

GMC response to The Department of Health consultation on 'Introducing 'opt-out' consent for organ and tissue donation in England'

Thank you for the opportunity to submit our views on your consultation on introducing 'opt-out' consent for organ and tissue donation in England. To put this reply in context I will briefly outline the role of the General Medical Council (GMC).

We are an independent organisation that helps to protect patients and improve medical education and practice across the UK.

- We decide which doctors are qualified to work here and we oversee UK medical education and training.
- We set the standards that doctors need to follow, and make sure that they continue to meet these standards throughout their careers.
- We take action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk.

Every patient should receive a high standard of care. Our role is to help achieve that by working closely with doctors, their employers and patients, to make sure that the trust patients have in their doctors is fully justified. We expect doctors to be familiar with and follow our ethical guidance and be willing and able to justify any departure from it.

In responding to this consultation our aim is to ensure that any obligations imposed on doctors will not be inconsistent with the standards we set for doctors' professional practice.

We support the need to do more to help patients who need transplants, and to create an environment where the wishes of those who want to donate are respected. A soft opt-out system which relies on silence to presume consent may create a risk that a potential donor is held to have consented when in fact they have not. It's important that whatever approach to consent is implemented, it operates in a way that allows doctors to meet their professional obligations, and respect the autonomy of their patients.

Question 1 - Do you think people should have more ways to record a decision about organ and tissue donation?

We agree that the process or processes for people to record and update a decision to opt out of organ donation must be simple.

However, it is also important that any record is accurate and up to date. With multiple ways to record a decision there's a risk that not all records will be consistent. There will be ways to mitigate that risk, for example the patient signing and dating each record and perhaps providing detail about the circumstances surrounding their decision (in particular where that decision has changed).

Question 2 - What do you think are the advantages or disadvantages of including personal information on someone's organ donation decision?

As the professional regulator we are not in a position to comment on the potential value of including additional personal information, without knowing what kind of information would be recorded, and what practical purpose it would serve.

If the goal is to make sure that more is known about an individual's values and preferences at the time a decision is being made, this is something that could perhaps be addressed by individuals being encouraged to talk to their families and their doctor, and keep a record explaining why they wish to

donate and what matters to them. This is in line with our guidance on *Treatment and care towards the end of life*:

54 Depending on the patient's circumstances, it may also be appropriate to create opportunities for them to talk about what they want to happen after they die. Some patients will want to discuss their wishes in relation to the handling of their body, and their beliefs or values about organ or tissue donation.

55 You must approach all such discussions sensitively. If you are unsure how best to do this or how to respond to any non-clinical issues raised by the patient, you should refer to relevant guidelines on good practice in advance care planning. If the patient agrees, you should involve in the discussions other members of the healthcare team, people who are close to the patient, or an independent advocate.

Question 3 - How can we make people more aware of the new rules on organ donation?

While we can't suggest any specific promotional methods, we support an extensive communications campaign and agree that this needs to be active both before and after any new legislation comes into effect. We see this as fundamental to making sure – as far as possible – that those who will move into the presumed consent group know when this move will happen and are aware of the options available to them.

We know from recent developments in the courts, and elsewhere, the greater emphasis which is being placed on making sure patients are provided with good, clear information to support their decision-making. Clear communication about the choices available, and the implications of those choices in practice will be essential; and this should include information to help understanding of the processes involved in donation, and the role their family might have in the decision-making after their death.

This is consistent with our guidance on [Consent: patients and doctors making decisions together, where](#) we say that it is important to ensure that the patient has the relevant information they want or need to make a decision, including their right to refuse treatment (or, in this case, to opt-out of donating their organs after death). It must also be clear that they can change their mind about this decision at any time.

When providing information to support a patient in their decision making, assumptions should not be made about their understanding or what factors they consider significant in making a decision. The information necessary to make the decision should be given in a way the patient can understand. People should be given as much support as they need to understand the information, make a decision and communicate their wishes. For these reasons we suggest that the communications programme will be critical to the successful introduction of new rules on organ donation.

