EUROPEAN JOURNAL OF HEALTH LAW 30 (2023) 428–448

European Journal of Health Law

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COVID-19 Vaccination and the Role of Informed Consent: England as a Case Study

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Received 10 October 2022 | Accepted 20 March 2023 |
Published online 22 May 2023

Abstract

Informed consent (IC), following the Supreme Court judgment in *Montgomery v Lanarkshire Health Board*, [2015] UKSC 11, constitutes a key patients' right. There is a vast literature exploring the significance of this right, while an analysis of the role that this has played in England during the COVID-19 vaccine distribution has been under-explored. Using England as a case study, this paper argues that IC has received limited protection in the COVID-19 vaccination context of the adult population, upholding at its best only a minimalistic approach where mere 'consent' has been safeguarded. It suggests that new approaches should be brainstormed so as to more properly safeguard IC in a *Montgomery-compliant-approach*, namely in a way that enhances patients' autonomy *and* medical partnership, and also to better prepare and respond to future pandemics.

Keywords

COVID-19 – informed consent – vaccination – England – pandemic – preparedness

1 Introduction

The 2nd December 2020[1] marked the start of the roll-out of COVID-19 vaccinations in England. Several vaccines[2] were approved for temporary supply and use by the Medicine and Healthcare Product regulatory agency. This was an historical turning point in the unfolding of the pandemic which was coupled with a feeling of hope towards a return to a more 'normal' life. A year after, on 2nd December 2021,[3] the opportunity to also receive a 'booster' jab, i.e. a third dose of COVID-19 vaccines, was also offered to the public. There is vast literature exploring the issue of vaccine allocation,[4] yet what this paper claims, is that the issue of informed consent (IC) has been left under-explored. That this gap is worth being explored is supported by the acknowledgement that IC, in light of the Supreme Court judgment in *Montgomery*, is clearly a key patients'

1 The first vaccine authorised by the Medicines and Healthcare products regulatory agency (MHRA) in England was Pfizer/Biontech. See: MHRA, Public assessment report Authorisation for Temporary supply Pfizer/Biontech, 2nd December 2020, available online at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/997584/COVID-19_mRNA_Vaccine_BNT162b2__UKPAR___PFIZER_BIONTECH_ext_of_indication_11.6.2021.pdf. (accessed 7 October 2022)

2 After the approval of Pfizer/Bionthec, on 30th December, MHRA, then gave temporary approval for the supply of Astrazeneca. This was then followed by the temporarily approval of: Spikevax (formerly COVID-19 vaccine Moderna) on 8th January 2021; Janssen, on 28th May 2021; See: MHRA, Public assessment report Authorisation for Temporary supply Astrazeneca, 30th December 2020, available online at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1003840/CMA_UKPAR_COVID_19_Vaccine_AstraZeneca_PAR_16.07.2021.pdf, (accessed 7 October 2022) ; MHRA, Public assessment report Authorisation for Temporary supply Moderna, 8th January 2021, available online at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/977367/UKPAR_COVID_19_Vaccine_Moderna_07.04.2021_CMA_Reliance_PAR__-__final.pdf (accessed 7 October 2022); MHRA, Public assessment report Authorisation for Temporary supply Janssen, available online at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/996096/COVID19_Vaccine_Janssen_suspension_for_injection_UKPAR.pdf (accessed 7 October 2022)

3 Department of Health and Social Care and Maggie Throup MP, press release, UK marks one year since approving COVID-19 vaccine with Boost Day, 2nd December 2021, available online at https://www.gov.uk/government/news/uk-marks-one-year-since-approving-covid-19-vaccine-with-boost-day (accessed 7 October 2022)

4 See on vaccine roll-out and allocation issues, for instance: J.W. März, A. Molnar, S. Holm and M. Schlander, 'The ethics of COVID-19 vaccine allocation: don't forget the trade-offs!', *Public Health Ethics* (2022) phac001, DOI: 10.1093/phe/phac001; E.J. Emanuel, G. Persad, A. Kern, A. Buchanan, C. Fabre, D. Halliday, J. Heath, L. Herzog, R.J. Leland, E.T. Lemango, F. Luna, M.S. McCoy, O.F. Norheim, T. Ottersen, G.O. Schaefer, K.-C. Tan, C. Heath Wellman, J. Wolff and H.S. Richardson, 'An ethical framework for global vaccine allocation', *Science* 369 (2020) 1309–1312.

right. This judgment asserts that patients have a right to be made aware of material information concerning risks, benefits and alternatives, related to the medical intervention in question. Using England as a case-study this paper will claim that the safeguard of IC in the context of COVID-19 vaccination of the adult population has rested on a minimalistic approach, namely on the protection of IC as a mere 'one-off event' rather than a process of information disclosure which upholds patients' autonomy. It will highlight the importance of a change in approach if this patients' right is to be more properly safeguarded. The rationale behind this paper is hence to fill a gap in the academic debate when it comes to the tie between IC and COVID-19 vaccinations, particularly in England.

It should be clarified that this paper does not aim to embrace a critical viewpoint on the roll-out of vaccination *per se* nor wants to ignore the challenges posed by a pandemic on the NHS; quite the opposite. It argues, however, that a pandemic context, in its uniqueness, should be no exception to a balanced and accurate process of disclosure of information. IC is a key patients' right in healthcare, and new ways should be formulated for its protection during pandemics. Furthermore, this paper will also not explore the 'what' of information disclosure, namely what information should be disclosed to patients, but will address the broader importance of communicative processes and hence the 'how' of information disclosure in a COVID-19 vaccines context. This analysis will also prove beneficial for the exploration of tailored policy responses to future pandemics.[5]

2 The role of Informed Consent in the COVID-19 Vaccination Context

The COVID-19 pandemic has been marked by a widespread of information, whose nature has not always been reliable. It is the case that the existence of an 'ocean' of information — also called 'info-demic[6] — has often jeopardised the

5 See for an analysis of legal preparedness and COVID-19 vaccination in Ireland: M.-E. Tumelty, M. Donnelly, A.M. Farrell and C. O Neill, 'COVID-19 Vaccination and legal preparedness: lessons from Ireland', *European Journal of Health Law* 29 (2022) 240–259. In this paper they highlight, amongst others, the challenges connect to the lack of a consent framework in Ireland; an issue which did not impact vaccine roll-out but impacted on legal preparedness.

