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Abstract

Ireland has been a leader in the COVID-19 vaccine rollout in the EU, with almost 80% of the eligible population (aged over 5 years) fully vaccinated at the time of writing. The success of the vaccine rollout in this jurisdiction notwithstanding, the legal frameworks supporting the rollout had significant lacunas. Two aspects in particular highlighted a lack of legal preparedness: the inadequacy of the legal framework for consent and the absence of a vaccine injury redress scheme. This paper explores these components of the COVID-19 vaccine rollout through the lens of legal preparedness. Whilst most often discussed in the context of command and control measures such as social distancing requirements and regional lockdowns, this paper argues for an expanded understanding of what it means to be legally prepared, highlighting the importance of the preparedness of domestic legal frameworks.

Keywords

COVID-19 – vaccines – legal preparedness – consent – redress – Ireland

1 Introduction

In March 2020, the World Health Organization (WHO) declared COVID-19 to be a global pandemic.¹ As at the time of writing, there are over 359 million cases of COVID-19 worldwide noted, and sadly, more than 5.62 million deaths from the disease recorded. Thus, the demand for a vaccine as a response to a global health challenge has never been more acute, and to-date, vaccination has largely been viewed as antidote to the pandemic.² There are currently a total of 334 candidate vaccines, with 140 in clinical development and 194 in pre-clinical development.³ A number of COVID-19 vaccines have been authorised for countries in the European Union (EU) by the European Medicines Agency (EMA) including two mRNA vaccines (Pfizer/BioNTech and Moderna (now Spikevax)) and two viral vector vaccines (AstraZeneca (now Vaxzevria) and Janssen).

In June 2020, the European Commission released the EU strategy for COVID-19 vaccines, setting out three core objectives: '1. Ensuring the quality, safety and efficacy of vaccines; 2. Securing timely access to vaccines for Member States and their population while leading the global solidarity effort; and 3. Ensuring equitable access for all in the EU to an affordable vaccine as early as possible.'⁴ Although the EU vaccine rollout began in late December 2020. It proceeded more slowly when compared with the United States and the United Kingdom due to availability of supply. Over time, it gained momentum and at the time of writing, 69.7% of the total EU/EEA population has been fully

1 World Health Organization, *WHO Director-General's Opening Remarks at the Media Briefing on COVID-19* (11 March 2020), available online at www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-COVID-19-11-march-2020 (last accessed 20 January 2022).

2 D. Calina, T. Hartung, A. Oana Docea, D.A. Spandidos, A.M. Egorov, M.I. Shtilman, F. Carvalho and A. Tsatsakis, 'COVID-19 Vaccines: Ethical Framework Concerning Human Challenge Studies', *Journal of Pharmaceutical Sciences* 28(2) (2020) 807–812.

3 World Health Organization, *COVID-19 Tracker and Landscape*, available online at www.who.int/publications/m/item/draft-landscape-of-COVID-19-candidate-vaccines (accessed 26 January 2022).

4 European Commission, EU Strategy for COVID-19 Vaccines COM (2020) 245 final, 2.

vaccinated.⁵ However, there has been a marked variation in uptake across the EU, ranging from 83% of the total population of Portugal being fully vaccinated to less than 30% of the total population of Bulgaria.⁶ Ireland has been at the forefront of high vaccination take-up, with 94.5% of the adult population and 77.8% of the total population having been fully vaccinated.⁷

Despite the success of the vaccine rollout, the legal framework supporting the rollout in Ireland was far from ideal. Two elements in particular indicated a lack of legal preparedness: the absence of a clear legal framework for consent and the lack of an appropriate vaccine redress scheme. These two issues form the basis for this case study in domestic legal preparedness. Whilst public health legal preparedness is often discussed in the context of disease surveillance and mitigation measures, such as quarantine and lockdown measures, the Irish example is a useful indicator of the need for a broader understanding of the term 'legal preparedness'. This reflects the point made by Graeme and Hunter that '[l]ack of clarity of law, or lack of clarity about legal rights and responsibilities, can seriously hinder or impede effective responses to public health emergencies.'⁸ The first part of the article discusses the concept of legal preparedness and the case for including an evaluation of a wider range of elements within domestic regimes. The rest of the article focuses on the Irish example. It begins by providing necessary background context, providing an overview of the rollout of the COVID-19 vaccination programme in Ireland, before examining in more detail issues of consent and capacity and thereafter the matter of redress arising from vaccine injury.

2 Legal Preparedness: What Does It Mean to Be Prepared?

Questions of legal preparedness in respect of vaccination need to be situated within broader academic debates concerning public health legal preparedness. Moulton et al. define public health legal preparedness as the 'attainment by a public health system ... of legal benchmarks essential to the preparedness

5 See <https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab> (last accessed 25 January 2022).

6 See <https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab> (last accessed 25 January 2022).

7 See <https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab> (last accessed 25 January 2022).

8 G.T. Laurie and K.G. Hunter, 'Mapping, assessing and improving legal preparedness for pandemic flu in the United Kingdom', *Medical Law International* 10 (2009) 101–137, p. 102.

of the public health system.⁹ This term recognises the crucial role law plays in public health.¹⁰ As Murphy and Whitty explain: ‘this is all about having the right laws in place and then using them in the right way in a time of public health emergency.’¹¹ Legal preparedness is important because, as Laurie and Hunter explain:

[L]aw is merely a social tool, but it is a tool of considerable import. This is never truer than when society, its fabric, foundations and core values are under threat. Public health crises represent such a threat and at such times the role of law becomes crucial in maintaining the delicate balance between order and chaos, between public and private interests, and between promotion of the common good and protection of civil liberties.¹²

