to conduct a more thorough evaluation of its safety.

b. Effectiveness

While the GACVS statement claims that "the impact of HPV vaccines on HPV-related clinical outcomes, including pre-cancerous lesions, is well established", in actuality, the effectiveness of the HPV vaccine is quite limited, as discussed below.

First, the only verified effect of the HPV vaccine is a preventive effect on pre-cancerous lesions (specifically CIN); the preventive effect on cervical cancer itself has not been established. The effects of the vaccines currently approved in Japan (Cervarix and Gardasil) on pre-cancerous lesions have been demonstrated only in the cases of HPV 16 and 18, which, according to the most reliable studies, represent only 50% of cervical cancer cases in Japan (41).

Further, 10% or fewer cases of high-risk HPV infection result in persistent infection that can cause cancer, while the large majority of any pre-cancerous lesions (CIN) that do develop resolve before becoming cancerous (42, 43). Therefore, only 0.15% of individuals infected with high-risk HPV develop (invasive) cancer (44, 45). Even if cancer develops, regular check-ups can help to detect it at an early stage and appropriate treatment (surgery, radiation and drug therapy) saves many lives. On the basis of these facts, the promotion of educational activity that emphasises the importance of screening and early detection, as well as the creation of an environment in which women feel more comfortable undergoing Pap testing, would be far more effective at preventing cervical cancer than would pressuring teenage girls to receive the existing HPV vaccination, with all its problems.

The proponents of the HPV vaccines claim that they are 98%–100% effective in preventing cervical cancer. In reality, however, the absolute risk reduction (ARR) provided by HPV vaccines is, at most, 0.1%–0.7%, on the basis of calculations using the existing data (46). Further, this indicates only the reduction in the risk of developing pre-cancerous lesions, while the risk of developing cervical cancer remains unknown.

The promotion of screening for cervical cancer is another important measure against cervical cancer. For a long time now, attention has been drawn to the low screening rate for cervical cancer in Japan compared to the western countries. In particular, young women with no experience of pregnancy are reluctant to undergo gynaecological examinations in Japan. Access to examinations by female doctors and an acceptance of self-sampling would undoubtedly increase the screening rates. In fact, the promotion of screening for cervical cancer significantly reduced the age-adjusted incidence of invasive cervical cancer in the UK (47).

III. Structural flaws: an ethics viewpoint

In the previous sections, we discussed various issues regarding the safety and effectiveness of the HPV vaccine. It is now appropriate to ask how such questionable vaccines have come into widespread use. The answer, at least with respect to Japan, can be found in a structural flaw, combined specifically with the following factors: (i) aggressive promotion by the pharmaceutical industry, (ii) trade negotiations by economic superpowers, and (iii) contemporary medicine, which is characterised by overconfidence in technology and a lack of humility with respect to listening to patients' complaints.

a. Immunisation Act and HPV vaccine promotion by manufacturers

Following the enactment of the Immunisation Act in Japan in 1948, numerous lawsuits were filed in response to vaccine-related injuries. This resulted in the establishment of a compensation system for victims and the amendment of the relevant laws and regulations. At present, vaccines are divided into three categories, as shown in Table 2(48).

According to the definitions in the Act, a vaccine for individual protection, such as the HPV vaccine, should be classified as an "optional" vaccination, which is solely the individual's choice. However, due to lobbying activities, the HPV vaccine was approved as a vaccine to be administered at public expense, and was included in the category "Routine vaccination A". Since it was recommended by the government, individuals felt obligated to receive the HPV vaccine.

The Japanese Expert Board for the Eradication of Cervical Cancer (49), one of the most powerful lobbying organisations in Japan, was founded in November 2008, around the time the HPV vaccine was being reviewed for approval. The executive members of various medical academic societies joined this group and exerted considerable influence on the legislative process, as well as on public administration and the shaping of public opinion.

Table 2
Vaccination and legal categorisation

Category	Responsibility of individual	Vaccination
Routine vaccination A	Duty to make effort to receive vaccination	Hib, pneumococcal, BCG, diphtheria, pertussis, tetanus, polio, measles, rubella, varicella, HPV, HB, Japanese Encephalitis
Routine vaccination B	No particular social duty	Influenza (for elderly), pneumococcal
Optional vaccination	Discretion of individual	Pneumococcal (for adults), rotavirus,etc.

According to information obtained by Medwatcher Japan(50) under the *Transparency Guideline for the Relation between Corporate Activities and Medical Institutions* (51) of the Japan Pharmaceutical Manufacturers Association, the funds received by the Expert Board from vaccine manufacturers amounted to ¥73,500,000 (¥35,000,000 in 2012 and ¥38,500,000 in 2013). In addition, the secretary of the Expert Board was found to have been working at GlaxoSmithKline Co. as the Director of Marketing for vaccines for up to eight months prior to the launch of Cervarix. These facts strongly suggest that the activity of the Expert Board was not altruistic, but was actually disguised promotion(52).

b. Pressure from outside Japan

The promotion of the HPV vaccine during Japan–US trade negotiationshas also created pressure on Japan to adopt the vaccine. For many years, the promotion of vaccination has been

one of the most pressing requirements in trade negotiations with the US, Japan's most important trading partner (53, 54). The Center for Strategic and International Studies, a civilian think tank that is part of the US military–industrial complex, criticised the indecisiveness of Japan's government in reports issued in May 2014 and April 2015, reflecting the irritation of US industries (55,56).

c. Medical professionals forgetting their role

Basic defects inherent in the medical community underlie the issue of the HPV vaccine. In 2004, Sheldon Krimsky pointed out the increasing influence of commercialism in academic science and biomedical research in his book, *Science in the private interest* (57). He wrote, "…the mix of science and commerce continues to erode the ethical standards of research and diminish public confidence in its results. "In the 13 years since the publication of the book, his warning has become a reality everywhere in the world, not only in the USA. Originally, public health and pharmaco-epidemiology were the scientific fields that aimed to protect the health of individual patients and the public. However, the current reality is very far from the ideal.

Science is now misused to protect the interests of the pharmaceutical industry, and has been used to deny the causal relationship between the drug and its adverse reactions. Many researchers and experts are attempting to exclude inconvenient truths from consideration. "The taxonomy of diseases represents the nearest science has got to nature, but it remains a theoretical construct. It is the theory that should be discounted when the patient's symptoms refuse to fit, not the patient's account of the reality of their experience."(58, 59) This means that doctors must be more humble and scientifically honest. Today's diagnostics and therapeutics were created by listening to patients' voices and conducting careful examinations. It is irresponsible to dismiss a patient's complaint as a psychogenic reaction or a general phenomenon among young women without conducting a thorough examination.

IV. Considerations for solving problems

As described in section III, the introduction of HPV vaccination in Japan was promoted with an emphasis on commercial interests rather than as a public health need. This situation is not unique to Japan and has also been observed in other countries. In Australia, for example, despite the considerable doubts of the Pharmaceutical Benefits Advisory Committee about the Gardasil vaccine, the committee's decision to reject the addition of Gardasil to the national vaccination schedule was hurriedly overturned, following political interference and lobbying by other vested interests (60).In the USA, Merck & Co, Inc promoted legislation to mandate HPV vaccination for school attendance by serving as an information resource, lobbying legislators, drafting legislation, mobilising female legislators and physicians' organisations, conducting consumer marketing campaigns, and filling gaps in access to the vaccine. Legislators relied heavily on Merck for scientific information (61).The responsibility to prove the efficacy and safety of a vaccine lies with the pharmaceutical companies, and the government is expected to monitor and guide these efforts. The current situation in which commercial interests drive government policy must be corrected from a medical ethics perspective.

At present, Japan is one of the few countries in which the active recommendation of HPV vaccination has been temporarily stopped; the regulatory authorities in other countries have not changed their policies. Although various groups of victims of vaccination have collaborated on wide-ranging activities in these countries, the regulatory authorities have not yet admitted the causal relationship between the vaccines and the victims' health injuries.

The Japanese government's decision to stop actively recommending HPV vaccination has, to an extent, encouraged regulators and patients in other countries to question the value of HPV vaccination. Japan's efforts to stop active recommendation might have been successful because of its historical background of cases of environmental pollution and drug-induced suffering (Minamata disease, thalidomide, SMON, dura mater graft-associated Creutzfeldt–Jakob disease, HIV transmitted by contaminated blood products, etc), which occurred during the post-war period of rapid economic growth. In the multi-plaintiff suits that followed the instances of environmental pollution and drug-induced suffering, the plaintiff groups sought not only compensation for damages, but also institutional reform and revisions to the law to prevent the repetition of the same mistakes (62).

This historical background has created a situation in which the mass media and regulators cannot easily ignore the victims' complaints about the side-effects of new vaccines. It is here that we may find a clue on how to solve this problem. It is necessary to enhance transparency at every step of the approval process for pharmaceutical products, from new-drug development to post-marketing surveillance. At the same time, it is crucial to strengthen the management of conflicts of interest, and develop a system by which citizens can participate directly and have a voice in the planning of public health policy(63–65).

Conflict of interest

All the authors are members of Medwatcher Japan. Masumi Minaguchi and Masato Sekiguchi are Lawyers for the plaintiffs in the HPV vaccination lawsuits.

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Identifying ethical issues in the development of vaccines and in vaccination

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Abstract:

Vaccines are a widely accepted public health intervention. They are also a profitable tool for pharmaceutical companies manufacturing vaccines. There are many vaccines in the pipeline, for various diseases, or as combination vaccines for several diseases. However, there is also a growing concern about vaccines and the manner in which they are developed and approved by the authorities. Approvals are fast tracked and adverse events and serious adverse events following vaccination are seldom reported once the vaccine gets its marketing approval. Thus, vaccines have been clouded with many controversies and their use as a public health tool to prevent diseases is constantly under challenge.

Public health and human rights have an intrinsic link, and any public health programme can be successful if the rights of people are respected, and upheld. A routine or compulsory vaccine programme tends to ignore rights of people that augment the legal and ethical issues relating to vaccinations. This article aims to identify the legal and ethical issues in the development of vaccines and in vaccination processes.

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Introduction

About 44% of the 27 million children born in India annually receive a full schedule of immunisation, consisting of the diphtheria, tetanus, pertussis, poliomyelitis, measles, hepatitis B, rotavirus and pneumonia vaccines (1). Despite the Universal Immunisation Programme (UIP) re-launched in India in 1985, with the aim of extending the coverage of the basic vaccines to all infants and pregnant women, 9.6 million children remain unimmunised (1).

The reasons for the low immunisation levels are primarily the low spending on routine immunisation, which is only about 2.1% of the national government's health budget, a shortage of trained personnel, low levels of education with regard to vaccines and vaccination programmes, adverse events following immunisation (1), lack of transparency in decision-making on vaccines and their safety, and the inclusion of new vaccines in the UIP without proper deliberations.

Vaccines that are often accepted as safe and effective can cause serious reactions or adverse events. In such cases, some people break their silence and make their suffering public. It is only then that the process of approval, the evaluation of safety and the information given to the parents of children being immunised is questioned, debated upon and re-evaluated. It is then that the inextricable link between public health and human rights is recognised. The vulnerability of people, disability and the premature deaths of children and young adults brings societal inequalities and discrimination to the forefront, and also underscores the indifferent attitudes of the State and other stakeholders.

This paper attempts to evaluate some of the legal-ethical issues pertaining to vaccines and vaccination, a medical intervention with inherent risks and benefits (2). Some of these legal -ethical issues are raised time and again, when the vaccine conundrum is re-examined right from the development stage of the vaccine to the evaluation of its safety, till it is finally approved and administered to human beings as a tool for the prevention of disease.

Research and development in vaccines

Ever since the success of the small pox vaccine in eradicating the disease, and in later years, the success of the polio vaccine (even though it caused non-polio acute flaccid paralysis in some), vaccines are perceived to be a cost-effective method of saving the lives of children (3). Much emphasis is now given to research for vaccines that can eliminate or eradicate diseases, not necessarily only infectious or childhood diseases. A lot of money is invested in the search for new vaccines against diseases (3), as their success can influence governments to include them in the Universal Immunisation Programme (UIP) or to recommend their use in the private sector, leading to long-term, sustained profits (4). However, one vaccine may not work for all populations, and hence, it is essential to carry out clinical trials on a population before marketing or providing the vaccine. Different vaccines may be required for different virus strains to prevent the same disease (5).

Vaccines for diseases that afflict a few people are not considered a commercial proposition. Diseases that are endemic in the developing but not in the developed countries are not a priority either and are therefore, not subject to much research in terms of the development of vaccines (4). Profits, rather than health, appear to be the focus.

The legal-ethical issues connected with research in vaccines pertain to the development of the vaccine, study design, population on which the vaccine is tested, and the location of the trial.

Safety

The issues involved in assessing the safety of a vaccine centre primarily around the safety of the vaccine in terms of possible side effects, as well as for quality and freedom from contamination (6). A vaccine would be unsafe if it caused illness, disease, injury or harm to the recipient (6). Independent experts should collect and analyse the safety data and the vaccine should be tested for contaminants (6).

Before seeking approval to market the vaccine, research companies must conduct animal studies and Phase I to Phase III clinical trials to ascertain the safety and efficacy of the vaccine. Multidisciplinary experts from the scientific, medical, social, public health and allied fields, are involved in developing and testing the vaccine. Many times, there is a conflict of interest between the researchers and institutes testing the vaccine for its safety and efficacy; this can compromise the vetting system of medical research. Research involves financial intertwining between the pharmaceutical companies, medical research professionals, academic institutions conducting the research, and government agencies (7). Due to financial interests, the truth about the safety, effectiveness and efficacy of the vaccine is often compromised, misrepresented and suppressed. It was found in the USA that 3 out of 5 FDA advisory committee members who voted in favour of the rotavirus vaccine had financial ties with the pharmaceutical companies producing the vaccine (7).

Unfortunately, the data produced in clinical trials are kept confidential, and the anonymised data are not provided to independent experts for scrutiny. This creates doubts about the robustness of the approval system, as the safety data are provided by the pharmaceutical companies that produce the vaccine. In fact, the refusal to share the complete and honest data is in itself a legal and ethical issue. There are growing doubts about believing clinical research data. Close monitoring of Phase III and Phase IV clinical trials by independent bodies may bring out the truth regarding the safety and efficacy of a vaccine.

The National Technical Advisory Group on Immunisation (NTAGI), established in 2002 by the Ministry of Health, recommends that vaccination be considered in the UIP and its reach be expanded to cover all children (1). The introduction of the rotavirus vaccine by the NTAGI in 2013 was clouded by controversy due to the low efficacy (only 56%) of the vaccine and because the safety data of the clinical trials were not

revealed for expert analysis (8). Today, when the rotavirus vaccine is prescribed against diarrhoea, it is not disclosed that the child is not protected against some major strains of rotavirus (9). The trials of the vaccine revealed that vaccinated children had a three times greater risk of suffering from intestinal bleeding and many other complications (9). It is, therefore, important to make data from clinical trials available in the public domain to improve scrutiny and knowledge regarding the truth about vaccines.

Trial design

The study design, too, may raise legal-ethical issues sometimes. In randomised controlled trials, the gold standard for evaluating the safety and efficacy of new interventions is the use of a placebo control arm or a no-treatment arm, even where standard treatment is available. International ethical guidelines require that the placebo control arm or no-treatment arm should be used sparingly and only in cases in which there is a no-treatment option. Interestingly, during the Ebola epidemic, clinical trials were conducted using the stepped-wedge design, in which the clusters or individuals were randomised to receive the intervention at different points of time (10). Of course, the assumption was that the intervention was useful and likely to do more good than harm (10). Nevertheless, international guidelines do speak of providing the intervention to the other arms of the trial, if it is proven to be efficacious and better than the standard treatment or no treatment. However, the protocol of the trials rarely requires companies to provide all the participants of the trial with post-trial access to the experimental drug or vaccine.

Population

Vaccines should be tested in varied populations to understand their efficacy and safety in populations of different ethnicity. Vaccines for children must first be tested on adults, and only then on children. Ethical and legal issues are generally raised when vaccines are tested on vulnerable populations or directly on children without providing them any safety or protection, or without following the norms of informed consent. Unfortunately, the best interest of the children being vaccinated and their human rights are completely ignored. The human papilloma virus (HPV) vaccine was approved in India on the basis of bridge trials (Phase IIIB) covering a small population. The approval process of the two HPV vaccines, Cervarix and Gardasil, has generated much controversy and cases are pending in the Supreme Court of India on the issue (11).

Location

The location of the trials is of much importance as several ethical issues arise when vaccines researched in developed countries are tested in the developing countries. One needs to make sure that the ethical standards of research followed in the developed country are followed in the developing country, even if the latter has a weak regulatory system. Further, factors such as the availability of healthcare facilities at the location where the trials take place, and the availability of screening and treatment at these locations can pose a challenge in developing countries. The ethical conduct of trials can be affected if such facilities are not available and advantage is taken of the vulnerability of those participating in the trial. A Phase IV trial for the HPV vaccine was conducted by the Program for Appropriate Technologies in Health (PATH) in rural and tribal areas in India. Seven girls died after being vaccinated. The trials took place at a location with hardly any healthcare facilities. The children and their parents had no idea about the nature of the disease or the vaccine (12). This case raised a lot of legal and ethical issues, including those relating to informed consent.

Once vaccines are approved by the regulatory authorities, they are marketed the world over. They are given a push to be included in national immunisation programmes by people in influential organisations, such as the World Health Organisation, the Global Alliance for Vaccines and Immunisation and the Bill and Melinda Gates Foundation, many of whom may have conflicts of interest.

Preventive vaccination programme

Vaccination is a preventive healthcare measure that benefits individuals and public health proportionately, but the harm and risks affect individuals disproportionately. Angus Dawson states that "the key elements of the prevention problem are that: (a) preventive public health measures are performed on asymptomatic individuals; (b) every such public health intervention will carry a risk of harm; (c) the benefits of such interventions lie at the level of populations, whilst the risks of harm are borne by the individual participants in the programme. Conclusion: Such preventive programmes are unethical (given distribution of risks and benefits." (13)

There appears to be an underlying assumption that vaccines are a hundred per cent safe. However, it is known that vaccines do not suit some people, cause adverse reactions and serious adverse reactions in some people. There is, therefore, a need to make an individualised assessment before vaccinating people in general. Jonathan Mann spoke of the inextricable connection between public health and human rights, "for human rights provide public health with an explicit response to its central dilemma: how to address directly the societal forces which determine, more than anything else, vulnerability to preventable disease, disability and premature death"(14). Unfortunately, diseases caused by vaccines and the deaths of otherwise healthy people do not appear to be acknowledged as a problem. In fact, more often than not, statistics and mathematical calculations are used to justify deaths and adverse reactions, with the claim that the death is "not related" to the vaccine, or that the number of deaths is miniscule and not significant enough to ring alarm bells about the safety of the vaccine. The legal issues and need for an inquiry into the death of a person after vaccination are simply brushed aside.

Infants and adolescents are now vaccinated not only against the common childhood infections or diseases, but also against diseases that they may not be exposed to, or for

which there are other simpler methods of prevention. Nations across the world are keen to see a world with "vaccine-preventable diseases" (irrespective of whether the child will ever be exposed to the disease). The idea is to promote such vaccination not only to protect the child in the future, but also to reach an optimal level of immunisation to create "herd immunity" so as to eliminate diseases! In such a scenario, the benefit at an individual level remains unknown, as one does not know whether the individual has been protected or is lucky enough not to have come in contact with the virus (13).

Unfortunately, the NTAGI has not been transparent in its dealings and decisions regarding the inclusion of some more vaccines under the UIP. Questions have been raised and legal battles fought with regard to the inclusion of the pentavalent vaccine (a combination of diphtheria, tetanus, whooping cough, hepatitis B and haemophilus influenza B [Hib]) in the UIP primarily on account of no scientific studies conducted by the government (15). Further, the low disease burden in India of meningitis caused by haemophilus influenza B (Hib) has been a reason to question its inclusion in the UIP. Studies have also shown that there no beneficial long-term impact of the pentavalent vaccine. It was also a matter of concern in India that the pentavalent vaccine was temporarily withdrawn from the neighbouring countries of Bhutan and Sri Lanka when there were reports of adverse events following immunisation in some children (16).

