

**Roundtable discussion on capacity to consent (for publication)**

**Roundtable Contributors**

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**Apologies**

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**Abstract:**

Obtaining consent from individuals for publication of their personal data is an integral legal and ethical step in the publication process. Where an individual is vulnerable or lacks the capacity to consent on their own behalf, there can be additional challenges for both authors and publishers. However, there is little guidance on best practice on this topic and the complexities involved in obtaining consent for these individuals can often lead to a higher rejection rate for research that involves vulnerable patient groups. To ensure our policies are both ethical and inclusive, BMJ held a roundtable discussion on capacity to consent to publication, where participants with expertise in patient consent policy, medical ethics, law and mental health fields were recruited to weigh in on key ethical questions that arise when obtaining consent for individuals who may lack capacity.

**Background**

**BMJ’s current position**

At a policy level, for BMJ Case reports, we do not allow publication unless we have received a signed BMJ consent form. However, since the appointment of the research integrity team we have the capacity to handle these on a case by case basis and we do consider content and context before making a publication decision.

Cases with patients involving mental health problems will often prove very challenging because often by necessity these case reports include additional psychosocial information, which is a valuable part of tier psychiatric history. This is where decisions can become very complicated.

**The problem**

There is no currently consensus in publishing on where the responsibility lies for ensuring appropriate consent has been sought. Does it rest with the author’s? or if we are talking about a research project, with the researchers? how much of it rests with the publisher/journal editors when we are making the decision to publish this (often in the public domain)?

**Assumptions for the purpose of the discussion**

1. We will assume full anonymisation can never be guaranteed (given the social media and use of A.I etc) and given the difficulty is where papers may have valuable information about the patient’s history, we will assume the patient is identifiable.
2. Consent for participation in research has been obtained (and is not for the purpose of this study) linked to consent for publication.

**Discussion**

*When considering to publish sensitive data about a vulnerable patient (i.e. who lacks capacity to consent to disclosure of their confidential information), how do we balance the value of the knowledge to the scientific community with the persons’ best interests and needs?*

* Consensus from both break out groups was that it is not possible to make a general decision to explicitly state when it is okay to publish information about an identifiable individual.
* Anonymisation may not always be enough to protect patients and again, should be considered on a case by case basis
* It will always be subject to the person involved, and their situation in order to make a best interest decision.
* It would be dangerous to be too engaged in the notion that there are clear circumstances when it is okay to proceed.
* The sensitivity of the data and its potential stigmatising effect should be considered
  + Including financially stigmatising effect in insurance based health systems such as the US

*Where does the responsibility lie in terms of making the best interest decision on behalf of the patient?*

* Irrespective of the presence of mental disorder, the law presumes all adults have capacity to consent.
* Legally, a best interests decision on behalf of the patient should only be made in the presence of incapacity.
* Value or personal value is relevant to informing best interest decisions
* Value / best interest has to be specific to the individual person: we can’t make a decision in general
* Just because someone lacks capacity, doesn’t mean that they can’t participate in decision making
* Consensus in both groups was that this should really lie with the author, because it is not feasible that an editor/publisher/journal would have the background to be able to make this decision or to gather the information needed i.e. about their values etc.
* We would have to seek information from their legal proxy, next of kin, loved ones and the researcher to determine what those values might be.

*When should the “best interest decision be taken?” Is it before the study is written up, at the submission? Or at point of publication?*

* It may be beneficial to have an on-going discussion with the individual involved in the research about the issue of publication starting at the point when consent is originally sought and revisited throughout the study. Using a similar model to that which is used to give consent to taking part in research as a participant
* If the individual is confirmed to lack capacity, then the best interests decision should be taken before the paper is written up and submitted to the journal.

*How can publishers manage the “vested interest” of authors/researchers, given they have a strong benefit for publication, in making the best interest decision on behalf of the patient?*

