National Institute for Health and Care Excellence

IP1553 Reducing the risk of transmission of Creutzfeldt–Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues

IPAC 12/09/19

These comments reflect responses both from the CJD Advisory Subcommittee and the School of Health and Related Research where appropriate.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS professional on behalf of The Royal College of Ophthalmologists	**ScHARR report**	Tonometry is NOT an interventional procedure its a contact procedure (as per NICE definitions),and should be removed from this NICE process.	Thank you for your comment. The committee accepts that tonometry is not an interventional procedure and has not referred to in the guidance. The surgical procedures regarded by the NICE committee as high-risk are discussed in the introduction of the ScHARR final report. The systematic reviews discussing CJD infectivity of other tissues/procedures that are not high-risk are only discussed in the section labelled as "Risks in surgery other than neurosurgery" (on page 43 in the ScHARR report).
2	Consultee 1 NHS professional on behalf of	**General**	The RCOphth current guidance on instrument decontamination is available on the RCOphth website. It confirms our position in relation to comment 1 and is based on published evidence. **https://www.rcophth.ac.uk/wp-**	Thank you for your comment. See response to comment 1

	The Royal College of Ophthalmologists		content/uploads/2014/12/Ophthalmic-Instrument-Decontamination.pdf.	
3	Consultee 2 NHS Professional on behalf of SBNS	**General & 1.6, 1.7**	To the vcjd committee, Many thanks for this interesting work. I wish to make the following comments and ask certain questions in no particular order. I have made a draft in a hurry and I sincerely apologise if it comes across as unduly harsh! I appreciate the hard work that a lot of people have put in and recognise that there is not enough evidence for many things and that assumptions have had to be made. **In general, I would like to know the mechanism and cost of tracking individual instruments. Also I think a modelling should be undertaken whereby only intradural instruments with high brain tissue residue like pituitary forceps are made single use instruments. I am so relieved that the recommendation to have separate sets for pre and post 1997 patients is being dropped. This seemingly simple advice has proved unworkable and very expensive to implement, in our experience.**	Thank you for your comments and agreeing with our recommendation in section 1.6 and 1.7 (on systems specifically for people born after 1996). The details on the cost estimates are provided in Section 3.3.3.9 (on page 108 in the ScHARR report). Sensitivity analyses were conducted on these values. ScHARR attempted to include only the instruments sets that came into contact with high-risk tissue. Implementation of NICE guidance is a matter for the NHS trusts.
4	Consultee 2 NHS Professional on behalf of SBNS	**General**	My comments/questions to the vcjd committee: 1. Considering that ipg196 was up for revision in 2012 ie 7 years ago, I think the consultation period is too short at only 4 weeks! This is not enough time to meet with our theatre teams and microbiologist and discuss with other interested parties.	Thank you for your comment. As per NICE Interventional procedures (IP) programme manual all consultations are normally run for 4 weeks. For this IP we have received feedback from stakeholders that 4 weeks was not adequate to respond to the consultation. NICE agreed that CJD has been through a different process and has longer consultation and supporting documents to review. Therefore, the consultation period was extended for

				another 4 weeks and closed on 22nd august 2019.
5	Consultee 2 NHS Professional on behalf of SBNS	**General**	2. The real work of the consultation is in the supporting documents section. Please let me know how many people have actually downloaded this. I suspect this number will be quite low. At the vcjd life long learning session at the York sbns in 2015 only 28 people were in the audience. And of those, less than half had really read the ipg196 document more than once. If it is the case that only a very few people are really taking this seriously, then it would be good to have a meeting of those people.	Thank you for your comments. The NICE draft guidance was informed by a systematic review of the literature, a risk assessment and decision analytic model (The Final ScHARR Report). The CJD Advisory Subcommittee and IPAC carefully assessed all the information available before reaching their recommendations issued for consultation. The NICE web team reported that between 19 June to 22 August 2019 there had been 33 downloads of the consultation documents and 28 downloads of the supporting document. NICE's role is to issue guidance and therefore arranging a meeting with SBNS lies outside the remit of this guidance. Implementation of the guidance is also a matter for the NHS.
6	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	3. Though not an expert in the methodology used, I am disturbed by the evident lack of credible data used to arrive at the assumptions. I appreciate that there are hardly any worthwhile published studies and it may be that the opinion of some learned people in the committee does carry some value. But is this really enough to run the simulations? Is this any better than asking a family enjoying their beach holiday to estimate the amount of sand grains on Mars? Some assumptions I have tried to highlight in yellow but there are a lot more than I have quoted. It would be good to list the assumptions made in	Thank you for your comments. As there is no clear data on the incidence, calibrations were necessary. Experts were sought to discuss the parameters. The resulting elicited distributions are wide which reflects the uncertainty in parameter estimates. Crucially, ScHARR calibrated the model so that only combinations of parameters that were concordant with observed data (taking into account misdiagnosis) were run through the model.

