RISK ASSESSMENT FOR vCJD AND DENTISTRY

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SUMMARY

Scope of the Study

This report analyses the potential risk of vCJD transmission through re-use of instruments in dental surgery. Based on an existing EOR model for hospital surgery, the analysis considers a wide range of scenarios to allow for multiple uncertainties. It covers procedures carried out in "high street" dental practice, rather than more specialised maxillo-facial surgery.

If patients are recognised as being at heightened risk of infection with any form of CJD, instruments used on them are already subject to special precautions against onward infection, being quarantined and if necessary destroyed. However this analysis concerns potential risks of transmission amongst the generality of patients, where instruments might unknowingly be used on someone incubating vCJD. Two potential transmission routes are considered:

(a) Expert consultation suggested an initial focus on the possibility of transmitting infection through accidental abrasion of an infective patient's lingual tonsils, these being the only relevant oral tissue for which there is direct evidence of vCJD infectivity in humans. Most of this analysis focuses on this topic.

(b) However, vCJD infectivity in other tissues encountered in dentistry – e.g. dental pulp - is implied by some animal models. Though such infectivity has not so far been detected in humans, the possibility cannot be ruled out. Furthermore there is evidence that some instruments used in endodontic surgery – e.g. files and reamers – are particularly difficult to clean, and may carry significant residues of material after washing. We therefore also include some illustrative calculations of the transmission risks that could be posed *if this residue were to carry vCJD infectivity*. It should be stressed that this part of the analysis is purely hypothetical.

Conclusions

Risks to individual patients

(a) On present evidence and advice, the chance of vCJD being transmitted via tonsillar abrasion appears remote. The previous analysis of hospital surgery provides some points of comparison. For example, if similar standards of instrument decontamination are achieved in the two settings:

- With assumptions about tissue abrasion as suggested by expert consultation, a single dental procedure on an infective patient would be about 1,000,000,000 times less likely to transmit vCJD than – say - a tonsillectomy. (The latter in turn would be much less likely to do so than a procedure involving the Central Nervous System or the back of the eye.)

- Even with very pessimistic assumptions about the chances of tissue abrasion, a differential of about 10,000-fold with tonsillectomy would remain.

(b) If tissues such as dental pulp were to be infective, the risks of transmitting vCJD would obviously increase. However the analysis suggests that even taking a pessimistic scenario, the risks per operation would still be low (at least 10 times lower than for a tonsillectomy).

Risks to Public Health

Any risk of transmission depends critically on the initial prevalence of the disease and the number of invasive dental procedures. As the former is unknown, a range of scenarios is considered. The number of dental procedures in the UK is very large – estimated at about 75 million annually, including both NHS and private treatment. Of these, around 2 million are endodontic procedures. Even so, any risk to public health posed by dental transmission appears small compared to that for hospital surgery in similar scenarios.

Risk Reduction Measures

As for hospital surgery, the key consideration in minimising any risk of transmission is assuring the efficacy of instrument decontamination, even though current methods cannot remove such risks completely. In line with existing SEAC advice, potential risks can be further reduced by introduction of more single-use instruments where appropriate, especially of difficult-to-clean items.

Qualification of Analysis

Almost all the analysis reported here is subject to two major caveats. The first is that decontamination procedures used in "high street" dentistry are not (in general) significantly less effective than has been assumed here. Though the assumptions used are intended to give fairly conservative estimates for the reductions in infectivity achieved, this continues to be an area of uncertainty. It therefore remains important to monitor actual decontamination practice and encourage its improvement.

CONTENTS

1. INTRODUCTION

1.1 Background: variant CJD

1.1.1 Variant (or "new variant") Creutzfeldt-Jakob Disease is a degenerative brain disease that has so far proven to be fatal in all known cases. To date, there have been over 130 confirmed or probable cases in the UK, and about ten-fold fewer elsewhere. While much remains to be learnt, infection appears to be associated with the presence of a deformed prion protein known as PrP^{Sc}. In contrast to sporadic CJD (or sCJD), which has had a long-tern incidence of about 1 in 1 million of the population per year, many of the victims are quite young. The agent that causes vCJD is presently indistinguishable from that which causes Bovine Spongiform Encephalopathy (BSE) in cattle. It is now widely accepted that it may have passed into the human population through consumption of BSE-infected bovine tissues, though alternative hypotheses are still advanced.

1.1.2 Whatever the origins of primary human infection, we need to consider the possible risk of secondary (i.e. person-to-person) transmission of vCJD. One potential transmission route is via the re-use of surgical instruments. Research suggests that the standard decontamination processes used in hospitals and other healthcare settings cannot fully eliminate vCJD infectivity, though they do substantially reduce it. Were instruments to be unwittingly used on an infective patient, any material picked up and not removed by decontamination procedures might then come into contact with subsequent patients, with some consequential risk of infection. While special precautions are applied to avoid the re-use of instruments used on known or suspected vCJD (and sCJD) cases, these would not avoid any risks associated with those incubating the disease but not yet showing symptoms.

1.1.3 The scale of any such risk depends how many people are already infected. This is unknown as yet, given present uncertainty about the length of the incubation period prior to symptoms appearing, and the absence to date of a reliable pre-clinical diagnostic test. Though there are no known cases of vCJD having been transmitted through surgery, sCJD has been transmitted through neurosurgery, as well as through tissue grafts. In the case of vCJD, PrP^{Sc} has been found elsewhere in the body (e.g. tonsils, spleen and lymph nodes), suggesting that a much wider range of procedures needs to be considered. In considering the possible risks associated with dentistry, the present study extends an existing line of analysis.

1.2 Analysing the Risk of Transmission via Dental Surgery

Basic Approach

1.2.1 A previous study, available in full at www.doh.gov.uk/cjd/riskassessmentsi.htm analysed the potential risks of vCJD being transmitted via surgery in hospitals. These appeared to be concentrated mainly around operations involving the Central Nervous System (CNS), eye or lymphoid tissue. The relatively small number of dental procedures carried out in hospitals was noted, but not examined as a separate risk category. The aim of this study has been to extend the analysis to all dental procedures, particularly the large number carried out in "high street" dental

practices. Parts of the analysis may also be relevant to related specialisms such as maxillo-facial surgery, but the scenarios considered here relate specifically to the common forms of dentistry rather than considering more elaborate procedures.