6 The Royal Society, *COVID-19 vaccine deployment: Behaviour, ethics, misinformation and policy strategies*, (2020), available online at https://royalsociety.org/-/media/policy/projects/set-c/set-c-vaccine-deployment.pdf 1, 2 (accessed 7 October 2022). See also on this point: R. Horton, 'Offline: managing the COVID-19 vaccine infodemic', *The Lancet* 396 (2020) 1474; see also two US-based studies on the ongoing impact of misinformation during the pandemic: A. Baines, M. Ittefaq and M. Abwao, '#Scamdemic, #Plandemic, or #Scaredemic: what

safeguard of patients' informative rights. This section will particularly aim to highlight that the protection of informed consent (IC) in the COVID-19 vaccination context has often rested on a minimalistic view upholding at its best only a consent approach. It will focus on a doctrinal analysis of the most recent case law on IC to show the existence of a friction between the 'law in theory' and the 'law in practice', namely the existence of a gap between the letter of IC and its lack of a safeguard in practice. Particularly, building upon the Supreme court judgment in *Montgomery*, it will argue that the safeguard of IC in the COVID-19 pandemic context has proved to be problematic because it has led to a consideration of IC as a mere 'one-off event', rather than a 'process' where a relationship of mutual trust between medical experts and patients is upheld and where patients' autonomy respected. It will be then suggested later that a re-framed involvement of clinicians can be one possible way of addressing this phenomenon and better protecting IC in a future pandemic context. Additionally, it will also be argued that further research is needed to unpack the extent of this phenomenon in the medical practice, so as so also brainstorm research-led future legal and policy responses.

IC, in light of the Supreme Court judgment in *Montgomery*, is rightly regarded as a key patients' right. It entails their right to be disclosed material information concerning risks, benefits and alternatives to a given medical treatment.[7]Patients as consumers,[8] have a right to be disclosed information whose relevance is assessed in light of their medical and personal needs and concerns. Patient-centredness is vital. Clinicians in the IC context are called to embrace a dialogical approach which is marked by the importance of listening to their patients and tailoring information accordingly. IC, rightly understood, is hence not a mere 'one-off-event' where information comes unilaterally from what the doctor deems to be relevant, or worse is oriented merely towards achieving a 'signature on paper'. IC is not a 'tick-box exercise'. Dialogue and communication between the parties are its crucial components. The dynamic nature of the doctor-patient relationship should also lead to a correspondingly dynamic process of disclosure. It is hence the case that IC, following the judgment in *Montgomery,* is better framed as an ongoing *process* of mutual

parler social medica platform tells us about COVID-19 vaccine', *Vaccines* 9 (2021) 421; R. Plitch-Loeb, E. Savoia, B. Goldberg, B. Hughes, T. Verthey, J. Kayyem, C. Miller-Idriss and M. Testa, 'Examining the effect of information channel on COVID-19 vaccine acceptance', *PLoS ONE* 16 (2021) e0251095. DOI: 10.1371/journal.pone.0251095.

7 *Montgomery* at [82].

8 For a critical approach on consumerism see: E. Jackson, 'Challenging the comparison in Montgomery between patients and 'consumers exercising choices', *Medical Law Review* 29 (2021) 595–612.

exchange of information where patients' needs and concerns are placed at the heart of the disclosure process.

In the IC context, it is possible to identify two relevant principles which, I claim, should guide the disclosure of information in the medical realm, namely a respect for patients' autonomy and medical partnership. As I have also argued elsewhere together with Cave [9] these two principles express the concurrent relevance of patients and medical expertise in the disclosure process. The former (i.e., autonomy) entails that respect should be given to patients' decision-making role in a medical context. Patients are no longer 'passive recipients of doctors' advice,'[10] but are right-holders, and their agency is key in the medical realm. The latter, medical partnership, highlights that the clinicians' role (as duty-bearers) also matters in the disclosure process. Clinicians' expertise and advisory role is at the heart of disclosure of information. Medical partnership, however, and as it shall be also clarified later, does not entail a return to a doctor-centred approach. Clinicians' role must be balanced with respect for patients' agency. It is very important, in this respect, that information is disclosed in line with the actual circumstances of the case and the peculiarity of the patient. A patient and fact-sensitive approach is ultimately what *Montgomery* aims to achieve.[11] It is hence the case that medical and patients' expertise can and should meet via a dialogical approach, which constitutes the relevant basis for the safeguard of IC.

2.1 *Informed Consent, Vaccination And A Pandemic Context?*

It is a valid claim, with which this paper agrees, that IC still stands as a key patients' right even in a pandemic context, as it was also highlighted by Turnham et al[12] and confirmed by the General Medical Council (GMC) in its pandemic-specific guidance.[13] However, a further series of interconnected questions might then arise: what is then unique about IC (1) in a vaccination

9 E. Cave and C. Milo, 'Informing patients: The Bolam Legacy', *Medical Law International* 20(2) (2020) 103–130.

10 *Montgomery* [75].

11 *Montgomery* at [89].

12 H.L. Turnham, M. Dunn, E. Hill, G.T. Thornburn and D. Wilkinson, 'Consent in the time of COVID-19', *Journal of Medical Ethics* 46 (2020) 565–568.

13 'All our ethical guidance continues to apply as far as is practical in the circumstances', General Medical Council, *Decision making and consent*, available online at https://www.gmc-uk.org/ethical-guidance/ethical-hub/covid-19-questions-and-answers#Decision-making-and-consent (accessed 7 October 2022).

context and (2) in a pandemic context?.[14] Ultimately, is it possible to safeguard IC and its principles even here?

