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CHRISTOPHER HODGES

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COVID-19 VACCINES:
INJURY COMPENSATION ISSUES

Professor Dr Christopher Hodges[1]

Summary

This analysis summarises the particular injury compensation arrangements that are needed to support adequate take-up of vaccines for Covid-19 and the compensation of those who are unlucky enough to suffer harm arising out of their use. It indicates the inadequacies of the standard liability rules and arrangements, and the advantages of compensation schemes. It notes the widespread use of vaccine compensation schemes but also differences in their design and evolution, before summarising the state of the art on the design of such a scheme for Europeans and on how it may be funded.

The Background

Vaccines are essential to protect humanity against more than 25 debilitating or life-threatening diseases, including measles, polio, tetanus, diphtheria, meningitis, influenza, tetanus, typhoid and cervical cancer.[2] Vaccines are generally extremely safe.[3] As at 2017, more than 30,000 vaccine doses were delivered per second globally, preventing an estimated 2 million to 3 million deaths a year,[4] with a rate of a serious adverse event of less than 1 in 10 million doses for tetanus toxoid vaccines, 1-2 per 1 million doses for inactivated influenza vaccine, and none for hepatitis A.[5] As at 2020, WHO reported, for example, no serious adverse events with oral or parenteral typhoid vaccines, whilst anaphylaxis and some other conditions are associated with inactivated influenza vaccine.[6] Hesitancy and misinformation were viewed in 2019 as the largest threats to achieving vaccine safety.[7]

Ultimate protection of humanity from a pandemic like Covid-19 depends (usually) on achieving herd immunity, from the development of antibodies in enough humans, either through natural exposure to the virus or from immunisation with a vaccine. Speed of development and then of production are essential. Around 180 possible Covid-19 vaccines are reported to be in development by academic and industry organisations.[8] Several different models are likely to be needed, for both medical and volume issues.

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[1] Professor of Justice Systems at Oxford University; Head of the Swiss Re Research Programme on Civil Justice Systems, Centre for Socio-Legal Studies, University of Oxford; Supernumerary Fellow of Wolfson College, Oxford; Fellow of the European Law Institute. Research funding is received from HM Government (various Departments and Authorities), the Swiss Reinsurance Company Limited, and the European Justice Forum.

[2] World Health Organisation, http://www.who.int/topics/vaccines/en/.

[3] SF Halabi, 'A Global Vaccine Injury Compensation Scheme' (2017) 317(5) *JAMA* 471.

[4] S Berkley, 'Global vaccine access as the critical intervention to fight infectious disease, antibiotic resistance, and poverty' in S Halabi, L Gostin and J Crowley (eds), *Global management of Infectious Disease After Ebola* (Oxford University Press, 2016).

[5] WHO vaccine reaction rates information sheets, World Health Organisation, 2016, cited by Halabi n 3 above.

[6] See vaccine reaction information sheets, at http://www.who.int/vaccine_safety/initiative/tools/vaccinfosheets/en/

[7] *Global Vaccine Safety. Blueprint 2.0. Background Research* (World Health Organisation, 2019).

[8] 'Moonshot' *The Economist*, July 4, 2020, 21.

Governments wish to arrange that both researchers and manufacturers make themselves available to design, develop, test, manufacture and distribute an adequate supply of vaccines as swiftly as possible. Yet existing regulatory and liability rules and systems present barriers.

Use of all medicinal products carries risk. Since the Thalidomide tragedy of the early 1960s, regulatory regimes have been imposed and refined to test the safety, efficacy and quality of products through a sequence of toxicological studies and human trials [9] The normal arrangements typically take around 12 years and cost US $1 billion or more.[10] They are then followed by increasingly closely monitored post-marketing vigilance systems lasting the lifetime of the product. But the speed that is necessary in the development and use of Covid-19 vaccines means that they must be tested for effectiveness very quickly and then used immediately and widely. Thus, UK MHRA recently approved a clinical trial in 7 days rather than the normal 60.[11]

Inapplicability of Standard Liability Regimes

Despite full care having been taken in the design and production of *any* vaccine, and observance of all regulatory requirements, it is well recognised that some patients may suffer harm from use of a vaccine. The standard response is to provide compensation arrangements for those to whom harm is caused, but the arrangements for vaccines differ from standard compensation regimes for 'normal' products. This note aims to explain the background to these situations, and how compensation arrangements for Covid-19 vaccines might be designed. The analysis has the advantage of drawing on the findings of extensive research into redress schemes for personal injuries across the world.[12]