1.2.2 As with hospital surgery, an analytical model is used as a framework for inputs based on published evidence where available, but also dependent on expert judgement and interpretation. A key aim of the study has been to bring together knowledge of dental procedures and practice, instrument design and decontamination, and research on vCJD itself. An overview of the expert consultation process underpinning most of this study is provided in **Annex A**, while published evidence is reviewed briefly in **Annex B**.

1.2.3 The many uncertainties surrounding vCJD make it futile to make predictions about actual transmission risks. Rather, the analysis aims to clarify the *possible* scale of any risk in different circumstances. It offers a framework to help set research priorities, and to make best use of new information as it comes in. It can also be used to explore the potential impact of risk reduction measures (e.g. improvements in decontamination methods, or the wider adoption of single-use instruments). However this paper is essentially confined to Risk Assessment rather than Risk Management.

Stages of analysis

1.2.4 We start from the simple presumption that some patients may be incubating vCJD but as yet showing no symptoms. Two possible routes of transmission are then considered – via tonsillar abrasion and via transfer of other tissues (should these turn out to be infective) as a result of endodontic surgery. In each case the Risk Assessment has two main stages.

- The *Sequential Operations Model* explores how many infections might result from *one dental procedure on an infective patient.*
- The *Snapshot Infection Rate Model* estimates the *annual number of infections* that could result from dentistry, taking into account the number of procedures carried out and using alternative scenarios for the number of patients that might be infective.

1.2.5 This approach follows the analysis for hospital surgery endorsed by the Spongiform Encephalopathy Advisory Committee (SEAC), though the first stage is extended – as explained below – when considering accidental abrasion. In the hospital risk assessment, a third stage used *dynamic models* to build longer-term scenarios for vCJD transmission. These allow for the potential effects of "feedback" caused by anyone infected then being a potential source of further infection. However the present analysis suggests that dentistry would add a small increment to any transmission risk posed by hospital surgery. This means that there would be little contribution to feedback effects, making dynamic analysis scenarios unnecessary.

Scope of the study

1.2.6 As discussed further in **Annex B**, evidence from animal models on the potential infectivity of dental tissues is rather contradictory. However the National CJD Surveillance Unit has recently been able to carry out post-mortem examination of tissue samples taken from known vCJD cases. Tests on tissues taken from two

patients (using both immunocytochemistry and Western blotting techniques) could detect no abnormal PrP in gingiva, dental pulp or alveolar nerve, or in oral mucosa. These as-yet-unpublished findings are provisional, and of course do not preclude the presence of PrP^{Sc} below the limits of detection. However they are of particular relevance as direct studies of human (rather than animal) tissue. It is also significant that the negative results were obtained after the onset of clinical disease – when the highest levels of infectivity might be expected.

1.2.7 These negative findings for dental tissues also contrast with evidence of infectivity in tonsillar tissue prior to the onset of symptoms. Given this contrast, much of this Risk Assessment concentrates on the potential for infective material to be picked up from patients' tonsils – which may be abraded by instruments during dental procedures – and deposited into subsequent patients. Of particular relevance are the *lingual* tonsils situated on each side of the base of the tongue, which may be vulnerable to abrasion during procedures carried out toward the rear of the mouth – e.g. on molar teeth. Scenarios for the resulting risks are set out in Chapter 3

1.2.8 However, the possibility of other tissues carrying infectivity cannot be ruled out. Chapter 4 therefore focuses on the re-use of difficult-to-clean instruments used in endodontic procedures, such as files and reamers, and analyses the scenarios that could occur *if the residue carried on these items were to be infective*.

2. OVERVIEW OF TRANSMISSION MODEL

2.1 Background: Sequential Operations Model for Hospital Surgery

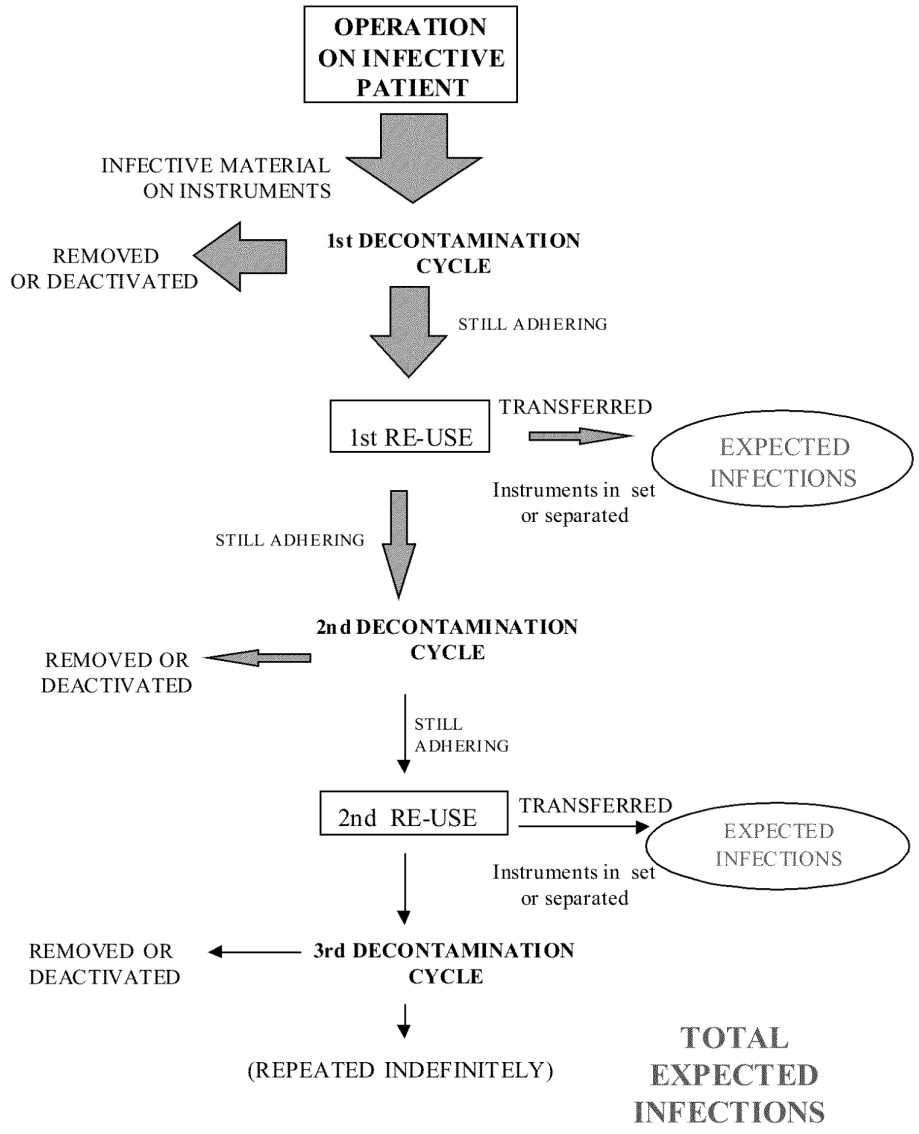
2.1.1 As in the previous Risk Assessment for hospital surgery, the model proposed here considers how many infections *could be* passed on by instruments following one operation on an infective patient. The underlying process is visualised as one in which instruments are used, decontaminated, reused, decontaminated again, and so on many times over – the instruments themselves having a very long working life. At some point, we suppose that instruments are used on a patient with vCJD and the analysis then tracks what could happen to any infective material picked up. The model for hospital surgery is summarised in Figure 1 below.