A number of core elements of preparedness have been identified in the literature. For Moulton et al. there are four core components to public health legal preparedness: 1. Laws or legal authorities: required to confer necessary powers on government and public health officials; 2. Competency: the people involved in the administration of public health and other professionals should have the ability to understand the law(s) and apply them effectively; 3. Co-ordination: legally based interventions should be co-ordinated across jurisdictions; and 4. Information: recognising the importance of the sharing of information about public health laws and best practices.¹³

These views of public health legal preparedness operate largely at an international level, and the issue of preparedness is most often discussed in the context of public health emergencies. However, where the discourse is focused on emergencies, insufficient attention is paid to legal preparedness in a broader sense. As Bernstein observes, ‘[f]or public health legal preparedness to be viable outside the context of emergency legal preparedness, the public health law community must develop practical tools to aid in the establishment of legal benchmarks in all areas of public health law practice.’¹⁴

9 A. Moulton, R.N. Gottfried, R.A. Goodman, A.M. Murphy and R.D. Rawson, ‘What is public health legal preparedness?’, *Journal of Law, Medicine, and Ethics* 31(4) (2003) 672–683.

10 *Ibid.*, at 674.

11 T. Murphy and N. Whitty, ‘Is human rights prepared? Risk, rights and public health emergencies’, *Medical Law Review* 17(2) (2009) 219–244, p. 220.

12 Laurie and Hunter, *supra* note 8.

13 Moulton et al., *supra* note 9.

14 J.A. Bernstein, ‘Beyond public health emergency legal preparedness: Rethinking best practices’, *Journal of Law, Medicine & Ethics* 41(Suppl. 1) (2013) 13–16, p. 14.

Whilst high-level thinking on public health legal preparedness is important, this paper argues that detailed consideration and analysis of the preparedness of domestic legal frameworks is also required. As Murphy and Whitty have argued, if the right laws must be in place at a time of emergency, governments should give due consideration to improving legal preparedness at a domestic level *before* they are faced with a public health crisis. Making decisions under time constraints to implement appropriate frameworks in a time of emergency is risky. Ireland was fortunate because its lack of legal preparedness did not substantially impede the vaccine rollout. However, the Irish experience is a useful indicator of why a more holistic understanding, incorporating aspects of domestic health law, of what it means to be legally prepared is required.

3 COVID-19 Vaccination Rollout in Ireland

As the potentially devastating impact of COVID-19 became apparent, the Irish government established the National Public Health Emergency Team (NPHEM), to deal with the outbreak. NPHEM was chaired by the Chief Medical Officer (CMO) (the most senior Government advisor on health-related matters) and included members from across the public health sector. In early June 2020, NPHEM recommended the establishment of a COVID-19 Immunisation Strategy Group to work alongside the National Immunisation Advisory Committee (NIAC),¹⁵ in order to categorise priority groups for vaccination.¹⁶ In November 2020, this Group presented its interim recommendations, based on the objective of ensuring 'equitable access to a safe and effective vaccine with the goals of limiting mortality and morbidity from COVID-19, protecting healthcare capacity and enabling social and economic activity.'¹⁷ Priority groups were identified 'according to the current and evolving understanding of the clinical, microbiological and epidemiological profile of COVID-19 internationally and in Ireland, with a focus on those at greatest risk from COVID-19.'¹⁸ A four-phase approach to the rollout of the vaccine was recommended, from highest to

15 NIAC is an independent expert advisory group established in 1998 which advises the CMO and the Department of Health on vaccines, immunisation, and related health matters to inform policies.

16 National Public Health Emergency Team (NPHEM), *Meeting Minutes* (18 June 2020), available online at <https://www.gov.ie/en/collection/691330-national-public-health-emergency-team-COVID-19-coronavirus/> (accessed 26 October 2021).

17 *Priority-groups-SARS-CoV-2-vaccine-021120-.pdf* (accessed 26 October 2021).

18 *Ibid.*

lowest priority.¹⁹ The criteria for prioritisation included: the risk of acquiring the disease; the risk of severe disease and death; the risk of a negative impact on society; and the risk of transmitting infection to others. This preparatory phase also included the introduction of legislation expanding the category of professionals authorised to administer the vaccine.²⁰

The vaccine rollout began in late December 2020 with frontline health professionals. This was quickly followed by the vaccination of residents in nursing homes. Initial progress was slow due to difficulty in accessing sufficient supply. In March 2021, the four-phase vaccination prioritisation was replaced (not without controversy) with a simpler, age-based model.²¹ In July 2021, vaccination of young people aged 16 years and over began to be followed by vaccination of children between 12–15 years beginning in September 2021 and children aged between 5 and 11 year commencing in late December 2021.

4 Consent and Capacity

Although there has been a move towards mandatory vaccination in some EU countries, including Austria and Italy, and towards mandatory vaccination of health workers in some others,²² there has been little political appetite for adopting equivalent measures in Ireland (although unvaccinated healthcare workers may be redeployed).²³ Accordingly, informed consent is a pre-requisite for vaccination in Ireland. Consent issues have primarily related to capacity to consent, either where an adult's capacity is impaired or where the vaccine is administered to children and young people.²⁴

19 Phase one included frontline healthcare workers; essential workers e.g. gardai; those at greatest risk of severe illness and death and their caregivers; Phase two included teachers and others essential to education; those in essential jobs and who cannot avoid a high risk of exposure; adults aged 18–64 living or working in crowded accommodation; and adults aged 55–64 years; Phase 3 included young adults (18–34) due to increased levels of social contact; and those in industries important to the functioning of society at moderately high levels of exposure; Phase 4 included adults aged 35–54 who did not have access to the vaccine in prior phases; and children.

20 The Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 inserts Regulation 4F into the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003).

21 NIAC-Recommendations-for-Vaccine-Prioritisation-29.03.2021-update-04.01.2021-1.pdf.

22 See, e.g. J. Wise, 'COVID-19: France and Greece make vaccination mandatory for health-care workers', *British Medical Journal* 374 (2021) n1797.