			table and perhaps ask for an independent review of the methodology used.	The protocol has been through an independent external peer review process organised by NIHR. The methodology used and the ScHARR final report is currently under peer review by NIHR. NICE consultation process also ensures the draft guidance is reviewed by stakeholders.
7	Consultee 2 NHS Professional on behalf of SBNS	**General**	4. Considering the lack of relevant published studies I think the committee should have set up their own studies to help better inform the modelling. For example doing site shadowing from operating theatre to sterilisation units to see how many instruments leave their sets.	Thank you for your comments. Setting up and/or funding new studies is not part of the remit of this guidance. The committee considered your comment and slightly amended proposed areas of research in section 1.9 to cover/strengthen how well systems work.
8	Consultee 2 NHS Professional on behalf of SBNS	**1.2**	5. Though there may be many instruments in a set, the number of instruments which would carry brain tissue residue are quite small. It would have been good to conduct a trial to see how much residue is transmitted from these instruments to the other instruments.	Thank you for your comments . Please see response to comment 7.
9	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	6. Many of the instruments which may contain heave brain residue are already disposable. For example, in a typical brain tumour operation the only instruments which touch the brain are a bipolar forceps and suction tube, both of which are disposable. An instrument which can have heavy brain residue is a pituitary forceps. This has very credible single use alternatives which are safe, effective and economical. The same goes for many microinstruments. Aneurysm clip applicators and endoscopes do not have very credible single use alternatives. But these are instruments that one would assume have low brain tissue residue. Again a trial would clarify this. I think after this, the modelling should consider	Thank you for your comments. Please see response to comment 7. IPAC agrees that it is difficult to precisely assess which instruments are at risk and it may vary between procedures. Also, it is not exactly clear what prion load is infective. Finally, the model is based on the evidence that no clear cases of surgically transmitted vCJD have occurred. The heuristics employed were based on the agreed number of instruments coming into contact with high-risk tissue. ScHARR had a meeting with the committee to specifically

			a scenario whereby any intradural instruments should be put on a separate tray and these instruments should be single use as far as possible. One would have to consider the scenario that other prions may become an important factor in the coming years and a push to use single use intradural instruments would seem wise. If only intradural instruments are considered, then the economics of the modelling might change.	agree the parameter values before embarking on the runs. The committee slightly amended section 1.1 to cover this.
10	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	7. I note that there was concern that a patient may have developed vcjd duing a shunt operation. But In a shunt operation under normal circumstances, it is unlikely that any reusable instruments would come into contact with the brain. So I think this scenario would be very unlikely to have transmitted vcjd.	Thank you for your comments. The modelling included all instruments that come into contact with high risk tissues. Any procedure appears unlikely to transmit vCJD unless performed using instruments from a patient with CJD. Section 3.4 (in the ScHARR report) details the calibration targets and stated that the committee members erred on the side of caution.
11	Consultee 2 NHS Professional on behalf of SBNS	**1.2**	8. The recommendation to track instruments seems sound advice. But is this to track sets or track individual instruments? According to our nurses, tracking sets is not enough as instruments are often swapped in and out in the sterilisation areas. But given that hardly any unit has the ability to track individual instruments, is this practical and what is the cost involved in doing so and who should meet this cost? As it is a public helath issue, surely the funding should be central not up to each unit. We have been trying to implement an etching and radiofrequency tagging method and this seems to be technically difficult and very expensive. I would be grateful if you can let us know which units have the ability to track individual instruments, so that we can see what they do.	Thank you for your comments. The model is based on tracking instruments. The costs are detailed in Section 3.3.9 of the ScHARR report. Recommendation 1.2 was primarily intended to convey that instruments must not be moved between sets. Hospitals can choose how they ensure this. The committee made a judgement that they wished to support that systems to track individual instruments should be developed.The committee considered your comment and amended section 1.2 to make it clearer.

				The specific reference to tracking individual instruments has been removed from recommendation 1.2 and a specific additional committee comment has been added to 4.3.This committee comment reiterates the advice already provided in HTM 01-01. The issue of funding lies outside the remit of this guidance. Guidance issued under the NICE Interventional Procedures Programme, which includes this guidance, does not carry with it a funding directive. Implementation is also a matter for the NHS.
12	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	9. Why havent there been more site interviews to better infiorm the modelling?	Thank you for your comment. NICE CJD Subcommittee felt that the combination of evidence reviewed by the experts was adequate to conduct sensitivity analyses and come up with the draft guidance.
13	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	10. What specific changes in your inputs have resulted in the removal of the recommendation in ipg196 to have different sets for pre and post 1997 patients? You have mentioned a couple of things but has the way the modelling has been done changed ?	Thank you for your comments. The modelling has remained largely the same, but some assumptions have changed (see sentence in the evaluation of cost-effectiveness section of the Scientific Summary-page 9 in the ScHARR report). The calibration has shown that there is not the possibility of a very large number of cases as was a concern in the earlier work. ScHARR have also assumed in scenario analyses that patient born prior to 1997 could have prions in high-risk tissue.

				The predicted outbreak of vCJD after BSE has not occurred and prions have been seen in post 1997 patients in appendix 3 study.
14	Consultee 2 NHS Professional on behalf of SBNS	**1.2**	11. It would have been good to publish the results of the survey by the sbns prior to the York sbsn into the preparedness of the neurosurgical units in implementing ipg 196.The results which I remember most were that the majority of the neurosurgical units were not following ipg196 and that the costs of this were upto a million pounds. Ipg196 therefore underestimated how difficult it was to implement the seemingly simple guidance to keep post 1997 and pre 1997 sets separate and the cost of doing so. Would the recommendation for tracking of instruments encounter the same problem?	Thank you for your comments. The ScHARR reports assumes that this can be done assuming the costs provided in Section 3.3.9 (page 108), as discussed with the committee. Instrument tracking is part of good theatre practice irrespective of CJD as recommended in the Department of Health and Social care's 2016 Health Technical Memorandum 01-01. In section 4.3 of the guidance a committee comment was added to support this. Effective decontamination of surgical instruments will be easier than maintaining pre and post 1997 sets.
15	Consultee 2 NHS Professional on behalf of SBNS	**1.6, 1.7**	12. In my unit, 6 drills have been bought so far for the post 1997 set. Each drill within six months gets mixed inadvertently with post 1997 kit and becomes contaminated and hence a new one has had to be bought we have therefor spent 240,000 pounds on drills alone! There have been 20 datixes submitted for breach of the vcjd policy based on ipg 196. There have been delays in in life saving surgery and a lot of valuable time spent by staff in investigating breaches. Millions of pounds have been spent on a now seemingly unnecessary exercise to keep the pre and post 1997sets separate. The trusts who have been proactive in trying to follow ipg196 are ironically the ones who are now feeling upset about the clinical incidents and the amount of money they have spent.	Thank you for your comment. IPG 196 was intended to prevent a self-sustaining epidemic of CJD as a result of transmission through high risk procedures. Time has shown that the risk was not as great as potentially had previously been thought in the earlier work (IPG196). Removing the 1996/97 divide may save money. IPG196 was written using the best evidence available at the time. The evidence has changed since then and the committee noted that drills used in neurosurgery are single use only.