2.1.2 Clearly, the risk of infection being passed on will depend on the effects of instrument decontamination. This normally involves both *cleaning* and *autoclaving* The former reduces the mass of material remaining, while autoclaving is assumed to partially deactivate it (i.e. to reduce its specific infectivity, but not necessarily its mass)

- If infective material is left after the first decontamination cycle, the risk of infecting the next patient will depend on how much of it comes off during re-use. As the residue has remained attached throughout a cleaning process, one might expect the proportion coming off now to be small. However, direct evidence on this is lacking.
- This logic continues through further cycles of decontamination and re-use, until a total can be calculated for the number of infections to be expected from indefinite re-use of the instruments.

2.1.3 In reality, the transfer of material from patient to instrument and vice-versa is likely to be a highly complex process, and we do not attempt to model it in detail. However it is unlikely that successive decontamination cycles will have similar effects. (For example, material surviving the first cleaning cycle may have been baked-on during autoclaving.) Even in a simple model it is worth distinguishing the effectiveness of the *first* decontamination cycle from that of second and subsequent ones.

Figure 1: SEQUENTIAL OPERATIONS MODEL FOR HOSPITAL SURGERY



2.2 Adapting the model to accidental abrasion

2.2.1 In the model just outlined, infective material is picked up on instruments *whenever* an operation takes place on an infective part of the body. For example, if a patient's brain tissue is infective, neurosurgery will necessarily encounter it. However much of the present study is concerned with the risk of picking up infective tissue by *accidental* abrasion of the tonsils during dentistry – abrasion that would have to be sufficiently severe to break through the protective outer layer (epithelium). To pass this transmission on, the instrument would then have to accidentally abrade a receptive site in a subsequent patient.

2.2.2 With this in mind, the model is extended as in Figure 2 below, to introduce two elements of chance:

- Given an operation on the infective patient, the probability of an instrument picking up tonsillar material
- On each re-use of the instrument, the probability of abrading a "receptive" site (i.e. one providing a route for inward transfer of vCJD infection).

2.2.3 The actual likelihood of such abrasions occurring is a key question. Note that to *pick up* infection an instrument must (specifically) abrade the tonsils, which are taken to be the sole source of significant potential infectivity.[1] However the chance of *depositing* any such infectivity in subsequent patients is subject to additional uncertainties. It is not certain which sites might provide efficient inward routes for vCJD transmission. Arguably, such sites may include not only tonsils, but also other soft tissue (e.g. gums or tongue). Evidence for such inward transmission appears in at least some animal models with other Transmissible Spongiform Encephalopathies.[2] In any case there is a lack of published studies on the likelihood any specific tissues being abraded during dental surgery. We have therefore been heavily reliant on expert judgement here.

2.2.4 The amount of material liable to come off on each re-use of an instrument is also unknown, so we consider a range of assumptions here. For simplicity, we assume that a given proportion of the mass present will become detached during each re-use, *whether or not* there is any abrasion on a receptive site. However if a receptive site *is* abraded, *all* the mass detached is taken to be deposited into that site. This second assumption may be regarded as pessimistic, as in reality some of it might go elsewhere.

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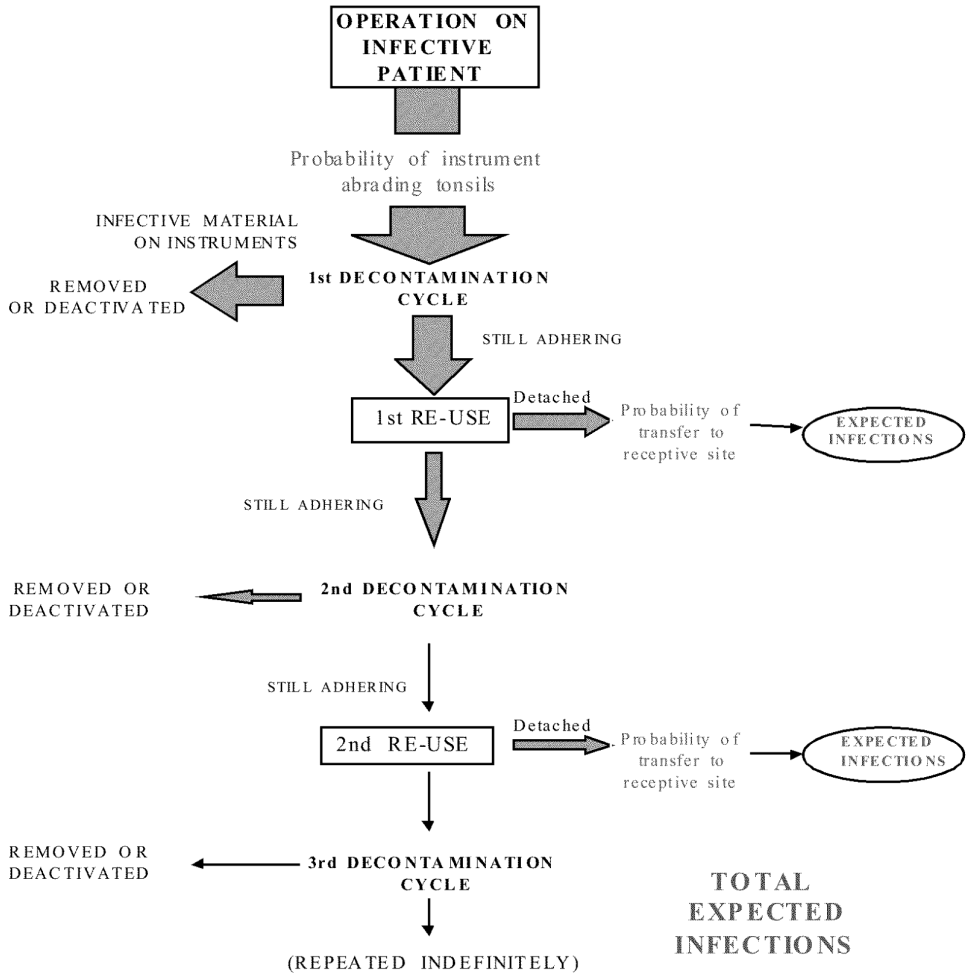
1 Some animal models suggest that the tongue might be a significant potential source of PrP^{Sc}. However later research indicates that this is liable to be localised in nerve axions inside the tongue rather than in superficial layers that might be subject to abrasion. See Bartz, JC, Kincaid AE and Bessen (2003): Rapid Prion Neuroinvasion following Tongue Infection" *J Virol* 77(1): 583-591