* People have a right to privacy, and this is enshrined in the General Data Protection Regulation (GDPR) which must also be taken into account. This means that it really must be questioned whether it is right to ever publish sensitive personal data without the person’s consent.
* Sensitive or personal data includes identifying that someone has cognitive delay for example, and so there must be a system of checks and balances that the publisher has in place pre-acceptance, taking into account best interests, to show that publication is needed to aid public interests in this case and furthering scientific knowledge.
* The journal is in the best position to make a decision on the scientific merit and the value to the literature, public health benefits etc. Though it is acknowledged that it can be extremely difficult to ascertain this. E.g if even one person is helped, is this enough to say there is a value? is it small enough to be discounted? How do we start to make these decisions and set these standards?
  + NB: it is particularly difficult to take this into account with single case reports - how beneficial are they to science / the literature?
  + It is also difficult for journals to argue something is in the public interest as journals have a very narrow view of this: need a protective presumption.
* Author’s are likely to consider their publication to be in the public interest, in this circumstance journals should ask authors to give substance to that argument and justify it. The group agreed that there is another role for journals to ensure that the interests of the researcher/author are not over prioritised when considered the best interest of the patient.
* The journal should have non-negotiable circumstances whereby, even if authors feel publication is in the patient’s best interest and these should be made available on the journal information for authors.
* Lastly, Publishers can manage vested interests by seeking authors assurance that the question relating to publication has been posed to a range of stakeholders who can assess the patient’s best interest, such as the multiprofessional group who comprise the ‘best interests meeting’ which must be called in the UK when making clinical, housing, welfare, financial and other decisions about the patient. This will include therapists, nurses, social worker/LA, family and befrienders, doctors.

*Can we rely on the Mental Capacity Act 2005 and Best interest decision legislation to inform guidance?*

* The Mental Capacity Act requires that when someone cannot make a decision for themselves about their care, that any decision made for them is in their best interests and has regard to the least restrictive option.
* However, the journals will get submissions from all over the world, so the journal cannot rely heavily on the MCA or government legislation as it may not apply elsewhere.
* In terms of jurisdiction, law should be a baseline rather than a ceiling. Journals should identify the ethical principles that you wish to uphold as the standard even, if legally publication would be permitted or defensible.
* For people with serious mental disorders, the MCA gives us a binary situation - the person does or does not have the capacity to consent. Contextual concerns e.g. vulnerability, insight make this more difficult in this context. Journals should be sure to consider the entire spectrum of capacity, including temporary loss of capacity, fluctuating capacity etc.
* The MCA has various flaws, but one of them is that by making it a person centered piece of legislation, it is open to interpretation by design. There is flexibility in this legislation: it doesn’t have the specificity that we would see with other legislation. Because of the nature of this legislation it is incumbent on institutions and organisations like BMJ to give clearer and better guidance to assist authors, researchers and other publishers in this.
* Making a best interest decision does not mean you are making a substituted judgement and you should also work the individuals to the furthest extent possible to determine their wishes and values in the consent process.
* Consensus from the group that as the legislation is lacking in specificity, and also not always applicable internationally, it would be useful for a Publisher like BMJ to create this action guidance for how to reach a best interest decision in a publishing context.
* Given the ambiguity of legislation and “best interest” it would not be helpful to just say - “this should be a best interest decision” but instead journals need to offer something more specific. BMJ should provide guidance instead to the factors that authors should consider if they are making a best interest decision and express the importance of this being person-focused.
* Other legislation which may relate to the decision to publish may include the “public interest” defence but it is likely that GMC, NHS and DoH guidance is likely to be most relevant

*Who should be involved in a discussion about “best interests”?*

* Whilst the MCA itself is binary, the accompanying Code of Practice used by clinicians and others is by no means binary, since it highlights (e.g. CoPs5 p 80-84) the great importance of the patient’s wishes and feelings and beliefs and values.
* Those involved in making a best interest decision (in this instance, the authors) should consider others, such as family, friends and those close to the person. They may not have a legal power to make decisions, but their views should still be part of the best interests decision.
* If there is a conflict between them and the publishers/authors it must be handled sensitively.
* The reasons for the conflict should also be carefully considered, especially in cases where the decision is to publish and those close to the person do not wish this to happen. An independent review or decision maker may be best placed to resolve this conflict as they will have an independent viewpoint of the factors and the balance of rights and interests in the case.
* Ultimately, there should be an open and honest discussion with the loved ones of the vulnerable patients so they are aware of the scientific benefits and the researchers are aware of concerns of the family. A decision can then be made collectively in a person-centred manner.
* If possible, it would be best to begin these conversations before the individual lacks

capacity to consent in case of conditions such as dementia. Or in instances of fluctuating capacity, during in the moments when the patient is deemed capable.

* There may be a role for ethics committees in this scenario and would sit well to be discussed during ethical approval. In guidance to authors the journal could encourage authors to take individual cases to their local clinical ethics committees if they were queasy about where best interests sit. This can be submitted to the journal when our checks query to determine if publication is in the best interests of the patients. TBMJ EC can review as final arbiter if the journal is still unclear.