23 See V. Clarke, 'HSE defends policy of redeploying unvaccinated healthcare workers' *The Irish Times* (20 August 2021).

24 'Children' is used in this article to refer to those under 16 years and 'young people' to refer to those over 16 years.

4.1 *Consent and Capacity: Adults*

Because the first stages of the rollout of the COVID-19 vaccination programme involved nursing home residents, a significant proportion of whom may have some degree of impaired capacity, the issue of capacity to consent to vaccination quickly emerged as a major issue. Difficulties arose because the relevant legal framework was (and still is at the time of writing) standing 'on the cusp of change'.²⁵ Although the Assisted Decision-Making (Capacity) Act 2015 (ADMCA) had been enacted in 2015, the substantive elements of the legislation will not be commenced until mid-2022. Until this happens, the only legislative framework in place for adults lacking capacity is the Lunacy Regulation (Ireland) Act 1871. This provides for admission to wardship and the appointment of a Committee in wardship, which is typically a single person who plays a role broadly similar to that of an 'adult guardian'. Wardship is a 'vastly outdated process', which is typically concerned with decisions about an individual's property and/or affairs.²⁶ However, in practice, wardship has led 'inexorably to healthcare decisions being made on behalf of the ward'.²⁷ The developed practice has been to seek the consent of the Committee of the ward for less serious decisions and procedures, and to obtain the consent of the High Court for more serious matters.²⁸ The judicial standard applied in such matters is the 'best interests' of the ward.²⁹ Most people with impaired capacity in Ireland are not wards of court.³⁰ Healthcare decisions, including decisions about vaccination, have typically been made on an informal basis. For many years, healthcare providers relied on 'next-of-kin consent', where (typically written) consent was provided by a family member of the person.³¹ However, as has long been recognised, next-of-kin consent is not recognised under Irish law.³²

Several stopgap legal measures were introduced to address the deficiencies in this antiquated legal framework in advance of the vaccine rollout. The President of the High Court, Irvine P, wrote to the CMO in December 2020,

25 S. Mills and A. Mulligan, *Medical Law in Ireland*, 3rd edn. (London: Bloomsbury Professional, 2017) p. 6.02.

26 M. Donnelly, 'The Assisted Decision-Making (Capacity) Act 2015: Implications for Healthcare Decision-Making', *Medico-Legal Journal of Ireland* 22(2) (2016) 65–77.

27 *Ibid* at 66.

28 *Ibid*.

29 *In re a Ward of Court* [1996] 2 IR 79.

30 There are currently approximately 2,500 wards of court in Ireland.

31 Donnelly, *supra* note 27, 66–67.

32 See, e.g., the Health Service Executive *National Consent Policy* (2013 as am), para. 5.6.1, available online at www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/national-consent-policy-hse-v1-3-june-2019.pdf.

confirming that there was no requirement to seek a court order for the administration of the vaccine.³³ A more formalised legal practice note on vaccination of wards was issued by Irvine P in April 2021.³⁴ This stated that unless an objection by the ward's Committee was specifically notified to the wards of court office, the ward's treating clinician should decide, having regard to the ward's medical history and a balancing of all relevant risks, whether the vaccination should proceed. If the ward's Committee objected to the vaccination, then they would be required to provide medical evidence that the vaccination was not in the ward's best interests. This would then be reviewed by the ward's treating clinician who would then be required to make a decision as to whether to proceed with vaccination. Unless the Committee referred the matter to court, then the vaccination would then proceed. If the ward objected, then their capacity would then need to be assessed: if the ward was found to have capacity to refuse, the vaccination should not be administered; if the ward was found not to have capacity and if the refusal would be likely to impact on the ward's placement, the matter must be listed before the court.

The legal position in respect of persons who are not wards is addressed by the Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020, which were introduced in December 2020.³⁵ The Regulations set out various formalities regarding the administration of vaccines, including the requirement that consent be obtained in advance. Where an individual lacks capacity to consent, the requirement is that 'the will and preferences of the person' must be established and the administration must be 'for the benefit of the person'.³⁶ Thus, the Regulations establish a legal basis for vaccination, addressing the legal lacuna identified above.

Additional guidance was developed by the Health Service Executive (HSE), which has responsibility for most of the vaccine rollout. A National Consent for COVID 19 Vaccination Working Group was established in December 2020,³⁷ and this Group produced a series of guidance documents,³⁸ emphasising the importance of consent and the importance of the will and preferences of the

33 M Carolan, 'High Court President Writes to Holohan over COVID-19 Vaccine for Wards of Court' *Irish Times* (11 December 2020).

34 Guidance Note on Vaccination of Wards of Court (April 2021).

35 S.I. No. 698 of 2020.

36 Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020, Regulation 10B.

37 One of the authors is a member of this group.

38 All of the guidance documents may be accessed at <https://www.hse.ie/eng/health/immunisation/hcpinfo/COVID19vaccineinfo4hps/> (accessed 26 October 2021).

person who lacks capacity.³⁹ Detailed guidance is provided on how to support the decision-making process, including the provision of accessible information provided in a manner that the person can understand and recognising that additional time may be required. The guidance also emphasises the importance of advance preparation, including talking about the vaccination in a natural manner and using social stories outlining what the vaccine involves.⁴⁰ It also reinforces the absence of any legal basis for next-of-kin consent but also recognises that family members who have a close ongoing relationship with the person may have an important role in ascertaining the person's will and preferences.⁴¹ At all times, the guidance emphasises that people who are assessed as lacking capacity and who do not wish to have the vaccination should not be given it against their will.⁴² The HSE's non-coercive approach was approved by the High Court in a case where a ward of court with dementia and various complex psychiatric conditions had refused consent to vaccination.⁴³ In handing down judgment, Hyland J identified the relevant factors in her conclusion as including the woman's individual situation; her existing medical condition; the fact that two injections would be involved; that the vast majority of residents in her nursing home had been vaccinated; that the woman was at a low risk of contracting the virus; and that coercive vaccination would greatly interfere with trust between the woman and the staff.⁴⁴

