



Human Tissue Authority

Summary of responses: Consultation on the Code of Practice
for the Human Transplantation (Wales) Act 2013

May 2014

Contents

Background	1
The Consultation	2
Engagement events	3
Public engagement	3
Professional engagement	3
Media and press coverage	5
Overview	7
Responses to the questions in the consultation document	8
Evidence that a person would not have wanted to be a donor	14
Appointed representatives	16
Ordinarily resident	18
Excepted adults.....	20
Changes made to the Code of Practice as a result of the consultation	23
Next steps	25
Annex A: List of organisations notified of the consultation on the draft Code of Practice	26
Other key stakeholders and organisations notified of the consultation	30
Annex B: List of respondents to the consultation.....	31

Background

1. This document summarises the responses to the HTA's recent consultation on the draft Code of Practice for the Human Transplantation (Wales) Act.
2. The consultation opened on 1 October 2013 and closed on 23 December 2013 to allow all interested parties the recommended twelve weeks to respond.
3. You can read the consultation version of the Code of Practice on our website at www.hta.gov.uk

The Consultation

4. A wide range of key stakeholders and organisations were notified of, and invited to respond to, the consultation. This included all Assembly Members in Wales, Members of Parliament for Welsh constituencies, UK Members of Parliament and Peers with an interest in organ donation and transplantation more generally, key charities, faith groups and members of the public.
5. The HTA received 85 responses to the consultation in total, 24 of which contained no information. An online consultation response form was available on the HTA website and this was used by 58 respondents in total, including the 24 blank responses. All other responses were received either by email or through the post.
6. Responses were received from a wide variety of individuals and organisations, including clinicians, charities, faith representatives, professional bodies and members of the interested public.

Engagement events

Public engagement

7. The HTA held three drop-in engagement events specifically aimed at providing members of the public with an opportunity to meet HTA staff and discuss the Code of Practice. These were held in Cardiff, Aberystwyth and Llandudno on the 11, 12 and 13 November 2013 respectively. A total of eight people attended these events.
8. Details of the events were published on the HTA website and in local newspapers across Wales including the Daily Post, Chester Leader, South Wales Argus and also the Wales NHS website and Health in Wales.
9. The HTA also promoted the events via the HTA Twitter Feed and Facebook account. Assembly Members and Welsh MPs with Twitter accounts were tweeted directly to encourage them to retweet the details of the events and 12 did so. Members of the Welsh press and professionals working in the transplant sector also re-tweeted the events to their followers.

Professional engagement

10. Invitation letters were sent in hard copy and via email to key stakeholders, parliamentarians and interested parties notifying them of the two professional engagement events being held.
11. An all-day drop-in engagement event was held on 24 October 2013 at the Pierhead in Cardiff Bay. Assembly Members, representatives from charities, faith groups and individuals working in the transplant sector in Wales were invited. 18 people attended, including five Assembly Members. Once again, this provided a useful opportunity for professionals to provide feedback, ask questions and discuss the Code of Practice with HTA staff and HTA Chair, Baroness Diana Warwick.
12. A second drop-in engagement event was held at the House of Lords on 30 October 2013. All Members of Parliament for Welsh constituencies and Parliamentarians and Peers with an interest in organ donation and transplantation were invited to attend, alongside Transplant Surgeons and representatives from other key organisations. The HTA welcomed 12 people to the event.
13. In addition, HTA staff attended relevant meetings to engage with professionals working in the organ donation and transplantation sector across Wales. These included the South Wales regional collaborative meeting on 17 October 2013 and the

'Towards 2020: Organ Donation and Transplantation in Wales' conference on 26 November 2013.