Compulsory/ routine versus voluntary

Most vaccination programmes, especially those included under the UIP, are coercive and paternalistic. Any kind of mandatory testing, treatment, quarantine and isolation that restricts the rights of people can be justified only if it is aimed at preventing infectious or contagious diseases (17). The limitations on the rights of people can only be justified if it is proportional to the public interest and its objective (17). John Stuart Mill stated that "power can be rightfully exercised against somebody against her/his will if it is done to prevent harm to others" (18). In the context of vaccination, such coercion is often justified on the ground of eradicating a life-threatening disease, provided that the harm or risk of the vaccine itself is low, it is not debilitating, and it guarantees protection (18). However coercion of this type should be used with a lot of care and can have counterproductive effects (18). "Information, campaigns which appeal to the rational capacities of people and to their sense of responsibility to others" would be better options and "may prove more successful in the long term" (18).

It is interesting to note that Italy moved from compulsory to voluntary immunisation in a programme that has been successful. The Italian National Vaccine Plan (2005–7) allowed certain regions that had reached the herd immunity level to suspend compulsory vaccination and move towards voluntary vaccination, while providing for effective monitoring of the incidence of disease and outbreaks of communicable diseases (19). In countries such as Finland, Germany and the Netherlands, the State relies on disseminating information and raising awareness of the benefits of immunisation to maintain high rates of coverage (19). Voluntary immunisation perhaps also suggests trust between society and the State. The attainment of herd immunity, ie when immunisation is voluntary, indicates that the State need not make immunisation compulsory or provide incentives for immunisation (as is done in Austria and the UK) (19). It is possible to implement such a programme in India and the developing countries. In India, awareness of the prevention and treatment of HIV was raised successfully, and the rights of the most vulnerable were protected, leading to the control of the spread of HIV. Similar programmes dealing with vaccines could also be developed to move from compulsion towards voluntary vaccination.

Voluntary immunisation would necessarily entail the inclusion of aspects of complete informed consent, which are often ignored in routine or compulsory vaccination programmes.

Informed consent

Ethical and legal debates on the implementation of vaccination programmes centre around whether informed consent should be taken prior to vaccination. There is an unfounded fear that if people are given information on vaccines beforehand, it may give rise to unnecessary fears and concerns regarding the vaccination process. Generally, written informed consent is not taken for the mass-scale implementation of a preventive vaccination programme, which is almost like a compulsory programme. However, the prospective vaccinees and/or their parents must be provided with information on the vaccine, the disease(s) it proposes to prevent, the known side-effects, adverse events, and serious adverse events that have been observed not only in clinical trials, but also in places where the vaccine is approved and is given to the population.

Informed consent is required both under the law and the code of medical ethics. After all, immunisation or vaccination is a medical intervention that is not risk-free, which obligates the healthcare provider to give the vaccinee complete information on the benefits and risks of the vaccine. The person must be given information on the number of shots required for protection from the disease and booster shots and the methods of preventing disease, whether or not he/she refuses or gives consent to be vaccinated.

It is essential to respect individual rights and autonomy, and to make respect for and dignity of human rights compatible with public health strategies (17). The principle of necessity to vaccinate and participatory decision-making involving the community could make a voluntary vaccination programme more successful than a compulsory one. Berkley stated that "Ethics and implementation issues can be addressed by adherence to global standards, and truly informed consent can be acquired with careful engagement of communities in which trials are done" (20).

Vaccination implementation

The lack of the basic necessities for health, nutrition, adequate safe drinking water and medicines in developing

countries gives rise to ethical debates on what the priorities of government health programmes should be, especially where resources are scarce and health is a low priority. Should it be vaccination and prevention of disease, or should it be making provision for safe drinking water, promoting hygienic conditions, etc, so as to prevent diseases that are more often than not born out of unsafe conditions? In 1980, the then Director General of WHO, Halfdan Mahler, opined that important lessons could be learnt from the eradication of small pox, but the idea that we should single out diseases for eradication was not among them (3). He said, "The idea is tempting but illusory." (3) Mahler's concern was that targeting eradication would divert attention and resources from the structural and economic roots of ill health, and from the commitment to strengthen primary healthcare (3).

Developing countries face the twin hurdles of not only allocating scarce resources for the purchase of expensive vaccines, but also, of providing for satisfactory implementation given the lack of healthcare facilities and infrastructure and vaccine delivery mechanisms in general. The inability to make the provision required for the implementation of a preventive vaccination programme may result in further complications. For example, the product could become contaminated or be rendered unsafe if not stored and transported in the proper manner.

Ethical and legal considerations related to the prices of vaccines and access to affordable and free vaccines require some deliberation. The new vaccines are priced much higher than the old ones. The major factors that keep the prices high are patents on vaccines and the profit motive. The rotavirus vaccine is very expensive, with GlaxoSmithKline selling it at Rs 2398 and Merck selling it at Rs 2700 per course (21). Generic competition from an Indian company, Bharat Biotech, has brought the price of its Rotavac vaccine down to Rs 63 per dose (22). Even at Rs 63 per dose, the vaccine may not be affordable to large numbers of people in India, though the amount that the government would need to spend on the vaccine would fall drastically. Further, pharmaceutical companies market their vaccines in the private sector, selling the idea to doctors of selling their vaccines, but without giving full information on the side-effects. They also try to push governments to purchase their vaccines and include them in the UIP, so that they may have a permanent source of profit (4). The adverse events associated with the vaccines are borne by the vaccinated individuals, who are seldom compensated.

Conclusion

Global health disparities and inequalities bring out the ethical dilemmas involved in the prevention of diseases. In countries where healthcare is lagging behind, and children are dying due to malnourishment and other conditions related to poverty, can it be ethical to introduce expensive vaccines that do nothing to improve the people's living conditions ?

It is essential to understand public health issues in the light of a population's vulnerabilities, human behaviour, and the social, cultural, economic and political needs of each country and individual, and to connect the public health programme to the human rights of people who live in varied conditions with different and peculiar diseases, disabilities and health issues. One vaccine may not suit all, and one solution may not solve all problems either. Further, it is important to address the legal and ethical issues relating to vaccines, as well as the process of the development of vaccines and of vaccination, not only by training the persons involved, but also through regulations and open and transparent processes, including decision-making processes.

Jonathan Mann aptly said, "We are at the threshold of a rebirth – a set of new perspectives – so clearly possible because (to paraphrase Newton) we stand on the shoulders of the giants – in health and in human rights – who have preceded us. Now we have the responsibility to move forward by recognising that true interdependence and real interconnectedness require that we -- from health and from human rights -- advance together, equal partners in the belief that the world can change."(14) How we define the legal and ethical issues related to vaccines and vaccination will determine what we do about them and how we will go about implementing ethical, accessible and better healthcare services, including preventive healthcare.

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An idea whose time has come: Compensation for vaccine-related injuries and death in India

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Abstract

This paper emphasises the urgent need for a compensation policy for those affected by adverse events following immunisation in India. In the absence of such a mechanism in the country, people claim compensation by taking recourse to tort law and have to face the ensuing uncertainty and challenges with regard to the award of compensation. The paper argues that people should be provided compensation in the event of death and serious adverse events following compulsory immunisation, irrespective of whether there is a causal association between the adverse event and the vaccine, on the basis of no fault compensation.

Introduction

The Oxford English Dictionary defines "compensation" as "something, typically money, awarded to someone in recognition of loss, suffering or injury" (1). The obligation to compensate a person for injuries is grounded in human rights and the ethical principles of justice and fairness. According to WD Ross**,** reparative justice (sometimes used interchangeably with compensatory justice) requires that when we inflict an injury on others, we have a duty to apologise and repair the wrong done (2). Ross states that reparative action is morally indispensable, not only to repair the damage, but also to acknowledge the injured party as a moral agent worthy of respect and entitled to a confession of fault (2). Even when the argument in favour of reparative justice is accepted in principle, its actualisation is limited or fraught with complexities, as is evident from the existing compensation frameworks.

In the context of clinical research, for example, compensation frameworks mandate that if an untoward event occurs or a participant in a trial undergoes a serious adverse event (SAE)[1], whether during or after the trial, medical treatment must be provided and adequate compensation ensured. Vaccines, which are generally administered on a mass scale to healthy people and mainly to children, often through the Universal Immunisation Programme (UIP), like other biological products and drugs, can give rise to adverse events following immunisation (AEFIs)[2]. However, these may be considered too statistically insignificant to warrant compensation. Globally, therefore, the issue of compensating people for harm or injury following the administration of vaccines remains a matter of debate, and only about 19 countries provide such compensation. Even where frameworks for compensation exist, in the case of AEFIs, their implementation differs across countries, with historical specificities and legal traditions shaping them.

This paper provides a brief overview of the existing mechanisms for compensation following the administration of vaccines in different countries. It asserts the need for compensation and recommends possible mechanisms founded on ethics and human rights for their implementation in India.

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The nature of vaccines and the need for compensation

Vaccines are the only biological products that are given to people on a mass scale and are viewed as one of the most successful preventive measures against the infectious diseases they are meant to target. Just as many medical interventions can cause adverse effects, vaccination can lead to AEFIs, which can result in injury, hospitalisation and sometimes, death due to the vaccine itself. Death might take place due to some known or unknown side-effects of the vaccine, which may occur in a few or a large number of people. Death might also occur because the vaccine is not manufactured, stored, distributed or administered properly.

However, a frequently asked question is - which injuries and deaths can be designated as vaccine-related? How do we establish the causal associations between the AEFI and the vaccine? Is itimportant for there to be a causal relation for the payment of compensation? Or should it be paid irrespective of the causal assessment? (3). Also, how do we go about investigating an AEFI, and then documenting and publicising the findings?

Given this scenario, fixing accountability for the occurrence of AEFIs becomes a matter of debate and contestation. Who should be held responsible and who will provide the compensation – the vaccine manufacturer, the healthcare worker, the physician administering the vaccine or the State implementing the immunisation programme? In case compensation is not provided, what remedies are available for those suffering AEFIs?

More fundamentally, have any studies been carried out on the vaccine, and what are the benefits and risks of a specific vaccine? What is the actual burden of the disease for which the vaccine is being introduced and do other preventive measures exist? What is the system of monitoring? What kind of responsibility would it entail to treat/ take care of any adverse events?

Global scenario

Almost 19 countries have instituted compensation mechanisms – whether through the courts or a compensation scheme payout – for individuals inadvertently injured by a vaccine programme or for death following vaccination. The timeline in Figure 1 indicates when different countries instituted vaccine-related compensation mechanisms. Germany and France initiated them in the 1960s, while in the USA, the Vaccine Injury Compensation Program (VICP) came into effect in 1988. The VICP is a federal "no-fault" system, designed to compensate individuals or the families of individuals who have been injured by covered childhood vaccines, whether administered in the private or public sector (4).The most recent compensation mechanisms were initiated in Slovenia and Hungary during 2004–05.Only two countries from Asia, ie Japan and Taiwan, have provisions for vaccine-related compensation.

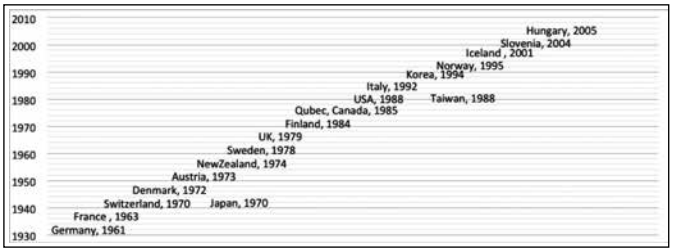

Fig. 1: Timeline for establishment of compensation mechanism for vaccine-related injuries in various countries. Source: Looker C, Kelly H, 2011 (5)

The elements of compensation in these countries include unreimbursed medical costs, disability pension, non-economic loss, funeral costs, cost of future care, lost wages and death benefits. The eligibility of particular people for compensation and the amount they may receive are decided by the national governments. Some of the factors that determine the eligibility to receive compensation are age, the time-frame within which compensation should be claimed, citizenship status, the location at which the vaccine was administered (public or private establishments), and whether the vaccine is recommended or compulsory.

Some factors that influence whether or not a vaccine is covered under the compensation programme are whether the vaccine is mandatory, or is administered as a part of travel or occupational requirements. The vaccines covered by the compensation mechanism vary across countries, as shown in Figure 2.

Country	Compensation eligibility
USA	Childhood vaccines, vaccines administered to the armed forces, influenza vaccines
UK	Childhood vaccines, vaccines administered to the armed forces, influenza vaccines In instances with more than 60% disability
Italy	Injuries from mandatory vaccines, vaccines administered as part of travel or occupational requirement
New Zealand	Severe injuries
Finland	Loss of functional ability for a minimum of 14 days
Germany	Injury that goes beyond a normal post-vaccine reaction; supplemental payments made if disability continues for more than 6 months
Denmark	Permanent injury caused by vaccination
Quebec, Canada	Permanent physical or mental injury or death caused by vaccination
South Korea	Injuries from vaccines included in the National ImmunisationProgramme Compensation for medical bills, fixed nursing fee, temporary indemnity for the disabled/ deceased, funeral service costs

Fig. 2: Eligibility for compensation for vaccine-related injuries under the compensation mechanisms of various countries (5,6).

The source of funds for the payment of compensation is also a matter of debate. The question arises as to whether it should be the government or the manufacturers' levy paid by the pharmaceutical companies. The source of funding for compensation largely reflects where the decision-making power lies. Several countries finance their programmes from

the national, state or municipal treasuries or, as in the case of Japan, a combination of all these. Finland, Norway and Sweden use the manufacturers' levy to finance compensation. New Zealand's scheme is financed from several sources, including levies on employers, employees and motor vehicle owners, government funding and investment returns. Taiwan (China) and the USA retain centralised government control over their schemes, which are funded from a vaccine tax. In Taiwan, the manufacturer or importer of the vaccine pays a tax of one New Taiwan dollar (US$ 0.034) per vaccine dose. In the USA, the tax is US$ 0.75 per dose.

In most countries, in general, patients receive primary support from public or private insurers. The compensation schemes can be relatively modest in size and do not need to cover the full range of expenses that might be considered in a tort or product liability case. For example, in Taiwan and the USA, a vaccine tax becomes the corpus for paying compensation for vaccine-related injury. According to the 2016data and statistics report of the US Department of Health and Human Services, a total of 17,437 petitions for compensation had been filed since the inception of the vaccine compensation programme in 1988. On an average, one case of compensation is filed per million vaccinations done. While 10,086 cases were dismissed; compensation was provided in 4954 cases, while the other cases are still being scrutinised. Nearly 3.4 billion dollars have been paid as compensation so far.

The compensation programme in Sweden is non-governmental and the decisions are not linked with legal proceedings. To curb malpractice in medicine, the Swedish national government started an insurance programme for patients in 1975. This was followed by pharmaceutical insurance, launched by pharmaceutical companies in 1978. As for South Korea, according to the 2013 report of the Korean National Immunisation Programme for Children, a total of 5,372 adverse events were reported from 2002 to 2011. Of the 471 requests for compensation, compensation was granted in 234 cases, while the remaining 237 requests were rejected (3).

As for compensation systems with regard to AEFIs, one of the important factors to consider has been whether there are any causal links between the injury suffered and the vaccine in question. It is very difficult to establish causation in vaccine-related injuries, given the lack of "markers". There is also a variety of views regarding the mechanisms to be used to probe the element of causation. One of the important epidemiological means to do so is to use the Bradford Hill criteria, which aid in sorting and sifting through observed associations that can be considered causal or non-causal. However, unlike epidemiological means, the mechanisms for establishing causality are different in tort law and other legal instruments. The incisive argument of Looker and Kelly is worth noting in this regard.

> *In tort litigation the defendant, or defective product, is on trial for 'causing' a specific individual's or group's adverse outcome. A direct link must be established between the particular action of that defendant or product and the adverse outcome. Legal causation is deterministic and requires proof of an allegation. In general, most compensation schemes offer a more liberal approach to standard of proof than the legal standard.* (5)

For example, in the USA, information on the risks and benefits of vaccines is disseminated by the providers of immunisation, who are directed by the law to channel the process through the Centres for Disease Control Vaccine Information Statements (5). For any of the vaccines included in this system, a claim for compensation can be initiated by any individual (or his/her parents, legal guardians, trustees, etc, in the case of children or incapacitated persons) who has suffered injury or death. However, the law requires that the claim should have a demonstrable link to the vaccine in question, with the vaccine being shown to be the causal factor. The types and nature of injuries that can be compensated for are listed in the Vaccine Injury Table of the Code of Federal Regulations, Section 2114 of the National Childhood Vaccine Injury Act. Injuries that are not on the list must be demonstrated to have a causal link with the vaccine and the onus of establishing this lies on the petitioner(s) claiming compensation (4).

However, in many of the countries (Figure 1) which have some mechanism for compensation, provision has been made to extend relief to the injured even before the investigative procedures are completed. This is not the case in India, where those who are affected have to wait till the culmination of legal proceedings under the tort law. In the subsequent sections in this paper, we explore this aspect in some detail.

The Indian context

In India, measures for the surveillance of AEFIs started being taken in 1986.The most recent version is the AEFI Surveillance Guideline of the Government of India (2014). Data and reports on AEFIs can be an important source for assessing injury for the purpose of compensation. However, the question of whether it is also necessary to move beyond the classification of AEFIs requires some thought. Figure 3 presents the classification of AEFIs.

The most important AEFIs reported from among those listed in this classification are A1 and A3, ie "Reaction related to

A1	Reaction related to vaccine product
A2	Reaction related to vaccine quality defect
A3	Reaction related to immunisation error
A4	Reaction related to immunisation anxiety
B1	Temporal relationship is consistent but there is insufficient definitive evidence that it is the vaccine that has caused the event
B2	Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunisation
C	Coincidental-underlying or emerging condition(s), or conditions caused by exposure to something other than vaccine
D	Unclassifiable

Fig. 3: Classification of AEFIs according to MoHFW guideline, 2014

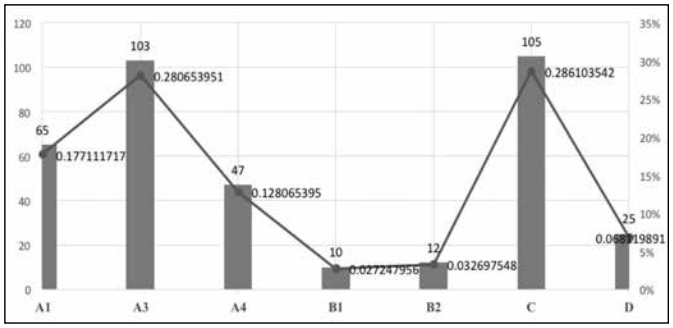

Fig. 4: Number of AEFI cases under various categories

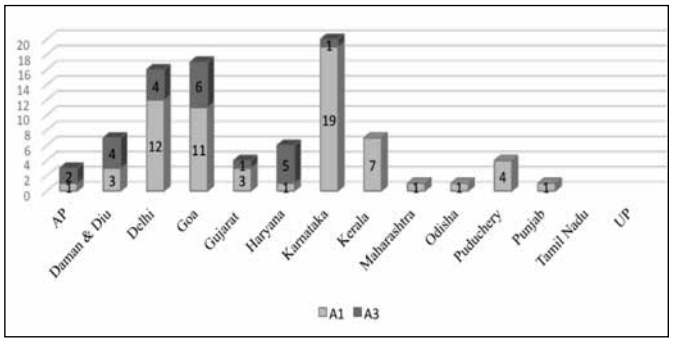

Fig. 5: State-wise distribution of A1 and A3 cases from among the 367 cases subjected to causality assessment by the Government of India

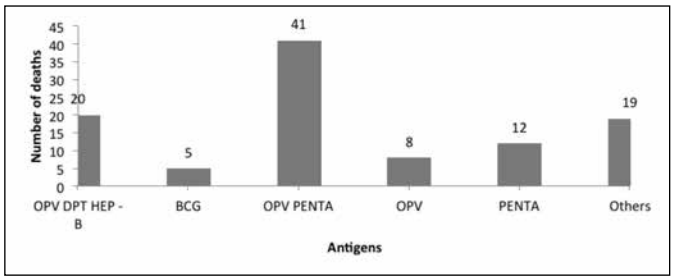

Fig.6: Total number of deaths caused by different antigens

vaccine product" and "Reaction related to immunisation error". The number of reported cases with a Detailed Immunisation Report, which allows for the assessment of causality, is considered to be an indicator of effective surveillance of AEFIs. In India, a causality assessment is undertaken by a sub-committee entrusted with the task of strengthening the national AEFI surveillance system, under the aegis of the Immunisation Division of the Ministry of Health and Family Welfare (MoHFW). This mode of assessment was modelled on the Causality Assessment Protocol of the World Health Organisation (WHO) and was finally reported to the National AEFI Committee. During 2012–14, the Committee examined and reported 367 cases of serious AEFIs from various states in India. The following are some of the insights gained from a preliminary analysis of these cases.