2 See Annex B, and especially the experiments on scrapie and transmissible mink encephalopathy reported in Ingrosso, L, Pisani, F and Pocchiari, M (1999): Transmission of the 263K Scrapie Strain by the Dental Route. *J Gen Virol* 80: 3043-3047 and in Bartz, *et al* (*op cit*) respectively.

Figure 2: SEQUENTIAL OPERATIONS MODEL FOR TONSILLAR ABRASION



2.3 Other key assumptions

Dose-Response Model

2.3.1 One key element in any analysis of infection is the relationship between the dose received and the "response" to it – i.e. the chance of developing the disease. The present analysis assumes a *linear* relationship, the chance of infection being proportional to the dosage received, with no lower threshold. Infectious doses are expressed in terms of ID_{50}s, one ID_{50} being the dose needed to infect 50% of those individuals receiving it. If someone receives 2 or more ID_{50}s, the model treats infection as certain. This has been endorsed by SEAC as a simple working model, and the other gross uncertainties about vCJD mean that little is gained at present by adding complexity.

2.3.2 However one alternative suggestion is worthy of note. This is that vCJD transmission might require no physical transfer of material, mere contact with PrP^{Sc} being sufficient to trigger a "chain reaction" of protein conversion. Recent

experimental evidence lends some plausibility to this hypothesis, suggesting that infective material held in place on a steel surface may act as a more efficient vehicle for infection than injection of infective homogenate.[3] Nevertheless these experiments so far relate only to material inserted directly into the brain, rather than into peripheral (e.g. dental or tonsillar) sites. The mechanism suggested for the greater efficacy of wire-bound infection, involving the clearance of unbound PrP^{Sc} from the brain, also seems more plausible in the context of intra-cerebral challenge. For peripheral infection, it appears intuitively more likely for transmission to require infective material to be left behind by instruments – especially as the instruments themselves may be in only fleeting contact with the relevant tissue. Nevertheless the model offered here can be adapted to reflect the contact-only hypothesis, while keeping the working assumption that the chance of causing infection is proportional to the infective load on an instrument.

2.3.3 The linear dose-response model used here has one significant consequence. Provided individual doses are small - as is the case in all the scenarios considered here - expected numbers of infections depend only on the total "number of ID_{50}s" transferred from patient to patient. Giving 2 ID_{50} s to one patient would have the same overall effect as giving 0.02 ID_{50}s each to 100 patients – i.e. 1 expected infection.[4]

Further Assumptions

2.3.4 All patients are taken to be susceptible to vCJD infection by this secondary route, though individual genotype may be relevant to primary infection.[5] Patients on whom instruments are re-used are assumed not to be already infected. This gives a potential for the analysis to overestimate the number of new infections due to "double-counting", but this effect is insignificant unless the prevalence of infection with the vCJD agent is already very high – of the order of 10% of the population.

2.3.5 A final key assumption is that *between decontamination and re-use*, any infectivity on an instrument remains roughly constant rather than decaying or growing "spontaneously". This appears reasonable given that instruments are generally reused frequently: by contrast the long incubation period for vCJD suggests that prion conversion is a rather slow process even within the body.

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[3] Flechig E, Hegyi I, Enari M, Schwarz P, Collinge J and Weissmann C (2001) Transmission of Scrapie by Steel-surface-bound Prions *Molecular Medicine* 7(10) 660-685

[4] If individual doses were high, infecting proportionately fewer people with greater doses would result in fewer infections. This situation might be relevant to infection via CNS surgery, and is considered in the risk assessment for hospital surgery.

[5] All known victims of vCJD so far have genetic characteristics shared by 40% of the population. While this may mean that genetic factors influence susceptibility, the influence may be only on incubation periods.

2.4 Snapshot Infection Rate

2.4.1 Given a scenario for the infections resulting from one operation on an infective patient, the annual rate of such infections within the population will depend on:

- the number of relevant procedures performed per year (say **N**)
- the proportion of patients who are infective (say **p**).

While there are some uncertainties around the first of these, the second is a major unknown. However broad-brush scenarios can be generated quite simply by using different "what-if" assumptions. The resulting infection rate is merely a "snapshot" against a given prevalence **p**. Over the longer term, **p** will itself vary.

2.4.2 Given the assumptions just discussed, the number of infections to be expected per operation in any scenario can be calculated by simple algebra, as summarised in **Annex C**. To allow rapid exploration of different scenarios, however, the model has been implemented in a spreadsheet. From inputs on mass and infectivity of any material picked up, effectiveness of decontamination, and (where appropriate) the chances of abrasion, this calculates:

- the expected number of infections at each reuse of the instruments, detailing how many patients are at what risk of infection
- the total number of infections to be expected from indefinite reuse.

2.4.3 Given further inputs for the proportion of patients currently infective and the annual frequency of the operation being considered, the spreadsheet also calculates:

- a scenario for the number of infections caused annually within the whole population.