Media and press coverage

14. The HTA issued several press releases and wrote to the Welsh media during the course of the consultation, as well as using Twitter and Facebook to raise awareness of the consultation.
15. Before the launch of the consultation, the HTA targeted specific titles and broadcasters, and gave background briefings on the consultation and surrounding issues. For the launch of the consultation, targeted news releases were sent to:
 - Welsh broadcasters - national, regional and local
 - Regional and local newspapers in Wales
 - Local newspapers in the English border regions
 - UK health correspondents
 - Welsh correspondents on national newspapers
 - Specialist medical/health trade media
 - Welsh language print and broadcast media
16. During the consultation news releases and letters were issued and targeted locally, promoting the public engagement events in Cardiff, Aberystwyth and Llandudno.
17. A news release was issued both in English and Welsh two weeks before the close of the consultation, advising potential respondents of the two remaining weeks to respond. These news releases received coverage in several media outlets:
 - BBC Online
 - Chester Leader
 - Corwen, Bala Free Press
 - Daily Post
 - Denbighshire Free Press
 - Flintshire Chronicle
 - Monmouthshire Free Press
 - North Wales Chronicle
 - South Wales Argus
18. A letter was also issued at the beginning of the consultation in response to a letter printed from a regional Assembly Member from North Wales. The HTA response was published in seven different local papers.
19. The HTA used social media streams Facebook and Twitter to promote messages throughout the consultation period in both English and Welsh. Overall, 107 re-tweets,

13 'favourited' tweets and 21 mentions were received during the consultation, including 28 from Assembly Members and Members of Parliament and several from Welsh newspapers. The HTA Facebook posts were the most shared and read the organisation has ever generated.

Overview

20. A full list of those invited to respond is provided at Annex A and a list of those that submitted a response is provided at Annex B. Where individuals opted to have their details remain confidential these are listed as anonymous.
21. The HTA is very grateful to those individuals and organisations that responded to the consultation. All responses have been carefully considered and, where appropriate, amendments have been incorporated into the revised Code of Practice.

Responses to the questions in the consultation document

Question 1: Are you completing this consultation as a member of the public or as a professional?

Member of the public: 32	Professional: 26	Did not answer: 2
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Question 2: Do you think the Code of Practice is easy to understand? If no, which part(s) are difficult to understand and how could they be improved?

Yes	No	Did not answer
69%	31%	0%

Key issues raised:

- The Code of Practice is not particularly straightforward or easy for lay people to understand.
- The Code of Practice is more detailed and lengthy than other Codes of Practice published by the HTA.
- There should be reference to the Human Tissue (Quality and Safety for Human Application) Regulations 2006 in the section on Licensing Arrangements and the need for an HTA licence.

Question 3: Do you think the Code of Practice is laid out in a logical order? If no, what improvements could be made?

Yes	No	Did not answer
84%	16%	0%

Key issues raised:

- 'Express and deemed consent', paragraph 74 onwards, would be better placed before the 'novel transplants' section.
- Definition of 'ordinarily resident' (first mentioned p8, explained p30) should be made clear earlier in the document.
- Can the most important information, relevant to SNODs in particular, be repeated in order that SNODs can remind themselves with ease rather than having to read and re-read the document?

Question 4: Are the examples in the Code of Practice clear and helpful? If no, what improvements could be made?

Yes	No	Did not answer
67%	33%	0%

Key issues raised:

- The section dealing with assessing evidence at paragraph 161 [concerning evidence which would satisfy a reasonable person that the person would not have given consent] is very helpful.
- There are many useful examples in the draft Code, but could there be additional case studies involving, for example, patients who are resident in Wales and one where the only family member is in another country.

Question 5: Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?

Yes	No	Did not answer
83%	17%	0%

Key issues raised:

- It needs to clarify absolutely that an appointed representative has a higher authority with respect to consent than family members, especially when children are involved (see paragraphs 89 and 90).
- Could it be made any clearer as to what happens when parents disagree or there is a conflict?

Question 6: Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?

Yes	No	Did not answer
57%	43%	0%

Key issues raised:

- Could the Code of Practice be more clear on what exactly the role of the SNOD is?
- Could the importance of information being available for Welsh residents who do not have English or Welsh as their first language be made clear.
- There seems to be too much emphasis placed on bereaved families to provide evidence that the person would not have wanted to be a donor. Could paragraph 165 be rewritten to lower the burden of proof on the grieving family or friends?
- It would be helpful if some of the language present in paragraphs 42 [concerning qualifying relationships] and 94 [concerning establishing whether deemed consent applies] were repeated in 174 so as to highlight 'the emotional impact this would have on family and friends' and the 'needs of all the people' involved.
- The Code should make clear that the obligations of the SNOD and other members of the healthcare team do not end with death but that professionals have a duty to show respect to the body of the deceased and also have a duty of care for the bereaved. This is explicit in the GMC guidance on Treatment and Care towards the End of Life (2010, paragraph 83-84).
- (i) Clearer clarification about the role of a medical Lasting Power of Attorney and rights with regard to decisions about organ/tissue donation after death. (ii) Clarity about tissue donation (the emphasis is on organ donation) and whether every family should be asked about cornea donation, for example. (iii) The definition of a "significant period", in relation to how long a patient has lacked capacity for prior to death (12 months), is clarified later in the current code document, but the term is mentioned frequently prior to that and it would be useful if this clarification was made earlier. (iv) The role of an Independent Mental Capacity Advocate (IMCA) could be made more clear, for people with no close family or friends.