One theoretical rationale for liability law is as an *ex post* regulatory mechanism, which forces a manufacturer to factor into its pre-marketing decisions the cost of subsequent harm (theoretically caused by lack of care) in the form of the later costs of compensation claims.[13] That rationale has a number of serious drawbacks as a reliable theory,[14] and by empirical evidence,[15] but it is in any event clearly inapplicable to vaccines generally and certainly in the current situation. Researchers and manufacturers have almost no ability to assess or quantify the risk of unknown spontaneous vaccine injuries. Potential liability exposure will have no particular effect on decisions taken before marketing of vaccines.

There are various reasons why traditional compensation arrangements cannot be relied on. Individuals who are suffer injury caused by a vaccine could try to sue for damages through the courts, relying on liability law theories of negligence or strict product liability.[16] But they might face considerable difficulties in proof, in addition to 'normal' litigation problems of

[9] C Hodges, 'The Regulation of Medicines and Medical Devices' in J Laing and J McHale (eds), *Principles of Medical Law*, (Oxford University Press, 4ed, 2017).
[10] See recently OJ Wouters, M McKee and J Luyten, (2020-03-03). "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018" (2020) 323 (9) *JAMA* 844.
[11] 'Moonshot', *The Economist*, July 4, 2020, 21.
[12] S Macleod and C Hodges, *Redress Schemes for Personal Injuries* (Hart, 2017). See also C Hodges, 'Affecting Future Behaviour: Deterrence or an Open Culture that Learns and Improves' in Chapter in P Vines and A Akkermans (eds), *Unexpected Consequences of Compensation Law* (Hart Publishing, forthcoming 2020).
[13] AC Pigou, *The Economics of Welfare* (MacMillan, 1920) and many subsequent works.
[14] See C Hodges, *Law and Corporate Behaviour: Integrating Theories of Regulation, Enforcement, Culture and Ethics* (Hart Publishing, 2015).
[15] If they ever do on other products: see S Macleod and S Chakraborty, *Pharmaceutical and Medical Device Safety. A Study in Public and Private Regulation* (Hart, 2019).
[16] In Europe, harmonised under Directive 85/372/EC on product liability.

cost, complexity and delay. The theoretical advantage of bringing mass claims, if it exists,[17] would under most 'class action-type' rules face the barrier that individual issues of causation would still predominate (so either the procedure would not be available or it would still be lengthy).

Attempts to make the litigation process more efficient, less costly and swifter have gradually led to reforms in procedure and the use of alternative dispute resolution (ADR) techniques. In the case of personal injury claims, some countries have introduced specific ADR-inspired mechanisms in the shape of compensation schemes for injuries. It is striking that although some countries (such as New Zealand, all the Nordic states, France and Belgium) have introduced medical product injury schemes (typically as part of larger patient injury schemes), far more countries have introduced schemes specifically for vaccines. The reasons for the introduction of vaccine schemes have less to do with improving safety, or to provide more effective mechanisms than litigation, or for 'regulatory' reasons aimed at trying to affect the behaviour or researchers or manufacturers, and more to do with wider considerations of public health and social solidarity.

Rationale for Vaccine Compensation

The primary reason why many states with advanced economies have introduced vaccine damage schemes is to support public confidence in vaccination programmes in view of their importance to public health. The purpose of vaccination is to achieve two goals: herd immunity of the population and protection of individuals from the consequences of harm. The collective public health goal has major importance in response to a risky and new virus. Hence, governments often require citizens to be vaccinated, or aim at least to ensure that enough citizens achieve herd immunity. Thus, vaccination is done for the benefit of society as well of individual citizens, but in rare instances might dramatically adversely affect individuals. The policy of social solidarity, of individuals sharing risk for achievement of the common good, is notably strong here.

Given the need to achieve extensive immunization of the population from the occurrence of these rare but serious and wholly unpredictable events, the public policy argument for providing *in advance* a system of protection and care of the unlucky victims is clear. A state might legally require its citizens to be vaccinated, but it certainly wishes a large number of them to undergo vaccination, whether voluntarily or otherwise, so as to achieve herd immunity. The policy is to reassure citizens that everyone will be treated equally and taken care of if they turn out to be one of the very few who is unlucky. This is intended to support public confidence in undergoing vaccination.