16	Consultee 2 NHS Professional on behalf of SBNS	**General 1.6, 1.7**	13. So was the recommendation of ipg196 to have separate sets for pre and pot 1997 patients wrong and if so , how did this happen and how can you be sure you are right this time? Would updating the nice guidance in 2012 as planned, have saved significant amount of money?	Thank you for your comments. IPAC noted your views. Time has shown that the number of CJD cases is not as great as potentially was thought might be the case in the earlier work (IPG196). Additionally, the committee looked at a scenario where patients could have prions in high-risk tissue from birth. At the time the guidance was based on the evidence available. The evidence base has changed and therefore so has the guidance. Whilst the delay may have cost money, the passage of time and observation of events has allowed the evidence to be more secure.
17	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	14. In page 38- if worldwide only 4 cases of cjd have been transmitted by surgical instruments, why is this not by chance alone? What are the statistics on this?	Thank you for your comments. We cannot discount that sCJD may have been wrongly attributed to iCJD and this may be by chance alone. However, the possibility of zero transmissions in England was within the calibration target.
18	Consultee 2 NHS Professional on behalf of SBNS	**General**	15. It would have been good to do dedicated autoclaving studies to look at the infectivity and transmission rates	Thank you for your comments. Setting up and/or funding new studies was not part of the remit of this guidance and the NICE committee had no resource to do this. The committee considered your comment and amended proposed areas of research in section 1.9 to cover/strengthen how well systems work.
19	Consultee 2	**ScHARR report**	16. Spleen and lymphoid tissue also have high infectivity. So does this not have implications for other specialties?	Thank you for your comments. Lymphoid tissue was considered of medium infectivity 4.5 log (see ScHARR final report)

	NHS Professional on behalf of SBNS			Previous work has shown there is little chance of onward infectivity at these sites due to reduced infectivity. Endoscopy and laryngoscopy have been removed from the guidance. The committee decided to not model these.
20	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	17. What are other countries like France or Usa who have huge cjd surveillance programs, doing and has there been any liasion with them in modelling techniques and coming up with recommendations? The USA did not accept beef form the UK till 2014 as they were still worried about BSE being in the British food chain. Yet they did not try and have separate instruments for performing neurosurgery on British patients(who may be harbouring latent vcjd as ipg196 was suggesting). My point is that the British response in ipg196 was different to the rest of the world.	Thank you for your comments. France follows EU guidelines. There has been no liaison with any institution or country in modelling techniques. The NICE draft guidance was informed by a systematic review of the literature, a risk assessment and decision analytic model (The Final ScHARR Report). The CJD Advisory Subcommittee and IPAC carefully assessed all the information available before reaching their recommendations issued for consultation.
21	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	18. Page 106 -post 97 patients are apparantly now also thought to be susceptible to vcjd. Where did this important piece of information come from? 108.--why you didnt include the low rate of compliance of ipg 196 and the fact that incidence if vcjd was quite low by 2012.	Thank you for your comments. This assumption came from the CJD sub-committee, on the basis of literature such as ref 15 and 16 as discussed in the Introduction (of the ScHARR report). ScHARR included proportions of units that did / didn't adhere and conducted sensitivity analyses. See Section 3.5.8 (of the ScHARR report). All CJD was considered, with the prevalence of those with prions in high-risk tissue taken from elicitation and modified by the calibration exercise.
22	Consultee 2	**ScHARR report**	19. P 108-There has been a fundamental change in this process since the earlier work as the possibility that patients who become symptomatic following infection with	Thank you for your comments. Advice provided to the NICE team in the earlier work was that it was impossible to

	NHS Professional on behalf of SBNS		CJD are misdiagnosed as having a different neurodegenerative disease is included. Why was this not included in your previous modelling and if it is that this was simply not thought of, then surely there may be other flaws in your current methodology?	miss a vCJD case. This assumption was reversed by CJD sub-committee members in the later work particularly when all CJD is considered and built into the model. Committee did consider the possibility of missing a vCJD case.
23	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	20. As per ipg196, there was a possibility of a self sustaining epidemic of vcjd if different sets were not used for post 1997. We now know that most neurosurgical units did not follow the recommendation of ipg196. And yet we clearly did not have the predicted epidemic. Does your current modelling take into account where the previous modelling failed?	Thank you for your comments. ScHARR have calibrated the model so that the number of cases are consistent with observed data. Previous work indicated that the number of cases was highly uncertain. Fortunately, we have seen that the smaller number of cases is more likely. A process was used as per NICE TA process and methods guide.
24	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	21. Page112- is it true that 90% of units were not following ipg196?	Thank you for your comments. The estimate provided by the Committee although sensitivity analyses were conducted, See Section 3.5.8 in the ScHARR report.
25	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	23. From a position of keeping instruments moist the cost per QALY of implementing IPG196 was estimated to be in excess of £1.6million.? How was this value calculated?	Thank you for your comments. This is calculated as approximately £750,000 divided by 0.415 (which is 0.874 0 0.459 – values contained in Table 26 in the ScHARR report).