During the period 2012–14,1346 million doses of antigens were administered and 1759 cases of SAEs were reported. Causality assessment reports were available for 367 of these cases. Among these, the highest number of 105 (28.6%) were classified as "C", ie coincidental; 103 as "A3", ie related to

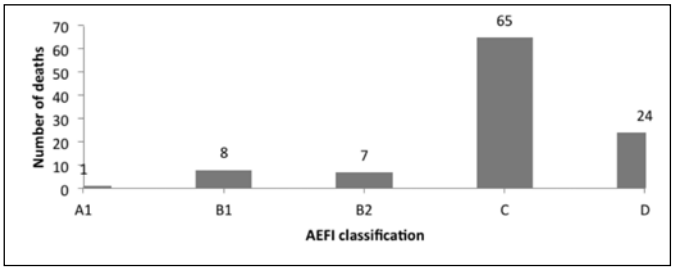

Fig.7: Number of deaths and their AEFI classification

immunisation error; and 65 as "A1", ie related to the vaccine product. Thus, A1 and A3 put together constituted 46% of the total of 367 cases subjected to causality assessment.

Figure 4 shows plots of the distribution of AEFI cases classified according to categories.

Among the 367 SAEs reported from the various states, the maximum number of cases was reported from West Bengal. Eighty of the 84 cases from the state in 2013 were linked to hepatitis B immunisation and the causality was established as immunisation error.

Excluding the 80 cases of immunisation error in West Bengal, Kerala and Bihar had the highest incidence of SAEs. The maximum number of product-related reactions occurred in Kerala, followed by Delhi and Goa. Maharashtra, Punjab and Kerala had the maximum number of immunisation errors. There were very few cases in Uttar Pradesh. However, the low number of cases may be indicative of a lack of effective surveillance or follow-up, rather than the absence of adverse events. Conversely, the high incidence of immunisation error reported from Kerala may be related to strong reporting mechanisms in the state.

In this classification, the most important categories for which compensation must be considered are A1 and A3. Figure 5 depicts the distribution of A1 and A3 cases across the states, according to the report.

On death as a "reason for reporting"

A striking fact that emerges from the causality assessment of the 367 AEFI cases reviewed and approved by the national AEFI committee is that in 105 cases, the reason for reporting was death. Of these cases, 86 were reported after the administration of five antigens (Figure 6): oral polio vaccine (OPV), diphtheria, tetanus and pertussis (DPT),hepatitis B, bacillus Calmette–Guérin(BCG), OPV pentad, OPV and pentavalent.[3]

It is to be noted that in the data on deaths, the AEFI classification for 65 cases was "C", ie "coincidental", and that for 24 cases was "D", ie "unclassifiable". Only one case was classified as A1, ie "reaction related to vaccine product" (Figure 7).

The causality assessment report of the MoHFW states: "Most of the reported serious AEFIs are coincidental."However, as demonstrated in this section and in Figure 4, the number of cases classified as "coincidental" is equal to the number of

cases the reason for reporting which was death, ie 105. The high number of cases designated C and D (Figure 7) warrants further investigation. One must keep in mind the underlying ethical concerns when looking into the fact that deaths are being reported in relation to vaccines, irrespective of the fact that the assessment of causality may indicate no causal association.

Compensation for vaccine injuries in India

India has no official vaccine compensation programme for vaccine-related injuries or deaths. The only option that complainants have is to approach the legal system, which is an expensive and protracted process, ranging at times from 10 to 15 years. Moreover, establishing causality and fault is an extremely challenging task.

In the *Dr Durga Nursing Home vs K Dhanasekaran* case in 2003 (before the State Consumer Disputes Redressal Commission, Chennai) (7), for example, the petitioner approached the district consumer court, alleging negligence and the use of expired vaccines. The court concluded that the nursing home did not have an effective storage system and its ambulance facility was inadequate, and thus, its services were deficient. It awarded a compensation of INR 100,000 for mental agony and hardship and INR 5000 towards costs. Both parties then appealed in the state consumer court. The latter declared that there was not enough evidence to comment on the quality of the vaccines used, but found that the instruments which were required were not maintained properly and there was no ambulatory service. The court held the hospital liable to pay and ruled in favour of a compensation of INR 300,000 for mental agony and hardship and INR 5000 towards costs. This is an important case that establishes the need to focus on injuries that are attributable to the overall process of vaccine administration, including the facilities for storage and ambulances.

In another case, the state of Gujarat appealed (8) against a compensation of INR 100,000 awarded to a petitioner on the ground that the petitioner had suffered permanent deformity and disability following negligent administration of a triple vaccine. The High Court upheld the appeal, reversed the decree of the trial court and stayed the execution of the money decree. While dismissing the claim, it maintained that the claimant had been unable to establish a causal linkage or the fact that there had been negligence. The decision of the High Court came 15 years after the petitioner had initiated the suit.

In 2013, a civil writ petition was filed in the Supreme Court by Sama: Resource Group for Women and Health and Others against the Union of India and Others (9), demanding compensation for the deaths of seven girls during the "observational study" of HPV vaccines[4] by the Programme for Appropriate Technology in Health (PATH). At the time of the submission of this paper, the case was still pending in the Supreme Court and no decision had been taken on compensation.

These cases underscore some critical issues. One is that the tort system places the onus of establishing adverse events on the affected parties, and this consequently has an impact on their claim to compensation. Even countries with established compensation mechanisms have attested to this difficulty inherent in legal mechanisms. They, however, continue to uphold the State's responsibility towards people who suffer injury or death.

The current scenario in India necessitates the recognition of an injury following vaccination and the formulation of an appropriate compensation policy. In the absence of such a policy, the affected parties will be left with no option other than to approach the legal system under tort law. Considering that the latter is an extremely challenging process, there is a need for a system that goes beyond it and is based on the right of the affected parties to receive comprehensive medical care, as well as compensation, in case of AEFIs.

Conclusion

India can gain a few important insights from the attempts being made by some countries to institutionalise compensation for adverse events following the administration of vaccines.

AEFIs, including death, are not rare and can occur despite the best care. It is possible for people to suffer AEFIs even if full attention is paid to the guidelines for the manufacture, storage and distribution of vaccines, and even if the selection of recipients and the technique of vaccination are appropriate. Since vaccination is a public health intervention, vaccines are administered to all people, of whom healthy children comprise the majority. Given that the notion of preventing disease and safeguarding health – either to protect people from certain diseases or to eradicate these diseases –underlies the administration of vaccines, it is of critical importance to provide complete medical management and compensation in case of AEFIs in general. This necessitates the existence of a clear framework or a mechanism of compensation which transcends the boundaries of a legal remedy that places the onus on the affected person. What is required is a comprehensive system that emphasises stronger and time-bound surveillance, reporting and remedial processes. It will not suffice to change the methodology of investigating AEFIs; it is crucial to make the process of assessment transparent to understand how the investigation is carried out, documented and publicised. One must ascertain whether the affected parties or their families, guardians, etc. are involved in the process; if not, the assessment will be biased and does not follow the principles of natural justice.

Data from the investigation of AEFIs must be placed in the public domain to work towards an ethical and transparent system. Serious consideration must be given to the question of compensation, irrespective of any causal association between the AEFI and the vaccine. Deaths and adverse events following compulsory immunisation must be adequately compensated on the basis of "no fault".

While further deliberations may be necessary among policy-makers and all stakeholders to develop a clear system for compensation, in principle, acceptance of the need for compensation should not be delayed any further. Finally, any compensation mechanism in the context of AEFIs must, besides awarding compensation, emphasise the acknowledgement of a "wrong" or "fault" towards reparation of the affected.

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Notes:

1 According to the "Good Clinical Practice Guidelines" of The Central Drugs Standard Control Organisation, an adverse event (AE) is defined as any untoward medical occurrence (including a symptom / disease or an abnormal laboratory finding) which takes place during treatment with a pharmaceutical product in a patient or a human volunteer and which does not necessarily have a relationship with the treatment being given. A serious adverse event is an AE associated with death, inpatient hospitalisation (if the study is being conducted on outpatients), prolongation of hospitalisation (if the study is being conducted on inpatients), persistent or significant disability or incapacity, or a congenital anomaly or birth defect, or is otherwise life-threatening. See: www.cdsco.nic.in/html/GCP1.html

2 According to the Report of CIOMS/WHO Working Group on Vaccine Pharmacovigilance, 2012, an AEFI is any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

3 The other antigens that were linked to the remaining 19 cases of death were: OPV DPT VIT - A, BCG, DPT HEP - B, BOPV BCG, OPV PENTA, DPT VIT - A, MEASLES, OPV, OPV DPT, EASY 4, OPV BCG PENTA, OPV DPT HEP MEASLES BCG DT, OPV DPT MEASLES, OPV DPT HEP - B BCG, OPV HEP - B BCG and OPV DPT BCG.

4 The "observational study" of HPV vaccines was carried out by the Programme for Appropriate Technology in Health, in collaboration with the Andhra Pradesh and Gujarat governments and with funding from the Bill and Melinda Gates Foundation. The vaccines were provided free of cost by the manufacturing companies Merck and GlaxoSmithKline, and the technical support for these "projects" was provided by the Indian Council of Medical Research. The vaccine projects were suspended in 2010.

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Public trust in vaccination: an analytical framework

VIJAYAPRASAD GOPICHANDRAN

Abstract

While vaccination is one of the most successful public health interventions, there has always been a parallel movement against vaccines. Apart from scientific factors, the uptake of vaccinations is influenced by historical, political, sociocultural and economic factors. In India, the health system is struggling with logistical weaknesses in taking vaccination to the remotest corners; while on the other hand, some people in places where vaccination is available resist it. Unwillingness to be vaccinated is a growing problem in the developed world. This trend is gradually emerging in several parts of India as well. Other factors, such as heightened awareness of the profit motives of the vaccine industry, conflicts of interest among policy-makers, and social, cultural and religious considerations have eroded the people's trust in vaccination. This paper develops an analytical framework to assess trust in vaccination. The framework considers trust in vaccination from four perspectives – trust in the health system, the vaccine policy, vaccination providers and specific vaccines. The framework considers specific issues involved in vaccination trust, including the increasing scepticism towards medical technology, perceptions of conflicts of interest in the vaccine policy, and of lack of transparency and openness, the presence of strong alternative schools of thought, influence of the social media. The paper will conclude by arguing that engaging with communities and having a dialogue about the vaccination policy is an ethical imperative.

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Introduction

Vaccination is one of the most successful public health interventions globally. The eradication of small pox and more recently, the concerted efforts to eliminate polio provide evidence of the success of vaccination programmes(1,2).It has been globally recognised that vaccination is an essential public health service in all nations (3). High coverage of vaccination against specific infectious diseases is required for the control of these infections(4)and 2. When the coverage is high, not only does it protect the vaccinated, but also provides herd immunity and interrupts the transmission of the infectious agent in the community.

The protection offered by the vaccination programme is influenced by the vaccination policy of a country. The policy sets out the types of vaccines to be included, the number of doses and the timing of the administration of the doses(5). The coverage of vaccination in the population depends on the availability of the vaccine, its accessibility, and the delivery of the vaccine in an effective manner. All these are functions of the health system. The key functionaries in the vaccination process are the healthcare providers, including physicians, nurses and community health workers, who administer the vaccines at the point of care. They have a strong influence on the success of the vaccination programme. At the next level are the people, who are the ultimate consumers of the vaccination programme; and their acceptance plays a vital role in the success of the programme.

While the public health system in India is grappling with issues concerning the supply side of the vaccination programme so as to be able to ensure the availability and accessibility of effective and safe vaccines to large numbers of people, there are important issues concerning the demand side which also need to be considered. In certain areas of the country, despite having easy access to vaccines, parents are hesitating to follow even the routine immunisation schedule for their children. Vaccine hesitancy is an emerging problem in the developed world and is gradually catching up in certain regions of India (6–9). According to the estimates of vaccination coverage, as per the 2015–16 National Family Health Survey (NFHS-4), full immunisation coverage among children between 12 and 23 months of age was about 60% (10). Though exact data on the proportion of refusals were not available, a UNICEF estimate from a sample survey shows that refusals contributed to almost one-third of the uncovered proportion in Bihar (11). There are scarce data on the proportion of refusals in the various states and this estimate from Bihar may not be representative of the rest of the country. However, the problem of vaccine hesitancy does exist at different levels in different parts of the country. It is in this context that we need to gain an understanding of the community's perceptions of, attitude towards and trust in vaccination.

This article will specifically explore the state of people's confidence and hesitancy with regard to vaccination from the perspective of trust. It will develop an analytical framework which will take into account the people's trust in the vaccination policy, and in health system, vaccination providers and specific vaccines. The framework will deal with specific issues relating to trust in vaccinations, including the increasing scepticism towards medical technology, perceptions of conflicts of interest in the vaccine policy, the availability of strong alternative schools of thought, the influence of the social media, misinformation regarding vaccinations, and the lack of transparency and openness. Finally, the article will highlight the ethical imperative to engage with communities to foster a dialogue about vaccinations to help them make informed decisions.

The vaccine decision-making model

Several decision-making models have been proposed for parents' decisions on vaccination. The health belief model, originally proposed to assess the uptake of polio vaccination in the USA, considers perceived susceptibility to the disease, severity of the disease if it occurs, perceived benefits of and, barriers to the vaccine, and cues to action(12). Sturm et al proposed a decision-making model in which institutional, personal/parental and sociocultural/environmental influences interface with the healthcare provider and shape parental decisions(13).

Decision-making regarding vaccination, especially in developing countries such as India, is very complex(14). Figure 1 shows a proposed decision-making model that requires empirical testing. Parents are provided information on vaccination by various sources, the most common being healthcare providers (15). This information is supplemented by information based on the experience of community members and by the media. It must be noted that all this information is not authoritative and credible. Most often, the only source of credible information, ie healthcare providers, provide inadequate information. The social media has become a powerful source of information in several urban areas and among the educated class (16). Among the less educated and rural populations, rumours are a potential source of information. All these sources create awareness (sometimes wrongly!) of vaccination. Educated and motivated people actively engage in their own healthcare, and evaluate the need for specific vaccines and their efficacy and safety(17). They access the relevant information through the Internet and social media and appraise it. However, the large rural population, whose educational attainment and health literacy levels are poorer, is not actively involved in healthcare decisions and shows passive conformism based on popular practices and trends. These people make certain decisions on vaccination because their healthcare providers have given them an "immunisation schedule card" and asked them to follow it, or because everybody else in the community does so. In certain underdeveloped areas, coercion and force are used to get people vaccinated. These people cannot really be said to make an informed vaccination choice. Among both these groups of people, several social, political, economic, religious and cultural influences play a role in determining the acceptance of vaccines (8). These include the social norm

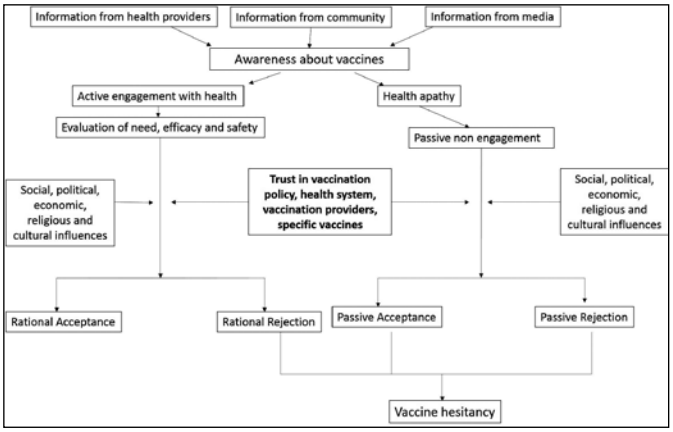

Figure 1: This figure shows the process of decision-making on vaccination in the community. Trust plays a vital role in influencing the community's decisions.

regarding vaccination, religious beliefs, historical anecdotes such as stories about vaccine failure and adverse events of vaccines, community experiences of adverse events, the cost of vaccines, perceptions of conflicts of interest among the vaccine industry and policy-makers, and the strong anti-vaccination propaganda (18).Together with these influences, trust plays a very important role in decision-making on vaccines (19). Trust, too, is influenced by sociocultural and political factors. On the one hand, there are those who accept vaccines rationally, on the basis of active engagement with the vaccination system. On the other hand, there are people who are at various stages of vaccine hesitancy, ranging from total rational rejection, partial rejection of specific vaccines, passive conformism and passive misinformed rejection. Against this background, it is important to explore the concept of trust in vaccination.

Trust in vaccination

Trust is the optimistic acceptance by people of their vulnerability in the belief that the trusted party will do whatever is in their best interest (20). Trust is inherent in healthcare and is an essential component of any healthcare relationship. In the context of vaccination, trust is not a phenomenon that involves just an interpersonal relationship. People's decision to accept vaccination depends on the trust they have at various levels of the vaccination programme, namely, policy, the health system, healthcare providers and specific vaccines (21,22).

A trustworthy policy on vaccination is one which is transparent, engages with the communities and is open to dialogue. Before introducing a new vaccine, modifying the schedule, or changing the route or mode of administration, policy-makers should engage with the communities and discuss the potential implications of such a change. This is essential to engender trust in the vaccination policy. Different countries have different vaccination schedules, as do different states within a country. This creates confusion and doubt in the minds of discerning decision-makers. In India, the policies of the public health system and the recommendations of the Indian Association of Paediatrics with respect to several childhood vaccines are competing and often conflicting (23). This conflict causes further confusion regarding the vaccination policy and leads to the erosion of trust.

Trust in the health system involves perceptions of the quality, competence, fairness and openness of the system (24,25). India has a thriving private healthcare system and a large, but rather weak, public system. While the level of trust in the public system may be low because of the perception that it lacks competence and quality, there may be doubts about the private system because of the profit motives and conflicts of interest involved (26). In 2014, a major sting operation by a private television news channel revealed that commissions, cut practice, kickbacks and such corrupt practices were rampant among private medical practitioners in New Delhi (27). This is only one example of why trust in the private sector has given way to scepticism in recent times (28). There are innumerable examples of the steady evolution of trust from blind faith in the health system to a questioning scepticism over the past three decades. The introduction in 1986 of the Consumer Protection Act, which covers medical care as well, is an indicator of the need for legal oversight of a system with diminishing values, a system which was blindly trusted for its virtues until then. Though a vast majority of people in India still seek private healthcare for their needs, the level of trust in the private sector *per se* has decreased substantially (29). There is a delicate balance between the perception of competence and fidelity of the private health system when it comes to trust in the system. While it is perceived that the level of competence of the sector is high, the level of fidelity is perceived to be poor, and this is the reason for the erosion of trust. The same dynamics of trust applies when it comes to the delivery of vaccines through the public and private health systems. In several parts of India, people trust the public health system more than the private one when it comes to vaccination because the latter is suspected to be driven by profit motives. Trust in the health policy and health systems is institutional in nature and, therefore, difficult to negotiate through interpersonal interactions(30). This is in contrast to the interpersonal trust that people have in vaccination providers.

The level of trust in vaccination providers is reflected in the people's perceptions of their competence, honesty, fidelity and confidentiality (31).The trust people have in their healthcare providers strongly influences their trust in vaccination since healthcare providers are the primary source of information on vaccinations for most people. The overriding factors determining trust in vaccination are those of efficacy and safety. Vaccines carry with them reputations that are based on reports of successful prevention of diseases and adverse events following immunisation (AEFIs). AEFIs lead to the erosion of trust in the specific vaccine. Given that no vaccine is completely free of adverse events, the vaccination policy should feature a sound surveillance system to detect AEFIs, and make provision for timely intervention and mitigation of the consequences. Following the introduction of the pentavalent vaccine in Tamil Nadu and Kerala in 2011, several vaccinated children were reported

to have died. After 14 deaths were reported, investigations into the AEFIs were carried out. It was found that six deaths were due to comorbid conditions, none of which was a substantial reason to attribute the deaths to the pentavalent vaccine. A detailed analysis of the deaths also revealed that a diagnosis of sudden infant death syndrome (SIDS) was highly unlikely. The callous attitude towards investigation, reporting, response and compensation for children who had suffered fatal AEFIs led to gross erosion of trust(32). The analytical framework of public trust in vaccination, specifically on the vaccine policy, health system, vaccination providers and specific vaccines is shown in Figure 2.

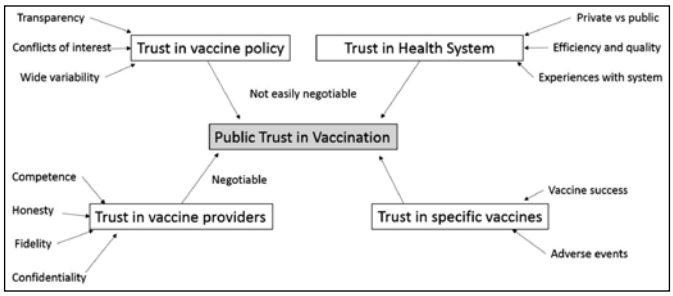

Figure 2: Analytical framework of public trust in vaccination

It is important to note that high vaccination coverage does not necessarily reflect trust in vaccination. There are situations in which the community is not engaged in decision-making, and trust may not be said to exist but there is passive acceptance of vaccination,and also, situations in which there is a high level of trust but poor coverage due to a lack of access.