Of course, the overriding objectives of the state should be to provide whatever care and support may be necessary. Countries that have free access to physical and mental healthcare and social care systems should be better placed to provide that response. But some countries fall back on the response that a legal system is capable of delivering, namely money, which a victim is enabled to spend on purchasing care (or not). It would be impressive if more countries were to focus on how (and whether) their systems deliver care and support instead of just money.

In addition to providing financial protection (compensation) for victims, a second reason for providing vaccine damage schemes is to protect the supply of vaccines. Manufacturers who produce vaccines are otherwise exposed to liability claims against them by victims of harm. The US Vaccine Scheme (VICP) was specifically introduced in 1988 after the volume of product liability claims against manufacturers of vaccines had massively increased in the

[17] See C Hodges and S Voet, *Delivering Collective Redress: New Technologies* (Hart, 2018).

1980s, resulting in huge price rises, a serious decline in immunization levels, evaporation in the manufacturers' ability to obtain insurance, and withdrawal of manufacturers from the market.[18] Only a single vaccine manufacturer remained in the market, and was likely to leave. The VICP gave protection to manufacturers through public funding of compensation payments, effectively therefore providing indemnity of manufacturers, in order to safeguard supply and confidence.

Models of Vaccine Compensation Schemes

A number of models exist for injury compensation schemes, which reflect evolution in the design of mechanisms. The initial schemes retained court-like characteristics whilst some have migrated to investigative designs. The investigative models have also enabled evolution in the criteria for making awards.

One of the first protective schemes was the US 1976 Swine Flu Vaccine Program,[19] which gave victims the choice of claiming in litigation or under an administrative scheme, in either case without the need to prove that the manufacturer was negligent. Its existence proved its worth when cases of Guillain-Barré syndrome appeared instead of swine flu.[20]

One option is for a scheme to mirror the litigation process, in which the victim has to make and prove a claim in a process that is adversarial, involving lawyers and a judge. An example is the US Vaccine Scheme (VICP). It operates like a court, with lawyers and judges. It is funded by a surcharge on all doses, collected from manufacturers and reflected in prices charged.[21] The process takes an average of 2-3 years. A claimant must use the VICP process before bringing a claim in court. In 2014, the US government enacted statutory immunity for manufacturers of Ebola vaccine in court claims.[22]

Another model is the UK Vaccine Damage Payment Scheme, introduced in 1979,[23] which is an administrative arrangement that provides a single one-off lump sum payment (currently £120,000) where a claimant is 'severely disabled (at least 60%) after taking a vaccine that is on a list. The success rate is, however, low, typically less than 10%.

In Nordic states, compensation for vaccine injury is included in a broader scheme for injuries caused by any medicinal product.[24] The medicine schemes in the Nordic states operate alongside (larger) schemes for compensation of patient injuries. The overall result is highly effective in providing compensation, support and confidence. Indeed, because the schemes are comprehensive, data from the schemes is collated and fed back to drive improvements in practice. These schemes use eligibility criteria that do not involve fault.

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[18] R Manning, 'Changing Rules in Tort Law and the Market for Childhood Vaccines' *Journal of Law and Economics* (1994) 37 (1) 247-75; R Manning, 'Is the insurance aspect of producer liability valued by consumers? Liability changes and childhood vaccine consumption' (1996) 13 *Journal of Risk and Uncertainty* 37-41.

[19] National Swine Flu Immunization Program of 1976,42 U.S.C. 5 247bG)-(1) (1976), available at http://www.gpo.gov/fdsys/pkg/STATUTE-90/pdf/STATUTE-90-Pg1113.pdf

[20] Macleod, 23, 381-384.

[21] Macleod, 23, 384-394.

[22] Ebola Vaccines were added to the Public Readiness and Emergency Preparation (PREP) Act, which provides US Government backed immunity under United States law against legal claims related to the manufacturing, testing, development, distribution, and administration of three vaccines for Ebola virus disease.

[23] Vaccine Damage Payments Act 1979. See Macleod 394-402.

[24] Macleod, chs 4-8.

Contemporary Design Features

Many vaccine compensation schemes were created around the 1980s and various improvements can now be suggested, based on experience and contemporary thinking in effective dispute resolution, including important recent developments in courts' use of online technology and significant transformation of consumer ADR systems in the past decade.[25] Some general principles can be stated.