4.2 *Consent and Capacity: Children and Young People*

As the European vaccination rollout has continued, attention has shifted to the vaccination of children and young people. Out of the vaccinations originally approved by the EMA, only Pfizer/BioNTech was approved for this group. Between May and July 2021, the EMA approved two vaccines – Pfizer/BioNTech Spikevax – for this age cohort.⁴⁵ Pfizer/BioNTech has also sought approval from the US Food and Drug Administration (FDA) to authorise use of this COVID-19

39 See *Guidance regarding Consent for COVID 19 Vaccination* (12 February 2021); *Consent for Vaccination for COVID-19: Guiding Principles* (5 March 2021).

40 See *Supporting the Consent Process for those who lack capacity and are anxious/or refusing vaccination* (5 February 2021).

41 *Consent for Vaccination for COVID-19: Guiding Principles* (5 March 2021), *supra* note 39.

42 *Ibid.*

43 M. Carolan, 'HSE correct not to seek coercive COVID-19 vaccination of woman, judge says' *Irish Times* (10 February 2021). The High Court's ruling is *ex tempore* and no written judgment is issued.

44 *Ibid.*

45 www.ema.europa.eu/en/news/COVID-19-vaccine-spikevax-approved-children-aged-12-17-eu (accessed 26 October 2021).

vaccine for children aged between 5 and 11 years.⁴⁶ As with adults, rollout has been varied across Europe.⁴⁷ The extension of the rollout to children and young people raises several consent related issues.⁴⁸ These include the point at which the child/young person can provide a legally effective consent to vaccination and the legal position where the child does not have capacity to consent and parents/legal guardians disagree with each other;⁴⁹ or with local authorities (where a child is in care)⁵⁰ about vaccination. The resolution of these issues depends on the underlying national legal framework. As evidenced below, the legal framework in Ireland does not provide a solid structure in this regard.

In reviewing the Irish legal framework, a distinction must be made between young people (aged 16 and 17 years) and children (aged under 16 years). In respect of young people, the Non-Fatal Offences Against the Person Act 1997 provides that ‘the consent of a minor who has attained the age of 16 years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his or her person, shall be as effective as it would be if he or she was of full age.’⁵¹ The applicability of this provision to vaccination is open to debate. It is not clear that vaccination can be described as ‘treatment’ within the meaning of the 1997 Act.⁵² Moreover, doubts have been raised about whether the relevant provision provides legal protection outside of the criminal law context.⁵³

For children, no legislation is in place. Parents and legal guardians⁵⁴ have legal authority derived from both the common law and the Constitution of

46 S. LaFraniere and N. Weiland, ‘Pfizer asks FDA to authorize its COVID-19 vaccine for children aged 5 to 11’ *New York Times* (7 October 2021).

47 vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab (accessed 26 October 2021).

48 S. Saxena, H. Skirrow, H. Bedford and K. Wighton, ‘COVID-19 vaccines for teenagers: conversations and consent’, *British Medical Journal* 374 (2021) 2312.

49 See, e.g., *F v F* [2013] EWHC 2683 (Fam); *M v H* [2020] EWFC 93 (England and Wales).

50 See, e.g., *Re H (A Child) (Parental Responsibility: Vaccination)* [2020] EWCA Civ 664; see C. Ó Neill, ‘Re H (a child) (Parental responsibility: vaccination): The merits of adopting a softer approach to vaccination of a child in care?’, *Medical Law Review* 28(4) (2020) 817–826.

51 Non-Fatal Offences Against the Person Act 1997, s. 23(1).

52 Treatment is defined in s. 23(2) as including ‘any procedure undertaken for the purposes of diagnosis’ and s. 23 is stated to apply to ‘any procedure (including, in particular, the administration of an anaesthetic) which is ancillary to any treatment as it applies to that treatment.’

53 See Law Reform Commission, *Children and the Law: Medical Treatment* (LRC 103-2011), para. 2.13.

54 Legal guardians are defined in accordance of the Children and Family Relationships Act 2015.

Ireland to consent to, and refuse, medical interventions on behalf of their child,⁵⁵ although this authority is restricted by the rights of the child (which are explicitly recognised under Art. 42A of the Constitution).⁵⁶ The Irish courts have not considered whether individualised competence assessments of the child's understanding (so-called *Gillick* competence)⁵⁷ should play a role in determining authority to consent to medical interventions. However, the High Court has held that treatment refusal should be viewed differently to consent to treatment and that the courts may intervene in such cases.⁵⁸ The lack of clarity in this area has been recognised by the Committee on the Rights of the Child, which recommended that Ireland should, particularly in the context of mental health care services, '[e]nact legislation that explicitly and comprehensively provides for children's consent to and refusal of medical treatment, and ensure that this legislation should be in line with the objectives of the Convention and encompass clear recognition of children's evolving capacities.'⁵⁹

The gap created by the absence of a clear legal framework in this area has, to a degree, been filled by professional guidance, which is based on a best interpretation of the legal position, and on the prioritisation of the best interests of the child.⁶⁰ Although it does not have formal status in law, such guidance may provide legal protection to healthcare professionals who act in accordance with it on the basis that such actions are reasonable and in accordance with the guidance. The specific issues raised by the vaccine rollout were addressed in separate guidance developed by the National Consent for COVID 19 Vaccination Working Group.⁶¹ This provides that the consent of a young person (who has capacity to make a decision about vaccination) is valid and that the consent of a parent/legal guardian is not required. It also affirms a general right of a young person to refuse the vaccine, notwithstanding that the courts

55 See *North Western Health Board v HW and CW* [2001] IESC 90.

56 See *Re JJ* [2021] IESC 1, para. 131.

57 From *Gillick v West Norfolk and Wisbech AHA* [1986] A.C. 112.

58 *HSE v JM and Anor* [2013] IEHC 13 and *XY a minor suing by her guardian ad litem Raymond McEvoy v HSE* [2013] IEHC 490. In this, the High Court followed the position which had been adopted by the Court of Appeal (EW) in *Re W* [1992] 3 WLR 758.