Evidence that a person would not have wanted to be a donor

Question 7: Do you think the Code provides sufficient information about who can provide this evidence?

Yes	No	Did not answer
77%	23%	0%

Question 8: Are the steps that the SNOD would need to take to assess the evidence easy to follow? If no, how could they be made clearer?

Yes	No	Did not answer
73%	27%	0%

Key issues raised:

- The Code of Practice helpfully clarifies that if a person has decided not to donate his or her organs then it would be unlawful to deem consent (paragraph 129) and rightly draws attention to the fact that the Human Transplantation (Wales) Act 2013 does not restrict how this decision is to be recorded. The Code should clarify that there is no restriction on who could provide evidence that a person had made such a decision.
- This is a vital section of the Code and the guidance is clear. However, this is an extremely difficult task for the professionals concerned.
- Could paragraph 125 [concerning significant period] be re-phrased for clarity to something like "...when they did not register their express consent (or non-refusal)"
- Repeating and cross-referencing to particular relationships specified in the Act (e.g. as mentioned at para 23) [concerning terminology] would make this clearer.
- What would be considered to make evidence stronger or weaker - some more examples would be useful.

Appointed representatives

Question 9: Do you feel confident this approach would work in practice? If no, what improvements could be made?

Yes	No	Did not answer
69%	31%	0%

Key issues raised:

- The process is cumbersome and in practice would surely take so long that donation would be unable to occur.
- There will inevitably be many opportunities for relatives and friends etc. to impose/present their own wishes rather than stating what they know to have been those of the potential donor. This problem is very difficult to deal with, especially when conflicts arise between relatives and friends.

Question 10: Do you agree that this approach is in line with other professional advice and guidance?

Yes	No	Did not answer
72%	28%	0%

Key issues raised:

- The Code does not appear to be in line with the GMC's Good Medical Practice.
- Could paragraph 34 [concerning who can seek consent] be redrafted to read 'should' rather than 'recommended'

Ordinarily resident

Question 11: Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?

Yes	No	Did not answer
68%	32%	0%

Key issues raised:

- Respondents raised concerns that the guidance on the armed forces and their families does not seem consistent, and that it does not seem logical that a person serving in the armed forces is not deemed to have given consent if they have been posted to Wales, but their family member is deemed to have given consent because they have accompanied that person.
- The draft Code is to be commended for stating explicitly that people are not ordinarily resident if their residence is not voluntary.
- Some respondents raised concerns about students and whether this group should be considered ordinarily resident.

Question 12: Do you consider that any information is missing? If so, what?

Yes	No	Did not answer
48%	52%	0%

Key issues raised:

- The existing HTA Code of practice 2 should be updated to reflect the changes in the Human Transplantation (Wales) Act.
- Could the Code of Practice explain that organs may not be transplanted into patients in Wales and that they could be transplanted into any patient in the UK?
- Could the Code of Practice include something on how the SNOD may deal with a request from a family member to make a directed donation, e.g. if another family member is on the organ donor waiting list.
- Should the Code of Practice contain information for those medical personnel who may have a conscientious objection to deemed consent?

Excepted adults

Question 13: Do you foresee any issues with how this will work in practice? Please explain your answer.

Yes	No	Did not answer
39%	61%	0%

Key issues raised:

- The definition of a "significant period", in relation to how long a patient has lacked capacity for prior to death (12 months), is clarified at paragraph 122 but the term is mentioned frequently prior to that – could the definition be provided earlier in the Code of Practice?
- There is already a Code of Practice that must be adhered to under the current system. SNODs are experienced in seeking information concerning people who lack mental capacity under this code.
- The law does not give a figure for what constitutes 'a significant period' without capacity but give a 'reasonable person' test: 'a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed to be given' (Paragraph 5(3)). As the law has deliberately avoided giving a set period of time, it seems the draft Code of Practice is departing from the legislation by giving the figure of twelve months as significant (paragraph 122).