First, compensation needs to be an appropriate level so as to give fair compensation (e.g. a cap such as that of the UK scheme is far too low for some cases). Indeed, second, in order to make schemes attractive and fair, it is advisable that they award the same level of damages as would courts, and that awards cover full compensation of victims' needs. Caps on total awards may be far too low in some cases. It would be useful if tariffs for compensation were developed that were universally applicable.

Third, schemes should be administrative (made under the social security system as in Germany or through an administrative scheme) rather than judicial and court-based. Fourth, it follows that they should be investigative rather than adversarial. These features deliver a process that is swift, user-friendly, efficient and cheap. Lawyers are unnecessary (the US VICP involves payment of significant costs to lawyers).

Fifth, governance requirements such as fairness, legality, independence, expertise and transparency should all be observed. Sixth, schemes should not deny citizens' access to courts (which is illegal in Europe[26]) but schemes can if necessary be prioritized to be used before litigation.

Seventh, there has been evolution away from either having to prove negligence or strict product liability to reliance on lists of medical criteria that are usually straightforward to apply (specific symptoms, and timing of occurrence after inoculation) and to establish acceptable evidence of causation. This design feature delivers notably efficient processes.

Funding

Interesting issues arise on who should pay for the compensation awards and the administration of the scheme. From the perspective of citizens, the risk of injury cannot be adequately predicted (as is usually the case with regulatory requirements on marketing only of safe products, and of availability of information of safe use and risk). Almost the entire populace is required to be vaccinated. Thus, there is no individual choice on whether to accept the product based on personal ability to assess risk, or to avoid the risk of possible harm. From the government and public health perspective, the overriding requirement is to maintain public confidence so that the acceptance of immunization is achieved as swiftly as possible.

From the perspective of manufacturers, arguments for protection from claims, through indemnification and/or creation of attractive compensation arrangements that will avoid their litigation risk, would be compelling. (The EU has just, ironically, agreed a new collective action procedure, which will affect liability risk and insurance even if, as suggested above, this type of claims will face difficulties individually or collectively.)

[25] C Hodges, I Benöhr and N Creutzfeldt-Banda, *Consumer ADR in Europe* (Hart Publishing, 2012); P Cortés (ed), *The New Regulatory Framework for Consumer Dispute Resolution* (Oxford University Press, 2017).

[26] European Convention on Human Rights, art 6; Charter of Fundamental Rights of the European Union, art 47.

The argument is further strengthened where it is not possible for vaccine companies (individually or collectively) to obtain commercial insurance so as to mitigate their commercial risk.[27] New technologies are being used for these vaccines for which there are no historical data points that could found reliable quantification of likely claims and sums payable.

Since immunization programs have an overriding societal purpose (or bundle of purposes), there is a strong rationale for funding of compensation to be from public funds, and for both researchers and manufacturers to be indemnified. This would be provided from general government funds (general taxation) or from a levy on sale of products (still involving public funds in many states). An additional factor that significantly strengthens the argument that funding should be solely from public funds is where the vaccine company makes the product available at cost price, as several have said they are planning.

Conclusions

Vaccines differ from many medicinal and other products and justify particular regulatory and compensation arrangements. The population has to be protected from risk both from the virus and potential vaccines. Public confidence arises from either assessible safety risk (which cannot be provided here) or from knowledge that the unquantifiable risk is shared by all. Hence, equal protection should be available to all. Equally, manufacturers have to be protected from legal risk. These considerations need particular legal arrangements.

A means of balancing these different considerations has emerged in the late 20th century that essentially involves collaboration between populations, researchers, producers and governments. Each contributes their own value, and risk is shared between them. This is particularly true where the commercial enterprises do not seek commercial reward (or the normal market level of reward) and accordingly bear all the risk. The mechanism has to operate swiftly and provide full compensation to citizens who are unlucky enough to be harmed through taking part in the collective enterprise in survival and defeating shared risk. Hence, administrative and investigative compensation mechanisms are required, since these are the most efficient and swift. The situation does not call for any adversarial culture or failure in fairness or solidarity.

There is a strong argument for provision of care and support, rather than just money. The opportunity can be taken to make some improvements can be made in some existing models. In fact, the response to the Covid-19 situation offers a significant opportunity to set a precedent for modernization of the compensation arrangements for all medicines and patient injury claims.

[27] Anecdotal evidence confirms that this appears to be the situation.