Additionally, we would urge that careful consideration is given to the scope of promotional efforts to make sure that information about the move to an opt-out system for donation and transplantation can reach all members of our society. Lack of appropriate and timely information, for those already disadvantaged in the healthcare system (those with poor literacy, people with no functional use of English, people with learning disabilities etc.) may mean that they are discriminated against in the way the new system operates in practice.

Question 6 - If the law changes and someone has died, and they have not opted out of organ donation, should their family be able to make the final decision?

If the same best interests principles apply to organ donation decisions after a patient loses capacity as apply to decisions about other treatments, then if a patient has not opted out, but not recorded an explicit wish to be an organ donor, then the family's view would be sought, in order to contribute to the best interests decision about organ donation. The family's role would be to say what they think the patient would want in the circumstances.

Having said that, care would need to be taken so as not to cause undue distress to the deceased's family, if the decision that is reached is in conflict with the family's own views about donation. There may be situations where it is appropriate – particularly if there is no recorded wish either way for the patient and nothing is known about the patient's views – to allow the family to have the final decision.

Question 7 - Do you think someone's family should be able to decide if their organs are donated, if it is different to the decision they made when they were alive?

If a patient has expressed and recorded an advance decision not to donate, and there is no reason to believe they have since changed their mind, then this must be respected and should not be overruled by family or the medical team when the patient loses capacity. The same principle would apply to a previously expressed and recorded decision to be an organ donor, if there is no reason to believe that the deceased has since changed their mind.

We understand that where an individual has either actively opted-in, or is known to have wanted to be an organ donor, there may be circumstances where respecting the deceased's wishes needs to be balanced against the potential of causing serious distress to the family.

On an individual level, we would highlight the importance of clarity about the purpose of consulting the family. Unless they have legal authority to make decisions on behalf of the patient, their role will presumably be to advise on whether they are aware of any (un)registered objection/wish to donate by the deceased. They should not be made to feel that their 'consent' is being sought ie that the decision on whether donation can proceed rests on their shoulders - ambiguity in this may make already distressing circumstances more pressurised and difficult for both family and medical staff.

In relation to treatment decision, we say, in [Consent: patients and doctors making decisions together](#):

76 You must also consider:

d any evidence of the patient's previously expressed preferences, such as an advance statement or decision

e the views of anyone the patient asks you to consult, or who has legal authority to make a decision on their behalf, or has been appointed to represent them

g what you and the rest of the healthcare team know about the patient's wishes, feelings, beliefs and values.

Under the proposed new arrangements, where no active decision to be a donor has been made, it may be difficult for the family of a potential donor to accept presumed consent as a clear basis for donation and they may refuse to allow donation to go ahead. To minimise this lack of clarity at the point at which organ donation becomes possible, it will be important to promote awareness and discussion of organ donation as widely as possible on an ongoing basis.

In our guidance for doctors on [Treatment and care towards the end of life: good practice in decision making](#), we have the following paragraphs on organ donation:

Organ Donation

81 If a patient is close to death and their views cannot be determined, you should be prepared to explore with those close to them whether they had expressed any views about organ or tissue donation, if donation is likely to be a possibility.

82 You should follow any national procedures for identifying potential organ donors and, in appropriate cases, for notifying the local transplant coordinator. You must take account of the requirements in relevant legislation and in any supporting codes of practice, in any

discussions that you have with the patient or those close to them. You should make clear that any decision about whether the patient would be a suitable candidate for donation would be made by the transplant coordinator or team, and not by you and the team providing treatment.

83 Your professional responsibility does not come to an end when a patient dies. For the patient's family and others close to them, their memories of the death, and of the person who has died, may be affected by the way in which you behave at this very difficult time.

Question 8 – Which groups should not be included in the proposed new rules about organ donation?

We agree that children and young people under 18, people who lack capacity to decide whether to opt out, visitors to England and those living in England for less than 12 months should be excluded from the opt-out model. We do not have any additional groups to suggest. However, we note that the option to opt-in will remain and consider that children and young people, and adults whose capacity is in doubt, should be supported to make their own decisions about donation where possible and appropriate.