Factors leading to mistrust in vaccination

Having reflected on the role of trust in vaccination in the decision-making process and the framework of trust in vaccination, it is important to address specific issues pertaining to mistrust in vaccination.

Increasing scepticism towards science and technology

In recent years, people have started to actively engage with the world of science. In the past, when people opposed science, they were called superstitious and were looked down upon. Today, however, it is common for people to be sceptical about science and question it, which indicates greater active engagement with current developments (33). This scepticism about science emerges from three important sources: (i) an inherent difficulty in dissociating beliefs from facts, (ii) an increasingly "post-truth" policy environment, and (iii) suspicions about the way evidence is generated. Often, technological advances in healthcare give rise to interventions which are difficult to believe and follow. When long-held notions of health and disease are challenged, it becomes more difficult to dissociate facts from beliefs. Even when rational thinkers accept scientific facts, they cling to intuitions which are shaped by beliefs. This results in a delay in the adoption of scientific advancements (34).The "post-truth" policy environment, in which objective facts and evidence are usually assigned less importance than "opinions","beliefs" and "emotional sentiments", has led to an increase in scepticism towards science(35). Finally, the way scientific evidence is generated has also been questioned thoroughly. The landmark paper by Ioannides in 2005 highlighted this aspect by declaring that most published research findings are false. He raised fundamental questions regarding study designs and statistical power, and concluded that most scientific research findings may simply be accurate measures of existing biases (36).The existence of financial and other conflicts of interest and research malpractices adds fuel to this suspicious approach to science, painting a negative picture of the actual practice of scientific research (37). Therefore, public health interventions are being questioned increasingly, especially when the intervention is a preventive one, such as vaccinationof healthy children. Moreover, success of vaccination itself poses a threat to continued vaccination as the reduction in the incidence of the infection, reduces the perceived threat among the people (38). Parents would rather not see their children suffer from adverse events following vaccination than prevent a disease which is not common and is only a hidden threat. To sum up, the perceived threat from diseases has decreased and the scepticism regarding vaccines has grown.

Availability of strong alternative schools of thought

In several sections of Indian society, especially the upper class, there is a move towards "natural measures for health". These include avoidance of processed foods, the promotion of herbal foods, medicines and toiletry products, and avoidance of chemicals, including medications. In these circles, vaccines are viewed as "artificial" and are looked down upon. This, along with the anti-vaccination lobby, as well as the popularity of complementary and alternative systems of medicine such as naturopathy, which oppose vaccination, has made a large contribution to the deficit of trust in vaccination (39).

Misinformation regarding vaccination

With the advances in information and communications technology, not only is information readily available to people, but it is also hidden within a huge amount of misinformation. Misinformation about vaccination spreads as fast as, or sometimes faster than, credible information. In certain districts of Uttar Pradesh and Bihar, there was serious resistance to the polio vaccination due to widespread misinformation among the minority communities that it was a western ploy to sterilise the minority populations and thus reduce their numbers (40). A deeper analysis of the social reasons for resistance to the polio vaccine in Uttar Pradesh revealed that other than the "misinformation" factor, the community was tired of the repeated rounds of the pulse polio campaign, which had led to suspicions, and the minority community was even less amenable to vaccination because the complete apathy of the mainstream health system towards their other healthcare needs had left them feeling marginalised and oppressed. The historical experiences of the minority communities with respect to the state led

to widespread dissatisfaction with the health system, and this only reinforced the negative attitudes resulting from misinformation (41). This highlights how trust in vaccination is strongly influenced by trust in the health system and the social, historical and political context. Similarly, widespread misinformation regarding the introduction of a sterilising agent in the routine tetanus vaccine led to a sharp fall in the coverage of the vaccine in the Philippines (42). More recently, the coverage of the diphtheria vaccine fell drastically in the Malappuram district of Kerala following widespread misinformation on the occurrence of serious adverse events with the vaccine. This information spread more rapidly among fathers working in the Middle Eastern countries and this, in turn, reduced the vaccination rates of their children back home. The result was a serious outbreak of diphtheria in this district (43).

Influence of Internet and social media

The ease of access to information through the Internet has significantly influenced decision-making on vaccination, especially among those who are actively involved in their own and their children's healthcare decisions. Adverse events following immunisation are no longer the subject of isolated newspaper stories that one reads, empathising with the victims. They are discussed in personalised narratives on blogs, social media platforms and virtual networks. They appeal strongly to the emotions of the audience and influence its trust in the vaccination process (44). The hugely notorious reports of an association between the Measles, Mumps and Rubella (MMR) vaccine and autism in the UK created a frenzy in the mainstream and social media, and led to an erosion of trust in the vaccination system in the country (45). In a study of anti-vaccination Twitter feeds in the USA, it was found that the people who took strong anti-vaccination stands were those who had a strong distrust of the government and were conspiracy thinkers. Those who had newly adopted an anti-vaccination stand, as traced from the Twitter feeds, were more social and actively questioned their beliefs (16).

Perception of conflicts of interest in vaccine policy

Doubts have been mounting about the intentions and motivations of the pharmaceutical industry. This holds good for the vaccine industry as well. The growing list of vaccines that are included in the vaccination schedule on the recommendation of private associations of doctors has given rise to concerns about the existence of a nexus between the industry and such professional bodies and policy-makers. A popular daily newspaper in India carried an item which discussed the existence of substantial conflicts of interest in the vaccination policy recommended by the Indian Association of Paediatrics Committee on Immunisation (IAPCOI). Of the IAPCOI's fund of Rs 27.8 lakh, Rs 26.8 lakh was contributed by vaccine manufacturers, including Sanofi Pasteur, GSK, Merck, Pfizer and the Serum Institute of India (46). However, the IAPCOI denied the existence of any conflicts of interest. When the popular press carries such information, it substantially influences the people's trust in the vaccination policy.

Lack of transparency and openness

Several adolescent girls died during the study of the human papilloma virus vaccine, conducted in Andhra Pradesh and Gujarat by PATH and the Indian Council of Medical Research. The study raised a controversy, and one of the important reasons for the erosion of trust in the vaccination system was the lack of transparency. The government stalled all efforts by civil society organisations to obtain the details of the study protocol. The government also failed to engage with the press or any form of media to explain these deaths. It was a detailed investigation by a civil society organisation that uncovered the malpractices and the details of the trial (47). Lack of transparency in the vaccination policy seriously hampers trust, and this influences the decisions of the parents.

Ethical imperative to engage with communities on vaccination

Active community engagement is one of the key measures for ensuring that the vaccination policy and health system are viewed as trustworthy (48). As mentioned earlier, trust in the vaccine provider, doctor, nurse or community health worker can be negotiated through active dialogue. However, it is difficult to build and sustain trust in the case of institutions such as the health system, since these are distant from the people; unless there specific measures are taken to promote engagement with the community. Trust is a double-edged sword. Too much trust, ie blind and unquestioning trust, can push people into a vulnerable position, while too little trust can keep them from participating in and reaping the benefits of public health interventions. To empower people with the right type and amount of trust, it is an ethical imperative to engage in a dialogue with the community (49). Active community engagement with respect to vaccination policies can comprise of the following:

1. having community representatives (parents of children in the relevant age group) in vaccination committees to hear their opinions and engage them in policy decisions
2. establishing a horizontal dialogue with communities during the introduction of new vaccines, change in the vaccination schedule, trials of experimental vaccines, etc., and not just focusing on the provision of information
3. establishing community-based vaccination surveillance, in which data on the incidence of vaccine-preventable diseases, vaccination coverage and adverse events following vaccination are collected and reported by community members
4. responsible engagement of community champions who spearhead the movement for the dissemination of credible, authoritative information on vaccines
5. adopting a judicious approach to informing the community about adverse events following vaccination, so that panic is not created and at the same time, appropriate

information is disseminated, ensuring transparency

6. establishing appropriate mechanisms of accountability with the participation of the community members, who should be empowered to question vaccination practices and make informed decisions for themselves

7. creating community ownership of the health of the children and their own future, and empowering communities to demand vaccination services and not act as just passive recipients of vaccinations

Active engagement of the community will assist those who make active and participative decisions on vaccination to be better informed. The objective of appropriate community engagement is not just to increase the acceptance of vaccines, but to promote a sense of self-determination that would allow the community members to make well-informed decisions on which vaccines to accept and reject for their children. To sum up, community engagement is an ethical imperative to help people realise their right to good health.

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Considering the "public" in public health: popular resistance to the Smallpox Eradication Programme in India

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Abstract

Public health initiatives, including large-scale vaccination and disease eradication programmes, regularly pit the rights of the individual against broader benefits to society. At times, the public resists such initiatives, with the World Health Organisation's Smallpox Eradication Programme (SEP) in India being a case in point. Here, we critically investigate resistance to smallpox vaccines in India and argue that while the SEP successfully eradicated a global killer; individuals were stripped of human rights through coercion, forcible vaccination and quarantine. In many cases, resistance to vaccination was linked to deep-rooted social, cultural and religious beliefs. Critical points made in this paper are applicable to contemporary discussions on required vaccinations, quarantine during the outbreak of diseases and the current campaign to eradicate polio.

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Introduction

Public health is concerned with improving and protecting the health of an entire population, typically defined by political boundaries. However, some have argued that public health actors and programmes, while advocating for the public, have theoretically and pragmatically subjugated the individual in the name of collective well-being (1–3). Due to the broad scope of public health, it is contended that it is impossible for its measures to be universally welcomed by an entire population. Therefore, the targets of public health measures may find their personal sovereignties – whether moral, physical, religious or spiritual – cast aside in the name of the greater good. This real or perceived stripping of liberties, though generally benign and benevolent in nature, has sometimes backfired and (re)emerged in the form of popular resistance (4–6)[1].

To demonstrate this contention, we employ examples from the Smallpox Eradication Programme (SEP) of the World Health Organisation (WHO) as it played out in India. Our intention is neither to discredit, nor devalue the historic process that

eradicated a global killer—the only currently eradicated infectious disease. Rather, our objective is to explore the age-old question of *how* monumental things are accomplished. While the historic achievement of smallpox eradication must be celebrated, a triumph of such magnitude should not be shelved without examining bioethical impediments to its success and the ways in which obstacles, in this case public resistance, were considered. In applying this approach, we investigate the theoretical and pragmatic rationale for opposition to mandatory vaccination measures such as those implemented in the WHO's SEP. Next, we provide critical accounts of popular resistance to the SEP in India. This examination of how smallpox eradication was accomplished allows one to identify why resistance transpired, which provides context for opposition to large-scale vaccination and public health programmes today. Thus, while the focus is smallpox vaccination in India, the paper is relevant to other public health challenges (eg polio, Ebola, cleft lip/palate), other public health measures (eg quarantine, large-scale provision of latrines, vector control), and other geographies (eg Pakistan, Nigeria, the United States).

The big picture

Setting the stage

It is useful to first provide a background on smallpox and the processes that led to the WHO's global eradication campaign. Smallpox infection is caused by exposure to the *Variola major* or *Variola minor* virus through direct person-to-person contact or contact with bodily fluids. The symptoms typically appear after a latency period of one to two weeks (7). A raised rash (which aided in the identification of cases during the SEP) is the most obvious symptom. The rash also indicates when an individual is the most contagious. Prior to the development of a vaccine, variolation was commonly used to inoculate uninfected persons with material from smallpox pustules.[2] This approach resulted from the work of Edward Jenner, who found that inoculation with cowpox conferred immunity to smallpox (8). The first vaccine was developed by Jenner in 1796 and, riding the wave of scientific optimism of the 1950s, public health officials promoted smallpox vaccination and were able to achieve eradication in most industrialised countries.

In 1967, the WHO initiated a global smallpox eradication campaign (ie the SEP), and the outcome was successful. The last known indigenous smallpox case was identified and treated in Merca, Somalia in 1977, making smallpox the only human disease to have been eradicated at present (9). It is estimated that 1.5–2 million lives and $1.35 billion are saved annually as a result of the $100-million SEP, the estimated benefit–cost ratio being 450:1 (10: p 684). To a great extent, what made eradication possible is that the symptoms manifested within a certain time frame and were easily identifiable with no need for laboratory tests; there were no asymptomatic carriers and thus no carrier state; and the vaccine was both effective and available in a formula that was not heat-sensitive. These conditions are not met in the case of many other diseases.

While the eradication of smallpox was a goal of the international community and the Indian bureaucracy, it would be erroneous to assume that it was the only major issue being confronted by India and the South Asian region. For example, politically, India and its neighbours were managing post-independence issues of governance, nation-building and border disputes, while establishing foreign relations. In terms of development, true to the Nehruvian legacy, technocratic undertakings, such as the construction of dams and the electrification of rural and urban India, were in progress. Finally, in terms of health, exposure to cyclones (and other disasters), a recent famine, taking advantage of the Green Revolution, and establishing piped water supplies were at the forefront. Thus, while this paper focuses on the eradication of smallpox in India, it does not do so myopically and instead recognises that India was confronting myriad parallel and competing issues, each of which could be considered equally pressing.

Theoretical and historiographical context

Resistance to the SEP in India must be framed within a much larger discourse. For purposes of this paper, opposition to vaccinations can be better understood through a social history of medicine perspective that examines how health technologies are perceived and adopted by society. As argued by Jordanova (11), the history of medicine is akin to the history of technology, and these two histories intersect when populations experience medicine first-hand through social–technological interactions with health practitioners. The social history of medicine serves to illustrate health technologies and the social processes that spawn them as distinct lived experiences that naturally include various social, cultural, religious and political perceptions and influences. Through the investigation of lived experiences, the social history of medicine has been used to describe the very different histories that have been created from the confluence of health technologies and the diverse peoples upon whom they are applied (12–14).

This paper must not be filtered through a temporally, spatially or developmentally reductive lens. Cases of vaccine resistance should instead be situated as existing across time, space and level of development, as evidenced by the breadth of historical and contemporary cases spanning both the global South and North. For example, there exists documented resistance to: smallpox vaccination in 19th-century England (15,16); smallpox vaccination in colonial India (17,18); the SEP in countries other than India (19,20); polio vaccination in the USA (4,21); polio vaccination in contemporary Nigeria, Pakistan and Afghanistan (22,23); and vaccines in general by religious minorities in the USA (eg Quakers and some Anabaptist sects of Amish, Hutterites and Mennonites, who are often granted the right to forego vaccinations).

Further, there have been many recent flare-ups regarding vaccinations and medical treatment in the USA, which underscores the continued relevance of such research beyond India and beyond the global South. In 2007, former Texas governor Rick Perry was criticised for an executive order

directing all girls to receive the HPV (human papillomavirus) vaccine before entering grade six. Critics argued that the order trampled on individual and parental rights, cited potential health risks of the vaccine, and questioned Perry's ties to vaccine producer Merck. Further, recent US presidential candidates Rand Paul and Chris Christie both acknowledged the importance of vaccines, but hedged their statements by claiming that freedom of choice in the matter was also critical, while President Donald Trump linked vaccines to autism in Republican debates and on Twitter. The false fear that vaccines may cause autism is a concept introduced by Andrew Wakefield's controversial, now discredited paper linking MMR (measles, mumps and rubella) vaccinations to autism (24). Despite the fact that Wakefield's article has been retracted, the vaccine–autism link remains in the public discourse and has driven resistance to vaccinations and related disease outbreaks. In 2015, a measles outbreak that began at Disneyland and spread to multiple locations was linked to efforts to resist vaccines in the USA. Many of the patients were widely reported by the media as being unvaccinated, either due to age (too young to receive the vaccine) or refusal to vaccinate. This resulted in Disney asking employees, but not visitors to the park, to stay home or provide proof of vaccination.

Similarly, the recent quarantining of Ebola cases – a controversial yet widely used tactic during the SEP – triggered widespread debates about patients' individual rights *vis-à-vis* legitimate fears regarding public safety, as well as discussions on whether quarantining would or would not help mitigate the spread of the disease. International calls were made by government officials, media outlets and the general public, demanding that potential Ebola cases be quarantined for 21 days (the incubation period of the disease) or longer. Some went further, demanding that such quarantine measures be put into effect for all travellers departing from Africa. Adding to these debates was the fact that medical and burial responders in West Africa were confronting their own forms of cultural, religious, and political resistance when attempting to quarantine infected patients and their bodily remains (25,26). Thus, the temporal, spatial and developmental extent of these cases demonstrates that critical investigations of vaccine resistance are constructive not only from a historical perspective, but from a contemporary, cross-cultural perspective as well.

Understanding resistance to vaccines and the SEP in India

Human rights and individual liberties

The establishment and expectation of inalienable rights and convictions related to them can be applied to resist vaccines. For example, the United Nations' Universal Declaration of Human Rights (27) – beyond Rawlsian understandings and rights codified in the constitutions of India and most nations – establishes basic liberties that should be guaranteed to all people, in all places and at all times; hence their universality. Proclaimed in the landmark document are rights to "freedom of movement" (27: Article 13.1), "freedom of thought, conscience and religion" (27: Article 18), and the authority to exercise such rights in "public or private," "either alone or in community with others", and both in "observance" and "practice" (27: Article 18). We cite these specific rights as they will surface as factors of resistance in accounts narrated later. Note that we are not using the Universal Declaration of Human Rights as a template to work from. Rather, we simply deem it appropriate to orient readers with a broad, recognised document on rights so that they can better understand why people may elect to resist a programme such as the SEP.

Democracy, corporal colonisation and martial law

The very idea of a compulsory public health campaign (eg the SEP in India) is inherently undemocratic. Compulsory vaccination can be perceived as a Leviathan-esque "colonisation of the body" that clashes both with classical (eg Locke and Rousseau) and contemporary ideals (28, 29) of democracy. For example, speaking on the SEP in India, Naraindas (30) argues that compulsory public health programmes necessarily render the masses "inert" and "subservient" to the will and authority of the state. Thus, it is no surprise that obligatory measures instituted by the government and external agencies often foment scepticism, apprehension and ultimately resistance; the SEP was no exception. The implementation of the SEP was never democratically debated within the Indian state. Thus, civilians were subjected to the will of not only the state, but also that of an outside entity (ie the WHO) and scores of foreign bureaucrats, physicians and epidemiologists. Further, the compulsory nature of the SEP meant that all people must be vaccinated, even if they had been previously vaccinated and could exhibit a scar as evidentiary proof (31). It is in this context that the concept of compulsory, non-democratically debated vaccination processes can be seen as a dictatorial colonisation of the body.

Greenough discusses how "armies" of vaccinators swept through Indian villages in the middle of the night, and goes on to describe the SEP's convoys of "force-massed policemen and jeeps" (31: p 225). Supplementing these panoptic measures were systematic house-by-house searches for smallpox cases, and WHO rhetoric, in which a portion of the SEP was termed the "attack phase"; the mission was "search and destroy"; each case was treated as an "absolute emergency"; "surveillance-containment" was the method; and guards were deployed for manpower (32–34). It was language and actions such as these that permit scholars to characterise the SEP's focal-ring containment strategy as a "military-style operation" (31), with Bhattacharya et al claiming: "The concepts of 'state power', 'intimidation' and 'coercion' need to be put into context to understand the far-reaching, and often culturally invasive, effects of the SEP on a linguistically and culturally heterogeneous society" (35: p 50). Given this virtual martial law, pausing of democracy and colonisation of the body, it is not alarming that public opposition surfaced during the SEP in India.[3]

Mobility and quarantine

Restrictions on mobility through the SEP's focal-ring containment strategy can also be viewed from the perspective of resistance, or better yet, as a method instrumentalised by vaccinators to surmount resistance. The eradication of smallpox was initially attempted using the method of large-scale, mass vaccination. However, after marked but limited progress, the WHO switched to a surveillance–containment strategy in which cases of smallpox were identified, entire villages were cordoned and everybody was forcibly vaccinated. Thus, when cases were identified, the infected individuals were quarantined in their homes (with guards outside), or placed in secure isolation hospitals; meanwhile, the village was cordoned and the rest of its population was vaccinated (36,37). In this manner, not only were cases subjected to house arrest, but the mobility of the entire village was restricted through a *cordon sanitaire,* which prohibited entry into and exit from the village for a specified period of time. Conditions are ripe for the emergence of popular resistance when freedom of movement is restricted, not the least when it hinders means of livelihood and the generation of income.