26	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	24. Page 11 'Threshold analyses exploring the maximum cost associated with IPG196 indicated that this value was approximately £140,000 (assuming a cost-effectiveness threshold of £300,000) and £15,000(assuming a cost-effectiveness threshold of £30,000) per surgical unit over a five-year period. - im sorry I didnt quite understand this and would be grateful if someone could shed some more light.	Thank you for your comments. This analysis gives the cost below which following IPG would be seen to be cost-effective at the given willingness to pay. So, if the NHS were prepared to pay £300,000 per QALY then it would be possible to spend up to £140,000 to follow IPG196 and be cost-effective.
27	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	25. What is the evidence for the long latent period of vcjd and how robust is this?	Thank you for your comments. See Section 2.4 about incubation periods of acquired TSEs in the ScHARR report. There is no clear evidence for the long latent period of vCJD but ScHARR allowed plausible estimates that were low.
28	Consultee 2 NHS Professional on behalf of SBNS	**General**	26. There did not seem to be a neurologist in your committee?	The NICE CJD Advisory Subcommittee has brought together key UK experts in the field of CJD. The members (by role/profession) were listed in appendix A in the draft guidance. A neurologist was included, and this has been clarified in appendix A.
29	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	27. Page 130 info- It was assumed that independent of whether the P96 group was assumed to be infectious, 10% of units adhered to IPG196 and guidance on keeping instruments moist, 30% of units adhered only to keeping instruments moist and that 60% of units neither followed IPG196 nor kept instruments moist.	Thank you for your comments. In the absence of clear incidence, ScHARR had to make assumptions; however, and these were all clearly stated in advance in both a written document and a presentation. The protocol has been through an independent external peer review process organised by NIHR. The methodology used and the ScHARR final report are under peer review by NIHR. NICE consultation process also ensures a wider review of the guidance.

30	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	28. 112 d. In discussion with committee members, it was assumed that this change, which is assumed to be related to guidance on keeping instruments moist prior to decontamination, would have occurred in 2012 in line with the purchase of new instruments for those units who had adhered to IPG196	Thank you for your comments. See response to comment 29.
31	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	29. In discussions with the committee the probability of an instrument being disposed of was reduced to 1/2500 with a range of 1/2000 to 1/3000.	Thank you for your comments. See response to comment 29.
32	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	30. P 120 That the probability of an instrument being swapped with a similar instrument in a separate set was 50%, whilst the set was undergoing the decontamination process. This value was selected following discussion with clinicians	Thank you for your comments. See response to comment 29.
33	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	31. Figure 5 on page 111 is black. And not visible. How many people have pointed this out? This Will indicate the level of scrutiny of the document	Thank you for your comment. This is visible in the version of the document put out for consultation. The team has checked and made sure it is visible in the final published ScHARR report.
34	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	32. P 120 Following discussion with the committee, it was assumed that the number of instruments coming into contact with high-risk tissue in brain operations was lower than previously thought with the number reduced to 14 (previously 18).	Thank you for your comments. See response to comment 29.

35	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	33. For simplicity, we have assumed that the costs, from an NHS and Personal Social Services perspective, in 2017/8 for a CJD case was £50,000.	Thank you for your comments. See response to comment 29.
36	Consultee 2 NHS Professional on behalf of SBNS	**ScHARR report**	34. The reference costs of sterilisation of a set and the costs of reusable instruments used are lower than our experience.	Thank you for your comments. See response to comment 29. The committee accepted the values used. It is unlikely that changes to these parameters would change the conclusions, particularly in relation to reusable instruments.
37	Consultee 3 NHS Professional on behalf of SBNS	**ScHARR report 2.2**	i. Considering the long incubation period of CJD – is it too early to be reassured that no cases of stCJD were reported between 2005 and 2018?	Thank you for your comment. The incubation periods used in the model are described in Section 3.3.4.2 of the final ScHARR report. The model will include patients who will develop CJD after 2018, but for the calibration period ScHARR needed to match against observed data hence restricting the comparison between 2005 and 2018 (which does not represent the full total of people infected). In Section 4.1 of the draft guidance 'The committee emphasised the importance of continued surveillance for all forms of CJD to identify trends in incidence rates. It noted that there are effective systems for doing this in the UK'.
38	Consultee 3 NHS Professional on behalf of SBNS	**ScHARR report**	ii. Are the conclusions from the ScHaRR report based on adequate evidence?	Thank you for your comment. The Final conclusions of the ScHARR report was informed by a systematic review of the literature, a risk assessment and decision analytic model. The CJD Advisory Subcommittee and IPAC carefully assessed all the information available before reaching

				their recommendations issued for consultation. The protocol has been through an independent external peer review process organised by NIHR. The methodology used and the ScHARR final report are under peer review by NIHR. NICE consultation process also ensures a wider review of the guidance.
39	Consultee 3 NHS Professional on behalf of SBNS	**Other**	iii. Is cost effectiveness a reasonable view considering that CJD is a dreadful disease and even 1 person being affected is too many	Thank you for your comment. Committee agrees that any deaths from preventable causes are dreadful. Equally there has to be a balance between the costs and effectiveness of prevention. Here the costs of absolute prevention by using full single use instruments so far outweigh the benefits that it would take resources away from other preventable diseases.
40	Consultee 4 NHS Professional on behalf of SBNS	**Appendix D**	1- spinal cord is considered high risk tissue as mentioned in page 2 of 16. appendix D: high risk procedures does not include any spinal cord procedures or spinal intradural procedures. we appreciate if this is looked into. and include in list of procedures.	Thank you for your comments. This error in appendix D in the guidance has been amended.
41	Consultee 4 NHS Professional on behalf of SBNS	**1.1**	2- we feel that the guidance should provide some recommendation to the various units about the measures recommended to keep instruments moist.	Thank you for your comment. Details are outside the remit of this guidance and are covered in the Department of Health and Social Care's **Health Technical Memorandum (HTM) 01-01**: Decontamination of surgical instruments and corresponding guidance in the devolved administrations' areas..