2.4.4 The spreadsheet has also been extended in several ways to allow for more complex inputs about the effects of decontamination. For example, the percentage of material removed by cleaning may depend on the original amount present, gross soiling being relatively easily removed. Autoclaving may reduce infectivity down to a "plateau", beyond which subsequent cycles have no additional effect.

3. SCENARIOS FOR TONSILLAR ABRASION

3.1 Introduction

3.1.1 This chapter introduces numerical scenarios for the risk of vCJD transmission via tonsillar abrasion, based on the models just discussed. We stress again that these are not predictions. Rather, they set out a range of situations that *could* occur given what is currently known. The principal focus is on public health outcomes rather than individual infection incidents, so input ranges relate to the generality of "high street" dental procedures and practices.

3.1.2 Many inputs are subject to large ranges of uncertainty. Assumptions are described as more or less "pessimistic" to the extent that they would lead to larger or smaller numbers of infections. *No judgement about likelihood should be implied*: as yet

there is no basis for telling whether more pessimistic assumptions are more or less likely.

3.2 Risks per Operation: Inputs

3.2.1 The following ranges of input values are used to generate scenarios for the number of infections resulting from an operation on an infective patient. They are based on a mixture of published research evidence and expert opinion – particularly on matters relating directly to dental practice – as detailed in **Annexes A and B**. The rest of this section sets out inputs for each of the variables in the model. Following the logic set out in Figure 2, we first consider the initial (hypothetical) operation on an infective patient, and the first decontamination cycle prior to instrument re-use. Key variables here involve:

- the likelihood of instruments abrading tonsils
- the mass of material that might be picked up following abrasion, and the proportion removed during the first decontamination cycle
- the potential infectivity of tonsillar material, and its reduction during the first decontamination cycle

3.2.2 Following some initial calculations, we then consider factors involved further down the "chain" of instrument re-use, i.e.

- the proportion of residual mass coming off the instruments on each re-use
- the likelihood of instruments abrading a site providing a route for inward vCJD infection
- the efficacy of second and subsequent decontamination (cleaning and autoclaving) cycles.

Initial use and decontamination

Abrasion of tonsils

3.2.3 In dental surgery, expert advice is that around 10 instruments are typically used per operation, but that only a few (in the majority view, only one) could plausibly abrade the lingual tonsils on any given occasion. Our initial scenarios are based on tonsillar abrasion by a single instrument. As discussed later, varying this will have a straightforward linear effect on model outputs.

3.2.4 Abrasion is an accidental process that has not been subject to any systematic study, so its typical frequency in dental practice is difficult to establish. On this topic, the Risk Assessment is heavily reliant on expert judgement, and the consultation process outlined in **Annex A** paid a good deal of attention to it. Following the convening of an expert panel on vCJD and dentistry, a questionnaire was circulated both to members of the panel and to others with first-hand knowledge of dental practice. A very wide range of estimates was offered (from tonsillar abrasion being a common occurrence, to it happening a few times in a dentist's entire career). Responses to the questionnaire were then summarised and circulated, and further clarification sought. In this way, it was possible to move some way toward a consensus.

3.2.5 Nevertheless, appreciable differences in view remained. Our baseline scenarios take tonsillar abrasion (of sufficient severity to pick up potentially infective material), to occur about once in every 100,000 dental procedures. This represents the majority response to the questionnaire, including that from the British Dental Association. However continuing uncertainties on this point are acknowledged, and addressed below by considering a wide range of alternative scenarios.

Mass of material on instruments

3.2.6 If abrasion *does* take place, the key question is the amount of material continuing to adhere *after* the first cleaning cycle (i.e. immediately prior to the instrument's first re-use). There are two ways of approaching this question:

- to consider the mass of material liable to adhere before cleaning, and then make some assumption about the proportion washed off
- to estimate directly the amount liable to adhere after washing.

3.2.7 The previous surgical risk assessment uses the first approach. For tonsillectomy, for example, the baseline assumption was of an average 10 mg of tonsillar material being picked up per instrument. (It was acknowledged that there would be a good deal of variation around this average, according to instrument type.) The first cleaning cycle was then taken to have an efficacy of at least 2 logs (99% removal), leaving a residue of 0.1mg (10^{-4} g). For dentistry, the consensus expert view was that prior to cleaning, an instrument accidentally abrading the tonsils would carry significantly (10- or 100-fold) less tonsillar material than a typical instrument following use in tonsillectomy.

3.2.8 From this, one approach would be again to assume at least a 2-log reduction on cleaning, leaving a residue of 0.01 – 0.001mg per dental instrument. Since the previous Risk Assessment however, further experiments on surgical instruments have been carried out. These suggest that more than 10 mg of material might well adhere initially, but that most is relatively easily removed. As a result, the previously assumed residue post-cleaning appears to be of the right order.

3.2.9 However the same experiments also suggest that the amount remaining after cleaning may be largely independent of the initial mass. It may therefore not be correct to assume that the same log reduction is achieved with the smaller masses supposedly adhering to dental instruments. Experiments specifically investigating dental instruments are currently under way. Pending results from these, we believe that a cautious approach is warranted. For a dental instrument abrading the tonsils, we therefore assume that 0.1– 0.01mg (10^{-4} – 10^{-5} g) of tonsillar material would remain after the first cleaning cycle.[6]

Infectivity of tonsillar material

3.2.10 If a patient is infected with vCJD, the specific infectivity (infectivity per unit mass) of tonsillar material is taken to be 10^5 – 10^6 ID_{50} /g if transferred into another peripheral site. This takes into account a presumed ten-fold reduction in the

[6] The upper end of this range corresponds to the baseline scenario used for tonsillectomy in the surgical risk assessment.

efficiency of transmission as compared with transfer directly into the CNS. The same working assumption for transfer of lymphoid tissue is used in the Risk Assessment for hospital surgery and has been endorsed by SEAC.

3.2.11 Specific infectivity is assumed to be reduced by at least 3 logs (i.e. to $10^2 – 10^3$ ID_{50} /g) by the first autoclaving prior to instrument re-use. This is in addition to the reduction in mass achieved through cleaning.

Re-use and Further Decontamination

Mass detached on re-use

3.2.12 When an instrument is re-used, some of the material adhering will presumably come off regardless of whether the patient's soft tissue is abraded (e.g. by being scraped off on the teeth). For simplicity, we take the proportion coming off to be the same on each re-use. This is essentially unknown. It is varied between 1% and 10% in the scenarios considered here, with higher proportions considered in sensitivity analysis. This is similar to the range used previously for hospital surgery. As already noted, if the instrument abrades a vCJD-receptive site, all the material detached is assumed to be deposited there.

