



Llywodraeth Cymru
Welsh Government

PUBLICATION

Human Transplantation (Excluded Relevant Material) (Wales) (Amendment) Regulations: summary of responses

Results from the 'Amendments to the organ donation regulations' consultation.

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Introduction

A system of 'deemed consent' or 'opt out' for organ donation has been in place in Wales since 1 December 2015. In May 2020, a similar system was introduced in England. As part of the implementation of the system in England, the UK Parliament recently passed the **Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 ('the England Regulations')**.

These Regulations set out the materials which will be excluded from deemed consent in England, and for which express consent for transplantation will always be required.

The England Regulations broadly mirror the **Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015 ('the 2015 Regulations')**, which are already in force in Wales, although they update the list by adding further materials.

As a result, the 2015 Regulations now require amendment to achieve parity across the UK wide system of organ donation, and to take account of advancements in medical science. This was the subject of a **recent consultation undertaken by the Welsh Government**.

What the consultation was about

The consultation asked for views on a set of amendment Regulations which will add to the existing list of tissues excluded from deemed consent in Wales. The Human Transplantation (Excluded Relevant Material) (Wales) (Amendment) Regulations 2020 ('the amendment Regulations') were published in draft as part of the consultation.

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The amendment Regulations would make the following additions to the 2015 Regulations to bring them in line with the England Regulations:

- addition of 'trachea' to the list of composite tissues within Regulation 2(2)
- addition of the following sexual and reproductive organs and tissues to the list of excluded relevant material within Regulation 2(3):
 - cervix
 - clitoris
 - fallopian tube
 - labia
 - vagina to vulva
 - prostate
 - perineum

Addition of a new section within Regulation 2 to include the following types of cells utilised in Advanced Therapy Medicinal Products (ATMPs) – medicines that contain tissues, cells or genes after manipulation in a laboratory and are used for the treatment of injuries and diseases:

- limbal stem cells
- liver cells
- lung epithelial cells
- pancreatic cells
- renal epithelial cells

The consultation asked a number of questions, including whether the reasoning behind these changes was clear and whether they would achieve parity with the system in England. This is important because of the cross border nature of organ and tissue donation and transplantation, particularly between England and Wales. We also asked if people agreed with the proposed additions. We asked whether 'eye' should be retained in the 2015 Regulations given that it was not included in the England Regulations. In addition there were a number of questions relating to Welsh Language.

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Details of the consultation and overview of the responses

The consultation was held between 27 February and 30 April 2020. The consultation document was available in bilingual standard format and contained a response form which could either be submitted via email or in hard copy. The amendment Regulations were also provided in English and Welsh for the consultation. All versions of the consultation were made available on the following web pages:

[Amendments to the organ donation regulations](#)

[Diwygiadau i'r rheoliadau ar gyfer rhoi organau](#)

The consultation was also issued to a number of key stakeholders.

Ten responses were received to the consultation broken down as follows:

- 6 from individuals
- 1 from a professional organisation
- 1 from an academic organisation
- 1 from an NHS organisation
- 1 from a citizen representation organisation

Two of the responses were emailed and 8 were sent using the online form.

It is acknowledged that there has been a low response to the consultation. This may in part be due to the fact that lockdown for COVID-19 began a month after it started. Whilst disappointing, it should be noted however that the response to the consultation held on the original 2015 Regulations only generated 17 responses, therefore a large number of responses was not anticipated to this latest consultation. We believe that because there has been a significant amount

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of publicity and public consultation on organ donation in Wales since the idea of introducing an opt-out system was first put forward in 2011, the population is more familiar with the system in place and may not feel a particular need to comment on relatively small changes.

Summary of responses received and Welsh Government response

Question 1. Do you believe the changes we are planning to make to the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015 are clear, achieve parity across the UK-wide system of organ donation and ensure we keep up to date with advancements in medical science?

Summary of the responses to Question 1

The overwhelming majority of respondents agreed that changes to be made to the Regulations are clear and achieve parity. Only one respondent disagreed although no reason was provided for that response. One respondent felt that whilst the changes were clear, the Welsh Government could have taken the opportunity to provide more information about the particular transplants listed for exclusion, even those that were not yet transplant possibilities. They also felt that the Welsh Government could have done more to gather views from the public on the donation of specific tissues rather than assuming that people would wish to see them excluded from deemed consent and that the changes should be based on whether the original policy aims were being served. The same respondent also felt that asking people whether the changes ‘achieve parity’ was

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not a question a member of the public could reasonably answer without a more detailed explanation of the other systems in the UK.

Welsh Government response

Whilst we appreciate the points raised in the consultation responses, we would make say that in proposing these amendments to the 2015 Regulations, it was not our intention to open up a wide ranging debate on the material which should be donated under deemed consent, or to seek to make wholesale changes to the existing Regulations or to push the boundaries of what might be acceptable. The idea of having exceptions to deemed consent was debated in some detail as part of the scrutiny of the Human Transplantation (Wales) Act 2013 ('the 2013 Act') when the sensitivities relating to certain materials, and the need to maintain public confidence in such a system was clear.

The opt-out system of consent to organ donation has been in place in Wales for almost five years, during which time it has been accepted and welcomed; but we must remember that as a system it is still relatively new, and must also now operate alongside the newer systems being introduced elsewhere in the UK. As such we do not think the time is right to undertake a review of the excluded materials as suggested.

In terms of achieving parity, we believe that it was made clear in the consultation that we were seeking to ensure operational parity, mainly with England, and to that end, the policy position in England was explained, with a link to their draft Regulations.

Question 2. Do you agree with the proposed new additions to the 2015 regulations (i.e. trachea to regulation 2(2); further sexual and reproductive tissues to regulation 2(3) and a new paragraph in regulation 2 about cells used

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in Advanced Therapy Medicinal Products)?