42	Consultee 4 NHS Professional on behalf of SBNS	**1.7**	3- there needs to be more clarity in draft recommendations paragraph 1.7 page 4 out of 16.	Thank you for your comment. Committee considered your comment and amended 1.7 to make it clear.
43	Consultee 5 SBNS	**3.3**	**Publication by Professor Peter Hutchinson** Hutchinson PJ A, White B etal. (2018) The relationship between neurosurgical instruments and disease transmission: Society of British Neurological Surgeons perspective. **Acta Neuropathologica** June 2018, Volume 135, **Issue 6**, pp 969–971	Thank you for your comment. This paper is a comment primarily regarding the potential transfer of amyloid beta from surgical procedures. No new evidence relating to CJD (that is not covered in the ScHARR report) are discussed in this editorial.
44	Consultee 6 Health Protection Scotland and National CJD Working Group, Scotland	**General**	As Chair of the National CJD Working Group for Scotland, we welcome the findings and conclusion of the systematic review. We ask for publication of the revision NICE guidance IP196 as soon as feasible.	Thank you for your comments. The revised guideline is due for publication in the third quarter (Oct-Dec 2019).
45	Consultee 6 Health Protection Scotland and National CJD Working Group, Scotland	**1.1**	In addition to keep instruments moist, there are other essential steps to facilitate removal of protein from instruments. These are not yet mentioned in draft consultation and suggest they be added. Removal of gross contaminants immediately after use (before applying moistening agent if used) Cleaning the instruments as soon as possible Validation of washer disinfector to ensure it has the capability to reduce protein to the level specified in ACDP guidance (5ug per instruments or lower level for high risk).	Thank you for your comments. Committee thinks that these good practice recommendation about other essential steps to remove prions from instruments and effective methods to keep instruments moist are well covered in HTM01-01 document and it is not IPAC's role to specify these again. Section 1.8 in the draft guidance recommends that this guidance should be used with the Department of Health and Social Care's **Health Technical Memorandum (HTM) 01-01**: Decontamination of surgical instruments

			It would also be beneficial to recommend the methods to keep instruments moist that are effective and efficient.	and corresponding guidance in the devolved administrations' areas.. The committee emphasised that clinicians must comply with this in section 4.6.
46	Consultee 7 NHS professional UCL Institute of Child Health, Great Ormond Street Hospital for Children NHS Foundation Trust	**2.2**	I am responding to this invitation to comment. I am the national co-ordinator of the Pituitary Growth Hormone Follow-up Study, based at UCL Great Ormond Street Institute of Child Health, funded by the Department of Health and Social Care. Para 2.2 states "In the UK, 85 iCJD cases were identified between 1970 and 2016. Eight were from dura mater grafts, 1 was from human gonadotrophin and 76 were from human growth hormones." My records indicate that there were in fact 78 deaths secondary to human growth hormone between 1985 and 2016.	Thank you for your comments. These data were extracted directly from the NCJDRSU 25th Annual Report (Accessed 11.07.2017) (The University of Edinburgh. The National CJD Research & Surveillance Unit (NCJDRSU). 2017. **http://www.cjd.ed.ac.uk/**. The figures in the most recent – and cited - version of this source, used for the report, are 77 for HgH. However, the figure can be updated to 78 if the data provided are published, definitive and up to date and the source can be cited (numbers change every year in the CJD surveillance reports, presumably due to new information).
47	Consultee 7 NHS professional UCL Institute of Child Health, Great Ormond Street Hospital for Children NHS Foundation Trust	**2.2**	Para 2.2. The documentation uses the term "growth hormones" on at least two occasions. This should read "growth hormone" in the singular. The singular has always been the accepted term since pituitary-derived human growth hormone treatment commenced in the UK in 1959.	Thank you for your comments. Errors highlighted in section 2.2 of the draft guidance (the term "growth hormones") has been amended.

48	Consultee 8 Imperial College	**1.6**	I would agree with the conclusion that the use of separate instruments for post-1997 neurosurgical procedures is not cost effective. In practice the restriction of instruments (especially sub-specialist instrument sets) for use in the post-1997 group, or the use of single use instruments, has lead to surgery being performed which is compromised compared to the pre-1997 group. It is my impression that this practice will lead to more harm due to delayed surgery or surgery with limited instruments, than is prevented given that the incidence of stCJD is so low.	Thank you for your comments and agreeing section 1.6 in the guidance.
49	Consultee 9 NHS professional University College London Hospitals NHS Foundation Trust	**1.1**	Please find below the combined responses from key stakeholders of UCLH regarding the NICE consultation document related to reducing the risk of transmission of CJD from surgical instruments used on high-risk tissues which has been circulated: <u>Decontamination</u> • Keeping instruments moist until decontamination can cause more issues not only with transportation but with possibilities of rust occurrence if instruments are damaged microscopically. There was no specific guidance in the documentation as to how this would be achieved, nor was there any guidance as to how long instruments should be kept moist for. Has guidance been sought from manufacturers regarding keeping instrument sets moist? Costs would increase as instruments would need to be transported more quickly (if moist) additional sets would need to be purchased to	Thank you for your comments. Guidance has not been sought from manufacturers regarding keeping instruments moist. Committee suggests that manufacturer's instructions on instruments should be followed. Defining specific criteria as how to keep instruments moist and for how long including costs is a very important task. Section 1.8 in the draft guidance recommends that this guidance should be used with the Department of Health and Social Care's **Health Technical Memorandum (HTM) 01-01**: Decontamination of surgical instruments and corresponding guidance in the devolved administrations' areas.. The committee emphasised that clinicians must comply with this in section 4.6.