Frequency of abrasion of any part of the mouth

3.2.13 If an instrument is carrying infective material, our working assumption is that transmission of vCJD to another patient requires abrasion of some tissue, but *not* necessarily the tonsils.[7] To derive an estimate for the likelihood of such abrasion, our expert questionnaire framed the question in terms of a differential in frequency between tonsillar and other abrasion. Largely independent of their views on the absolute values, respondents were agreed that other tissues (e.g. gums or tongue) would be substantially more likely to be abraded than tonsils – as a rough consensus by a factor of 100. We therefore use this as a baseline assumption. (A further consideration is that if the receptive site is already wounded, little or no abrasion might be required to transmit infection via material deposited directly onto the wound. However we believe that the ranges of uncertainty used with regard to abrasion are sufficient to allow for this point.)

3.2.14 Matched with a likelihood of 1 in 100,000 for tonsillar abrasion as discussed above, this means that on each re-use, an instrument would have a 1 in 1,000 chance of abrading a receptive site.[8] As with the former estimate, however, we consider a wide range of alternative estimates.

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[7] Since the analysis underpinning the Risk Assessment was completed, further support for this cautious approach has been provided by the experiments of Bartz *et al* (*op cit*, 2003)

[8] In the questionnaire (see Annex A), respondents were asked to compare the chance of abrading tonsils with that of abrading some *other* potentially-receptive site. For the purposes of calculation, however, the relevant probability for the second event is that of abrading any receptive site, *including* tonsils. We use this second (slightly higher) probability to generate the scenarios below. Given that tonsils are much less likely to be abraded, this distinction makes no significant difference to the results.

Subsequent Decontamination

3.2.15 The efficacy of both cleaning and autoclaving on second and subsequent decontamination cycles (i.e. after the first re-use of an instrument) is highly uncertain. In the case of cleaning, any material left by this stage will already have survived a complete decontamination cycle, and may have been baked onto the surface of the instrument. For autoclaving, there is some limited evidence that repeating the process has less effect, with residual infectivity reaching a plateau, perhaps as high as 10^{2-3} i/c ID50 /g.[9]

3.2.16 We therefore take second and subsequent decontamination cycles to have substantially less effect than the first. The worst-case assumption is of no effect at all, varied in sensitivity analysis to 1 or 2 logs (after which further improvements would have only a marginal effect on the expected number of infections).

3.2.17 A summary of all the values and ranges just discussed appears in Table 1 below.

Table 1: Sequential Operations Model: Summary of Inputs

Variable	Details	Value/range	Units
At-risk instruments per dental operation	Number of instruments at risk of abrading tonsils.	1	N/a
Chance of abrading tonsils	Estimated mean	1 / 100 to 1 / 1,000,000 (baseline = 1 / 100,000)	Probability
Mass adhering after first decontamination	Estimated mean	0.1 – 0.01	mg
Mass reduction at 2nd + subsequent cleaning	Estimated mean	0 (minimum)	Log reduction
Specific infectivity for tonsillar tissue	Initial infectivity (if patient infected), for inter-lymphoid transfer	10^5 to 10^6	ID_{50}/g
Infectivity reduction on decontamination	First cycle	3 (minimum)	Log reduction
	Subsequent cycle	0 (minimum)	
Mass detached per operation	Proportion of residue detached on each re-use of instrument	1% to 15% (baseline = 10%)	Percentage
Chance of abrading other soft tissue	Estimated mean (for each instrument re-use)	1 / 1 to 1 /10,000 (baseline = 1 / 1,000)	Probability

[9] Taylor DM et al (1998): Observations on stable subpopulations of the unconventional agents that cause transmissible degenerative encephalopathies *Vet Microbiology* 64, 33-38

3.3 Initial Scenario

3.3.1 The inputs just outlined generate some illustrative scenarios for the number of infections to be expected per operation on an infective patient. This section details the relevant calculations for one scenario, using the "baseline" inputs just noted, i.e.:

- For each dental operation there is a 1 in 100,000 (10^{-5}) chance of one instrument abrading tonsils.
- If tonsillar material is picked up, the first decontamination cycle would leave a residue of 0.1 mg (10^{-4} g) – the higher end of the range discussed.
- If the patient is infective, this tonsillar material would have an initial infectivity of 10^{6} ID_{50}/g for deposit into a receptive site – again the higher end of the range discussed – reduced to 10^{3} ID_{50}/g during the first decontamination cycle.
- Second and subsequent decontamination cycles have no effect on residual mass or infectivity.
- The instrument then has a 1 in 1,000 chance of abrading a receptive site on each re-use.
- 10% of the infective mass remaining comes off at each re-use, whether or not a receptive site is abraded.

3.3.2 Given these assumptions, the expected number of infections for indefinite re-use of the instrument would be **5×10^{-10}** (0.0005 per million such operations). Figure 3 below tracks the distribution of infection risks down the chain of instrument re-use, showing how this estimate is arrived at.

3.3.3 After the first decontamination cycle, there is a 10^{-5} chance of the instrument carrying 10^{-4} g of material with infectivity 10^{3} ID_{50} /g. 10% of this (i.e. 10^{-5} g) is detached in any case, with probability 10^{-3} of transfer into a receptive site. As shown in Figure 3, the number of expected infections at this stage is:

0.5 x (expected dose transferred)

= 0.5 x (chance of infectivity present) x (dose transferred if present)

= 0.5 x (chance of infectivity present) x (residual infectivity x mass detached x chance of abrading receptive site)

= $0.5 \times 10^{-5} \times (10^{3} \times 10^{-5} \times 10^{-3})$

= 5×10^{-11} infections

3.3.4 After the second decontamination cycle (which in this scenario has no further effect) the instrument will still be carrying the 9×10^{-5} g left after its first re-use. 10% of this (9×10^{-6} g) will be detached on second re-use, its infectivity remaining as before. Calculating the number of infections at this stage will be exactly as above, except with a mass detached of 9×10^{-6} rather than 10^{-5} g. The number of expected infections will thus be:

$0.5 \times 10^{-5} \times (10^{3} \times 9 \times 10^{-6} \times 10^{-3})$

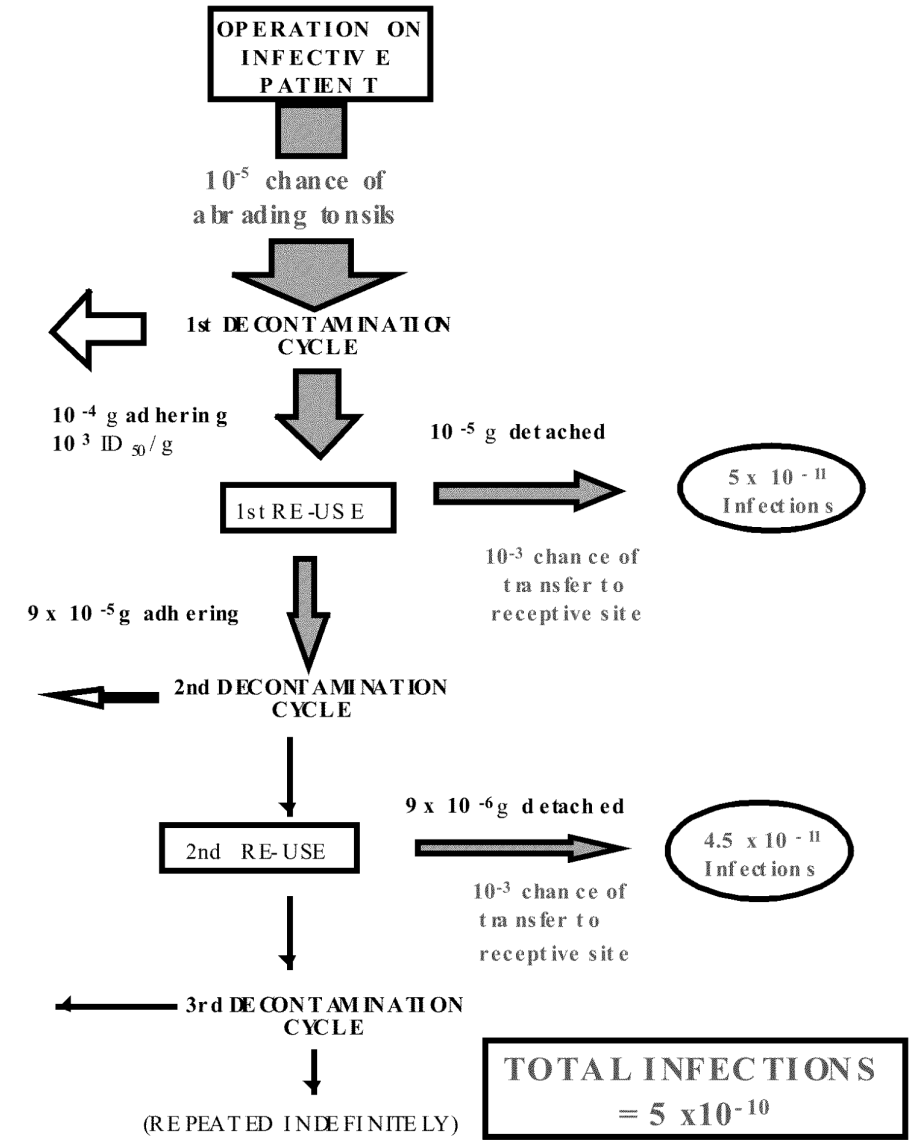
= 4.5×10^{-11} infections

Continuing these calculations down the chain leads to a total number of infections of:

$$(5 + 4.5 + 4.05 + \ldots.) \times 10^{-11},$$

This is a convergent series summing to 5×10^{-10}

Figure 3: SEQUENTIAL OPERATIONS MODEL FOR TONSILLAR ABRASION: ILLUSTRATIVE SCENARIO



3.4 Varying the inputs: scenario ranges

3.4.1 In this section, we briefly consider scenario ranges generated by varying some of the key parameters, i.e. those to do with tissue abrasion and the efficacy of instrument decontamination. Some further sensitivity analysis is presented in Chapter 4 below.

Likelihood of tissue abrasion

3.4.2 Varying individual inputs to the analysis quickly reveals that some are much more critical than others. Unsurprisingly, key variables include the likelihood of instruments abrading tissue and the efficacy of decontamination. We consider abrasion first.

3.4.3 In the baseline scenarios just set out, abrasion is taken to be rare. Note that two distinct probabilities are involved:

(a) The chance of instruments abrading and picking up tonsillar tissue (occurring once in 100,000 operations in the baseline scenario)

(b) The chance of instruments abrading any tissue - including tonsils - that might act as a receptive site for inward transmission of vCJD (1 in 1,000 operations in the baseline).

3.4.4 While these estimates reflect a majority view of dental experts consulted, both are subject to great uncertainty. This is therefore a key area in which to explore alternative assumptions – particularly those that make abrasion more frequent. Illustrative results are shown in Table 2 below, keeping all other inputs (e.g. on infectivity of tissue and effects of decontamination) at their previous – generally pessimistic – values.

3.4.5 The table shows numbers of infections expected per million operations on infective patients (this scale being shown to aid presentation of the figures).

- *columns* vary the chance of an instrument abrading a patient's tonsils between 1 in 100 and 1 in 100,000
- *rows* vary the chance of an instrument abrading any receptive site for inward infection between 1 in 10 and 1 in 10,000.

The latter chance is always taken to be at least 10 times greater than the former: hence the blank cells in the lower left of the table. The original baseline scenario is shown in the shaded cell.

3.4.6 This table may serve to illustrate the very wide range of scenarios created by varying the frequency of abrasion – even when all other variables are held constant. This suggests a need for some empirical research in this area. The top-left scenario may plausibly be regarded as an overall "worst case", given that other inputs are also set at pessimistic values.