59 See Committee on the Rights of the Child, *Concluding Observations on the Combined Third and Fourth Periodic Reports of Ireland* (2016), p. 12.

60 See Medical Council, *Guide to Professional Conduct and Ethics for Registered Medical Professionals* (8th edn, 2016 as am), para. 18; *National Consent Policy* (2013 as am) Pt. 2, available online at www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/national-consent-policy-hse-v1-3-june-2019.pdf.

61 See *Guidance on Consent for Vaccination of Young People 16–17 Years (v.2)* (May 2021); *Who can give consent for vaccination of a young person aged under 16 years?* (August 2021), available online at <https://www.hse.ie/eng/health/immunisation/hcinfo/COVID19vaccineinfo4hps/who-can-give-consent-for-young-people-aged-under-16.pdf>.

have identified a different approach to consent and to refusal.⁶² This is on the basis of an assessment of the degree of risk to young people of refusing the vaccine which, except in exceptional circumstances, is relatively low.⁶³ For children under 16 years, parental consent and the assent of the child is required. In line with the position taken in the HSE National Consent policy, the consent of only one parent is necessary. Where parents disagree, the guidance indicates that they should be encouraged to discuss the matter and to consult the child whose views are recognised as being important. Ultimately, the matter is likely to require resolution in the courts. In the absence of a court ruling, the guidance of the National Consent for COVID 19 Vaccination Working Group indicates that if one parent makes an objection to vaccination known to the service, 'every reasonable effort' should be made to avoid vaccination of the child.⁶⁴ The guidance is also clear that because of the nature of the vaccine rollout, it is not possible to give an absolute guarantee in this regard.⁶⁵

Notwithstanding the legal uncertainties, the vaccine rollout to children and young people has thus far not produced much in the way of legal controversy. This likely reflects the fact that the applicable guidance indicates that vaccines should not be administered where one parent has objected. The only case to date saw the High Court approve the vaccination of a 15-year-old boy with disabilities who was in foster care, notwithstanding his mother's objections.⁶⁶ From the media reports, the decision was made on the basis of the boy's best interests and his own expressed desire to receive the vaccination. This case was unusual, given that the boy was in foster care and had a range of medical issues; it is not clear that a similar finding would have been reached had these circumstances not arisen.

5 Vaccine Injury and Redress

Like all medical interventions, COVID-19 vaccines may give rise to side-effects. Significant attention was paid to addressing safety concerns involving virus vector vaccines, such as AstraZeneca (now Vaxzevria) and Janssen. In March 2021, an EMA safety committee commenced an investigation into a batch of

62 See Guidance on Consent for Vaccination of Young People 16–17 Years, *supra* note 61.

63 *Ibid.*, p. 2.

64 Who can give consent for vaccination of a young person aged under 16 years?, *supra* note 61, p. 3.

65 *Ibid.*

66 G. Deegan, 'Judge says COVID vaccine can be given to boy with disability in foster care against the wishes of his biological mother' *Irish Independent* (22 October 2021). No written judgment is available at time of writing.

the Vaxzevria vaccine after Austria and other EU Member States suspended the use of the vaccine due to reports of blood clots.⁶⁷ Ultimately, however, the committee maintained the position that the benefits outweighed the risks and advised that the vaccines could continue to be administered. Concerns about side effects have also been raised in relation to mRNA vaccines, such as Spikevax and Pfizer/BioNTech. The EMA safety committee has advised that two heart conditions – myocarditis and pericarditis – must be listed as possible side effects of the two mRNA vaccines.⁶⁸ Pharmaceutical companies sought indemnification for COVID-19 vaccine related injuries and a key consideration in the vaccine roll-out globally has been the existence and establishment of appropriate state vaccine injury compensation for any resulting damage.

Compensation for vaccine injury can be pursued in two ways: first, under the Product Liability Directive⁶⁹ or secondly, through the law of tort. The conversation on vaccine injury compensation schemes is largely in response to the actual and perceived shortcomings of these options, including the costs involved and length of time that such cases take to litigate, and, in tort claims, the difficulty in proving clear causation. The World Health Organization (WHO) has previously argued for vaccine injury compensation schemes, noting:

A vaccine-injury compensation scheme removes the uncertainty of tort liability for manufacturers and provides a more fair, efficient and stable approach for injured parties ... Apart from the reluctance of governments to move away from the adversarial approach to providing compensation, we believe there is a strong argument for widespread implementation of these programmes in other developed countries.⁷⁰

Many jurisdictions have well established vaccine injury compensation schemes, both within and outside the EU.⁷¹ The WHO has also established the “COVAX” scheme for low to medium income countries in order to ‘significantly reduce the need for recourse to the law courts, a potentially lengthy and costly

67 <https://www.ema.europa.eu/en/news/COVID-19-vaccine-astrazeneca-prac-preliminary-view-suggests-no-specific-issue-batch-used-austria>.

68 <https://www.ema.europa.eu/en/news/comirnaty-spikevax-possible-link-very-rare-cases-myocarditis-pericarditis>.

69 Directive 85/374/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [1985] OJ L210/29 as amended by Directive 1999/34/EC, [1999] OJ L 141/20.

70 C. Looker and H. Kelly, ‘No-fault compensation following adverse events attributed to vaccination: a review of international programmes’, *Bulletin of the World Health Organization* 89(5) (2011) 371–378.