Further rationale for resisting vaccines and the SEP

As discussed above, resistance to vaccines can arise for many reasons: in the context of human rights, the undemocratic–colonial–martial notions underlying a compulsory programme, and restrictions of mobility through an imposed focal-ring containment strategy. These reasons are supplemented by a battery of additional factors: suspicion and distrust of the state; anxiety regarding vaccine-related morbidity and mortality; bad memories of a previous vaccination campaign; fear of new or unknown technologies/scientific advances; and superstition, ignorance, apathy, etc. Still other justifications include religious beliefs, pregnancy, protection of infants, and fear of pain (from the lancet or needle).

Accounts of popular resistance to the SEP in India

Equipped with a non-exhaustive framework for understanding opposition to vaccination programmes, it is now our task to narrate actual accounts of popular resistance to the SEP in India. Resistance to the SEP ranged from passive concealment of cases to eruptions of physical violence and outright counterattack. However, the WHO's official histories of the SEP boldly claim that "vaccination acceptance is [was] good" (38: p 727), and that resistance in India was "a limited phenomenon" that did not leverage "substantial influence on the programme" (39: p 114). Further, Bazin (40: p 170) contends that there were "no religious or moral problems in its [smallpox] prevention". While the authors may be right in asserting that resistance to the SEP in India was not necessarily widespread, resistance did affect the implementation of the SEP and its role should not be downplayed. Thus, rather than sweeping acts of opposition under the rug, we seek to bring them to light in order to glean knowledge that is useful for future vaccine and public health programmes in India, Asia and elsewhere. Again, our goal is to analyse the SEP to better understand *how* a milestone of such scope was achieved in practice.

Religious bases for resistance constituted a primary form of opposition to the SEP in India. In fact, the WHO itself refutes Bazin's (patently false) claim that the eradication programme faced no religious barriers, explicitly stating that individuals deliberately concealed cases and evaded vaccinators on the basis of religious objections. The WHO stated that resistance often surfaced among "female members of strict Muslim families", sometimes making it "impossible for a male vaccinator to vaccinate" or "[even] to examine a female suspected smallpox case in these families" (39: pp 112–113). Hinduism, the predominant religion in India, was also a source of resistance. Hindus have historically followed a system of social, economic and spiritual stratification, known as the *varna* system, or caste system. Under the strictures of this system, some would consent to vaccination only by individuals from their own caste. Thus, friction arose due to caste mismatches among vaccinators and vaccine targets.

In some cases, programmes have utilised strategies under which religious leaders are coerced to proclaim the safety and benevolence of a public health measure to obtain the consent of a group, smallpox vaccination being a case in point. In the WHO's official text on the SEP in India, Basu et al (39) state that many tribal and minority groups accepted vaccination only when directed to do so by their chiefs, leaders or religious figures. Thus, the consent of local leaders was often the key to gaining the consent of villages. Further, in its authoritative post-eradication text, the WHO recounts an outbreak of smallpox at a Jain pilgrimage in Puri (in the state of Odisha) in which: "A special appeal was made to the principal religious leader, who agreed, reluctantly, to recommend vaccination. The entire village was quarantined by the Bihar military police." (38: p 782) Dr Mahendra Dutta, a WHO vaccinator present at the pilgrimage, claims that many pilgrims refused to be vaccinated until the SEP eventually "won the cooperation", having "persuaded [the pilgrims] to submit to vaccination through their religious head" (41: p 429). The use of religious leaders to endorse vaccinations reflects the existence of religious resistance to vaccinations. The stature of local religious and faith-based leaders makes them critical to the achievement of vaccination goals. With them (through coercion or genuine support), vaccination programmes may be more successful; without them, vaccination efforts may very well face additional resistance.

A fascinating example of religious resistance is situated within the Hindu pantheon. Hindu beliefs across South Asia, particularly in India and its state of West Bengal, attribute the smallpox virus to the goddess Sitala. When worshipped properly, she is peaceable, but when crossed she unleashes fever, pustules and pox (42, 43). Thus, by ignoring or challenging Sitala's will, devotees risk incurring her divine wrath, with the result being that "some persons resisted vaccination, fearing that it would anger the goddess" (38: p 715). The Centers for Disease Control and Prevention's (CDC) history of smallpox eradication describes opposition stemming from belief in Sitala as the "most colorful" form of resistance encountered by vaccinators in India (44: p 100). An example of

this unique composite of smallpox, religion and resistance may be found in Marsh Kieselstein's first-hand account of *adivasis* (tribal or aboriginal population) in Bihar:

> *[T]he Adivasis refused vaccination on religious grounds. They believed that smallpox is caused by the wrath of the goddess "Sitala Mata" and that the way to prevent, as well as cure, smallpox is by Puja, or prayer meeting. At the Puja, the priest builds a smoky fire and as the house fills with smoke, prayers are recited to drive away the evil. At the end of the prayer recitation, a chicken or goat is slaughtered and everyone leaves the Puja site without looking back. In order to protect themselves from infection, people burn sandalwood or ghee (fat), producing a scent which drives away the ghosts. The smallpox patient is worshipped by the flowerman or the most religious person of the family, as it is believed that the goddess resides within the patient. In order to drive smallpox away, anything that remains after worship is put in an earthen pot and thrown out of the village. . . . But the most noteworthy restriction is that treatment and vaccination are strictly prohibited as they may displease the goddess.* (36: pp 73–74)

This primary account reveals that, in the *adivasis'* eyes, vaccination might well offend Sitala. Kieselstein uses the account to buttress his contention that religious "superstitions" constituted a formidable source of resistance and one of the most significant "obstacles to the success" of the SEP in India (36: p 73). He then goes on to relate another instance of Sitala-based opposition in the southern state of Tamil Nadu:

> *[S]ome 15 miles from the Christian Medical Center at Vellore (90 miles west of Madras), we discovered a smallpox patient in a small Hindu temple on the outskirts of the village. The man was completely covered with pustules and obviously delirious with fever. When we asked some of the village elders why this had not been reported to the health authorities, they answered that since smallpox was a punishment from the gods, the best place for the patient was in the temple. They wanted no part of vaccination and insisted that the Pujas they performed would be sufficient.* (36: p 74)

This first-hand account ends with the infected individual being smeared with paste from a neem tree for curative and symptom-reducing purposes. The incident is a great example of how some Hindu priests dismissed (allopathic) vaccination and insisted on their own cultural-religious remedies (see *Ayurveda* and *Unani*). Interestingly, in order to surmount this form of resistance, the WHO decided to popularise slogans such as, "Worship the goddess, but to please her take vaccination."

The most dramatic case of religious resistance to smallpox vaccination comes from Lawrence Brilliant, a WHO physician-epidemiologist on the ground in a tribal region of Jharkhand. Brilliant narrates an episode in which Mohan Singh and his family were vaccinated against their will:

> *In the middle of the night, an intruder burst through the door of the simple adobe hut. He was a government vaccinator, under orders to break resistance against smallpox vaccination. Lakshmi Singh awoke, screaming, and scrambled to hide herself. Her husband leaped out of bed, grabbed an axe, and chased the intruder into the courtyard. Outside, a squad of doctors and policemen quickly overpowered Mohan Singh. The instant he was pinned to the ground, a second vaccinator jabbed smallpox vaccine into his arm. Mohan Singh, a wiry 40-year-old leader of the Ho tribe, squirmed away from the needle, causing the vaccination site to bleed. The government team held him until they had injected enough vaccine; then they seized his wife. Pausing only to suck out some vaccine, Mohan Singh pulled a bamboo pole from the roof and attacked the strangers holding his wife. While two policemen rebuffed him, the rest of the team overpowered the whole family and vaccinated each in turn. Lakshmi Singh bit deep into one doctor's hand, but to no avail.* (45: p 637)

Why was Singh so determined not to be vaccinated? The reason was rooted in his *dharma* (righteousness, moral duty, or what people must or must not do), as conveyed by Singh in a public speech delivered to the medical team and fellow villagers:

> *My* dharma *is to surrender to God's will. Only God can decide who gets sickness and who does not. It is my duty to resist your needles. We must resist your needles. We would die resisting if that is necessary. My family and I have not yielded. We have done our duty. We can be proud of having been firm in our faith. It is not a sin to be overpowered by so many strangers in the middle of the night. Daily you have come to me and told me it is* your dharma *to prevent this disease with your needles. We have sent you away. Tonight you have broken my door and used force. You say you act in accordance with* your *duty. I have acted according to mine. It is over. God will decide.* (45: p 637)

For Singh, resistance to smallpox was rooted in religion and fatalism. Singh's philosophical paradigm holds that it is unjust to impose ones *dharma* on others; disease is God's territory, and only God can propagate and mitigate disease. Ultimately, judgment will ensue and one *dharma* – Singh's or the vaccinator's – will triumph over the other. This example upholds Greenough's contention that many felt that the SEP was being "jammed down the throats of Indian tribals and peasants" (31: p 225), and they did not want to submit to health on someone else's terms.

The altercation between Singh and Brilliant is an example of physical, more combative resistance to the SEP in India. In many instances, opposition in the form of running, hiding and striking vaccinators was documented (although violent resistance was admittedly rare). WHO vaccinator S.I. Music candidly acknowledges that in India, "women and children were often pulled out from under beds, from behind doors, from within latrines, etc. People were chased and, when caught, vaccinated. . . . When they locked their doors, we broke down their doors and vaccinated them" (31: p 207). Further, the WHO has made public an incident that took place in Bihar in which a mother and child attempted to remain undetected by the vaccinators' needles:

The patient and his mother left Painathi on March 29, two days before containment began. The mother was enumerated but the existence of a child was not made known. They returned on 14 April, but their presence was concealed by the father. Searchers went daily to each house in the village to vaccinate and to inquire about fever and rash. Dr Khan and Dr Briedert personally visited this house to find out if all the vaccinations were successful and if this woman had returned. The father of the child, however, lied to them.

The family had been resistant and uncooperative from the start. After enumeration, vaccination was possible only when we climbed over the compound walls and forcibly inoculated each family member. After a rumour reached Dr Khan, who had been staying in the village, he had to use a trick to gain entrance to the house. He asked for a glass of water and this was denied. He knew by custom that they had a case of smallpox inside the house because nothing can be given when a case of smallpox is in the house of a member of this religious sect.

Dr Briedert is now staying inside *the infected house. . . . The mother was vaccinated on 2 May. . . .We are nonetheless isolating her and keeping her under close observation for the next 14 days.* (38: p 783)

Thus, not only did targets of vaccination attempt to remain physically unnoticed, some were deceitful and refused to cooperate from the very beginning. In this case, resistance was countered by posting an in-home guard for one fortnight. The use of guards in such vaccine-related conflicts can be unnerving the nearby residents. These sentiments are warranted, as Naraindas speaks of an incident in which a *mohalla* (village or district of a city) refused to surrender to vaccination and so, according to the vaccinator, "we [SEP vaccination team] threw a barbed wire fence around them, posted guards for six weeks, and allowed the disease to smoulder and die" (41: p 450).

Perhaps the most violent incident of resistance to the SEP in India was encountered by WHO vaccinator T. Stephen Jones, who forcibly vaccinated a "chubby, somewhat effeminate man" in Bihar (46: p 638). After unwillingly receiving the vaccine, the individual concocted a story that the men in the vaccination team were robbers. Later, the vaccinators heard a commotion brewing outside. Sensing that they were in danger, the team went outside to face the mob:

[W]e went outside and there was a whole bunch of the villagers, and the story was . . . that we were reported to be robbers, thieves. And they began pushing my PMA [physician's medical assistant]. It was an aggressive crowd, no questions. There were 20 or 30 men with bamboo sticks, lathis. *With a brass fitting on the end of the* lathi. *So they pushed him, and I set myself between him and the people who were pushing him, for that was my experience – that I was invulnerable. And then I felt dizzy. And then I sort of crumpled down on the ground and found that I had blood in my eyes and a laceration on the top of my scalp.* (45: p 638)

Finally, resistance also arose from lack of respect for social norms. The failure to recognise and be sympathetic to local customs may backfire, as seen in the case of vaccinators who did not bother to consult with and show deference to elder populations:

Indian society is also patriarchal and offers great respect to the older experienced members of the community. It was to these people that the uneducated villager would turn for advice on whether to accept vaccination. Not infrequently, a young, aggressive vaccinator would fail to observe the courtesies and respect due to these older people, an action which provoked resentment and animosity, rather than cooperation. (39: p 113)

This case reveals two salient closing points. First, it demonstrates that resistance can be rooted in the social, cultural and religious beliefs of the target population. This is evident in the WHO's assertion that "difficulty lay among the tribal and minority groups. Proud of their own traditions, and often suspicious of the motives of the outside world…" (39: p 113). However, it also demonstrates that while many of the origins of cultural resistance are endogenous, some are triggered by culturally insensitive actions on behalf of the vaccinator or vaccination team. Second, this case (and other cases and arguments outlined in the paper) demonstrates that the authoritative histories of the WHO, among other texts (40), are false in claiming that resistance to the SEP in India failed to rise to a level of pragmatic, programmatic and human rights consideration. It is merely the public within public health that we seek to consider. The perceptions and reactions of the diverse public can not only help us to understand how public health milestones are achieved, but how to move forward with public health measures in a manner that is more culturally sensitive and based on human rights.

Conclusion

Popular resistance to the SEP and public health programmes in general is understandable and perhaps to be expected. Resistance does not equate to an indictment of large-scale public health programmes. Rather, it signals that a more sympathetic approach – combined with the application of the lessons learned – should be adopted to reduce future friction among stakeholders. Cases of opposition are understandable when one pauses to consider the many rationale for resistance, whether an epistemology of culture, religion, personal liberties, or reasons that cannot be fully expressed or understood. It must be reiterated that we do not intend to discredit or devalue the eradication of smallpox, nor demonise SEP vaccinators. In fact, many of the accounts cited above culminate with the vaccinator expressing remorse for resorting to coercive and intimidating actions (although this stopped short of regret since vaccinators believed that they were engaged in a worthy humanitarian crusade). Further, the vaccinators themselves undoubtedly confronted personal health and security risks while vanquishing a deadly pandemic. This cannot be underestimated as it represents a present source of concern among polio vaccinators in Pakistan and

Afghanistan as well as responders to medical crises such as the Ebola outbreak in West Africa.

The eradication of smallpox should be viewed as a milestone for biomedicine, public health, India and the world. We have been freed from the shackles of a fatal virus and that is a commendable achievement. However, one has a moral duty to examine historical milestones in order to understand *how* they were achieved. Through this critical lens, we argue that it is rare, if not impossible, for an accomplishment of such magnitude to be realised without eliciting elements of distrust or outright resistance in the target population. The global eradication of smallpox was no exception. While opposition to the SEP in India may not have materialized at a large scale, its role should not be downplayed – it should instead be harnessed as knowledge to avoid a repetition of past mistakes.

After considering the WHO's official narrative on the SEP in India (coupled with primary accounts and theoretical rationale for mounting resistance), we argue that it is valuable to critically evaluate how and why vaccine resistance manifests. This begins by employing Bhattacharya's casting of the SEP as a complex process:

> *[The official literature] suggests that India's freedom from smallpox had been accomplished with relative ease as a result of concerted collaboration between the country's central government and the WHO. The problems encountered during the push for eradication are represented merely as temporary setbacks, quickly overcome through the efforts of a committed national government and generous technical and financial assistance from the WHO. The impression generally given is one of a united front, certain of its methods and assured of its success. The reality was far more complex.* (46: pp 163–164)

The SEP in India was overlaid on a diverse social, cultural and geographical context.[4] This milieu, along with perceptions that the campaign was being "jammed down the throat", ultimately fashioned an interface for resistance. Portions of society were simply reluctant to be healthy on someone else's terms, and public health professionals should bear this in mind in the implementation of current and future programmes. This is particularly relevant to the ongoing campaign to eradicate polio, which is encountering its own forms of cultural, religious and political resistance.[5]

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Notes:

1. In this paper, popular resistance is defined as opposition to the Smallpox Eradication Programme (SEP) by individuals, families or groups of the Indian public. It does not imply massive, widespread public demonstrations, which were rare. See Foster (47) for cases of active public participation in campaigns to eradicate smallpox.
2. Indians had developed and practised a method for variolating for smallpox prior to the SEP; however, this paper will not discuss the indigenous Indian practice of variolation.
3. It should be mentioned that disease prevention through elaborate military-style exercises became a model for malaria control in India, where it failed spectacularly. The approach damaged the development of health services in the country and was replaced with approaches focusing more on participation, community engagement and the dissemination of information (48,49).
4. See Bhattacharya (50) for a review of the geographical and environmental factors that affected the SEP in India.
5. While efforts to eradicate polio have been effective (reduction in cases from 350,000 in 1988 to 72 in 2015), the process has not been without challenges (51). As recently as January 2016, a polio vaccination clinic was the target of a suicide bomber in Quetta, Pakistan (52). Reports linking polio vaccination resistance to religion, more specifically Islam, are justified, although that may be oversimplifying the issue. Bhattacharya and Dasgupta (53) argue that the situation is complex, and resistance appears, in some areas at least, to be related to socioeconomic differences and the use of vaccination as a bargaining tool for local development projects.

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AUTHORS, PLEASE NOTE

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Vaccine delivery to disease control: a paradigm shift in health policy

T JACOB JOHN, YOGESH JAIN, SAROJINI NADIMPALLY, AMAR JESANI

Abstract

India's Universal Immunisation Programme (UIP) has resulted in the creation of infrastructure, human resources and systems for the procurement and delivery of vaccines. Recently, new vaccines have been added and there are plans for the introduction of more. However, the outcomes in terms of reduction of the diseases for which the vaccines are being administered remain ambiguous. This is evident from the persistent health issues that children continue to experience, despite immunisation. This situation raises a fundamental ethical question for public health: vaccinations are one of the tools of disease control, but are they properly aligned to the control of disease so as to produce the expected public health utility or benefit?

To meet this challenge in public health ethics, and focusing on the issues raised in a recent national seminar on new vaccines, this paper argues for the need for a paradigm shift in health policy in the context of immunisation – a shift towards transforming the programme to one of disease control. It is necessary to focus on the latter to reduce the disease burden, which is not commensurate with the investments in immunisation. The paper also makes recommendations on the planning and governance of a shift towards disease control in India.

Introduction

A national seminar on "New vaccines for all: why, which, when?", jointly organised by the Jan Swasthya Sahyog (JSS), Sama Resource Group for Women and Health (SAMA), *National Medical Journal of India* (NMJI) and Forum for Medical Ethics Society (FMES), was held on October 20–21, 2016, at the National Institute of Health and Family Welfare (NIHFW), New Delhi.

The seminar sought to facilitate a dialogue on "New vaccines" in the spirit of public health and deliberations of high scientific quality towards building perspectives and consensus, where possible, on all issues. The participants included representatives from the Ministry of Health and Family Welfare (MOHFW), the Indian Council of Medical Research (ICMR) and the World Health Organisation (WHO). Many individuals from health economics and public health fields/institutions, civil society organisations, academic institutions, medical colleges/hospitals and research institutions also participated. The key points emerging from the deliberations at the seminar were expected to contribute to policy-level recommendations for the future.

The conceptualisation of the seminar was prompted by recent developments in the area of vaccines. First, a few years earlier, the hepatitis B vaccine had been included in the UIP, which initially had only six vaccines. Second, the pentavalent vaccine – a combination vaccine against diphtheria, whooping cough, tetanus, *Haemophilus influenzae* type band hepatitis B – was introduced nationally, in a phased manner. Third, the injectable inactivated polio vaccine (IPV) was included in the UIP in 2015 and a slew of new vaccines against rotavirus, rubella and pneumococci are to be rolled out in the near future. Punjab and the Union Territory of Delhi are in the process of introducing the human papillomavirus (HPV) vaccine in their immunisation programme (1, 2).

This paper is informed by the seminar's deliberations on the role and fundamental objectives of the immunisation programme; however, it does not report each of the elements that were discussed. We have used certain aspects of the framework of public health ethics to analyse the issues raised (3, 4). In particular, we focus on the utility and benefits of the immunisation programme. While the UIP is one of the tools of disease control, it needs to be a part of the overall public health measures that yields the maximum benefit in the control of diseases.

The paper is divided into three parts. The first part provides an outline of the UIP, while the second explains the deficiencies of the programme. The third part discusses issues pertaining to the relationship between the immunisation programme and disease control. The paper ends with some concluding recommendations.