*Who is an appropriate proxy for a patient who lacks capacity?*

* A proxy is helpful in contributing to the discussion about what the patient would have wanted, but we would still like to include a wider best interests discussion rather than rely on proxy consent alone.
* In England & Wales, other than the donee of an LPA or a court appointed deputy no person can provide consent on behalf of an incapacitated adult[RW1] .
* Ideally, patients should be encouraged to discuss the appointments of proxies (LPA) at a point when they have capacity to make decisions about their representatives in the future.
* Patient and public involvement is key to making understanding and establishing who the appropriate proxy may be.
* This would be the role of an attorney acting under a Lasting Power of Attorney for Health and Welfare (as per BMJ Legal team), and possibly a deputy for health and welfare if their court order gives them this power – this is for England and Wales. An attorney or deputy must also follow the rules of the MCA, and so can only make decisions that are in the person’s best interests and have regard to the least restrictive option.

*Should BMJ encourage the use of independent mental capacity advocates (IMCA) in these conversations?*

* To address the matter of conflicts, if the author was making the decision, they would need to involve consultees and the choice of consultees is important and also can again become a matter of interpretation.
* Journals could advise about the inclusion of IMCAs in the decision (mental capacity advocate) and to ensure the patient is being looked at as their own person.
* IMCAs can only be invited if the patient is unsupported or if there is a reason to believe the person is not acting in the patient's best interest, so whilst it would be helpful to advise this, the practicalities of getting an IMCA are difficult.
* The authors should be justifying to the journal, explaining why they believe it is in the best interest of the patient, based on the facts. They need to tell editors in plain english why they think publication is in the patient’s best interest: this can ultimately still be the editor’s decision and if they are not convinced by the author, editors can open that discussion with the author.
* Given jurisdictional norms and complications, things like IMCAs are rather too specific, and even in England and Wales quite peripheral overall (i.e. in the sense that they might be useful, but only in a relatively small proportion of instances).

*What should be included in guidance for authors on decisions in best interests?*

* We should keep in mind the Mental Capacity Act and its principles:
  + Presume capacity
  + Unless behaviour causes us to doubt their ability to consent
  + The focus should be on the person’s ability to make the decision, the cognitive test, and not the person’s disability.
* Under the MCA you are required to provide all practicable support as necessary and appropriate to aid the person to make their own decision. This should be person centred, and not just assumed that because one person with a mental condition was helped by doing one thing this will help someone else with the same condition, instead it needs to be person centred to see what will help them (as an individual).
* Recognise that decisions relating to control of confidences are more subtle than consent for an otherwise unwanted touch. Disclosure of confidences require greater cognitive ability, so do not assume that the patient who establishes their capacity to consent for dental extraction must per se have capacity to consent for disclosure of her medical information
* Examples of support to improve capacity for decision making can be simple things such as
  + turning off background noise
  + choosing a better time of day for that person
  + providing information in different formats and breaking it down
  + pictures or objects as prompts
  + having someone else present who knows them to support them
  + if the person has good days and bad days be prepared to gain consent another time
  + With the right support in place someone may be able to provide (or refuse) consent and so make this decision for themselves which should always be the desired outcome

*Do we have the right to prevent someone from participating in research as an endeavour for “the public good” just because they lack capacity? Is this considered a harm to the patient?*

* Referring to Section 4.6.c of the MCA
* You must consider other factors that indicate what the patient would have been likely to do (i.e. did they express support for medical research, were they in favour of scientific publication?)
* There could be an argument to be made, that unless you have a reason to believe otherwise, the default position of a patient who is a member of society and the public, there is a reasonable assumption that they are public spirited, unless we have a reason to believe otherwise. Therefore they can be assumed to want to contribute to the public good.
* Considering the Best interests approach - this does include the person’s past, present and future preferences, so someones previous actions and stated wishes could possibly be an argument that it could be in their best interests. For example, if a person with dementia has always been a private person, not sharing their medical information with anyone and not interested in publicising their medical history this must be considered as it is likely that they wouldn’t have previously given consent.

If they have shared this information in the past, or expressed wishes when they were able to do so, this can be considered a reason to believe this would be in their wishes and denying the opportunity would be a harm.

* Examples of this being in their wishes include
  + if they had agreed to medical research
  + published stories and blogs and shared their experiences of living with cognitive disorders or illness online then they may have been more likely to have given their consent
* Ultimately, as is the theme throughout this discussion, this is not a question for the journal but for the clinician/researcher, as they are the ones who must justify the decision to publish.