Firstly, COVID-19 vaccinations entailed a series of single medical interventions, which were tied to a maximum of three different, though interconnected, consent processes (i.e. as related to the first, second and third/booster dose), depending on how many doses the patient decided to receive. In this sense, vaccinations don't share, for instance, the same opportunity for a process of disclosure and trust with clinicians to be developed over a long-term as it is for other medical intervention (e.g., chronic illnesses diagnosis and treatments). Secondly, COVID-19 vaccinations were also placed within a public health crisis context, which clearly posed challenges that were absent in a 'normal' (i.e., outside pandemic) medical context. Questions of balancing the individual good (personal autonomy) with the broader public good (vaccine intake and herd immunity), together with issues of allocation of resources and time-related constraints were some of its key elements. It might be then argued, *prima facie*, that both the nature of COVID-19 vaccinations, and the broader pandemic context, did not and could not foster any process of IC which upholds the principles of medical partnership and patients' autonomy. For instance, there was technically no real opportunity for a process of disclosure to be unpacked over time, or trust to be gradually developed with the clinicians. Partnership and autonomy might, in this sense, only work with a medical intervention that entails longer diagnostic/care acts and outside of a pandemic context.

Looked more closely the safeguard of IC and of its principles of medical partnership and patients' autonomy should stand in both scenarios (1) and (2), while also asking for a more tailored approach. What this means is that IC is a key patients' right in the medical context widely framed, and its guiding principles are to be embraced, though in a nuanced way, even in the context of a pandemic and, in this case, COVID-19 vaccinations. In this sense, it is true and crucial that IC is mindful of the broader pandemic context and considers also the nature of vaccinations. However, its safeguard cannot and should not be jeopardised. In this respect, for instance, time and resource constraints, as I will also clarify later, should call for brainstorming new ways of fostering patients' informative rights and dialogue with clinicians in a time of crisis. Particularly IC, in light of both the nature of vaccinations and the

14 For an overview of informed consent to vaccination and how its ethical framework, particularly concerning patient's autonomy, has been tailored in practice in USA and Israel see: D. Rubinstein Reiss and N. Karako-Eyal, 'Informed consent to vaccination: theoretical, legal and empirical insights', *American Journal of Law and Medicine* 45 (2019) 357–419.

broader pandemic context, with its call for a patient-centred dialogue, asks for an attention to be paid to the unique patients' circumstances and for the provision of accurate medical advice in a timely manner for each vaccination dose, while also being aware of the broader public health stages and its needs and challenges (e.g., lockdowns, resource constraints). Ultimately, IC is not to be confined only to 'normal' (i.e., outside pandemic) circumstances, nor to only specific medical interventions. If the judgment in *Montgomery* is to be taken seriously- as it should- the shape and form of IC can change, but its existence cannot be questioned.

The key question that this paper is addressing is hence how the information disclosure process has been tailored in the COVID- 19 vaccination context, where a variety of interests are at stake. Subsequent sections will argue that the latter poses questions of *timing* of disclosure and appropriateness of opportunities of dialogue between the relevant parties, both at the trial stage and after the vaccination roll-out. IC stands as a key patients' right even during a pandemic, though the process of disclosure needs to clearly take into account the broader public health emergency context.[15]

2.2 *Conclusions*

The significance of the right to IC, in light of the *Montgomery* case, goes beyond the mainstream medicine context to which the judgment was originally addressed. This right is of crucial significance even within a COVID-19 vaccine context. Though this might seem an obvious claim, there has been little academic discussion on the extent to which this right has been upheld, and on what a *Montgomery-compliant* IC process should have looked like for the COVID-19 vaccination context. The latter is a crucial question not just for an analysis of the approaches brought forward during the COVID-19 pandemic, but more so also to better prepare for future pandemic scenarios. This section has highlighted that the concurrent relevance of both principles of medical partnership and patients' autonomy has to be upheld within a *Montgomery-compliant approach*. Later sections will then claim that these 'guiding principles' do not entail a 'one-size-fits-all' approach, but need to be tailored in light of the broader pandemic circumstances in which the disclosure process has to be placed.

15 For a reflection on the importance of wider communitarian aspects within COVID-19 public health decisions, see: T.C. De Campos-Rudinsky and E Undurraga, 'Public health decisions in the COVID-19 pandemic require more than 'follow the science'', *Journal of Medical Ethics* 47 (2021) 296–299. In particular within the paper express reference is made to the importance of vaccination as a tool to uphold common good during a pandemic.

3 What is the Role that Informed Consent Has Been Playing in the COVID-19 Vaccination Context?

Having provided an overview of how IC should be framed in light of *Montgomery*, it should be then asked what is the role that this right has played in the COVID-19 vaccination context.

Some clarifications are needed here. The *prima facie* sentiment towards a discussion concerning IC, might be that of an inherent scepticism[16] towards vaccines and towards the impact that this can have on patients' health. This is not the approach of this paper. A conversation on IC is not driven by a desire to prove nothing, but that the vaccination context is no-exception to the relevance of this patients' right in the healthcare context widely considered. A pandemic context asks law and policy maker to tailor the protection of this right, for instance in light of the pandemic stages, but is not an exception to its protection altogether. This section, offering England as a case study, will claim that the question of IC is a substantial one and involves exploring to what extent a disclosure process of material information has been put into place. Crucially, to date, there is very limited data on IC and COVID-19 vaccination, that which there is is mostly derived from freedom of information requests (FOI). This section will then critically assess the NHS approach concerning information disclosure and COVID-19 vaccination of the adult population. It will be claimed that the safeguarding of IC has been mostly confined to IC as an *event*, whereby it is the mere provision of standardised information, the main means in place to safeguard this right. Such an approach, however, risks failing to uphold the whole picture of IC, where the relevance of an informative *process* is and should be upheld. Additionally, the safeguarding of IC is broader than the one of vaccine intake. Though the high number of vaccinations achieved in England[17] is a very welcomed phenomenon in a pandemic context — as a key act of prevention and containment of the spreading virus —, this does not implicitly signify that IC has been also safeguarded. A reflection on IC, as a key patients' right, needs to find wider space even in a

16 For a wider reflection on the challenges connected to vaccine scepticism see: A. Giubilini, F. Minerva, K. Schuklenk and J. Savulescu, 'The 'ethical' COVID-19 vaccine is the one that preserves lives: religious and moral beliefs on the COVID-19 vaccine', *Public Ethics* 14 (2021), 242–255.