The UIP: an outline

The Expanded Programme on Immunisation (EPI), launched in India in 1978, was renamed the UIP in1985, with the ambitious objective of protecting all children with vaccination against childhood diseases that were assigned priority at the time – childhood tuberculosis, diphtheria, pertussis, tetanus, polio and measles. Since the establishment of the National Technical Advisory Group on Immunisation (NTAGI) in 2001, vaccines against Japanese encephalitis (JE), hepatitis B and *H. influenzae* b have been included in the UIP. Recently, vaccines against rotavirus, pneumococcus and rubella, too, have been approved for a national roll-out.

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A robust vaccine delivery platform has been envisaged by the UIP. Procured vaccines are required to be kept in cold chain to preserve their potency, and there is a national grid of cold chain points (5). The programme requires all vaccinators to be well trained and periodically re-trained. Sterile, one-time use, auto-disable syringes and needles are to be used for all injections. The responsibility of vaccine delivery is shared between the Union and state governments. Over four years, the Union government's annual budget for the Immunisation Division doubled from the allocation in 2013 to over USD 1400 million (6).

From the beginning, the success of the EPI/UIP was monitored by surveying the numbers of eligible children reached with the scheduled doses of vaccines in the first year of life – this is the metric called "immunisation coverage". For the sake of convenience, the third dose of the diphtheria–pertussis–tetanus (DPT) vaccine and the first of the measles vaccine form the reference for coverage – a child who has taken them being defined as "fully vaccinated". Apparently, the programme is not able to reliably capture immunisation coverage data from registers documenting vaccine utilisation. Given this gap, some agencies, such as the WHO and UNICEF, use data from multiple sources that report on periodic local, regional or national coverage surveys (7).

Immunisation coverage improved during the early decades of the EPI/UIP, but going by the results of various surveys, it seems to have stagnated at around 70%–80% in the past decade (7). To improve coverage, pre-planned campaigns for immunisation were launched in low-performing districts in 2014, under the banner of "Operation *Indradhanush*"(8).

The deficiencies of the UIP

The polio, diphtheria and hepatitis B vaccines are used to illustrate some of the deficiencies in the design of the UIP. In 1980, India introduced immunisation against polio and in 1988, accepted the global polio eradication agenda. In the absence of public health surveillance of polio, the UIP was unable to properly plan disease monitoring, an essential component of eradication. Instead of bridging the gap, the government chose to establish a separate vertical National Polio Surveillance Project for polio eradication.

Although the goal of interrupting the transmission of wild polioviruses was achieved (9), the new design did not help in strengthening the UIP. Moreover, in the absence of surveillance of every case of polio to determine its aetiology, the problem of vaccine-associated paralytic polio (VAPP) remained unaddressed. Thus, one may ask what the prevalence of polio would be if there was no vaccination, and what the prevalence of paralysis is with vaccination. Has vaccine-related paralytic polio led to an increase in paralysis? Could the disease have been controlled better if adequate measures had been taken to prevent it by other means, such as basic hygiene? Thus, in the interest of disease control, it is important to ascertain whether the exclusive focus on the oral polio vaccine obfuscated the need to emphasise the social determinants of the disease. At the same time, had the magnitude of VAPP been monitored, the definition of eradication would have been zero incidence of polio caused both by wild and vaccine virus. This could have facilitated the early introduction of the safe IPV, which could have been a more appropriate public health strategy from an ethical and epidemiological perspective.

In 2015, the WHO recommended that the IPV be introduced in the UIP in preparation for the sequential withdrawal of serotypes of vaccine viruses in the oral polio vaccine. However, the closure in 1993 of the IPV-manufacturing unit established by the Government of India in 1987 hindered the introduction of the IPV. Since the IPV is not manufactured indigenously and that available in the international market is quite expensive, the UIP is facing serious shortages of the vaccine (10).

Diphtheria toxoid has a high vaccine efficacy and effectiveness when administered to children at the recommended doses. Yet, diphtheria continues to occur sporadically and in the form of localised outbreaks (11).This reflects three flaws: (i) the failure to prevent diphtheria to the maximum potential (the objective of immunisation investment); (ii) the delay in the detection of the first case in the community as a signal of an impending outbreak; and (iii) the lack of capacity to launch an immediate public health response when the disease is detected. The response ought to include an active case search, a rapid survey of the immunisation coverage and immediate "catch-up immunisation". The root cause of localised outbreaks of diphtheria is the lack of case-based surveillance, which the UIP is not empowered to carry out since it is merely a vaccine delivery platform by design.

Monitoring and implementation in the case of other vaccines currently under the UIP, such as hepatitis B, JE and *H influenzae b*, are fraught with various problems. The hepatitis B vaccine was introduced in 2003, but no convincing information on its contribution to the reduction of the frequency of infection or of the chronic carrier state is available. However, one research study has shown that vaccination has not led to any significant reduction in the incidence of acute or chronic infection (12, 13, 14). In spite of the fact that people are vaccinated against JE in all JE-prone districts, outbreaks of the disease continue to occur, resulting in many deaths (15, 16). The *Haemophilus influenza b* vaccine is also in the UIP schedule, but its impact in terms of a reduction in the incidence of either meningitis or pneumonia is not being monitored. Thus, we are not detecting and correcting various gaps in the outcome or impact of immunisation in a programme mode. We do not know if the level of reduction of the incidence of diseases is commensurate with the volume of vaccines provided. Are we reaping the full benefit of investment?

Discussion: immunisation and disease control

The discussion on this topic at the seminar focused on two aspects. The first was "disease control". Vaccines are one of many tools to achieve disease control, ie they are a means to an end and not an end in themselves. Vaccines are administered to healthy individuals and like any other medical intervention, can produce adverse effects – injuries and sometimes death,

albeit in small numbers. The alternative options, particularly interventions relating to the social determinants of the diseases against which vaccines are used, are relevant and their benefits may go beyond mere disease control by improving the quality of life. At the same time, when vaccines are used, it is necessary to ensure that vaccination and the disease control programme do not operate in silos.

The second aspect, though not discussed in this paper, is closely related to the above. It concerns the question of which new vaccines should be added to the UIP and what considerations should shape the policy decisions in this area. Any new vaccine must be introduced only after it has been critically assessed for human use in terms of the epidemiological need for it and suitability, safety, protective efficacy and affordability. Moreover, whether the government's health management system has the organisational capacity to deliver additional vaccines according to an appropriate age schedule, without affecting the coverage of the existing vaccines or other health services, should be evaluated in conformity with the National Vaccine Policy. Further, the decision to introduce some of the new vaccines must be taken after considering the other existing or essential public health measures for disease control, so as to ensure that the vaccines do not shift the focus away from the latter.

Coming back to the focus of this paper, all evidence of the deficiencies of the UIP demonstrates that the design of the programme limits it to function as a vaccine delivery platform, rather than serve as a comprehensive disease control programme. The assessment of the UIP should, therefore, include monitoring of performance measured through immunisation coverage surveys, along with monitoring of the efficiency of performance. The goal of the UIP is to maximise the prevention of disease to the point of reaching the lowest incidence that can be achieved, given the variability in the efficacy of vaccines. If the disease occurs in spite of immunisation, there should be mechanisms to identify the factors causing this. Disease reduction (for all vaccine-targeted diseases) or infection reduction (for example, hepatitis B) must be conducted in a denominator-based manner, monitored with reliable evidence.

These additional elements must be built into the UIP, but the UIP will not be able to fulfil the demands of this new design as a vertical programme. Public health surveillance should be case-based and comprehensively cover all healthcare facilities in the public and private sectors. As mentioned above, every reported case has to be responded to, with investigation and intervention.

The present situation of the UIP thus poses three key ethical challenges.

The practical separation of immunisation from disease control seriously limits the availability of a robust database to measure the positive impact of immunisation on disease control. Before making a long-term investment and sustenance of the programme, it is essential to monitor the impact of each of the vaccines under it.

Operating in isolation, the UIP precludes any discussion on the other measures, particularly those pertaining to social determinants, necessary for disease control.

The absence of a direct linkage to disease epidemiology raises the unhealthy possibility that the UIP might take arbitrary decisions on the inclusion and exclusion of vaccines. In other words, it might become more vulnerable to the marketing strategies of vaccine producers.

Conclusion

The government should adopt a paradigm shift from immunisation delivery through the UIP to disease control as a much broader strategy. When the WHO launched the EPI, India did not have a public health infrastructure to subsume it as a disease control programme. Consequently, the EPI was adopted as a vertical vaccine delivery programme. Forty years later, India still lacks a public health system that can utilise vaccine delivery as an intervention for the control of vaccine-preventable diseases.

Comprehensive disease control is virtually impossible without public health infrastructure, as illustrated by the inability to control many communicable diseases, such as tuberculosis, malaria, cholera and typhoid fever. As for the control of vaccine-preventable diseases, the essential intervention is already in place and what is of vital importance now is a paradigm shift from mere vaccine delivery to disease control. Disease control entails, among other measures, public health surveillance and a focus on the places where the target diseases are detected. Together with a paradigm shift within the UIP to work towards the control of diseases, both vaccine-preventable and others, it would be useful to create the nucleus of a public health infrastructure around the UIP. Moreover, the focus on diseases and on the most efficient and beneficial interventions for their control would necessarily lead to the examination of interventions related to the social determinants of such diseases, to supplement or use in place of vaccines, or use both in equal measure.

Once a public health platform is created, the burden of diseases which can potentially be controlled through the introduction of new vaccines can also be included in surveillance. Thus, measurement of the disease burden can be built in to obtain reliable baseline data. It will also help one follow the trajectory of disease reduction after the introduction of any new vaccine.

In summary, the UIP could serve as the nucleus for constructing a public health infrastructure within the MOHFW. Ideally, a division of public health should be established and the UIP merged with it. Eventually, all vertical programmes for the control of tuberculosis, AIDS, malaria, kala azar and other vector-borne diseases could also be merged with the division of public health, the purview of which could be expanded to cover all other communicable diseases. This division should be in a position to design, initiate and implement inter-ministerial

interventions for addressing the social determinants of the diseases, as well as be in charge of the inter-sectoral coordination between the interventions.

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COMMENTS

Ethical concerns related to mandatory reporting of sexual violence

JAGADEESH N, PADMA BHATE-DEOSTHALI, SANGEETA REGE

Abstract

The provision of care for survivors of sexual violence is a medico-legal emergency. However, due to social issues, healthcare providers face several ethical and legal dilemmas when administering care to such survivors at hospitals. Added to these are the compulsions under mandatory reporting laws, which oblige healthcare providers to abide by the ethical commitments of care and treatment, and make it mandatory for them to report cases of sexual violence to the police, failing which they face legal sanctions. This article draws on global evidence related to mandatory reporting of violence against women and children and the lessons learnt from it. While doing so, it presents the current status of mandatory reporting by healthcare providers in India and the challenges faced by them in operationalising the survivors' autonomy, ensuring confidentiality and overcoming obstacles that may impede treatment and care.

A 17-year-old girl was brought to a public hospital by her parents for an abortion. She was 18 weeks pregnant. She and her parents disclosed that she had been sexually abused by her uncle, who had subsequently been thrown out of the house. They did not want to report the matter to the police. The doctor explained to the parents that according to the law, he had to inform the police, but also assured them that the police would not force them into anything and that the doctors were with them. However, the girl absconded.

A man brought his nine-year-old son to a public hospital as he complained of pain in the anal region. The father told the doctor that his own brother had sexually assaulted his son. He had confronted his brother, informed his elder brother and sent the former back to his village. The doctor informed him that treatment would start immediately, but the police would have to be informed. The father explained that they did not want to file a case against his brother as the burden of the brother's family would fall on him. He said they would leave the hospital if the police was contacted.

Both situations pose several challenges to a health professional. Should it be mandatory for a health professional to report rape/sexual assault even if it is without the consent of the survivor and his/her family? Does this not violate the confidentiality of the doctor–patient relationship?

Does abiding by the provision of mandatory reporting amount to denial of treatment, as illustrated above? Will it prevent patients from disclosing the cause of injuries and/or ill health? Will it deter survivors from seeking healthcare, thus putting them at further risk?

Does mandatory reporting take into account the dynamics and circumstances surrounding rape/sexual assault? How does the law on mandatory reporting harmonise with other existing laws, especially those on seeking informed consent (Section 164A,Code of Criminal Procedure [CrPC]) (1) and on ensuring the confidentiality of the survivor, particularly in the case of medical termination of pregnancy (as per the Medical Termination of Pregnancy(MTP) Act, 1971 and MTP Regulations, 2003)(2).

These are some of the vexing questions posed by the new laws against sexual violence, ie the Protection of Children from Sexual Offences Act, 2012 (POCSO) (3) and the Criminal Law Amendment Act, 2013, (CLA) (4). Both laws make it mandatory for all health professionals to report every case of sexual violence. This paper discusses the concerns arising from the "mandatory reporting of rape/sexual assault survivors to police" by health professionals and its effect on the survivors. It also raises questions pertaining to the very concept of mandatory reporting in the absence of good-quality services for protection or additional options for survivors to heal from abuse. The paper suggests that such forced reporting may, in fact, amount to a disservice to the survivors, especially those who go to a health facility in search of treatment and care.

The legal provisions

It is important to note that both these laws aim to punish the perpetrator. The consequences of the assault on the victim's health are well documented and health professionals play a critical role in mitigating them. However, the new role that they are required to play (mandatory reporting) is most likely to jeopardise their therapeutic role.

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Section 357C, CrPC after the CLA, 2013(4) states that all hospitals, private or public, run by the central or state governments must provide first aid or medical treatment, free of cost, to the victims of any offence covered under sections 326A, 376, 376A, 376B, 376C, 376D or 376E of the Indian Penal Code (IPC), and shall immediately inform the police of the incident.

Section 166B, IPC (4), states that any person in charge of a hospital, whether public or private and whether run by the central government, state government, local bodies or any other person, who contravenes the provisions of section 357C of the CrPC, 1973 shall be punished with imprisonment for a term which may extend to one year, or with a fine or with both.

Section 19 of the POCSO (3) states that any person (including a child) who fears that an offence under this Act is likely to be committed, or has knowledge that such an offence has been committed, shall inform the special juvenile police unit or the local police. Section 21 of the POCSO states that a person who fails to report the commission of an offence under subsection (1) of section 19 shall be punished with imprisonment of either description that may extend to six months, or with a fine or with both.

Global evidence on mandatory reporting

There has been considerable debate on the issue of "mandatory reporting" to law enforcement agencies in instances of rape/sexual assault and of non-reporting of domestic violence (including sexual violence by intimate partners). Several concerns have been raised by studies conducted in different parts of the world. There is research evidence that women are likely to not access healthcare if the requirement for mandatory reporting is enforced. Studies from the United States have shown that non-white women are less likely than others to support mandatory reporting. This could have to do with their experience of coming up against an unresponsive system and also, negative experiences of formal systems, such as the criminal justice system, which are racially biased against non-white people. Similar biases can be observed in the context of women belonging to the minority communities in India, with those subjected to violence being afraid of mandatory reporting. In India, there is a dearth of services for the survivors of violence and in the absence of these the application of mandatory reporting should not violate the victims' right to autonomy and agency.

In 1994, the USA passed the Violence against Women Act (VAWA), which encouraged several states to adopt the policy of mandatory reporting to law enforcement, with the hope that this would help to curb violence against women. However, as the literature shows, strong criticism has been levelled against such reporting. A report published by a centre providing services to survivors of date rape states that teenagers are reluctant to report date rapes because of fears related to "mandatory reporting" laws. They fear unwanted disclosure of their personal information, and this has discouraged young women from seeking prenatal, reproductive and sexual healthcare. The report also warns that health professionals themselves are becoming increasingly reluctant to provide services to such teenagers as they are constantly in a conflict about reporting cases, on the one hand, and fulfilling their role as carers, on the other (5). In a survey in California, which has provisions for mandatory reporting, at least one in two physicians reported that they did not comply with mandatory reporting if the patient objected (6).

Following a review of the VAWA, several changes were introduced. Amendments in different states pushed for an expansion of mandatory reporting and suggested that it go beyond merely intimating the law enforcement agencies. An example is that of the state of Kentucky, which expanded the requirement of mandatory reporting to Adult Protective Services (besides the law enforcement department). This enabled survivors to access services required for dealing with the aftermath of violence. Protective services help women and children to deal with the effects of any form of violence and recover from its effects by working out safety plans, which include emergency and long-term shelter services, housing, nutrition and healthcare services, counselling and therapy. In fact, in Kentucky, it is a social worker who contacts the survivor and not the police, enabling the survivor to receive support and care and make an informed decision. The survivor is offered social or/and legal services, as determined by her/him, and the course of action is determined on the basis of a dialogue with her/him. The Kansas state domestic violence and sexual assault support programme has laid down a model policy regarding mandatory reporting. The policy states that the decision to report to law enforcement agencies or to social and rehabilitation services lies with the survivor. It also states that specific personnel directed by the VAWA to mandatorily report cannot dismiss their responsibility by merely intimating the police machinery, and that their responsibility is also to provide psychosocial interventions and put survivors in touch with appropriate support agencies (7).

A review carried out by the National Coalition for Child Protection Reforms in the USA clearly states that mandatory reporting has, in fact, increased the burden on protective agencies. According to the review, undertaken in 2012, fear of penalties may lead stakeholders responsible for reporting to start reporting people without adequate scrutiny, creating an unnecessary burden on services. Another study conducted to understand health professionals' perceptions of mandatory reporting demonstrates how they are compelled to act in consonance with the law even if it violates medical ethics. Health professionals acknowledge the difficulty of striking the inevitably difficult balance between patients' safety, patients' autonomy, legal requirements and potential police protection. A recently published article in *Time* magazine (February 2013) has raised questions related to the operational aspects of the VAWA with respect to mandatory reporting. The article states that the rate of prosecution has increased as a result of the VAWA, but there is no evidence to suggest that the Act has been able to reduce the incidence of violence against women. Given the evidence on problems

related to the "mandatory reporting laws", especially VAWA, lawyers, feminists and human rights experts suggest that the funding for law enforcement agencies be redirected to prevention, job training and additional services to heal those who have already faced violence.

As a response to the growing concern about the lack of therapeutic care for survivors of sexual violence, several countries, such as Denmark, Norway and Sweden, have developed healthcare-based models to maximise the medical response to the victims. These models provide comprehensive care, including forensic medical examination, psychological counselling and follow-up, as well as complete medical care. The healthcare services recognise the fact that survivors may visit the facility to avail themselves of care and may not have decided to file a police complaint. At the Copenhagen Centre for Victims of Sexual Assault at Rigshospitalet in Denmark, the situation is explained to the survivor, who is offered the option of getting evidence collected and given three months to decide whether or not to file a police complaint. According to the centre, those reporting to the police after sexual assault are more likely to report non-genital assault, ie physical assault, and sexual assault by a stranger/non-family person. Victims identifying a friend as the perpetrator of the sexual assault are more likely to report to the hospital-based centre. This may indicate that before the availability of dedicated sexual assault centres, this "silent" group of adult victims of sexual assault (by friend/family member) may not have received services, even if they had the same needs of medical treatment. It does make a case for reporting of sexual assault at the level of health settings because these settings allow for voluntarily reporting and the provision of healthcare (8).

In South Africa, there is a contradiction between the laws on mandatory reporting of sexual assault and the Children Act, 2005 (Act no. 38 of 2005), which allows sexually active children access to condoms, contraceptives, abortion and medical care. McQuoid-Mason argues that the provision on mandatory reporting violates the constitutional principle of ensuring the "best interests of the child", and unreasonably and unjustifiably limits the constitutional rights of children to bodily and psychological integrity and privacy (9). The Teddy Bear case, as it is now referred to, is significant as the court recognised that adolescents of 12–15 years of age have a right to engage in "healthy sexual behaviour" (paragraph 107). Thus, for the first time in South Africa, a court recognised that the disparate approaches to adolescent sexuality in the Sexual Offences Act, 1957 and Children's Act, 2005 were not in the best interests of children. Strode et al argue that this is the first step towards developing a more coherent approach to adolescent sexuality, which has both public health and human rights benefits. However, doctors and researchers remain in a dilemma about whether or not to report in certain circumstances (such as when the child is under the age of 12; when a 12–15-year-old is having consensual sex with a much older partner; when a 16–17-year-old is having consensual sex with a partner more than 2 years younger; or when the child is having sex with a person over 18). They argue for further debate on reforms that would give service providers some discretion in determining when reporting a consensual sexual offence would be in the best interests of the child (10).

Mandatory reporting contradicts the existing laws in India

Making it mandatory for hospitals to report all cases of rape and sexual assault to the police under section 357C,CrPC(4) and section 21, POCSO (3), respectively, is in contradiction of various existing legal provisions. These are as follows.