Question 14: Please provide any further comments you have on the Code here:

Key issues raised:

- The point about deemed consent meaning that donation is legal, but not compulsory, is an important one. Important to recognise that the law is permissive but not compulsive.
- Clear and well written and the flow charts extremely useful.
- Reassuring that there appears to be caution applied where families/friends are concerned.
- The sentence regarding DCD could be interpreted by a lay person as allowing organ donation before the patient is dead – could this be made clearer?
- Typographical errors to be aware of:
 1. Paragraph 139 should read "then donation should go ahead" not "then donation should not go ahead"
 2. Paragraph 68. Table 2. Point 4 should read "adult" instead of "child"
 3. Should paragraph 164 read "the reasonable person test?"
- Could it be made clearer that it is not SNODs alone that are responsible for decision making? Decisions are made in conjunction with other experienced clinical colleagues.
- There is a concern that too much emphasis is placed on solid organs and not enough information on tissues.
- Helpful in clarifying a number of issues that are unclear in the legislation, and in drawing attention to professional standards and other requirements of good practice which are needed in order to apply the law appropriately.
- Some further details / advice on how this code links with NHSBT guidelines would be helpful.
- It would be helpful to have further information and guidance on what happens when there is family conflict or disagreement, particularly between parents or people of the same ranking on the list.
- It is essential that paragraphs (42, 93, and 174) [concerning qualifying relationships, establishing whether deemed consent applies, the role of the family and friends] are not weakened and indeed that they are strengthened to draw attention to the

requirement to consider the needs and feelings of relatives, which in general is also what the deceased would have wanted.

Changes made to the Code of Practice as a result of the consultation

22. A number of changes have been made to the Code of Practice as a result of the responses received during the consultation. The HTA made changes to correct typographical errors, provide more detail and clarify sections where some of the information may have been less clear.
23. The order in which information has been presented has been changed in order to provide an introduction, a section on practical advice and guidance and a section on further relevant information, which may not be of interest to the public.
24. Other changes include:
- A section has been added to make it clear how a person can record their decision to either opt-in or opt-out on the NHS Organ Donor Register.
 - Several responses suggested that additional examples would be helpful to practitioners and these have been added.
 - A table has been added to clearly explain when the list is ranked in accordance with section 27(4) of the Human Tissue Act, and when it is not.
 - An explanation has been provided to provide assurance that all SNODs work within the decision making structures of NHS Blood and Transplant and do not make decisions in isolation.
 - Further information has been provided on married 16 and 17 year olds to clarify the qualifying relationship list in that situation.
 - Clarification has been provided as to the role of people with parental responsibility when the case involves a child.
25. The HTA received a number of responses which expressed the respondents unhappiness with the introduction of deemed consent in Wales. While any points from such responses that were relevant to the Code of Practice have been noted, the legislation is now passed and deemed consent will become operational in Wales on 1 December 2015.
26. A number of responses referred to assurances which had been given by the Welsh Government during the passage of the legislation as to how the law would operate in practice. The HTA is only able to provide advice and guidance on the basis of the legislation as passed, it is not the role of the regulatory body to reflect in its documentation undertakings which are not enshrined in the law. That is not to say

that additional advice and guidance in such areas as donation not proceeding in the face of significant family distress will not be provided in due course by other bodies.

27. As above, the HTA is only able to provide advice and guidance on the basis of the legislation as passed. Where comments were not accepted, the HTA considered that the comments were either not compliant with the legislation, or went beyond the HTA's remit.
28. Should staff working in the field of organ donation and transplantation have any concerns of an ethical or conscientious nature, we would advise them to consult their representative professional bodies for advice and guidance.

Next steps

29. The Code of Practice requires approval by both the Minister for Health and Social Services in Wales and the Secretary of State for Health.
30. The updated Code of Practice has been published alongside this document and will be laid in both Westminster and Cardiff.
31. The intention is for the final Code of Practice to have received approval and be published at the end of 2014.