17 See latest report of vaccination uptake in England, available online at https://coronavirus.data.gov.uk/details/vaccinations (accessed 9 February 2023). See also Tumelty et al., *supra* note 5, where, looking at the Irish context, they highlight that the question of consent is different from a question of vaccine intake. The latter can be a successful one, but does not imply that consent has been safeguarded.

pandemic context. This is also because in a pandemic context act(s) of prevention (e.g. vaccine compliance) and acts of care (e.g. safeguard of IC) need to go hand in hand. Ultimately, what will be argued is that IC has risked playing a minimalistic role in the COVID-19 vaccination context in England. Such approach has been based upon a misunderstanding of what IC *is* and has risked upholding at best a *mere consent* oriented approach.

Three publicly available FOI request responses on COVID-19 vaccines and IC can help having an overview of the NHS approach in this ambit. A first relevant FOI was addressed to Public Health England (PHE). Here a citizen was asking how IC was carried out during COVID-19 vaccinations. PHE replied via making no more than a general reference to its consent forms to support its statements:

> 'Thank you for your request for information concerning how informed the UK public are when taking the coronavirus vaccine and any possible side effects that are currently known. All adults who have currently been offered a coronavirus vaccine are asked to sign a consent form that is accompanied with a fact sheet explaining what vaccine they are receiving and what if any possible side effects are currently known. I include links to the consent form and the information factsheets on the coronavirus vaccine [...]'.[18]

A second relevant FOI was addressed to a local NHS provider, South Sefton Clinic.[19] The applicant asked for, amongst others, data on staff trainings on IC and COVID-19 vaccinations. The local provider was partially able to fulfil this request, referring to the existence in principle of such trainings, while being unable to provide data on the extent to which staff members actually undertook these trainings.

In a further FOI addressed to NHS Wales[20] the response was more detailed than the formers. NHS Wales outlined how IC has been intended to be

18 *What they know, Proof of informed consent, 14th April 2021*, available online at https://www.whatdotheyknow.com/request/proof_of_informed_consent?utm_campaign=alaveteli-experiments-87&utm_content=sidebar_similar_requests&utm_medium=link&utm_source=whatdotheyknow, p. 4 (accessed 7 October 2022).

19 *What they know, Informed consent, 25th May 2021*, available online at https://www.whatdotheyknow.com/request/informed_consent_3#incoming-1817717 (Accessed 3rd October 2022).

20 *What they know, Violation of informed consent enquiry, 8th April 2021*, available online at https://www.whatdotheyknow.com/request/violation_of_informed_consent_en?utm_campaign=alaveteli-experiments-87&utm_content=sidebar_similar_requests&utm_medium=link&utm_source=whatdotheyknow (accessed 7th October 2022).

administered, via both the provision of pre-appointment leaflets and conversations on the vaccination day. NHS Wales made also reference to the 'training slides' used for clinicians:

> 'Public Health Wales training slides on informed consent (which we base ours on) state: ·Before giving COVID-19 vaccine, immunisers must ensure that they have obtained informed consent from the patient or that a best interest decision has been made if the patient does not have mental capacity at the time of vaccination. ·In order to be able to consent to vaccination, the vaccinee should receive an explanation of the treatment and its benefits and risks, either verbally from a clinician, or in the form of a leaflet and letter'.[21]

Furthermore it added that:

> 'In addition to this, citizens have several opportunities and are encouraged to ask questions prior to being vaccinated. The UHB are able to provide the Specific Product Characteristics (SPC) information if requested. Furthermore, all consent gets documented on the Welsh Immunisation System'.[22]

It is the case that the first FOI offers little help in identifying the approach of the NHS, as it only highlights the existence of consent forms. The second highlights the existence, as a matter of principle, of staff training, while not being able to provide any figures on this issue. The latter, though referring to NHS Wales, seems to suggest that a wider approach beyond the mere information provision was to be put in place for a process that protects IC. The latter showing at least some good intentions to embrace the safeguarding of IC as something more than a mere 'one-off event'.

To have a better understanding of how IC has been safeguarded in the COVID-19 vaccinations domestic context, it is also useful to divide the issue into two crucial moments: (1) trial and recruitment of volunteers, and (2) vaccine distribution (particularly looking at adults with capacity). Both moments share the importance of safeguarding IC, for volunteers in the case of (1), and for the broader adult population in case of (2). An overview of these two crucial moments is able to show the broad limitations in the safeguard of IC as opposed to the approach that *Montgomery* would have called for. It should be

21 *Op. cit.* above.

22 *Op. cit.* above.

also clarified that there is also a further broader issue that merges both (1) and (2) which concerns the disclosure and offer of vaccine alternatives;[23] a choice that was often very limited. This issue, though important, is only mentioned here as it raises questions of allocation policies and, more broadly, of the 'what' of disclosure, something that is intentionally left outside of this paper, whose focus is on the broader dynamics of disclosure and on its wider challenges.

The first moment in time where IC has to be assessed is the trial stage. This marks the phase, prior to the vaccine approval and subsequent allocation, where recruitment of volunteers was necessary. The right to IC of volunteers was also of crucial importance, as this would have protected their right to be made aware of material information concerning an experimental treatment.[24] O Neill[25] in November 2020 expressed hopes in the use of informative processes when recruiting participants, particularly via the use of shared decision-making practices. The latter, as the act of tailoring information between clinicians and patients, could have helped, in O Neill's perspective, safeguarding both volunteers' autonomy and their trust in clinicians. However, Emmanuel et al.[26] highlighted that the safeguard of IC was at risk of being significatively jeopardised already at the vaccinations trial stage. Particularly, the provision of written consent forms was claimed not to be able to safeguard patients' right to IC. Such forms were often very lengthy, and the information enclosed inaccessible in nature. The information hence was often hard to grasp, rendering the informative process purely nominal, and at best upholding a minimalistic approach where only patients' consent was protected. This phenomenon was also not confined within a domestic context and was further supported by a US study run by Bothun.[27] He highlighted that even in

23 See on this point: E. Cave and A. McMahon, 'Should states restrict recipient choice amongst relevant and available COVID-19 vaccines?', *Medical Law Review* (2022) fwac042. DOI: 10.1093/medlaw/fwac042.