Summary of the responses to Question 2

There was a mixed response to this question. Most agreed with the new additions to the 2015 Regulations. However, one respondent felt that more clarity was needed in relation to liver and pancreas cells because some specific liver and pancreas cells may be included under deemed consent when taken as part of a solid organ retrieval. Another respondent said that they did not see the logic of adding trachea to the list of excluded materials as it is not currently excluded as part of heart-lung transplant; they felt that donors and their families may not see the distinction of the transplantation of the trachea as a novel form of transplantation to be particularly important. The same respondent had no particular objections to the addition of further sexual and reproductive organs and tissues to the list of excluded materials but felt that it was highly unlikely that any of these structures would be transplanted or indeed even possible.

A further respondent put forward the argument that as more parts of the male and female sexual and reproductive systems were being added, then there could be an argument for adding other sensitive parts of the anatomy to the list of exclusions, such as anus, rectum, breasts and nipples. They also stated that additions to the list should not just be based on how contentious they are, but on considerations such as whether people would be willing to donate the donation-type if the question was explained properly to them and if the transplant would be life-saving or quality-of-life enhancing.

Welsh Government response

In terms of liver and pancreas cells, we believe that as drafted the amendment Regulations make clear provision for these cells to be excluded only if they are

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being used either in whole or in part as an Advanced Therapy Medicinal Product. The use of these cells as part of solid organ transplants is not excluded from deemed consent. Therefore there is no need to state this in the Regulations.

Trachea transplantation in itself is a novel and very technical form of transplantation, therefore we believe it should be separated from the more routine removal of a portion of the trachea as part of a heart-lung transplant. This is clearly provided for in the amendment Regulations.

We accept that there could always be arguments for adding more materials to the list, but feel that overall it strikes the right balance in favour of those sexual and reproductive organs that were discussed both during the scrutiny of the 2013 Act and as part of the consultation on the England Regulations, without breaking down all the anatomical structures in detail. In addition, to add those further tissues to the list in Wales would potentially mean that England would need to revisit the Regulations which were made earlier in 2020. We would prefer to consider any future additions or removals from the list in tandem with England so as to minimise amendments to both sets of Regulations.

Question 3. Do you agree that ‘eye’ should remain in regulation 2(4), so that were the eye(s) ever able to be transplanted as part of a face transplant, express consent for the transplant of the eye(s) would always be required?

Summary of the responses to Question 3

The overwhelming majority of respondents answered yes to this question. One respondent expressed a view that because the eyes and face are distinguishing features, and that some people may be concerned about donor resemblance,

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consent for the transplantation of the eyes as part of a face transplant should continue to be required to maintain public confidence. One respondent felt that the eye should be treated the same way as other organs and should not be on the list of exclusions.

Welsh Government response

As there appear to be no strong feelings on this issue, the eye will remain listed as an exclusion if taken as part of a face transplant.

Question 4. We would like to know your views on the effects that the changes we want to make to the 2015 regulations would have on the Welsh language, specifically on opportunities for people to use Welsh and on treating the Welsh language no less favourably than English. What effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?

Question 5. Please also explain how you believe the proposed changes could be formulated or changed so as to have positive effects or increased positive effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language, and no adverse effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than

the English language.

Summary of the responses to Questions 4 and 5

Over half the respondents had no opinion or made no comment on either question. Some respondents stated they did not see how the Welsh Language would have any effect of the proposed changes whilst another said the NHS is starved of cash in Wales and saw little point in duplicating everything in Welsh. One respondent stated that Welsh language users, particularly older people, would be informed of new technologies, in their first language through the Regulations. Another respondent felt that people should be able to access services in Welsh at every available opportunity.

Welsh Government response

There appear to be no substantive issues raised in relation to the Welsh Language. We will continue to work with NHS Blood and Transplant to encourage the appointment of Welsh speaking staff who can speak to donor families in their first language, which is important at such an emotional time. The translation of the materials in the legislation would help staff in these circumstances.

Question 6: We have asked a number of specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them

Summary of the responses to Question 6

Most of the respondents left this section blank. One respondent took the opportunity to reiterate their view, expressed earlier, that the Welsh Government could have gathered more views on the list and the policy and that they felt an opportunity had been missed. On the other hand, another respondent commented that they were reassured that the list had not changed significantly, because many of the transplants, were they to be possible, would raise technical and ethical issues which would need to be fully discussed with donor families. The earlier respondent also commented that the consultation period was shorter than the usual 12 weeks which might have affected the number of responses, particularly in light of the COVID-19 pandemic. The same respondent also suggested that the Organ Donor Register should be updated to allow people to record their donation preferences in relation to excluded materials as this would be a better way to obtain consent for novel or contentious transplants. One respondent felt that there was no need for any type of exclusion list and that all parts of the anatomy should be available unless the person has opted out.

Welsh Government response

The consultation was slightly shorter than the normal 12 weeks since it was felt the issues were non-contentious and mirrored a similar consultation which had only recently taken place in England. We also did not anticipate a high number of responses – see comments on page 7 above. Updating the Organ Donor

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Register to allow for recording donation preferences in relation to excluded material is something that would need to be taken forward on a UK-wide basis and we are not aware there is any intention to make such changes. However we will draw these comments to the attention of NHS Blood and Transplant.

Next steps

Following the above analysis and consideration of the consultation responses, we do not propose to make any further changes to the amendment Regulations as present in the consultation. The Welsh Government will lay the amendment Regulations before the Senedd as soon as is practicable. The laying and debate dates are dependent on the current requirements to prioritise COVID-19 and other essential legislation and therefore is unlikely to be in the remainder of this term.

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