Informed consent

Section 164A of the CrPC, amended in 2005(1) made it binding for medical professionals to carry out the medico-legal examination only after seeking informed consent. This meant that no part of the medico-legal examination could be conducted without the survivor's consent. The underlying principle was a recognition of the fact that survivors are autonomous individuals and can make informed decisions. The process of informed consent allows the survivor to understand the rationale and scope of the medical examination, areas of the body that would be examined, relevance of the evidence collected from the body and nature of the treatment. Such a dialogue with survivors puts them at ease about the procedural aspect of medico-legal examination. It recognises their right to undergo a partial examination. The doctor has to mention in the medico-legal case report that informed consent was obtained for all parts of the examination and treatment. Therefore, it becomes mandatory for doctors to document informed refusal for any part of the procedure. Section 357C, CrPC contradicts this, as it makes "providing treatment and informing police" compulsory in every case. So when survivors tell the doctor that they do not want the hospital to inform the police but only want treatment and/or evidence collection, the doctor will be in a dilemma regarding what to do, or may end up having to deny treatment.

Voluntary reporting

Both the POCSO (3) and CLA, 2013(4) recognise the right to treatment and voluntary reporting to hospital (this means that survivors can directly approach a hospital without a police requisition for treatment and evidence collection). This has come about after a long period of struggle. A landmark Supreme Court judgment in the case of State of Karnataka vs. Manjanna as far back as the year 2000 called rape a medico-legal emergency and made it obligatory for health facilities to provide survivors with immediate healthcare. The judgment also highlighted pathways by which survivors could go to a health facility – either voluntarily, by police requisition or through a court directive. It recognised that survivors may visit a health facility to receive treatment and, therefore, they ought to be provided services immediately, without any police requisition. When we speak of voluntary reporting, we recognise the fact that survivors may go to hospitals for treatment before they report to the police, since they may need time to decide whether they would like

to take legal action. The judgment was intended to make access to healthcare enabling for survivors of sexual violence. Mandatory reporting contradicts the concept of voluntary reporting, as the former deters survivors from seeking treatment. This is a setback.

Abortion law

The MTP Act (2) makes it mandatory for doctors to keep all information on those seeking abortions confidential. It lays down that the facility must keep all records in sealed envelopes. On the other hand, the POCSO Act, 2012,makes it mandatory to report all sexual activity(whether consensual or not)in the case of those under 18 years of age to the police. Thus, all sexual activity under the age of 18 years is regarded as statutory rape and must be reported to the police. According to this law, if a girl wants to undergo MTP on humanitarian grounds but does not want to file a police complaint (when pregnancy is an outcome of sexual assault/rape),the doctor must inform the police that the cause for pregnancy was rape. This is in contravention of the MTP law, as it violates the principle of confidentiality.

Right to privacy

Article 21 of the Constitution (11) recognises the right to privacy and, therefore, nothing can be done against the will of a person. However, while Rule 5.2 of the POCSO Act states that "emergency medical care shall be rendered in such a manner as to protect the privacy of the child", Section 21 of the Act contradicts this by making reporting mandatory.

Mandatory reporting –conflict with medical ethics

Violation of informed consent

The law requiring mandatory reporting by health facilities severely compromises the principle of informed consent. Survivors who go to a health facility confide in the health professional on the basis of an implicit contract of "confidentiality of information". However, when a health professional tells the survivor that s/he has to reveal the information to the police, irrespective of the survivor's consent, the survivor feels cheated. Informed consent then becomes irrelevant since the survivor's autonomy to make a decision on whether or not the matter should be reported to the police becomes a mere formality. Mandatory reporting, therefore, raises concerns about the health professional's primary responsibility as a carer and stereotypes survivors as helpless people incapable of making decisions for themselves. Complying with the requirement of mandatory reporting may lead health professionals to feel that their job is done by simply reporting to the police, and they might make no effort to either develop support strategies to heal the survivors or refer them to psychosocial services.

Threat to confidentiality

The health provider–patient relationship is based on an assurance of confidentiality. A contract of confidentiality helps patients to have honest and open discussions with their providers. At the same time, health professionals are able to provide comprehensive and complete treatment if the patient gives them all the information. However, mandatory reporting poses a challenge to the assurance of confidentiality. Survivors who do not wish to involve the police may not reveal that they were abused and may also not mention all the injuries/health consequences suffered by them, thus compromising on their health. In a primary research study undertaken in the state of Michigan to understand survivors' opinions on mandatory reporting by medical professionals, it was found that most participants did not support such reporting. They stressed that they should be allowed to consider all the potential consequences of reporting before their experience of violence is reported to the police. Some of the reasons cited by the participants for opposing mandatory reporting were the fear that the child would be separated from the non-abusive parent, the apprehension that their history would become public and fear of being deported (12). Victims may not report abuse due to financial and emotional dependence on the perpetrator; not wanting to go through the court system; not wanting the perpetrator to be arrested if he is a family member; and wanting time to think or make a decision on the matter.

Clashing obligations

Health professionals have a duty to provide first-line psychological support, besides medical treatment. Some of the basics of first-line psychological support are to probe and ascertain how safe the survivor is; assess whether there is any suicidal ideation; work out a safety plan, reassure the survivor; and discuss sexual violence as an abuse of power (13). However, the recent laws do not allow health professionals to engage in a constructive dialogue with survivors. Mandatory reporting will deprive survivors not wishing to take the route of the criminal justice system of the chance to communicate honestly with the health professional. Health professionals can get caught in an ethical dilemma between the provision of care versus mandatory reporting as it would be difficult to decide whether to fulfil their obligation to the survivor or be accountable to the state.

Positive step in setting standards for healthcare – establishing right to health

There has been much discussion on the need for healthcare providers to adopt an ethical, legal and gender-sensitive approach (14), along with the dissemination of standard protocols and guidelines. The Union Ministry of Health and Family Welfare (15) realised that the contact between survivors seeking care and the healthcare system is critical, and provided clear directions to health systems on dealing with the aspect of "mandatory reporting". According to the ministry's guidelines, in instances in which survivors may not want to report to the police and have gone to a health facility only for treatment, health professionals have the responsibility of informing them of the benefits of reporting to the police; if they decide against reporting the matter,

"informed refusal" should be documented and treatment should not be compromised upon. In cases in which doctors feel that informing the police would result in the denial of treatment to the patient, documenting "informed refusal" is a way forward. However, the ministry's guidelines must be supported by corresponding legal amendments. Simultaneously, efforts must be made to refer cases to services that are designed to provide protection to survivors and heal and reintegrate them into their daily routine of life. In the process, the violence would get reported to the protection services and not mandatorily to the police. In order for such a change to occur, there is a need to address the absence of comprehensive and quality services for the protection of victims.

To conclude, we must ask the basic question as to who benefits from laws for mandatory reporting. Mandatory reporting clearly aims to punish offenders and reduce crime, and does not directly focus on the best interest of survivors or what they desire. Against this background, when we analyse the reasons why survivors do not report crimes, they include the fear of losing shelter; apprehensions about retaliation by the perpetrator; anxiety that others will come to know about the assault; and fear of losing community support. Those working with survivors of sexual violence need to collate data related to "mandatory reporting" and the challenges it poses. This would provide much-needed evidence for the formulation of policy decisions/directions. The need of the hour is to set up more services that provide comprehensive healthcare, including crisis intervention, so that more survivors are able to seek care and support.

Conflict of interest

The authors state no competing interests and have received no funding support to write this article.

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Living kidney donation and masked nationalism in Israel

MIRAN EPSTEIN

Abstract

This paper draws attention to a current trend of masked conditional-nationalist living kidney donation in Israel, to which the local transplant system has been turning a blind eye. The paper seeks to make the international transplant and bioethics communities aware of this disturbing trend. It also explains why it is wrong and suggests how to tackle it. Finally, it calls on the Israeli system to bring the practice to a halt for the benefit of all parties involved.

Introduction

In a better world, all organ donations would be unconditional, made to the global pool with no strings attached. Further, the organs would be allocated strictly on the basis of need. Economic considerations, social standing, class, race, ethnicity, faith, gender, nationality, age, reciprocity, friendship and even kinship would play no role in the decision-making process. Social solidarity would be the sole driver, means and end of the transplant enterprise.

Things are different in our world. The vast majority of living donations are conditional. In many cases, the system goes along with the donor's demands. However, even when the donor makes none, as is typically the case with deceased donation, the allocation system often sets its own conditions. Priority to local patients over aliens (also called the *principle of self-sufficiency*) and to those willing to donate to the organ pool over "free riders" are frequently cited examples (1:p 5b; 2).

Whether from the deceased or the living, conditional organ donation takes two general forms. First, it can be *directed to a related or unrelated individual*. In this case, it would be ethically acceptable and effectively binding, subject to certain terms and conditions. Second, it can be *directed to or withheld from certain groups or types of people*. This form of conditional donation is often sweepingly referred to favourably as *socially directed donation* (3). In the following, I will use the term *sectarian donation*, which I believe is more appropriate, accurate and informative.

Sectarian donation, which is the focus of this article, may under certain circumstances seem moral, or at least not immoral. For example, donation that is directed specifically to children or to a social group that happens to have relatively poor access to organs may arguably be moral. By contrast, donation that actually or even just ostensibly involves racism, nationalism, chauvinism or bigotry of some sort is probably, not to say evidently, immoral, though some scholars would not reject it on this ground alone. They argue that even divisive donations save lives, saving lives being the highest value (4–6).

In any case, putting aside subjective moral sentiments, sectarian donation is almost invariably in breach of the prevailing international transplant ethic. In other words, the current codes happen to consider it immoral and unacceptable *regardless of the nature of the conditions laid down by the donors*. Exceptions are rare and, at any rate, tangential to solid organ donation. For example, the Australian Assisted Reproductive Technology Act 2007 (New South Wales) explicitly permits gamete donors to discriminate against potential recipients on any basis, including race, ethnicity and sexual preference (7).

It is likely that most transplant systems would reject deceased or living organ donations if the donors were to be plain about their sectarian motives. The ethical positions of national systems may not always be set forth in detail, but there is no doubt as to their anti-sectarian spirit.

In 1998, the next-of-kin of a deceased British white man specified that his organs could not be allocated to non-whites. The organs were accepted and allocated to white people who, by coincidence, would have been the recipients anyway. However, following criticism in the British media, a Department of Health investigation concluded, among other things, that that "racist conditions are completely abhorrent" and should be prohibited (8, 9).

The National Health Service (NHS) Blood and Transplant policy is even wider: "It is a fundamental principle of the UK donation programme that organs are freely and unconditionally given."(10).

The Transplantation Society (TTS) takes a similar position and so does the US United Network for Organ Sharing (UNOS). According to the former,"…[conditions] imposed on the selection of recipients interfere with the principles of justice and equity, and sometimes also the principle of utility. In this situation, the rights of the recipients based on these ethical principles overrule the donor's right to autonomy. Despite the organ shortage, the offer for donation should, therefore, be declined."(11).

Elaborating on the ethical principles in organ donation, the UNOS states: "UNOS has long opposed donations directed to a social group (based on race, religion, gender, or sexual orientation)."(12).

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In view of this global ethical stance, one may assume that sectarian donations can take place only if they conceal themselves behind some ethical guise.

This paper draws attention to a current trend of masked sectarian living kidney donation in Israel, to which the local transplant system has been turning a blind eye. The paper seeks to make the international transplant and bioethics communities aware of this trend and the way it conceals itself. It also explains why it is wrong and suggests how to tackle it. Finally, it calls on the Israeli system to bring the practice to a halt for the benefit of all parties involved.

The Israeli case

The 2008 Declaration of Istanbul on Organ Trafficking and Transplant Tourism marked the launch of a concerted international campaign against these disturbing practices (1). As part of this campaign, one article drew attention to the hitherto ignored potential of altruistic, directed, individual-to-individual living unrelated donation (LURD), which is, in principle, ethically acceptable and widely encouraged, to conceal commerce in organs(13). The risk still exists. Most transplant programmes require a detailed psychological evaluation to assess the donor's capacity to make an informed and free decision, and to rule out commerce (14). However, the tests remain weak for two reasons. First, monetary transaction is difficult to identify as both donor and recipient are usually coached to deceive the system of oversight. Second, and perhaps more crucially, the transplant system fears that more rigorous tests would be likely to diminish the number of acceptable donations (15).

There is, however, another hazard associated with altruistic individual-to-individual LURD that has so far received no attention at all: the risk that it conceals a sectarian condition.

The Israeli media have recently reported an increasingly popular trend of conditional living kidney donation from Jews to Jews, disguised as altruistic, directed individual-to-individual LURD. It is definitely a trend, and not some isolated cases. Taking place between total strangers, the donations are brokered by a Haredi charity, called *Matnat Chaim* (Gift of Life) – Volunteers for Kidney Transplantation, which matches donors and recipients. It has recorded more than 331 donations since 2009, against a waiting list of 850(16–18). The trend now seems to involve other countries as well. The charity reports that on May 18, 2016, the London-based Royal Free Hospital performed a transplant involving an Israeli donor and a British recipient, who had been "brought together" under the auspices of the charity (19,20).

The chairman of *Matnat Chaim*, Rabbi Yeshayahu Haber, regards this trend as wonderfully unique: "This is the only country in the world with so many people donating their kidneys voluntarily to strangers"(in the following, all translations from Hebrew are mine, M.E.)(18). Haber also reveals the motivation: "Most donors wish to 'save a Jewish soul'; thus most recipients are Jews."(21). Interviewing a group of volunteers of the charity, one reporter writes:

> *Would you be willing to donate a kidney to a non-Jew as well? They find the question difficult to answer. Rabbi Shapira volunteers to answer on their behalf: "One person says, 'I am willing to donate a kidney to my brother, or even to my cousin, but not to my neighbour. I am saying I am willing to donate to my brother, and also to my cousin, and also to the cousin of the cousin, and also to my people in general. Thus my family includes my people. I have no problem donating to an Arab … but on condition that someone from his family donate a kidney to a Jew. I am willing to put myself at risk so that eventually my extended family – that is, my people – will live; I don't mind if this is achieved directly or indirectly."(17).*

Another reporter notes:

> *But if everything so far has seemed philanthropic, pure and altruistic, we now arrive at the most controversial point about Matnat Chaim: the charity allows the donors to direct their donation to recipients of some specific kind. They can choose the sex of the recipient; they can choose their age; and they can choose their nationality. So far, all donors have made one condition: the recipient must be a Jew (22).*

What is more, the Israeli transplant community and its system of oversight have been collaborating to keep this sectarian trend alive, turning a blind eye to the fictitious nature of its ethical guise. Paulina Katz, a transplant coordinator in a major Tel Aviv hospital, says, "Those who donate through the National Transplant Center may not decide who will receive their kidney. The charity, which connects donor and recipient, is in fact a bypass. … They come to us as a couple, and we do not intervene in the matching process."(21).

Professor Eytan Mor, one of Israel's most senior transplant surgeons, adds, "Honestly, I avoid talking about this phenomenon in international conferences. I know we will be criticized."

Interestingly, it is not the sectarian-unethical nature of the practice that he seeks to hide from potential critics. Apparently, it is well hidden from him, too. Rather, he wishes to avoid accusations that "the donation reflects not free will, but rabbinical pressures" (17). Such pressures exist, so he seems to suggest, but they do not trouble him too much either.

A clarification

The trend in question is evidently sectarian. However, it is important to note that it is driven neither by religion, nor by any special needs of the population of Jewish patients. Rather, it is nationalist, as the following points indicate, and this makes it particularly disturbing.

First, while the *Halacha* – the Jewish orthodox law and jurisprudence – forbids deceased organ donation, it has no principled objection to living organ donation. Nor does it place any conditions, whether religious, national or other, on such

donation. It does not prohibit donation to a Gentile, then. Nor does it prioritise Jewish recipients.

Second, with respect to the disturbing trend in question, the recipients are Jews, but not necessarily orthodox or even religious.

Third, as far as living donations are concerned, the Jewish patients on the waiting list do not form an underprivileged group.

Finally, while the vast majority of donors consists of orthodox Jews, many of them happen to be ultra-nationalist West Bank settlers. The fact that many are "repenters"– people who embraced the religious faith only recently – may partially explain their susceptibility to rabbinical pressures to donate an organ. However, it does not explain their preference for donating an organ to a Jew and only to a Jew. Their nationalism does. This paper focuses on the problem with this particular motivation. Issues pertaining to the donors' vulnerability and the possibility of undue influence warrant a separate discussion.

What is wrong with conditional-nationalist donation?

The complicity of the Israeli transplant system with this conditional-nationalist trend is undisputedly unethical (masking it behind an ethical cloak makes things even worse). But is it also morally unjustifiable? Moreover, is the trend itself morally unjustifiable?

It is not easy to be sure about the answer. The charity could argue that notwithstanding its silent nationalist ideology, it is not directly exclusionist; thus it should not be perceived as offensive by those whom it does not serve, notably, the Israeli Palestinian population. The charity could even say to this population, "Look, we take care of our people. This is normal. Everybody does it. Why don't you do it too? In fact, we would be more than happy to share our experience with you and help you set up a similar charity for your own people." The charity could also argue that, in fact, it benefits the Palestinians as well. By removing Jewish patients from the waiting list, it effectively shortens it. Regardless of the points made earlier, the donors, the charity and the complicit transplant system could argue that they all save lives, and saving life overrides any objection one may raise.

These arguments may sound convincing. The question is whether they are relevant. I wish to argue in brief that they are not, given the current Israeli political and medical contexts.

Israeli Palestinians, who number more than 1.7 million and constitute about 20% of the total population, are effectively treated and certainly feel that they are treated as second-class citizens. Israel fosters these feelings. For example, it explicitly regards itself as a Jewish state, not a state of and for all its citizens. It discriminates against the Israeli Palestinians in the matters of public funding, social integration, economic status and mobility. It hardly ever allows them to unite with their non-Israeli family, unless they are willing to emigrate. Kibbutzim would not accept Palestinian members. A policy of Jewification of areas densely populated by Palestinian citizens has been followed for decades. Senior politicians and others are calling for the transfer of the Palestinian population or parts of it. Attempts to ostracise Palestinian MPs are also increasing. Even the mere idea of a coalition government with their parties is deemed national betrayal. During the last general elections, the Israeli Prime Minister warned the Jewish voters, "The Arabs are moving in droves to the polling stations."(23) This deeply disturbing bias is all-pervasive. It affects the Israeli healthcare system as well. It has recently been reported that some hospitals separate Jewish and Palestinian women in maternity wards upon the request of the former (24). Many regard what is currently going on in Israel as some form of apartheid. Recently, the Israeli army's deputy chief of staff suggested a parallel between present-day Israel and the Germany of the 1930s (25). The continuing occupation in the West Bank and the siege on the Gaza Strip, which affect millions of non-Israeli Palestinians, are another matter.

Against this backdrop, a Jewish-sectarian donor–recipient matching programme cannot be perceived as anything but a segregationist, exclusionist enterprise. The Israeli transplant system's pseudo-ethical complicity with the programme thus becomes particularly disturbing. Instead of bringing peoples together, the imperative of the hour, this complicity helps to tear them apart. While saving the lives of the few, it mirrors the murky political stream that threatens the lives of the many. If only for these reasons, it is necessary to bring an end to this complicity.

What is to be done?

In our troubled world, the risk of altruistic individual-to-individual LURD concealing sectarian (and, of course, commercial) donations is likely to rise. Perhaps it may not be avoided completely. However, the international transplant community can reduce it significantly by embracing the default fictitious-but-realistic assumption that something is bound to be wrong with unrelated donations that are directed to recipients identified through the Internet (eg matchingdonors.com), or through third-party organisations (eg *Matnat Chaim*). The system must reject such offers without exception, regardless of how convincing the explicit motives of the donor may sound and irrespective of how close the donor–recipient relationship may seem.

Conclusion

With all respect to patients on waiting lists and their caring doctors, some forms of kidney donation are utterly unacceptable: "donations" from vendors, "donations" from executed prisoners, and also conditional-divisive donations. The Israeli nationalist trend and the complicity of the local and other systems therewith must stop at once. Israel has done a lot in recent years to combat organ trafficking and transplant tourism, phenomena that were once pervasive in the country. It does not need another scandal to undermine its commendable achievements. Nor does its deeply divided

society need it. Nor do Jews worldwide need it. Sectarianism and exclusion have caused them enough suffering.

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Use of pellet guns for crowd control in Kashmir: How lethal is "non-lethal"?

SIDDARTH DAVID

Abstract

The use of pellet guns during the recent unrest in Kashmir as a method of crowd control has been questioned because of several deaths and numerous injuries. Across the world, these rubber pellets have been shown to inflict serious injuries, permanent disability, and death. The volatility of mob violence, inaccuracies in aim of the pellets, over-use of the pellet guns, and the perception of their harmlessness enhances the destructive potential of these so-called non-lethal weapons. There is also the larger ethical question whether any form of pain, however minimal, could be inflicted to control violent crowds.