71 K. Watts and T. Popa, ‘Injecting Fairness into COVID-19 Vaccine Injury Compensation: No-Fault Solutions’, *Journal of European Tort Law* 12(1) (2021) 1–39.

process.⁷² Although vaccine injury compensation schemes are not new, they have recently come under the spotlight given regulatory approval of a number of COVID-19 vaccines in a relatively short period of time in the 2020–21 period. Although the vaccines have a risk of rare, but in some instances, serious side effects, as Farrell notes ‘the risk-benefit calculus is heavily weighted in favour of the collective public health over that of the individual.’⁷³ This is largely due to the potential of vaccination to assist in combating both the high death rate and widespread illness and caused by COVID-19, as well as to facilitate the removal of necessary restrictive disease prevention measures such as lockdowns. As such, in addition to pragmatic arguments which support vaccine injury compensation schemes, such as the need to encourage and maintain vaccine uptake, there is a strong ethical argument for appropriate compensation where serious side effects arise, given the emphasis on achieving ‘herd immunity’ for the collective good.⁷⁴ Against this backdrop, this section of the paper identifies the lack of a framework for vaccine injury compensation in Ireland as part of legal preparedness.

5.1 *Vaccine Injury Redress: Variations in Approach*

Internationally, including within the EU, there are different models for vaccine injury compensation. Such schemes remove the requirement to pursue compensation via litigation, whether the claim relates to breach of the Product Liability Directive or negligence by either the manufacturer of the vaccine or the healthcare system and/or provider in administering the vaccine. No harmonised approach to vaccine injury compensation exists in the EU. Vaccine injury redress schemes can be vaccine-specific or may cover a wide variety of immunisations. Austria,⁷⁵ France,⁷⁶ and Germany⁷⁷ are all examples of EU Member States with vaccine injury compensation schemes which cover a variety of vaccines. In the UK, the Vaccine Damage Payments Scheme, which

72 <https://www.who.int/news/item/22-02-2021-no-fault-compensation-programme-for-COVID-19-vaccines-is-a-world-first>.

73 A.M. Farrell, ‘The politics and legalisation of vaccine injury’ (forthcoming, 2022).

74 S. MacLeod, ‘Vaccine Injury Compensation Schemes’ in: S. MacLeod and C. Hodges (eds.), *Redress Schemes for Personal Injuries* (London: Bloomsbury Publishing, 2017) chapter 15, p. 381.

75 Vaccine Damage Act (*Bundesgesetz vom 3. Juli 1973 über die Entschädigung für Impfschäden or Impfschadengesetz*).

76 In France, a distinction is drawn between compensation for mandatory vaccines and voluntary vaccines. In relation to a compulsory vaccination, an individual may lodge a claim with the National Office for Compensation of Medical Accident (ONIAM), Article L3111-9. Special provision has been made in the case of COVID-19 vaccines. For a full discussion, see Watts and Popa, *supra* note 71.

77 German Infection Protection Act (*Infektionsschutzgesetz* or IfSG), s.60.

was established by the Vaccine Damage Payments Act 1979, provides redress to individuals who are left with severe disabilities following the administration of a vaccine,⁷⁸ including a COVID-19 vaccine.⁷⁹ In contrast, despite the existence of a broad vaccine injury compensation scheme in the United States (the National Vaccine Injury Compensation Program),⁸⁰ COVID-19 vaccine injuries are covered under the ‘Countermeasures Injury Compensation Program’.⁸¹ Whilst there are differences across the various schemes, most operate on a ‘no-fault’ basis and do not require proof of liability.⁸² Instead, the intention is to remove the necessity of pursuing a fault-based mode of redress i.e. litigation. The ethical and pragmatic arguments for the operation of such schemes have long been recognised.⁸³ Additionally, some commentators have also argued that vaccine injury compensation schemes can play a role in addressing vaccine hesitancy. For example, Heppinstall notes ‘[s]ome individuals may feel more inclined to have the vaccine, and thus to contribute to the national effort to acquire herd immunity, if they knew that they would be financially supported in the event of a side-effect causing them to become disabled or ill.’⁸⁴ The ECtHR has also recently emphasised the moral obligation of States to ensure redress for injuries arising from vaccination. In *Vavříčka and Others v the Czech Republic*,⁸⁵ a case which considered the compatibility of compulsory childhood vaccination with the European Convention on Human Rights (ECHR), the Court affirmed the importance of the availability of adequate compensation for those who suffer harm noting ‘... under the principle of solidarity, which itself was the basis for making vaccination compulsory, the State ordering such a measure for the benefit of everyone must be required to pay compensation to those who experience harmful side-effects.’⁸⁶ Whilst this

78 Severe disability means that the person must be at least 60% disabled, which includes both mental and physical disability.

79 Vaccine Damage Payments (Specified Disease) Order 2020.

80 National Vaccine Injury Compensation Program, available online at <https://www.hrsa.gov/vaccine-compensation/index.html> (accessed 3 November 2021).

81 <https://www.hrsa.gov/cicp> (accessed 3 November 2021).

82 It should be noted that other obstacles may exist. For example, some schemes set high thresholds for injury before a claim can be made. In the UK, under the Vaccine Damage Payments Scheme, the threshold is one of ‘severe disability’ which means that the individual must be at least 60% disabled (including both mental and physical disability). For a full discussion, see MacLeod, *supra* note 74.

83 M.M. Mello, ‘Rationalizing vaccine injury compensation’, *Bioethics* 22(1) (2007) 32–42.

84 A. Heppinstall, ‘COVID-19, Vaccines, Brexit and Vaccine Damage Claims’, *European Pharmaceutical Law Review* 4 (2020) 104–106, p. 106.