*Is the nature of the illness important i.e. whether the person has fluctuating, temporary or permanent impairment?*

* It is unhelpful to put “patients who lack capacity” into one broad category
* The consensus was that the temporary or permanent nature of the impairment does matter and should be considered.
* The persistence of their lack of capacity is important: if they can be expected to regain capacity, any decision should wait until that point
* Where there is an opportunity to work with the patient to enable them to be able to provide consent on their own behalf then this is important (i.e. in case of fluctuating capacity).
* Alternative categories could be:
  + Permanent incapacity, unlikely to recover (e.g. severe dementia)
  + Recovery expected (e.g. after a stroke)
  + Relapsing and remitting (e.g. schizophrenia)
  + Young children
  + Children who are less mature
  + Children who are more mature (ref. Gillick competence)
* NB: We advise considering children and adults differently when obtaining consent, even if the principles end up being broadly similar. Those under 16 have no status with respect to capacity, and parental responsibility muddies the water

*Do publishers/researchers have a duty to protect patient “dignity” even though the patient may not be able to comprehend “dignity” or the impact of publication?*

* Is it plausible ethically to discuss dignity harms, when the patient may never experience for themselves those dignity harms?
* Even though they cannot experientially inhabit their dignity, as publishers we should recognise dignity harms are still relevant for a patient who permanently lacks capacity as for a patient who has capacity.
* Dignity harm can also be experienced by and have an impact on family members, children, other relatives etc.
* We still have a duty to protect patient dignity
* It should be noted that publishers are not held to the same boundaries of medico-legal case law. However, we can consider it as good practice, since publishers should not collaborate with clinicians whose professional standards fall below the reasonable standard of care.

*How do we identify patients who lack capacity to consent?*

* As publishers we must recognise that there is an enormous spectrum of mental disorders and that in fact it may be more important to be able to ensure we distinguish between patients who lack capacity, and patients who have the capacity to consent but who are vulnerable.
* The law presumes that all adults and young people have capacity to consent and with patients who suffer mental disorders, it is a small percentage that actually lack capacity.
* Where a patient can be definitively identified as permanently lacking capacity, decision making is often more straightforward than for those who may have fluctuating capacity or patients who are vulnerable but who actually have the capacity to consent.
* Where consent is concerned, It is important to consider the following groups separately despite overlaps between them:
  + 1) patients who lack of capacity
  + 2) patients who lack insight
  + 3) patients who are vulnerable.
* We need to be able to support vulnerable patients who have capacity to consent but may lack insight into the impact of their mental disorder and the impact of publication. This lack of insight is what makes them vulnerable.
* Follow up questions for journals and authors to consider
  + how we might distinguish between these cases?
  + When can we assume capacity from the content of the submission and what flags would require us to seek additional involvement from authors or relatives?

*Do we require a difference in procedures for adults who lack capacity vs children who lack capacity?*

* Author's advice should include that ‘best interests’ for people under 18 (at least in England & Wales so likely mirrored at least in the Commonwealth) do not segue into adult practice.
* Best interests are only engaged in adults when they develop incapacity, whilst we frequently act in the best interests of competent children and capacitous young people in the family courts and medical arenas. Not invariably with their agreement, which of course has a bearing on the control of the child’s personal information.
* There is often a concern that parents will surrender their child’s confidences without sufficient consideration of consequences; in some instances equating to not acting in good faith.
* Another difference is that incapacitated adults have no obvious proxy for consent; ‘next of kin’ not being a legal entity. So for adults the best interests decision is for the clinician author in the first instance (in the absence of an LPA for H&W, or very rarely, a court appointed deputy).
* Whilst a child’s natural proxy is the person who possesses parental responsibility. The clinician author must then consider whether they agree that the parent of the incompetent child is acting in the child’s best interests.
* By contrast, based on *Axon* the competent child can defend their own confidentiality (i.e children can refuse to consent to share information - [reference: (Axon) v SS [2006] EWHC 37 (Admin)]
* Finally, the young person (16 & 17) poses some real difficulty, since as a child their parents still have the diminishing influence of parental responsibility; even if capacitous under the MCA 2005 the young person may lack *Gillick* competence; and the 2019 Supreme Court decision in *Re D* casts doubt over the ‘zone’ of parental responsibility for some decisions, which might well include disclosure of confidential matters ‘in best interests’.
* For all these reasons you may wish carefully to distinguish between adults and children in your general advice.

**Contributors:** The final write up of the roundtable was written by SR and CC and reviewed by all members of the roundtable prior to publication.