24 The issue of IC and vaccine trial was addressed also within a literature-based study. In this context it was analysed whether clinicians should disclose the risk of antibody-dependent-enhancement (ADE) to patients participating to COVID-19 vaccine trial. T Cardozo and R Veazey, 'Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical diseas', *International Journal of Clinical Practice* 75 (2021) e13795.

25 J. O'Neill, 'The COVID-19 vaccine, informed consent and the recruitment of volunteers', *Blog BMJ* (23 November 2020), available online at https://blogs.bmj.com/medical-ethics/2020/11/23/the-covid-19-vaccine-informed-consent-and-the-recruitment-of-volunteers/.

26 E.J. Emanuel and C.W. Boyle, 'Assessment of length and readability of informed consent documents for COVID-19 vaccine trials', *JAMA Network Open* 4 (2021) e2110843.

27 L.S. Bothun, S.E. Feeder and G.A. Poland, 'Readability of participant informed consent forms and informational documents: from phase 3 COVID-19 vaccine clinical trials in the United States', *Mayo Clinic Proceedings* 96 (2021) 2095–2101.

a US context patients' participating in COVID-19 vaccine trials were not safeguarded in their right to IC.[28] Particularly, in the phase 3 vaccination trials the readability of the informed consent forms was low, this leading to a difficulty for the participants in 'comprehending the information provided in the consent forms and informational documents'.[29] The provision of written consent forms to volunteers at the trial stage seems to show friction with a safeguard of IC. This right was protected at best as a one-off-event, where little opportunity for a tailored process of disclosure appeared to have been offered.

When it comes to the subsequent relevant moment in time, namely vaccine distribution, the question of seeking IC from the adult population is also crucial, possibly even more so, as this also involves a wider scale of population, compared to the trial phase. In England, the provision of information from the NHS during this phase was mostly demanded to two further moments in time. The first, through the provision of standardised written information via post before a vaccination appointment was booked[30] by the patient. The second moment was the provision of information immediately before receiving the jab.[31] The act of sending written standardised information via post, pre-appointment, could serve as a toolbox of 'preparatory information' to be used, at least theoretically, in the latter context (i.e. on the vaccination day).[32] In other words, the information provided before the appointment could

28 A further critical analysis of IC within the trial stage in a US context is provided by Haik. See: Y. Haik and E. Polymenopoulou, 'COVID-19 vaccines and their pitfalls in informed consent', *Hastings Science and Technology Law Journal* 12 (2021) 147–184.

29 Bothun et al., *supra* note 27, 2095.

30 Further forms of written information were also produced by professional bodies such as the Royal College of Obstetricians and Gynaecologists and the Royal College of midwives. See their leaflet for pregnant women: RCOG, *Information sheet and decision aid*, available online at https://www.rcog.org.uk/globalassets/documents/guidelines/2021-02-24-combined-info-sheet-and-decision-aid.pdf (accessed 7 October 2022)

The GMC also produced decision-aids for clinicians, in the format of online Q&A. See on this point: GMC, *Coronavirus your frequently asked questions*, available online at https://www.gmc-uk.org/ethical-guidance/ethical-hub/covid-19-questions-and-answers#[Vaccines] (accessed 7 October 2022).

31 This was also the time when a further leaflet was handed to patients. For an example of this see concerning Pfizer/Biontech see: MHRA, *Package leaflet information for the user*, available online at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1033607/Comirnaty_PIL_clean.pdf (accessed 7 October 2022) See also consent forms for adults : Public Health England, *COVID-19 vaccination: Consent forms and letters for adults*, 2020, available online at https://www.gov.uk/government/publications/covid-19-vaccination-consent-form-and-letter-for-adults (accessed 7 October 2022).

32 Similar considerations apply also to the provision of booster jabs, where the only information provided is limited to the time of the 'vaccination-day' per se.

offer (if read) an outlook of information that could be further brainstormed on the vaccination day. Though the extent of the phenomenon is currently left unexplored, as patients' data is lacking on this issue, it is still possible to identify some preliminary challenges through the lenses of a *Montgomery-based-approach.* Particularly, as IC stands, the risk is that in both circumstances (i.e., before a vaccination appointment and on the vaccination day) the provision of information might be once again set as a *one-off and unilateral event* which provides a standardised approach and gives little wait to a patient-centred and fact-centred approach. It seems to demand that patients either 'do their own research', or 'blindly' undertake the vaccination without having had a real opportunity of being informed, in this sense also feeding the possibility of further misinformation to be spread. Furthermore, when it comes to the disclosure of information disclosed on the vaccination day, the risk of reiterating a standardised approach can be supported via reference to National vaccine protocols.[33] According to the latter, medical staff involved in the vaccination process were required to address IC primarily via making sure that written information was handed to the patient. These protocols also seemed to hint that additional information had to be provided only in 'exceptional cases' (e.g., pregnancy, breastfeeding, immunosuppressed patient),[34] rather than embracing a patient-centred approach. The protocols themselves could risk framing even the opportunity of a more one-to-one conversation surrounding material information on the vaccination day, as a nominal one. However, even assuming that a more tailored conversation took place, it should be well wondered to what extent this was at least a *timely* opportunity. The latter timeframe (i.e., vaccination day) is often very limited, the decision already made and the opportunity of a real dialogue between the parties often hampered by time-constraints. It is the case that both, the provision of leaflets via post and the conversation on the vaccination day can risk being only nominal opportunities to safeguard IC, rather than actual ones. Crucially, the risk of failing to uphold a *Montgomery-compliant approach* is far from removed.