85 Appl. Nos 47621/13, 3867/14, 73094/14, 19306/15, 19298/15, and 43883/15, 8 April 2021.

86 *Vavříčka and Others*, *supra* note 1, para. 127.

case related to mandatory vaccination, the decision highlights the importance of appropriate schemes for vaccine injury compensation at a national level. Additionally, although COVID-19 vaccination is, in many EU countries, voluntary, the introduction of measures such as 'COVID-19 passports' raises questions as to true voluntariness, given that there are significant incentives for vaccination. Thus, it could be argued that the decision in *Vavříčka* serves as a warning to countries who are yet to implement a vaccine injury compensation scheme. Given the emergency nature of the pandemic and the race to mitigate against severe illness and death, as part of the advance purchase and purchase agreements for COVID-19 vaccines, the European Commission agreed to provide indemnity to vaccine manufacturers.⁸⁷ However, the issue of indemnity has ultimately been devolved to Member State level. Watts and Popa have criticised the devolution due to the 'fragmented' approach to vaccine injury redress across Member States.⁸⁸ They further argue that the absence of vaccine injury compensation schemes in some Member States means that, in some instances, individuals in the EU will have less access to redress than those covered by the COVAX scheme.⁸⁹

5.2 *Vaccine Injury Redress: Ireland*

Unlike many other EU Member States, there is no State vaccine compensation scheme in Ireland. Despite the current absence of a vaccine injury compensation scheme, those who suffer harm resulting from vaccination may pursue traditional means of redress, such as a civil claim for negligence and/or a breach of the provisions of the Liability for Defective Products Act 1991 (which transposed the Product Liability Directive). However, such litigation is frequently onerous, and a number of hurdles must be surmounted, most notably, in tort actions establishing causation. Similar to claims for clinical negligence, causation can act as a significant hurdle to surmount in the context of vaccine injury claims. This is because individuals seeking redress for vaccine injuries must prove that the vaccine in question caused their injury. Watts and Popa have argued that the obstacle of causation 'may prove to be insurmountable'⁹⁰ in the context of new vaccines, such as the COVID-19 vaccines. While the same level of causation difficulties do not arise under the Product Liability Directive,

87 https://www.europarl.europa.eu/doceo/document/E-9-2020-006775-ASW_EN.html (accessed 3 November 2021).

88 Watts and Popa, *supra* note 71, p. 9.

89 *Ibid.*

90 *Ibid.*, p. 12.

compliance with the Directive's requirements poses its own challenges, especially in the respect of the COVID-19 vaccines.⁹¹

The costs associated with legal claims may also prove prohibitive for some claimants. In Ireland, the High Court has jurisdiction to hear cases about claims for damages of over €60,000 in the context of personal injuries. It is conceivable, therefore, that where smaller claims arise the costs associated with pursuing a claim of this nature may dwarf the damages awarded for injury. Notwithstanding the challenges associated with this type of litigation, claims for vaccine injury in Ireland have been brought in the courts. For example, high profile cases such as the narcolepsy cases, which arose following the administration of the Pandemrix "swine flu" vaccine, have been in the Irish courts for the past decade.⁹² Unfortunately, following inoculation a number of individuals suffered injuries including the development of narcolepsy. Due to the absence of a vaccine injury compensation scheme in this jurisdiction, those who wished to seek redress for injuries suffered had to revert to the Courts.⁹³ A number of claims in this regard have been pursued.⁹⁴

Although those are injured following the administration of a vaccine may pursue redress in the courts, the current absence of a statutory compensation scheme in this jurisdiction is problematic, as highlighted by the Pandemrix cases. Internationally, the current absence of a vaccine injury compensation scheme in this jurisdiction has not gone unnoticed. Watts and Popa observe the problematic nature of this warning 'Irish COVID-19 vaccine injury victims will be forced with this kind of decades-long liability and litigation struggle.'⁹⁵ The need for an appropriate redress mechanism has also been recognised at a national level, where the oft-had conversation on vaccine injury redress has been ongoing in this jurisdiction since 2001.⁹⁶ In 2007, a Vaccine Damage

91 See D. Fairgrieve, P. Feldschreiber, G. Howells and M. Pilgerstorfer, 'Products in a Pandemic: Liability for Medical Products and the Fight against Covid-19' *European Journal of Risk Regulation* 11 (2020) 565–603.

92 *Benjamin Blackwell (A Minor Suing by his Mother and Next Friend Natalie Blackwell) v The Minister for Health and Children, The Health Service Executive, The Health Products and Regulatory Authority and Glaxosmithkline Biologicals SA* [2021] IEHC 124.

93 Similar to the indemnification of COVID-19 vaccine manufacturers, the Pandemrix vaccine was indemnified by the Irish State.

94 See, for example, T. Healy, '€1.28m settlement for 16-year-old girl diagnosed with narcolepsy four years after swine flu jab' *The Irish Independent* (8 May 2021); A. O'Loughlin, 'Settlements of €4.5m in three swine flu cases approved' *The Irish Examiner* (29 July 2021).

95 Watts and Popa, *supra* note 71, p. 10.

96 For example, in 1977, an *ex gratia* compensation scheme was established in relation to the whooping cough vaccination. From an assessment of 93 cases, 16 were awarded *ex gratia* payments of £10 000. <https://health.old.gov.ie/wp-content/uploads/2014/03/vaccine>

Steering Group was established and its report was published in 2009.⁹⁷ Ultimately, the Steering Group recommended that an *ex gratia* scheme be established although no further progress was made at the time in terms of furthering this recommendation.