			ensure turnover from decontamination centres to ensure availability of sets. • Reliance on a protein detection system that has proved highly contentious has not been universal adopted and the methods adopted subject to commercial drivers is to us potentially flawed - national standards have not been able to provide a universally adopted process for detection both in terms of procedure, levels to be achieved or actions to be taken if triggers have been reached.	
50	Consultee 9 NHS professional University College London Hospitals NHS Foundation Trust	**1.2**	<u>Set Integrity and Tracking</u> • The non-migration of instruments cannot be guaranteed as there will always be human error. There are incidences now of migration of instrumentations from one set to another set even with designated post 1996 sets. To reduce the risk of non-migration of instruments each instrument in every single set would need to be traceable and that in itself would have major cost implications.	Thank you for your comment. This is what is modelled. The committee assumed a cost of £750,000 to ensure this. Committee agrees with your views about set traceability and think that when proper systems are in place risks related to migration can be reduced. Section 1.2 in guidance has been amended to make this clear.
51	Consultee 9 NHS professional University College London Hospitals NHS Foundation Trust	**1.3**	<u>Supplementary Instruments</u> • Supplementary instruments are just that, supplementary used as and when they are required. They are not assigned to given sets, if this were to happen the costs of maintaining supplementary instruments would increase and set lists would need to be changed constantly. Once again every supplementary instrument would need to be traceable. This in itself would be difficult as if instruments are only supplementary, a system would need to be created to reduce migration of supplementary instruments.	Thank you for your comment. The model assumes that the supplementary instrument joins the existing set to stop the risk of multiple stCJDs and every instrument should be tracked. Section 1.3 in the guidance has been amended.

52	Consultee 9 NHS professional University College London Hospitals NHS Foundation Trust	**1.6, 1.7**	Systems specifically for people born after 1996 • Removing the requirement to use different instruments would increase the risk of a higher risk of migration of instruments if designated post 1996 sets were not available.	Thank you for your comment. The committee agrees with your views. Evidence from the model does not support that there should be instruments specifically for people born after 1996.
53	Consultee 9 NHS professional University College London Hospitals NHS Foundation Trust	**2**	CJD • The disease process is slow (ScHARR report shows 1-42 years) there could still be cases yet to show symptoms, just because there have been no reported cases between 2005 and 2018 does not mean there would not be any in the future. People in the UK who were exposed to BSE are in effect 'silent carriers'. Until a blood test has been developed to determine CJD then precautions should not be altered, as we are uncertain about the future risk of surgically transmitted CJD (stCJD).	Thank you for your comment. The committee agrees with your views, and patients who might develop symptoms at a later date are modelled. But for the calibration period ScHARR can only look at the time period for which there is data. Section 2.2 in the draft guidance also clearly states the uncertainty about future risk of surgically transmitted CJD. Because of this uncertainty Department of Health maintains continuous surveillance of CJD.
54	Consultee 9 NHS professional University College London Hospitals NHS Foundation Trust	**3.3**	Evidence • Limited number of systematic reviews were undertaken in the ScHARR Report, most of which were descriptive. No formal critical appraisal of the study quality was undertaken. Until there is more compelling evidence or as previously mentioned a blood test has been developed to determine carrier status of CJD then the precautions of having designated post 1996 sets should remain in place.	Thank you for your comments. It is correct that formal critical appraisal was not performed on the studies included in the reviews; this is discussed and justified in Section 2.1.2 of the report. However, the protocol has been through an independent external peer review process organised by NIHR.The methodology used and the ScHARR final report are under peer review by NIHR. NICE consultation process also ensures a wider review of the guidance.

				Evidence from the model does not support that there should be systems specifically for people born after 1996 and removing the requirement to use different instruments for this group of people would not markedly increase the risk of surgical transmission of CJD as stated in section 1.6 in the guidance.
55	Consultee 9 NHS professional University College London Hospitals NHS Foundation Trust	**1**	Additional comments • There is no mention of monitoring and auditing of protein on instruments. Further guidance on this needs to be given.	Thank you for your comments. Committee thinks that these are well covered in HTM01-01 document and it is not IPAC's role to specify these again. Section 1.8 in the draft guidance recommends that this guidance should be used with the Department of Health and Social Care's **Health Technical Memorandum (HTM) 01-01**: Decontamination of surgical instruments and corresponding guidance in the devolved administrations' areas.. The committee emphasised that clinicians must comply with this in section 4.6.
56	Consultee 9 NHS professional University College London Hospitals NHS Foundation Trust	**1.6, 1.7**	Additional comments • If we are trying to minimise risk to patients being subjected to transmission of CJD from surgical instruments, why are there potential recommendations introducing more risk to patients born after 1996, as we still do not know the extent of the 'silent carriers' of CJD. Surely we should maintain current recommendations.	Thank you for your comments. Evidence from the model does not support that there should be systems specifically for people born after 1996 and removing the requirement to use different instruments for this group of people would not markedly increase the risk of surgical transmission of CJD as stated in section 1.6 in the guidance.
57	Consultee 9 NHS professional	**General**	Additional comments	Thank you for your comments. The purpose of the guidance is to reduce the risk of the development of a self-sustaining