33 For an overview of all the national protocols concerning COVID-19 vaccinations see: NHS, *National protocols for COVID-19 vaccines*, available online at https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanisms/national-protocols-for-covid-19-vaccines/ (accessed 7 October 2022) The issue of informed consent is particularly highlighted within section 1.b, it is however rather remarkable that the protocol invites the provision of written information through handing a series of listed documents, again reiterating the risk of a standardised approach.

34 See as an example the National protocol for Spikevax. UK Health Security Agency, *National protocol for Spikevax*, available online at https://www.gov.uk/government/publications/national-protocol-for-covid-19-vaccine-moderna (accessed 7 October 2022), 14, 17–19.

On a closer look, the risk connected with the use of mere written information and of a medical consultation on the vaccination day, can reveal a misunderstanding of what IC, in a *Montgomery-compliant-approach*, actually entails. As Cave argued, consent and IC are not the same thing 'informed consent is not necessarily valid (if it is not voluntary or capacitous) and consent that is valid is not necessarily adequately informed. This flows from the different informational thresholds that apply in battery and negligence'.[35] The approach that has been brought into place in England, could be hence framed, at best, as safeguarding mere-consent through the offer of *standardised* information. The demand of IC is different. Patient-centred practices don't call for mere provision of generalised information, but for a process of disclosure that is tailored and meaningful for the *actual* patient.

Using the lenses of a *Montgomery-compliant approach* this section has offered a possible view on some of the challenges connected to the safeguard of IC in the COVID-19 vaccination context. The latter can well resemble an event, safeguarded via the mere provision of information. This was a challenge already during trial stage. The subsequent vaccine distribution phase did not bring any significant hope for a change in approach in the safeguard of IC. It is the case that IC, in light of the interpretation provided of the judgment in *Montgomery*, cannot be deemed to be safeguarded where opportunities of dialogue and support are not provided, where both the needs and concerns of the patients are not necessarily heard, and material information offered in a way that is accessible and relevant for the actual patient. IC is a *process*, not an event and a pandemic context cannot be an altogether exception to this.

4 What Should Be the Role of Informed Consent?

In light of the *Montgomery* ruling, the limitation of the current IC approach in the context of COVID-19 vaccination become clearer. This section will be addressing what should be the role of IC in a COVID-19 vaccination context, and hence how to better safeguard this patients' right during both current and future pandemics.

Montgomery, as also highlighted above, claims that IC is structured around two key principles: patients' autonomy and medical partnership. The two constitute two sides of the same coin. The former, patients' autonomy, supports the importance of disclosure of information as a tool to uphold patients' agency, the latter, medical partnership, recognises that clinicians' advisory role

35 E. Cave, 'Valid consent', *Journal of Medical Ethics* 47 (2021) e31.

can prove to be beneficial in this context. This also finds support within the latest GMC guidelines on consent[36] where forms of supported-decision-making are offered as the best suited to safeguard IC. Supported-decision-making entails that both patients' autonomy and medical partnership can find a space in the disclosure process when time and space are allocated for a fruitful and patient-centred dialogue[37] around material information which are both scientifically accurate in nature as well as relevant and understandable for the actual patient. Particularly in the context of COVID-19 vaccinations, IC becomes hence a key tool to support the decision-making process, and to also offer the opportunity to tackle wider social phenomenon (e.g., possible vaccine hesitancy[38] or misinformation).[39]

It is hence important, moving forward, that new ways are brainstormed to uphold this right and to address the minimalistic approach described in previous sections. Firstly, there is a crucial research gap in exploring the impact of IC on adult patients, whether vaccine hesitant or not. It is of key preliminary relevance that this research gap is filled as this will help better understanding the breath of the phenomenon and how to best tackle it. Secondly, it is the case that the role of clinicians can, and should, be also reframed in this context as a tool that can help upholding the medical partnership pillar of IC. One possibility in this respect might be to reconsider how GPs can be better involved in the disclosure process. GPs are indeed those 'closer' to the needs of patients and can potentially better respond to their informative needs. In this sense, a research study in the COVID-19 vaccination context has revealed that GPs[40] often perceive themselves as not confident in their own abilities to support patients' decision-making process concerning COVID-19 vaccinations. This challenge, however, can also reveal the importance of better equipping GPs and providing them with the necessary trainings. For instance, this can be tackled via fostering a wider knowledge of national protocols on the administration

36 GMC, *Decision making and consent, 2020*, available online at https://www.gmc-uk.org/-/media/documents/updated-decision-making-and-consent-guidance_pdf-84160128.pdf (accessed 7 October 2022).

37 On the relevance of tailored forms of communication from 'trusted sources' which included those coming from healthcare providers, offered particularly as a tool to overcome hesitancy. See: M.S. Razai, U.A.R. Chaudry, K. Doerholt, L. Bauld and A. Majeed, 'Covid-19 vaccine hesitancy', *Britsish Medical Journal* 373 (2021) n1138.

38 See on this point: K. Sonawane, C.L. Troisi and A.A. Deshmukh, 'COVID-19 vaccination in the UK: Addressing vaccine hesitancy', *The Lancet Regional Health* (2021) 100016. DOI: 10.1016/j.lanepe.2020.100016

39 See on this point, The Royal Society, *supra* note 8.

40 R. Armitage, 'GP confidence in counselling patients about COVID-19 vaccines: a cross-sectional survey', *Public Health in Practice* 2 (2021) 100113.

COVID-19 vaccination[41] and how to best translate them into patient-centred disclosure practices. The latter will help them filling this 'knowledge gap' and provide GPs with a greater sense of confidence in their informative role.