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Nearly 90 days, 80 deaths and more than 10,000 injuries later, the protests and mob violence accompanied by paramilitary and police action to control them continue in the Kashmir Valley in India (1,2). The unrest that began in July 2016 over

the killing of a local insurgent leader by the security forces has brought to the fore the use of pellet guns to disperse the protestors. The use of pellet guns to control the crowds has left nearly 1000 people injured (3). Considered a "less-lethal" or "non-lethal" weapon, rubber or plastic-coated non-live rounds are used across the world to manage agitating mobs with the intention of causing no severe injury or death (4, 5). However, studies across the world (4–7), including from Kashmir (8, 9), have repeatedly shown that the use of these "non-lethal" weapons often leads to serious injuries, permanent disability, and death.

First used in response to the civil unrest in Northern Ireland in the 1970s, such "non-lethal" weapons have been documented to cause injuries and death (10). In India, the paramilitary forces first used pellet guns during mob demonstrations in 2010 in Kashmir, which resulted in the death of 120 people; since then these guns have been used for crowd control in Kashmir (11).

The "non-lethal" guns are reported to be shot guns of 12-gauge pump action, which are primarily used in hunting with a wide range of pellet sizes and numbers (12). The smaller the size of the pellet, the larger the number of pellets in one cartridge; so a No.1 cartridge has a fewer number of bigger size pellets while a No.12 cartridge has a larger number of smaller size pellets (12). In the current protests in Kashmir, mostly cartridges No. 6 (300 pellets of 2.79 mm each) and No. 9 (600 pellets of 2.30 mm each) were used (12). For both these very small size pellets, what matters is the distance from which the pellet guns are fired. Usually, they have a range of around 45 metres and hence stipulated to be shot only from a distance beyond 50 metres (12,13). If used at closer ranges, the pellets do not have enough time to disperse and travel in a compact group which move at very high velocities, making them extremely harmful, almost behaving like hand gun bullets, enough to penetrate deep and cause severe damage to bone and tissue (12,14).

Apart from keeping a firing distance of more than 50 metres, instructions for using the pellet guns in crowd control only under dire circumstances include aiming for the lower body parts, thus causing minimum injury. These conditions have been outlined in the United Nations' "Basic Principles on the Use of Force and Firearms by Law Enforcement Officials" and India's own laws on crowd control (15,16). But reports have repeatedly shown that these conditions are often impossible to follow given the stressful situations under which crowds have to be managed (5,17). Moreover, studies have indicated that even beyond the distance of 50 metres the pellets may disperse haphazardly and hit at other parts of the body, even if aimed at the legs (4,18). This wayward behaviour of pellets combined with improper aim and range of use is responsible for severe injuries and death from these non-lethal weapons.

Clinical studies on survivors and victims of pellet gun injuries in Kashmir show that only one-third of the injury sites were the lower limbs, the remaining affected other parts of the body with more than one-fourth hitting the head region (8, 9,19). A study of ocular pellet gun injuries in Kashmir showed that one-third of the survivors permanently lost their eyesight (20). This is consistent with other studies from around the world (5–7). Additionally, often bystanders and those observing from their homes also get hit by the pellets (11). The outcomes of these injuries documented in the literature are amputations, permanent disability or loss of life. Apart from physiological and psychological damage, the costs for treatment, disability costs and loss of livelihoods pose a life-long economic burden on the survivors. Thus, far from being a benign non-lethal weapon, pellet guns have far-reaching human costs.

Various human rights groups including Amnesty International have repeatedly condemned the use of pellets by the security forces and have asked for a ban on their use (21–23). The response from the government has ranged from promises to set up a panel to consider alternatives instead of pellets to claiming it a "necessary evil" for crowd control (24,25). The response by the security forces to a petition filed in the Jammu and Kashmir High Court by lawyers to ban the use of pellets was that such a ban would push the use of guns for crowd control leading to more deaths (26). The court ultimately ruled that the use of pellets cannot be banned as it felt that the use of force was necessary to tackle unruly crowds and it was up to the police and security forces to decide what kind of force was to be used (27). Thus, the courts perpetuated the discourse that use of force was legitimate in dealing with mobs and moreover, it was the discretion of the security forces to decide on the nature of the force. Rather than restraining the mobs, the mortality and morbidity caused by pellet guns have further propelled more people out on the streets, thus questioning the tactical policy of using pellet guns.

Many law enforcement agencies and paramilitary bodies believe that options such as pellet guns reduce the likelihood of use of more deadly force that would put the protestors at greater risk (28). But a study on police officers from Australia shows that the use of non-lethal weapons is often employed to reduce the level of risk to which the police officers themselves are exposed than to reduce the level of risk faced by the protestors (29). It is also pointed out that the use of "non-lethal" weapons would be much more indiscriminate without exploring other strategies to control the mob that require no force at all because these weapons are considered less harmful (28,30). In other words, access to "non-lethal" weapons seems to encourage their use in situations where they are not required. This point is underscored by the fact that nearly 1.3 million pellets were used by the paramilitary forces in just a month in Kashmir (31). Additionally, in the Indian context, such pellet guns have been used only in mob protests in Kashmir and Manipur, which have active insurgencies (11), but not to control recent violent mob agitations in other parts of the country such as Gujarat and Haryana. This raises the questions whether the disproportionate use of force was an extension of counter-insurgency operations and whether there is lack of political will to address the reasons behind crowd agitations (11, 32).

The use of non-lethal weapons only in self-defence and to protect life is contrary to the UN principles and India's own

police laws. Evidence suggests that the self-defence argument is not always valid because there is a wide scope of incorrect use and even misuse. There the larger ethical dilemma concerning the use of non-lethal weapons: is inflicting some form of pain necessary to deter a person from indulging in violent rampages? Can unruly crowds be effectively controlled only through the use of force? Even the most commonly used crowd control mechanism globally, ie tear gas, is under scrutiny given the range of health issues it causes (33). Moreover, the Chemical Weapons Convention which was adopted in 1997 and to which India is a signatory bans the use of any form of chemical agent (34–35), yet tear gas is still used across the country to manage crowds.

While there is a need to develop strategies to address and manage agitating and violent mobs with minimum force, there are few non-lethal weapons that can do this without inflicting injuries. Not many weapons can cause effects that are temporary and reversible without any medical intervention, yet unpleasant enough to ensure crowd compliance; certainly not pellet guns. The fact that volatile conditions, inaccuracies in the aim of the pellets, over-use of the pellet guns and the perception of their harmlessness exacerbate the damaging effects of these guns. There is an urgent need to debate the use of non-lethal weapons especially pellet guns in crowd management. Highlighting their lethal effects and the counter-effect of fuelling more protests need to be considered to advocate for change in policy on their use. The fig-leaf of "necessary evil" or "protecting national interests" cannot be used to cover up the overwhelming evidence that pellet guns can seriously injure and kill. Public discourse is required on what would be ideal and less-harmful methods to control crowds as well as on how harmless should non-lethal be.

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DISCUSSION

Should a medical ethics journal discuss the actions of the security forces?

RAVINDRA B GHOOI

This refers to the comment "Use of pellet guns for crowd control in Kashmir: How lethal is 'non-lethal'?" by Siddarth David in the *Indian Journal of Medical Ethics* (1). My objection is not to the ethics of the use of pellet guns, but to the ethics of publishing such an article in a journal devoted to medical ethics.

Every coin has two faces, and every story two sides. When one discusses the violence in Kashmir following the gunning down of the self-proclaimed terrorist Burhan Wani, two versions emerge, one in favour of the protesting population and the other in favour of the security forces. Pellet guns did cause much pain and agony to the victims, this is not denied; but whether the security forces had an option needs to be discussed from an ethical point of view.

Gangs of protestors put women and children in front and threw stones, grenades and other lethal missiles at the security forces. This was a unique situation where mobs tried to set fire to bunkers, injure other citizens and the armed forces, and kill the men in uniform by various methods. It is true that stray pellets hit some people but major injuries were caused near the bunkers of the security forces. So what could our armed men have done? These men are soldiers by training, and not ethicists and armchair philosophers.

The sovereignty of the nation is supreme, and anyone who challenges it will face the forces meant to protect the same. The army, Border Security Force (BSF), and police have no personal grudge against the protestors, but they are mandated to protect the nation and they do so with whatever means they have at their command. Soldiers are not supposed to question authority. When ordered to go into the valley of death, they have gone forth, without a thought for their own lives.

As an Indian, I would certainly question terrorists like Wani and separatists like Geelani. Do they represent the will of the people? These separatists have never won an election, hence their popularity is questionable. Even a victory in elections is meaningless, since the electorate is carefully manipulated. One community in Kashmir has been harassed and chased out of their homes, systematically, over the last 25 years. The electorate now is only made up of people whose sympathies lie in one direction.

The author states that various NGOs (including Amnesty International) have condemned the use of pellet guns; but have these organisations condemned the actions of terrorists

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and separatists? To be fair to the author, he concedes that the Jammu and Kashmir High Court refused to ban the use of pellet guns. So who is right, Amnesty International or the Jammu and Kashmir High Court? In most cases the rule of law is above all, but when it contradicts a particular belief then the courts are under fire.

The *IJME* is meant to discuss issues related to medical ethics; defence of the country's sovereignty, counter-insurgency and the effects of the same should not feature on this platform. It is unethical to raise questions on the actions of the security forces, knowing full well that no one among them can respond. Let us leave it to the newspapers and television channels to debate such issues; let us discuss only what we understand.

Conflict of interest statement

The author owns up to a conflict of interest. His son has been fighting anti-national forces for the last 12 years as an officer of the Indian Army.

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A question of ethics, not nationalism: author's response

SIDDARTH DAVID

The aim of the comment "Use of pellet guns for crowd control in Kashmir: How lethal is 'non-lethal'?"(1) was neither to disparage the armed forces, nor recommend counter-insurgency strategies, nor support any particular community or group. It sought to raise discussions around the question pointed out by the responder (2) himself, namely, "the ethical point of view" on the use of pellet guns in controlling violent mobs. The author also feels that the question is not so much about "favouring" the protestors or the security forces, but whether an instrument that causes significant fatalities and morbidities among bystanders should continue to be used as a method of crowd control.

Additionally, the author accepts that the conflict in Kashmir involves complex political dimensions, tragic human costs on all sides, and multiple ethical issues that need to be addressed; but concedes that this is a subject too vast to be addressed in a 1200-word commentary. The use of pellet guns would surely be one of several ethical aspects of this conflict and no one ethical consideration takes precedence over the other.

While the author is not a spokesperson for Amnesty International, human-rights groups have condemned violence perpetrated by any group. Raising questions on judgments by the judiciary is a part of democracy, and the author feels that he, as an Indian, is entitled to do it.

Finally, the author believes that ethical questions can be raised by any person be it a protestor, security personnel, academician, scientist, farmer and even a doctor, as ethics deals with principles of right and wrong. Hence, the author (whose grandfather was a decorated lieutenant commander in the Indian Navy) feels that having or not having a family member in the armed forces is not a test, or a conflict of interest, while talking about ethical issues. And it is surely not a badge of nationalism.

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STUDENTS' CORNER

Bias in medicine in the context of the film *Aligarh*

AISWARYA SASI

In today's world, I feel another sin needs to be added to the list of the seven deadly sins, viz the sin of intolerance. We hear this term on the news every other day and see society display this attitude more often than not. While the movie *Aligarh* raised myriad social issues, as a medical student, I would like to speak of one in particular– the influence of stigma on healthcare.

On the occasion of the cultural and medical festival, *Inquisitio* 2016, held at St John's Medical College, Bengaluru, the Health and Humanities Department had organised a screening of the 2015–16 film, *Aligarh*, in the presence of the story writer, Ishani Banerjee. The audience consisted of medical students at various stages of their course, students from other college, and faculty members from the medical college and the research institute. The discussion that succeeded the film provided a lot of food for thought.

Aligarh is an Indian biographical film directed by Hansal Mehta. Set in the city of Aligarh, Uttar Pradesh, this movie depicts the unjust events that transpired in the life of the award-winning Shrinivas Ramachandra Siras, a Professor of Marathi at Aligarh Muslim University. The story begins with Professor Siras, Reader and Chair of Modern Indian Languages, being sacked as a direct consequence of his sexual orientation. The remainder of the film portrays the myriad difficulties that plague him, a long-drawn-out court case and the various instances of stigma with which he is faced (1).

One part of the film shows that as the court case against his dismissal from Aligarh Muslim University is underway, Siras is at the receiving end of a lot of negative media attention. Society at large ostracises him and treats him like a criminal because "homosexuality is a sin". This is illustrated by a scene in which Siras is extremely fatigued, waiting for a doctor to see him in a clinic nearby. He waits for hours, but his turn never comes and he is rudely sent away. At this point, I thought to myself "How does this make you feel as a future entrant into the medical field?" Frankly, I was disgusted and angered all at once. Has the Hippocratic Oath lost its meaning? I see no connection whatsoever between a person's sexuality and his need for medical care. Not only sexuality, but also factors such as caste, religion, skin colour and language, and all the other ways in which human beings differ from one another should have no bearing on the delivery of adequate medical treatment. Do men who are sexually attracted to men or women who are sexually attracted to women carry a different, infectious form of, say, hypertension? Is there some distortion in their very anatomy and physiology that makes them unworthy of medical attention? I think bias in medical care is irrational and completely unpardonable. The plight of the doctorless patient is unimaginable. I fail to see the point in studying for close to a decade and acquiring oceans of knowledge if you are going to refuse to apply that knowledge to serve people who require it the most.

Another point I would like to bring up relates to the bias and stigma that doctors create unknowingly. At one point, Mr Siras says, "This generation likes to stick labels on everything possible." I could not agree more with this statement. Diagnostic labels used by healthcare professionals to classify individuals for treatment and research purposes have become a huge source of concern, despite their clear benefits. According to a research paper, the stigma associated with labels such as "dementia", "depression", "mild cognitive impairment" and so on can have a negative impact not only on the labelled individual's mindset and optimism, but also on their interpersonal relationships and the way society perceives them (2). Diagnostic labels allow clinicians to assume that all members of a group are homogeneous in terms of the underlying nature of the illness, regardless of whether there is some variability in the presentation of symptoms or the circumstances surrounding the onset of the illness. (This is similar to the way the whole of society urged Mr Siras to embrace the title of a "gay" man.) Research in the area of psychiatric illness suggests that individuals may choose not to seek professional help as a means of protecting themselves from embarrassment and feelings of inferiority or incompetence (2). In situations like these, the doctor might actually worsen the person's condition rather than treating it. I cannot think of anything more counterproductive.

Taking the ethically holier-than-thou view is, however, easier in theory than practice. The primary dilemma here is that at the end of it all, doctors are human too. Human beings tend to live in a bubble of their own, constructed intricately out of moral codes and core value systems. When human beings chance upon other human beings who may not adhere to these codes,

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the seeds of intolerance are sown. I think the only solution is for us to recognise that different people have their own definitions of what is right, and live in their own little bubbles. It is okay to have your own bubble and apply its principles to your own life, but what is not acceptable is to try and drag other people and their personal lives into your bubble. As Mr Grover, the lawyer who fights Siras's case in the film, says, "If people were punished according to each person's definition of 'immoral', we'd all be penalised, because in some way, we're always violating somebody's concept of morality. Morality in itself is a fluid, volatile concept."

Let us think of the case of a man with a stick. He is allowed to hold on to his stick for as long as he wants. But the moment he uses that stick to beat up other people, he commits a crime. Here, the stick symbolises the man's personal beliefs. Doctors should realise that when they refuse to treat a patient with no rational basis for this refusal, they impinge upon the patient's right to healthcare, which is a basic constitutional right.

In the context of *Aligarh*, I really do not see how something as beautiful as love can be the basis of such deplorable bias. People should realise that one's sexuality doesn't define everything about oneself. "Live and let live" is a motto that everyone should implement in their day-to-day lives.

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LETTERS

"Trust the researchers": flying in the face of evidence

There are always rival hypotheses to explain away the one that is posited as the most likely to be true. Context and Occam's razor – the principle that among competing hypotheses, the one with the fewest assumptions should be selected – ultimately point to which hypothesis is the most likely to be true.

Ian Harris (1) shows his hand when suggesting that Mark Wilson (2) is invoking a "conspiracy theory" to explain the relationship between the editorial and financial staff at the *NEJM*. Organisations usually have a culture that blends their production and financial staff. The CEO is attentive to inputs received from all staff, especially those responsible for keeping track of money. It is far-fetched to suggest that the interactions between a journal editor and the editorial and financial staff when reaching decisions point to some kind of "conspiracy". Occam's razor abhors complicated explanations when the simplest explanation will suffice. Conspiracy theory, indeed!

That said, Ian Harris reveals his bias when he says, "I do not think that the role of journals is to check the data supplied by authors. They may be sceptical in some cases, but at the end of the day, they have to trust the authors; it is not possible for them to check the data contained within each article. We all have to trust the researchers."

"Trust the researchers" . . . now that is fantastical thinking in the face of the avalanche of evidence which demonstrates that researchers are less than trustworthy (3). There is also evidence to suggest that some journal editors provide cover for authors who manipulate their results and report biased findings (4).

Besides, empirical science demands replicability, and how would one be able to replicate without fully knowing the nitty-gritty of the methods and procedures that produce the data on which "findings" are based?

"Trust but verify", the now famous reminder of former US President Ronald Reagan to Mikhail Gorbachev in December 1987 after signing the Intermediate-Range Nuclear Forces Treaty, is a better guide to evaluating researchers' claims.

Journals proceed at their own risk if they rely on the trustworthiness of the authors. Why bother to subject a manuscript to peer review instead of simply asking the author to certify "trustworthiness" in some way or the other? Perhaps one could go by an honest face and earnest gaze. To rely on the trustworthiness of an author is a fool's errand, considering the repeated revelations that pharmaceutical companies routinely write reports and recruit high-status academic leaders to lend their signatures to these reports (5).

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Is MCI over emphasising publication for promotion of medical teachers?

Over the past year, there has been constant debate in various journals on the circular issued by the Medical Council of India (MCI) in September 2015, regarding the requirements for promotion of teaching faculty. The lack of a time-bound promotion system of medical faculty results in higher stress, dissatisfaction, lower productivity and quality of life and work. The critics have highlighted several issues in assessment of publication for teacher's promotion, eg the exclusion of publications in "electronic-only" journals, awarding points only to "original research" papers and first or second authors, listing of indexing databases for journals, categorising journals as national or international (1, 2). The relevance of a journal's impact factor as a measure for assessment of publication has also been appraised (1). Thereafter, the Indian Association of Medical Editors has recommended revised guidelines which include a revised list of indexing databases, types of papers and authorship as criteria for assessment of publications (2). Recently, serious issues in research infrastructure and funding and lack of uniformity in medical education in the country have been reported. About 57.3% medical colleges did not have a single publication in the decade 2005-2014, whereas only 4.3% institutes have published 40.3% of the total publications (3). Despite a scarcity of research publications, India has been ranked highest for the rate of research misconduct globally (4). Surprisingly, even scientists at the premier institutes in the country have been implicated in such activities (4). Mandatory publication for promotion may give rise to more plagiarism, unethical research reporting practices, authorship controversies and burn out of researchers. Further, publication as the only accountable incentive for teachers may take them away from academic and clinical duties. Teaching

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and clinical skills were given the highest weightage for promotion of medical teachers in the US and Canada (5).

There is a need for more comprehensive assessment for teaching faculty in terms of teaching activities, clinical skills, research, mentoring and role-modeling; and social reputation and extracurricular qualities. Such assessment may be done by including teaching awards, student and peer feedback, number of publications and citations in indexed journals, grants awarded for projects, number of presentations at national and international meetings, invited papers, chair sessions, membership in organising committees of meeting and conferences, and of institute committees and professional associations, and participation in faculty exchange programmes, etc. Some similar steps have already been taken by the University Grants Commission by framing an objective scoring "Academic Performance Indicator (API)" for promotion of teachers. In addition to the recommendations made by Aggarwal and colleagues (2015)(2), we suggest the inclusion of number of citations in indexed journals in their guidelines. Further, we suggest that MCI should develop a multipronged objective assessment guideline for a comprehensive assessment of clinical-academic-research abilities of medical teachers; rather than over-emphasising research publication. This may be cumbersome but is essential for bringing productivity and uniformity into the medical education system of our country.

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I, …Sanjay S Nagral… hereby declare that the particulars given above are true to the best of my knowledge and belief.

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