	University College London Hospitals NHS Foundation Trust		• The costs of a claim if exposed to CJD from surgical instruments would far outweigh the costs of setting up risk reducing systems.	epidemic of CJD thought surgical transmission. It is not intended to completely eliminate the risk of any transmission, but the current evidence suggests this risk is very low.
58	Consultee 9 NHS professional University College London Hospitals NHS Foundation Trust	**3.3**	Additional comments • We are concerned that on page 10 of the guideline it admits a critical appraisal has not been performed on the quality of the studies the guideline is based on	Thank you for your comments. It is correct that formal critical appraisal was not performed on the studies included in the reviews; this is discussed and justified in Section 2.1.2 of the ScHARR report. However, the protocol has been through an independent external peer review process organised by NIHR. The methodology used and the ScHARR final report are under review by NIHR.
59	Consultee 9 NHS professional University College London Hospitals NHS Foundation Trust	**1.6, 1.7**	Finally we would like to add that the cost to organisations has been significant in creating a separate pool of instruments in line with guidance and internal risk assessment, without robust evidence based national guidance supporting that this continues it will be difficult for organisations to continue to have a funding stream made available to support continued investment. There is strong feeling that to change guidance without having robust evidence to support this will be a backwards step for centres that the consultation document is relevant to.	Thank you for your comments. Evidence from the model does not support that there should be systems specifically for people born after 1996 and removing the requirement to use different instruments for this group of people would not markedly increase the risk of surgical transmission of CJD as stated in section 1.6 in the guidance.
60	Consultee 10 Director of Public Health and Health Policy NHS Lothian	**1**	I am replying to the public consultation on this document on behalf of NHS Lothian Decontamination Programme Board. The Board met on August 20 and for various technical reasons, it was not possible to submit this before 5pm today. I have set out the response to the recommendations. **1.1** Very supportive	Thank you for your comments and supporting our recommendations 1.1, 1.2, 1.4 and 1.5. The guidance does refer to keeping supplementary instruments in the set as stated in section 1.3 in the guidance. This has been amended.

			1.2 Support phased implementation of set traceability in order of reducing risk of infection/consequences of decontamination failure **1.3** Potential supplementaries should be included in the set at source when these cases are planned; only in exceptional circumstances should supplementaries be required in an unplanned way. If this occurs, they should be treated as single use and discarded or added to the set as a planned supplementary for future use. **1.4** Support. Single use flexible neuroendoscopes can be used in exceptional circumstances. **1.5** Support – not everything is available as single use. **1.6** And 1.7 This is a major change and we will seek more detailed local advice on implementation from our expert advisers (who have also been involved in the development of the guidance). Some guidance on seeking expert advice regarding local implementation and audit would be helpful.	NICE intends to support implementation where possible but suggests that is primarily a matter for the NHS.
61	Consultee 10 Director of Public Health and Health Policy NHS Lothian	**Other**	Other comments Implementation of this guidance should be considered within a wider strategy of minimising healthcare associated transmission of pathogens. Current wisdom would consider that if the risk of prion-related disease can be minimised then the risk of transmission of other pathogens is also minimised; the conditions under which this assumption holds should be tested and modelling of potential future risks included in a technical supplement to the final guidance. It would be helpful to cross reference the requirement to comply with medical devices directives and to	Thank you for your comments. The committee agrees that there are potentially several ways of minimizing transmission of pathogens, however this guidance is limited to CJD. There is extensive cross referencing in the guidance to the need to comply with **Health Technical Memorandum (HTM) 01-01**: Decontamination of surgical instruments and other relevant guidance and standards.

			provide guidance to manufacturers and those procuring equipment and systems on the assumptions this document makes regarding compliance.	
62	Consultee 11 Public Health England	**Page 1 lay description**	"There is a chance that surgical instruments could spread (CJD) from 1 patient to another, even when they have been properly washed and disinfected". Most surgical instruments are washed, disinfected and sterilized. Of these, the process most relied on to produce patient safety is the sterilization step. This should be included for example. "There is a chance that surgical instruments could spread CJD from 1 patient to another, even when they have been properly washed, disinfected and sterilized".	Thank you for your comments. This section has been amended.
63	Consultee 11 Public Health England	**Page 2 last para, page 3 first para, page 4 para 1.8, first bullet**	These are all referring to the same guidance. The Advisory Committee on Dangerous Pathogens' (ACDP) guidance. The Spongiform Encephalopathies Advisory Committee (SEAC), was abolished in 2011 and its responsibilities transferred to the Advisory Committee on Dangerous Pathogens. The reference to SEAC should be removed. • Pages 2 and 3: The link is to an old, and superseded, version of the guidance. The current version is available at the following url: https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group • The collective title for the suite of guidance is "Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection". Although Part 4 is the relevant foundation document for healthcare settings, other documents in the collection will also be relevant, so the specific reference to "Part 4" should be removed.	Thank you for your comments. These sections have been amended.

			• Page 4, para 1.8 –“Minimise transmission risk of CJD and vCJD in healthcare settings” –is the description of the set of guidance on GOV.UK. However, this is the same guidance as above.	
64	Consultee 12 NHS professional CJD lead, Public Health England	**Page 2, 3**	Bottom of page 2, unnumbered para beginning "The recommendations do not apply....." The guidance at the link is a very old version and the SEAC committee was dissolved around 2012 or so, better to refer to the ACDP TSE subgroup Who took over the guidance The up to date version of the guidance is at this link https://www.gov.uk/government/publications/guidance-from-the-acdp-tse-risk-management-subgroup-formerly-tse-working-group Although the webpage is titled "minimize transmission risk of CJD....." the suite of documents are still called "transmissible spongiform encephalophathy agents, safe working....etc" - Ie the hyperlink text in your draft guidance is correct - but the link itself is directed to the wrong place. The TSE subgroup was dissolved at the end of March this year – -but all the guidance is still labelled as being from the T.S.E subgroup. The parent group A.C.D.P still sits and has taken over the oversight for TSEs too (TSE subgroup referred in section 1.8 and 3.2 also) Top of next page 3- the same applies - links to old version of the guidance, use current link above	Thank you for your comments. These sections have been amended.
65	Consultee 11 Public Health England	**1.1**	**Page 3** 1) The term “decontamination” is used but not defined, starting in section one. As many variations of this	Thank you for your comments. This section has been amended.