The involvement of clinicians in a broader sense (i.e., beyond GPs) can also well resemble the provision of a 'counselling support'.[42] Relevant in this sense is also the suggestion formulated by Chervenak[43] to a form of professional counselling for the COVID-19 vaccination context. Clinicians, in his view, can exercise a supportive role particularly towards patients who are pregnant or considering to be, or are breastfeeding or considering to breastfeed. He uses this context as an example of one where, despite the limited evidence available at the time he was writing, mistrust and hesitancy appeared to be spreading. Challenged by the risk of pregnant/breastfeeding patients contracting COVID-19 and at being of a possible enhanced risk of contracting more grave forms without being vaccinated, Chervenak suggested that clinicians should have provided a crucial advisory[44] role in the decision-making process. Building upon the relevance attributed to clinicians' contribution, Durand et.[45] al have also emphasized the role that shared-decision making[46] can play in the COVID-19 vaccination context. When defining

41 *Ibid.*

42 L.S.-C. Law and E.A.-G. Lo, 'Counselling for COVID-19 vaccine is necessary: balancing the autonomy, beneficence and non-maleficence in the context of accelerating vaccine development', *International Journal of Clinical Practice* 75 (2021) e14015.

43 F.A. Chervenak, L.B. McCullough, E. Bornstein, L. Johnson, A. Katz, R. McLeod-Sordjan, M. Nimaroff, B.L. Rochelson, A. Tekbali, A. Warman, K. Williams and Amos Grünebaum, 'Professionally responsible coronavirus disease 2019 vaccination counseling of obstetrical and gynecologic patients', *American Journal of Obstetrics and Gynecology* 224 (2021) 470–478. For a critical approach see: M. Habiba, Professionally responsible COVID-19 vaccination counseling- response to Chervenak et al, Am J Obset Gynecol, (2021), *American Journal of Obstetrics and Gynecology* 225 (2021) 355.

44 See also for a consideration of the broader role that clinicians should play in the disclosure of information concerning COVID-19 vaccination Pruski, arguing that clinicians should also aware of how the vaccine was developed, produced and tested so as to be able to offer this information to those patients who consider this a relevant piece of information. M. Pruski, 'Conscience and Vaccines: Lessons from Babylon 5 and COVID-19', *The New Bioethics* 1 (2021) 13–14.

45 M.A. Durand, P. Scalia and G. Elwyn, 'Can shared decision making address COVID-19 vaccine hesitancy?', *BMJ Evidence-Based Medicine* (2021) 111695. DOI: 10.1136/bmjebm-2021-111695.

46 On a different approach see O'Neill, arguing that it is mutual persuasion that should be used in the covid-19 vaccination context as a way to foster rational decisions. J. O'Neill, Case for persuasion in parental informed consent to promote rational vaccine choices. *Journal of Medical Ethics* 48 (2022) 106–111. DOI: 10.1136/medethics-2020-106068; J. O'Neill, 'A lesson from COVID-19: persuasion can be a more powerful tool than mandates in improving

shared-decision making Durand et. al. emphasize the relevance of the provision of evidence-based information, while also giving weight to patients' values and preferences in the disclosure process. This approach, in their opinion, is particularly beneficial for tackling possible vaccine hesitancy, health literacy/illiteracy and risk communication. This also asks clinicians to develop an ability to listen, in an empathetic way, to the needs of patients, while also providing an accurate picture of relevant information. Particularly, when it comes to disclosure of risks, whose nature is inherently uncertain, Durant et al. emphasize, amongst others, the importance of not 'just' knowing the probability of the risk arising, but also the relevance attributed to certain risks by the patients. It is hence not the call of the clinicians to 'eliminate' the uncertainty with false claims, in a desire to bring forward a specific outcome, but to provide a truthful picture of the status quo of scientific knowledge in a way that is significant for the actual patient.

The relevance of both Chervenak and Durand's reflections is key in our context, as they emphasise the concurrent importance of patients' agency and the positive role clinicians can play in upholding patients' informative rights (IC). However, the approach that they propose seems to suggest that clinicians should 'nudge' patients with the only aim of increasing vaccines intake. The latter, though a positive aim in a pandemic context, might risk going 'too far' and with it also missing what IC is there for, namely to provide the 'informative package' based also upon which patients can reach their own final decision and hence take their own 'risks'.[47] Partially disagreeing with them, it is claimed here that IC should stop at the gates of providing informative advice to patients, without the need to reach a mutually agreed decision or forcing a decision on the patient,[48] as it is in a model of shared-decision-making. This does not entail ignoring the importance of vaccination as a public good during a pandemic, but can contribute to supporting IC in the wider context of non-compulsory vaccinations, as it has been the case in England during the COVID-19 pandemic.

vaccine uptake', *Journal of Medical Ethics Blog* (28 Apr 2020), available online at https://blogs.bmj.com/medical-ethics/2020/04/28/a-lesson-from-covid-19-persuasion-can-be-a-more-powerful-tool-than-mandates-in-improving-vaccine-uptake/ (accessed 7 October 2022).

47 P. Huang, COVID-19 vaccination and the right to take risks, *J Med Ethics* 48 (2022) 534–537. DOI: 10.1136/medethics-2021-107545.

48 On a different approach see: A. Giubilini and J. Savulescu, 'Vaccination, Risks and freedom: the seat belt analogy', *Public Health Ethics* 12 (2019) 237–249, arguing in favour of compulsory vaccinations in a wider public health ethics context.

IC, in the context of COVID-19 vaccinations,[49] and in a *Montgomery-compliant approach*, calls for a more patient-centred interaction between the parties. This interaction, in line with the recent suggestions formulated by the GMC concerning supported-decision-making practices, gives due consideration to the uniqueness of the circumstances of the patient and their medical background, while also acknowledging the broader pandemic circumstances. In the future, a model of supported-decision making will be hence more suitable for a pandemic context, since this will frame the medical encounter as an opportunity for patients who wish to be better equipped in their decision-making process and to receive more tailored and reliable information.

5 Tackling Possible Criticism: Some Ethical and Practical Concerns

However, the claim that the involvement of clinicians can be of key importance for better supporting IC in the COVID-19 vaccination context and in future pandemics, might be deemed contentious on both an ethical and more practical standpoint.