The need for a State vaccine injury compensation scheme was again highlighted by an Expert Group appointed to review the law of torts and the current system managing clinical negligence claims in 2018. In its report, the Expert Group observed that ‘there is a strong moral argument that the State, which actively encourages vaccination, should accept responsibility for those who suffer harm as a result.’⁹⁸ The Group ultimately recommended that a vaccine compensation scheme be established ‘as a matter of urgency.’⁹⁹ The majority view of the Group was to establish an *ex gratia* scheme for redress. The Group noted that such a scheme would not require liability to be proven and would also ensure the injured individual’s right to bring court proceedings. The Group also recommended that compensation should be ‘reasonable and based on proven loss’ and that the scheme should cover reasonable legal costs and expenses. Whilst one of the driving goals of the scheme is to minimise the adversarial nature of the claims process, the scheme bears similarities to the civil process. For example, the Group recommended that medical evidence be required to establish that the vaccine in question caused or contributed to the injury complained of, and noted that the panel would be entitled to instruct their own medical expert and other experts to advise on a number of issues, including causation.

Despite the publication of the report by the Expert Group in 2020, little progress has been made notwithstanding a recent statement by the Irish

_report.pdf. Additionally, in 2001, the issue of childhood immunisation was examined, and a Joint Oireachtas Committee on Health and Children recommended that a vaccine injury compensation scheme be established as soon as possible.

97 The Group, which examined a number of international schemes, recommended in its 2009 report that an *ex gratia* payment scheme be established and a tiered payment structure, depending on the severity of damage suffered, be introduced. See J. Hough, ‘Report recommends payouts for vaccine damages’ *The Irish Examiner* (18 November 2009).

98 Mr Justice Charles Meenan, Expert Group Report to Review the Law of Torts and the Current Systems for the Management of Clinical Negligence Claims, January 2020, 7.

99 *Ibid.* In respect of the operation of such a scheme and compensation, the Expert Group noted that a variety of views were expressed in terms of quantum for vaccine injury. The Group noted that whilst there was a view that awards made by such a scheme should be in line with that which would be made by the court i.e. general and special damages, there was more support for a scheme where awards were below the level of those made by the court where liability was established. There was more support for an *ex gratia* compensation scheme, which would not require liability to be proven but would also ensure the plaintiffs right to bring court proceedings.

Government that it was committed to introducing a vaccine injury compensation scheme.¹⁰⁰ The urgency of establishing such a scheme is increasing, and there are strong ethical arguments for the introduction of an appropriate model of redress. This was brought into sharp focus during the COVID-19 vaccination rollout although ultimately it seems to have had little adverse impact, given that 94.5% of the adult population in Ireland are now fully vaccinated.¹⁰¹ The success of the rollout notwithstanding, the strong ethical argument for appropriate redress for vaccine injury remains. Additionally, given the rapidly evolving nature of the pandemic, the emergence of new variants of the disease, and the likelihood of future unknown public health emergencies, there is a need to “ensure maximum public support” for both the current, as well as likely subsequent vaccine rollouts.¹⁰² Where an individual has suffered harm as a result of vaccination and is forced to pursue costly and time-consuming litigation, public confidence in such vaccination programmes may dwindle. Although vaccination is not mandatory in Ireland, similar to other jurisdictions, the Irish Government has introduced the use of measures such as ‘COVID-19 passes’ to access pubs, restaurants, and theatres,¹⁰³ which may impact voluntariness. Such incentivisation may be, as Archard et al. have argued in their commentary on *Vavříčka* (previously referred to), mandatory childhood vaccination may be ‘more proportionate and socially acceptable’ than mandating vaccination.¹⁰⁴ However, as the European Court of Human Rights made clear in its judgment in the case, strong state support for taking such an approach to vaccination must necessarily be accompanied by the state providing appropriate modes of redress where vaccine injury may occur as a result.

6 Conclusion

The COVID-19 pandemic has highlighted the need for legal preparedness to ensure a rapid and effective response to public health emergencies. As Bennett and Carney argue that ‘[c]larity in the legal frameworks for public health is a critical part of providing an enabling infrastructure to support the work of

100 C. O’Loughlin, ‘Government to establish compensation scheme for those injured by State vaccines’, *The Irish Independent* (13 August 2021).

101 <https://graphics.reuters.com/world-coronavirus-tracker-and-maps/countries-and-territories/ireland/>.

102 *Ibid.*, at 450.

103 Health (Amendment No. 2) Act 2021.

104 D. Archard, J. Brierley and E. Cave, ‘Compulsory Childhood Vaccination: Human Rights, Solidarity, and Best Interests’, *Medical Law Review* 29(4) (2021) 716–727, p. 727.

public health officials when responding to public health emergencies.¹⁰⁵ This article has provided a critical analysis of legal preparedness through an examination of two key aspects of the legal frameworks in Ireland which supported the COVID-19 vaccine rollout. The discussion has highlighted the shortcomings in the national legal consent framework and the absence of a legislative redress scheme for those who suffered injury as a result of administration of the COVID-19 vaccine. These legal lacunae did not substantively impact on the rollout of the COVID-19 vaccine (or the booster vaccine) in Ireland, they nonetheless indicate the steps which the Irish legislature needs to take in order to be legally prepared for ongoing vaccination programmes in the context of managing threats to public health in the future.

Looking beyond Ireland, we suggest that the analysis here offers some more generally applicable lessons on legal preparedness. First, the issues of consent and appropriate redress for vaccine injury are universal and we suggest that states should critically evaluate their legal frameworks around these aspects of vaccine programmes and ensure that they are effective and appropriate. Secondly, the case study shows why a broader understanding of legal preparedness, which looks beyond emergency response measures, is needed. Governments should pay due attention to the legal frameworks which are required to facilitate a cohesive response to public health emergencies, whilst respecting the fundamental rights of citizens. The COVID-19 pandemic has highlighted the essential role of public health legal preparedness. The challenges faced serve as a stark warning on the importance of ensuring adequate public health systems and legal frameworks to address the issues raised by this and future public health emergencies.

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105 B. Bennett and T. Carney, 'Law, ethics and pandemic preparedness: the importance of cross-jurisdictional and cross-cultural perspectives', *Australian and New Zealand Journal of Public Health* 34(2) (2010) 106–112, p. 108.