			term are used (for example, in the United States of America it means just the cleaning step) it would help readers if it were defined. In the United Kingdom it is the combination of cleaning plus disinfection plus (for surgical instruments) sterilization; for heat sensitive instruments such as endoscopes, it is just cleaning and chemical disinfection. 2) The specific step in decontamination being referred to in 1.1 “All surgical instruments that have come into contact with high-risk tissues during an interventional procedure must be kept moist until decontamination.” is the cleaning step. This could be made clear.	
66	Consultee 11 Public Health England	**1.4**	**Page 3** 1.4 “Rigid neuroendoscopes (rather than flexible neuroendoscopes) should be used if possible. They should be of a type that can be autoclaved and must be thoroughly cleaned and autoclaved after each use.” An autoclave is any vessel that accommodates steam under pressure. The term “steam sterilizer” are those autoclaves specifically set up to sterilize surgical instruments. This is the term used in Department of Health and Social Care decontamination guidance such as the HTM 01-01 series. Suggest change to: “Rigid neuroendoscopes (rather than flexible neuroendoscopes) should be used if possible. They should be of a type that can be steam sterilized and must be thoroughly cleaned and steam sterilized after each use.” This guidance can be viewed at:	Thank you for your comment. This section has been amended.

			https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care.	
67	Consultee 11 Public Health England	**Appendix**	**Appendix D** The ophthalmology procedures in Appendix D should align with the list of surgical procedures in the ACDP Guidance: Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Annex L: Managing CJD/vCJD risk in Ophthalmology. This guidance was developed in 2009 following the publication of NICE IPG 196 and specifies procedures that should be considered high risk. The list of high risk posterior segment eye procedures and their codes is at Appendix one of that document At: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/209770/Annex_L_-_Managing_CJD_vCJD_risk_in_ophthalmology.pdf.	Thank you for your comments. This section has been amended.
68	Consultee 12 NHS professional CJD lead, Public Health England	**2.2**	**Para 2.2 section on iatrogenic CJD**. Best to remove the parenthesis "(including endoscopes, laryngoscopes and electroencephalograph needles)", not looked at in this review, and now with the passage of time and new risk assessments done it is inconsistent with the retrospective management of CJD incidents (laryngoscopes) and also with more recent guidance on gastroendoscopes. **Para 2.2 section on variant CJD** https://www.cjd.ed.ac.uk/sites/default/files/figs.pdf Will be worth capturing that these are now very rare indeed. 0 or 1 person diagnosed in each of the last 8 years. In each of the other categories have expressed a relative quantity. In recent years have been more	Thank you for your comments. This section has been amended.

			iatrogenic cases than variant. So these are the least likely to be seen now. This might also be the place to mention the 1996/7 date – as otherwise the section above about systems for those born after 1996 doesn't relate to anything. this date was chosen as it aligned with the last of a series of measures put in place to protect the food chain (by re-enforcing the feedban to prevent new animals being infected with BSE) – and without anything to confirm or contradict was a reasonable date to assume that people born after that date would not be exposed to BSE in their diet. http://www.fao.org/3/y2038e/y2038e.htm	
69	Consultee 12 NHS professional CJD lead, Public Health England	**2.3**	Para 2.3...."but shorter durations have been reported in cases of stCJD". Suggests that durations shorter than 1 year have been reported, but I think means that durations towards the shorter end of the range have been reported (see the table about incubation periods in the SCHARR report) Para 2.3 last line "subtypes of the CJD" - would read better as "subtype of CJD"	Thank you for your comments. This section has been amended.
70	Consultee 12 NHS professional CJD lead, Public Health England	**2.4**	Para 2.4 - I have never seen ID50 written as a plural before like a unit measure, conversely microgram is written out in full (unusually) and should probably be plural. Suggest that the para is reviewed by an infectious disease expert/lab specialist	Thank you for your comment. This section has been amended.
71	Consultee 12	**3.1**	Para 3.1 please remove the bullets about use of reusable and single use endoscopes, laryngoscopes and related	Thank you for your comment. This section has been amended.

	NHS professional CJD lead, Public Health England		accessories - conflates with other guidance, but more importantly was not considered (not even really in the literature review) and also please remove "and endoscopes" from the following bullet. There is a whole other HTM document about endoscopes, we did not consider them here.	
72	Consultee 12 NHS professional CJD lead, Public Health England	**3.2**	Para 3.2 - all copied directly over from the previous guidance - probably okay - but arguably not current. e.g. MHRA don't have any institutional memory or written guidance about materials of bovine origin for example. To update The MSBTO guidance is now under the ownership of SABTO The ACDP TSE Risk management group became the ACDP TSE subgroup	Thank you for your comments. This section has been amended.
73	Consultee 12 NHS professional CJD lead, Public Health England	**3.3**	Para 3.3 last bullet - the model assumes that..... The first two phrases follow grammatically, but the last part , "and calibration of predicted model inputs" - doesn't as it's not an assumption.	Thank you for your comments. This section has been amended.
74	Consultee 12 NHS professional CJD lead, Public Health England	**4.6**	Para 4.6 - this link is also to the old version of the guidance.	Thank you for your comment. This section has been amended (see 4.7 in the guidance).

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