Annex A: List of organisations notified of the consultation on the draft Code of Practice

Abertawe Bro Morgannwg Community Health Council
Abertawe Bro Morgannwg University Health Board
Academy of Royal Colleges Wales
Age Alliance Wales
All Wales Renal Network
Aneurin Bevan University Health Board
Alzheimer's Society
Anscombe Bioethics Centre
Anthony Nolan
Archbishop of Wales
Archdiocese of Cardiff and Catholic Bishops of Wales
Association of Medical Research Charities
Bereavement Services Association
Betsi Cadwaladr Community Health Council
Betsi Cadwaladr University Health Board
Bishop of Menevia
Bishop of Wrexham
Board of Community Health Councils
Brethren Christian Fellowship
Brecknock and Radnor Community Health Council
British Association for Tissue Banking
British Heart Foundation Wales
British Liver Trust
British Lung Foundation Wales
British Medical Association
British Organ Donor Society
British Red Cross
British Transplantation Society
Bro Taf Local Medical Committee
Cambridge University Hospitals NHS Foundation Trust
Cancer Research UK
Cardiac Care Network
Cardiff and Vale University Health Board
Cardiff and Vale Community Health Council
CARE
Care Quality Commission
Central Manchester University Hospitals NHS Foundation Trust
Chief Medical Officer Wales
Children in Wales
Children's Commissioner for Wales

Christian Medical Fellowship
Citizens Advice Cymru
Cognition
College of Emergency Medicine
Critical Care Implementation Group
Critical Care National Specialty Advisory Group Wales
Critical Care Networks
CRUSE Bereavement Care
Cwm Taf Community Health Council
Cwm Taf Health Board
Cystic Fibrosis Trust
Department of Health
Diabetes UK Cymru
Disability Wales
Donor Family Network
Dyfed Powys Local Medical Committee
Epilepsy Action
Equality and Human Rights Commission
Faculty of Intensive Care Medicine
Farmers Union of Wales
General Medical Council
General Optical Council
Golden Jubilee National Hospital
General Practitioners Committee (GPC) Wales
Gwent Local Medical Committee Ltd
Haemophilia Society
Hafal
Healthcare Inspectorate Wales
Hywel Dda Community Health Council
Hywel Dda Health Board
Information Commissioner
Intensive Care Society
Inter Faith Network for the UK
Islamic Medical Association
Islamic Society for Wales
Kidney Research UK
Kidney Wales Foundation
The King's Fund
Kings College Hospital NHS Foundation Trust

Learning Disability Wales
Leeds Teaching Hospitals NHS Trust
Live Life Then Give Life
Medical Research Council
Mencap
MIND Cymru
Mission and Public Affairs Council of the Church of England
Montgomery Community Health Council
Morgannwg Local Medical Committee
Muslim Council of Wales
National Association of Funeral Directors
National Autistic Society Cymru
National Black, Asian and Minority Ethnic (BAME) Transplant Alliance
National Council for Palliative Care
National Institute for Health and Care Excellence
National Kidney Federation
Newcastle upon Tyne NHS Foundation Trust
NHS Blood and Transplant
North Wales Local Medical Committee
Northern Ireland Government
Nuffield Council on Bioethics
Nuffield Trust
Nursing and Midwifery Council
Office of the Chief Rabbi
Older People's Commissioner for Wales
One Voice Wales
Oxford Radcliffe Hospitals NHS Trust
Paediatric Intensive Care Society
Papworth Hospital NHS Foundation Trust
Parkinson's UK Wales
Patient Concern
Powys Teaching Health Board
Royal Brompton and Harefield NHS Foundation Trust
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of Nursing
Royal College of Ophthalmologists

Royal College of Paediatrics and Child Health, Wales
Royal College of Pathologists
Royal College of Physicians
Royal College of Radiologists
Royal College of Surgeons
Royal Free London NHS FoundationTrust
Royal Infirmary of Edinburgh
Royal National Institute of Blind
Scottish Government
SENSE Cymru
Shelter Cymru
Society for the Protection of the Unborn Child
The Church in Wales
The Conference of Religious
The Coroner's Society
The Stroke Association
The Wales Orthodox Mission
The Welsh Intensive Care Society
Transplant 2013
UK Donation Ethics Committee
University Hospitals Birmingham Foundation NHS Trust
University Hospital of South Manchester NHS Foundation Trust
Wales Council for Voluntary Action
Wales Organ Donation Implementation Group
Wellcome Trust
Welsh Health Specialised Services Committee
Welsh Independent Healthcare Association
Welsh Kidney Patients Association
Welsh Language Commissioner
Welsh Local Government Association
Welsh Medical Committee
Welsh Neurological Alliance
Welsh NHS Confederation
Welsh Paediatric Society
Welsh Scientific Advisory Committee
Welsh Nursing and Midwifery Committee
Welsh Optometric Committee
Welsh Refugee Council