As far as an ethical standpoint is concerned, this proposal might risk being framed as a form 'paternalism disguised', namely a context where 'doctors' are the ones who know best what and how to inform patients. In this vein, IC might be framed as the 'business' of clinicians alone. On a deeper level, such criticism is the result of a clear misinterpretation of IC. What this paper is proposing is not a return to a paternalistic perspective, but to a disclosure process where clinical expertise and patients' autonomy can be reconciled. Patient-centredness is hence, as said above, key. Material information is tailored in light of medical expertise *and* patients' needs and circumstances. The goal is not to reach a shared-decision, as per a shared-decision making model, but to support patients in their decision-making journey. That this is the case, it is also supported by the related idea, as expressed also in *Montgomery*, that the patient has also the right to refuse such information, should this person wish to exercise the right not to be informed.[50] This proposal also wishes to tackle the risk of patients' being abandoned to[51] their own fate, in navigating the ocean of not-always-reliable information, as it has been the case during

49 For a broader analysis of the role of IC in the COVID-19 context widely understood, see also: X.M. Jones, O. Zimba and L. Gupta, 'Informed consent for scholarly articles during the COVID-19 pandemic', *Journal of Korean Medical Science* 36 (2021) e31.

50 *Montgomery* at [85].

51 See: A. Maclean, *Autonomy, Informed Consent and Medical Law* (Cambridge: Cambridge University Press, 2009) pp. 23–29.

the COVID-19 pandemic context. Clinicians' advisory role can appear to be in this sense *an* opportunity, tailored in light with patients' needs, to support the decision-making process and the vulnerabilities and hesitations that patients can experience concerning COVID-19 vaccinations. Dialogue and communication around reliable and accessible information are hence the place where IC can be best unpacked and also where both doctors expertise and patients' voice can find a place.

On a more 'practical' standpoint, however the proposed involvement of clinicians might appear to be misplaced in a pandemic context. Given the immense pressure under which the NHS has often been during the COVID-19 pandemic, this additional request could not and should not find room for a realistic implementation. A clarification is important here. What this paper is saying is that the current understanding of IC, mostly resting on a consent-based approach, risks failing to safeguard IC. A call for a change in approach, however, does not mean ignoring the broader public health emergency context in which COVID-19 vaccinations are placed. In this sense, the safeguard of IC can and should be tailored in line with the different pandemic stages, yet it cannot be altogether denied. On this latter point also Turnham et al. pointed out that a pandemic is no exception to the safeguard of IC.[52] In this sense, the availability of forms of telemedicine (i.e. understood as forms of online/remote consultations) can, for instance, support the safeguard of IC when seasons of full lockdown are in place. However, the opportunity of face-to-face encounters, particularly when restrictions are lifted, could be also offered. Take as an example the case of those aged 16–29, who have formed one of the most vaccine hesitant categories in England since the early stages of the pandemic.[53] It is the case that the offer of a first dose of vaccination for them was only provided in June–July 2021. During the time between the start of the vaccine roll-out (December 2020) and the actual opportunity to book an appointment (June–July 2021), the provision of standardised written information could have

52 Turnham et al., *supra* note 12.

53 In an earlier report, January–February 2021, the age group that has registered the highest number of concerns was those aged 16–29. ONS, Coronavirus and vaccine hesitancy, Great Britain: 13th January–7th February 2021, available online at https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandwellbeing/bulletins/coronavirusandvaccinehesitancygreatbritain/13januaryto7february2021 (accessed 7 October 2022). This has been followed by a progressive decrease according to the latest ONS reports, see: ONS, *Coronavirus and vaccine hesitancy, Great Britain: 9th August 2021*, available online athttps://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandwellbeing/bulletins/coronavirusandvaccinehesitancygreatbritain/9august2021 (accessed 7 October 2022), 2.

been integrated by the offer of an express opportunity of more tailored disclosure, through for instance videocall(s) or face-to-face encounter(s) or use of decision-aids tools, depending on the stage of the pandemic. What this example wants to show is that IC is not to be framed as an extra burden upon the NHS during a time of crisis, but as an opportunity both for patients and doctors to find *new ways* to support the decision-making process before the decision of taking the vaccine takes place.

The protection of IC in the COVID-19 vaccination context in England has often rested on a minimalistic stance. It has been suggested that a *Montgomery-compliant approach* would call for a re-framed involvement of clinicians and patients in a way that upholds both principles of medical partnership and patients' autonomy. The contribution of both, patients and clinicians, matters for the safeguard of an IC process. While calling for more research in this field, the suggestions formulated above could be framed as *an* opportunity, or better one possible way of attempting to address the phenomenon and to better prepare for future pandemics.

6 Conclusion

This paper has analysed the role that the right of IC has played in the COVID-19 vaccination context. In England, despite the very positive overall vaccination intake numbers amongst the adult population, the importance of respecting this right has been often undervalued. The positive goal of achieving the greatest vaccination numbers across the population, has somehow shadowed the relevance of patients' informative rights. In this sense, IC has been framed at best as a 'one-off event' and not as a 'process'. The provision of standardised written information has offered the opportunity to support consent, but has risked failing IC. To respect IC as a process, in light of the Supreme court judgment in *Montgomery*, would have asked that opportunities for a dialogical and more patient-centred process between clinicians and patients were put into place.

After an analysis of the *status quo* and of its possible limitations, this paper has then moved to exploring new ways in which IC should be safeguarded in this context, while also raising issues of preparedness for future pandemics. It has highlighted firstly the importance of promoting research into patients' informative processes both pre and after the vaccination appointment. There is indeed a crucial lack of available data which needs to be addressed. On a wider scale it has claimed that a truthful, while patient-tailored approach, has

to be considered as the way forward. The importance of preparing for future pandemics also asks law and policy makers to brainstorm new ways in which the right of IC can be safeguarded. A reframed involvement of medical staff and patients, through for instance a better use of telemedical practices and decision-aids, has been suggested as one possible way to support the protection of IC, while also acknowledging the pressure under which the NHS is during the different stages of a pandemic.