

16 February 2021

Organ Donation Consultation
Department of Health
Room 1 Annexe 1
Castle Buildings
Stormont Estate
Belfast
BT4 3SQ

To whom it may concern,

Public Consultation on the introduction of a statutory opt-out system for organ donation for Northern Ireland: GMC response

- 1 We welcome the opportunity to comment on the consultation: 'introduction of a statutory opt-out system for organ donation for Northern Ireland'.
- 2 Some of the questions in the consultation fall outside our regulatory remit. We have therefore restricted our comments to a small number of areas. For these reasons, as well as for ease of reading, we have chosen to respond to the consultation in the form of a letter.

The GMC's role and remit

- 3 The General Medical Council (GMC) is an independent regulator 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. There are approximately 337,000 doctors on the UK medical register. Of these, approximately 299,000 have a licence to practise.
 - 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.
- 4 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.

Key comments

- 5 The GMC does not take a position on statutory opt-out organ donation. In responding to this consultation our aim is to ensure that any obligations imposed on doctors will be consistent with the standards we set for their professional practice.
- 6 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.
- 7 It seems to us that to ensure public and professional confidence in a statutory soft opt-out system, it will be important to have an accessible, simple process for individuals to exercise their right to opt-out. It should also be easy for professionals and family members to check whether such an objection has been registered, when a patient has died and donation is being considered. This would reduce the scope for disagreements and the challenges that may be faced by healthcare staff involved in advising or supporting family members who are asked to consider whether organ donation is in line with a patient's wishes and values.
- 8 As consent to any medical intervention relies on patients being provided with good, clear information about their options and any risks and benefits; it seems to us that 'deemed consent' has to be based on a strong public awareness programme supported by easily accessible information to ensure a reasonable level of community knowledge about the implications of the opt-out system and how to exercise choice within it.

Question 6 Exemptions to Opt-out Legislation

- 9 We agree that adults who lack capacity to make a decision about organ donation should be excluded from any opt-out system.
- 10 It is difficult to see how someone who lacks capacity, for example to understand the idea of an opt-out system and/or what it would mean in terms of what happens to their body after death, could be deemed to have given consent to donation.

- 11** However that does not mean that a person who lacks capacity in relation to exercising or expressing a choice about opting in or opting out of organ donation, will not have wishes and preferences that would be relevant to a decision about donation made by a family member after the person has died. There should be a clear expectation that decisions made about donation by a person who was exempt from 'deemed consent' will take account of that person's previous wishes, preferences and values and not solely rely on those of their partner, carer or family.
- 12** It would be helpful, especially for clinicians, to understand what "lack of capacity" means in this context. Does it refer to a patient who lacks capacity to understand the concept of an opt-out organ donation scheme and what it might mean for them to either opt-out/ do nothing, or capacity to exercise a choice about donation after death?
- 13** It would be difficult for clinicians to operate a system where a person's exempt status changes with each change in their decision-making capacity. We note that in England and Wales adults are only excluded if their lack of capacity lasted for 12 months, or more, prior to the time of the decision about donation. It might be helpful to explore whether there is any learning from Wales to inform where a threshold for exemption might sensibly be set.
- 14** In a scenario where there is no clarity about a dying patients exemption status, it would be helpful to have information about the appropriate steps needed to determine this. Are clinicians able to rely on a statement by a patient's partner or family, that the patient is 'exempt', or would they be required to check this before letting the partner or family decide on donation?

Question 7-9 The Role of the Family and Loved Ones

- 15** Speaking to the patient's loved ones can be invaluable when trying best to determine what a patient would have wanted and whether the patient's organs may be suitable for transplantation. A patient's loved ones may be able to inform the doctor if:
 - i** they are aware of any (un)registered objection/wish to donate by the deceased;
 - ii** they are aware of the patient's last known views. For example, the patient may have changed their mind since they last registered their preference on the Organ Donation Register;
 - iii** they are aware of the deceased's views on organ donation;
 - iv** they know anything about the patient's health or lifestyle that would help determine whether the organs would be safe to transplant;

- v they can offer any insights into the deceased values or beliefs (including religious beliefs) that may have shaped their views about donation.
- 16** If the best interest principle applies, as with other treatments, the families of patients who lose capacity have a role in contributing to best interest decisions about organ donation, i.e. if a patient has not opted out, but not recorded an explicit wish to be an organ donor, the family's role would be to say what they think the patient would want in the circumstances.
- 17** 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.
- 18** As well as family and loved ones, the Department of Health (NI) might want to consider if there's value in highlighting the possibility of consulting with other health or care professionals involved in a person's care, where that's practicable.

Question 12 Faith and Beliefs

- 19** We agree that a patient's faith should continue to be taken into consideration as part of the donation discussion after any move to an opt-out system. [Our *Personal beliefs and medical practice* guidance](#) explains that:

In assessing what is of overall benefit to adult patients, you must take into account their cultural, religious or other beliefs and values.

- 20** Our guidance also makes clear that a patient is entitled to receive care that is consistent with their personal beliefs. Equally, this is consistent with the responsibilities of Health and Social Care (HSC) Trusts to ensure they are promoting equality of opportunity between persons of different religious beliefs, in line with Section 75 of Northern Ireland Act (1998).

Question 13 Raising Awareness of the Change in Legislation

- 21** While we can't suggest any specific promotional methods, we support an extensive communication campaign and believe 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 deemed consent group know when this move will happen and are aware of the options available to them. Those who wish to opt-out will need to be well informed about how to do this, and the families and carers of people

who are exempt will need clear accessible information about what their roles might be in making decisions about donation.

- 22** Clinicians and the health and care teams they work with will need access to good quality patient information and resources, to support conversations with patients and others about the implications of the change.
- 23** Recent developments, in the courts and elsewhere, have placed greater emphasis on making sure patients are provided with good, clear information to support their decision-making and control over matters that impact their health and wellbeing. Clear communication about the choices available, and the implications of those choices in practice will be essential; and this should include information to aid understanding of the processes involved in donation, and the role their family might have in the decision-making after their death.
- 24** 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.
- 25** 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.
- 26** 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.
- 27** 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.
- 28** We recommend engaging with the Department for Health and Social Care and Department for Health and Social Services to explore lessons learnt from implementing a statutory opt-opt organ donation system in England and Wales.

29 We hope these comments are helpful and we would be happy to explore or clarify any aspect of our response with you further.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'C Melville', with a stylized flourish at the end.

Professor Colin Melville, Medical Director and Director, Education and Standards