Wye Valley NHS Trust

Other key stakeholders and organisations notified of the consultation

Assembly Members, County Councils in Wales, Organ Donation Committees in Wales, Transplant Surgeons across the UK, Clinical Leads for Organ Donation, Specialist Nurses for Organ Donation, Members of Parliament in Wales, Members of Parliament and Peers with an interest in organ donation and transplantation.

Annex B: List of respondents to the consultation

The table below shows individual responses. The number against each name cross-references with the text of their response, published separately to this document.

1	Gloria Owens
	Blank
	Blank
	Blank
2	Anonymous
3	Anonymous
4	Anonymous
	Blank
	Blank
5	Pauline Elliott
	Blank
	Blank
6	Dr Nigel Page, School of Life Sciences, Kingston University
	Blank
7	Zoe Goodacre, Critical Care Network Manager, Llanfrechfa Grange Hospital
	Blank
8	Clare Small
	Blank
	Blank
9	Shelley Jones
	Blank
	Blank
	Blank
10	John Biggs
	Blank
11	Nicola Ruck
12	Dr Peter C Matthews on behalf of the Faculty of Intensive Care Medicine (FICM), the Welsh Intensive Care Society (WICS) and the Royal College of Anaesthetists Advisory Board (Wales)
	Blank
	Blank
	Blank
13	Dr Alex Manara on behalf of the Faculty of Intensive Care Medicine (FICM)
14	Dr Alison Ingham, Consultant in Anaesthesia and Intensive Care Medicine & Clinical Lead in Organ Donation, Betsi Cadwaladr University Health Board (West)
	Blank

15	British Kidney Patient Association
16	Janet Eleanor Lochain Secluna Thomas
17	Anonymous
18	Carol Reisman
	Blank
19	Mair Crouch
20	Islamic Medical Association/UK
	Blank
	Blank
21	Dr Iain J Robbé, Clinical Medical Educationist
22	David Brynley Webb, Chairman ABMUHB Organ Donation Committee
23	Dr Katja Empson, Clinical Lead for Organ Donation, University Hospital of Wales
	Blank
24	William John Armitage, Director of Tissue Banking and Professorial Research Fellow, University of Bristol
25	Royal College General Practitioners, Wales
26	Church in Wales
27	Anscombe Bioethics Centre
28	Dylan Harris, Consultant in Palliative Medicine, Cwm Taf Health Board
	Blank
29	Benedict Biddulph
	Blank
30	CARE
31	Ursula Cunliffe
32	Michael W Thomas
33	Kidney Wales Foundation
34	Vivienne Harpwood, Professor of Law, Cardiff Law School
35	Patient Concern
36	Royal College of Radiologists
37	Kevan Blomeley
38	NHS Blood and Transplant
39	Anonymous
40	Royal College of Nursing, Wales
41	Welsh Language Commissioner
42	National Kidney Federation
43	Darren Millar, Assembly Member, Wales
44	Angela Burns, Assembly Member, Wales
45	Citizen's Advice
46	Dr Grant Duncan on behalf of Welsh officials
47	Nuffield Council on Bioethics
48	Children's Commissioner for Wales

49	Welsh Kidney Patients Association
50	UK Donations Ethics Committee
51	British Heart Foundation Cymru
52	Welsh Jewish Representative Council
53	Michael Joyce
54	Helen Burt, Living Donor Coordinator, Swansea
55	BMA Wales
56	National Institute of Health and Care Excellence (NICE)
57	Anna de Lloyd, Acute Physician, Cardiff
58	Stuart Taylor and David Thewlis
59	Assistant Commissioner, Wales
60	Hywel Dda University Health Board

*please note of the blank responses, 10 had supplied some personal details but had not answered or supplied any further information relating to the consultation. Where respondents submitted a response both online and via email / post, this has been counted as one response.