Table 2: Scenarios for infections per **1 million** dental procedures on infective patients

Assumptions: 1st cleaning leaves 0.1 mg on 1 instrument, of infectivity 10^3 ID_{50}/g after 1st autoclaving. Subsequent decontamination has no effect. 10% of material detached on each re-use. Shaded cell indicates baseline scenario for abrasion

		Chance of abrading tonsils (per operation)			
		1 in 100	1 in 1,000	1 in 10,000	1 in 100,000
Chance of abrading receptive site	1 in 10	50	5	0.5	0.05
	1 in 100		0.5	0.05	0.005
	1 in 1000			0.005	**0.0005**
	1 in 10,000				0.00005

Variations in Decontamination

3.4.7 As noted, the above scenarios are based on rather pessimistic assumptions about decontamination. Varying these inputs reveals that:

- The efficacy of *first* decontamination is *always* critical: an increase of 1 log efficacy (through any combination of mass and infectivity reduction) always reduces the expected number of infections by a factor of 10.
- If *second and subsequent* decontamination cycles have an efficacy of 1 log (rather than no effect), the total number of expected infections would also fall about 10 - fold. However further increases in efficacy would produce only a small further reduction.

These findings mirror those in the previous Risk Assessment for hospital surgery: results of sensitivity analysis are provided in further details in **Annex D**.

3.5 Infections within the population

Further Inputs

3.5.1 Even if the risk of any given dental operation transmitting infection via tonsillar abrasion is very small, the large number of dental procedures carried out still needs to be considered. Specifically, the potential number of vCJD infections transmitted annually as a result of tonsillar abrasion will be governed by the number of operations carried out on infective patients. This in turn will depend on two further factors:

- the number of relevant procedures carried out each year, and
- the prevalence of vCJD amongst patients.

We now discuss each of these in turn.

Annual number of procedures

3.5.2 There is some uncertainty as to the number of procedures carried out that might carry some risk of tonsillar abrasion. Numbers of visits to dentists are not recorded centrally, and a course of treatment (recorded for purposes of reimbursement) might entail one or more visits. Conversely, some visits may entail no treatment invasive enough to be relevant here. The number of private treatments carried out is significant but difficult to quantify in itself. In line with expert advice, we take the annual number of procedures carrying some risk of tonsillar abrasion to be roughly 75 million in the UK.

3.5.3 Though this is imprecise, some rough cross-checking has been carried out by comparing recorded payments for courses of treatment with estimates derived by multiplying a rough number of active dentists in the country by the number of patients likely to be seen. In any case the uncertainties here are much smaller than elsewhere in the analysis. It seems highly likely that the 75 million figure is of the right order – i.e. that there are many millions of such operations, but not many hundred millions.

Prevalence of infective patients

3.5.4 Because the number of people currently incubating vCJD is unknown, we need to consider a wide range of values. As might be expected, prevalence has a straightforward linear impact on the number of infections caused (unless it approaches 1 in10, when double-counting effects start to become significant).

3.5.5 The Risk Assessment for hospital surgery takes a range of scenarios, from 60 to 600,000 people currently infective within the UK population – i.e. a prevalence ranging from roughly 1 in 1,000,000 to 1 in 100. A slightly simpler approach is to estimate the number of new infections annually *per 1,000 people already infected*. This avoids having to consider so many scenarios. Taking this approach, (and ignoring any age cohort effects on the chance of those infected having dental treatment), one would expect the number of dental procedures on infective patients to be roughly

75,000,000 x 1,000 / 58,800,000 = **1300** per year, per 1000 infectives

Numerical scenarios

3.5.6 To continue the previous pessimistic illustration, scenarios for the number of transmissions per year via tonsillar abrasion can now be generated from Table 2. As these give expected infections *per million* operations on infective patients, the previous figures must be multiplied by a factor of 1300 / 1 million, or 0.0013. This gives the range of scenarios in Table 3 below. The "baseline" scenario on the likelihood of tissue abrasion (based on the majority expert view) is again shaded. Note that in this case - and even given the pessimistic assumptions on

decontamination - there would be a less than 1 in 1 million chance of a dental transmission occurring per year for every 1,000 existing infections.

Table 3: Scenarios for secondary vCJD infections via tonsillar abrasion, per year, per 1,000 existing infectives

Assumptions re infectivity, decontamination etc as in Table 2. Shaded cell indicates baseline scenario for likelihood of abrasion.

		Chance of abrading tonsils (per operation)			
		1 in 100	1 in 1,000	1 in 10,000	1 in 100,000
Chance of abrading receptive tissue	1 in 10	0.07	0.007	0.0007	0.00007
	1 in 100		0.0007	0.00007	0.000007
	1 in 1000			0.000007	**0.0000007**
	1 in 10,000				0.00000007

3.5.6 To take the analysis one step further, we can use a single illustrative scenario for the background prevalence of the disease. Suppose that 6,000 people in the UK were carrying the disease – i.e. a prevalence of about 1 in 10,000 patients. Then the expected numbers of infections in the equivalent scenarios to Table 3 would be as shown in Table 4 below:

Table 4: Scenarios for secondary vCJD infections per year via tonsillar abrasion in the UK, with 6,000 patients infective (i.e. prevalence approx 1 in 10,000)

Assumptions re infectivity, decontamination etc as in Tables 2, 3. Shaded cell indicates baseline scenario for likelihood of abrasion.

		Chance of abrading tonsils (per operation)			
		1 in 100	1 in 1,000	1 in 10,000	1 in 100,000
Chance of abrading receptive tissue	1 in 10	0.4	0.04	0.004	0.0004
	1 in 100		0.004	0.0004	0.00004
	1 in 1000			0.00004	**0.000004**
	1 in 10,000				0.0000004

3.6 Commentary

3.6.1 Though one can generate a very large range of scenarios, the examples in Section 3.4 suggest that the chance of transmitting vCJD infection from one patient to another via tonsillar abrasion would be very small. Even in the "worst case" scenario of Table 2, there would only be about 50 vCJD transmissions expected per million operations on infective patients. In other words, even if a patient incubating vCJD were to undergo a dental procedure, the instruments would be very unlikely to infect anyone else in this way – the chance being about 1 in 20,000 for indefinite instrument re-use.

3.6.2 One way of scaling this risk is to compare it to that estimated for other forms of surgery in similar scenarios. Here, it may be appropriate to compare scenarios for tonsillectomy within the surgical Risk Assessment. If similarly-pessimistic assumptions are made about tonsillar infectivity and the efficacy of instrument decontamination, the expected number of infections caused by a tonsillectomy on an infective patient would be approximately 0.6. So on a per-operation basis, the risk of passing on infection from tonsillar tissue via dentistry on an infective patient would be *at least 10,000 times* less than for a tonsillectomy.[10]

3.6.3 Considering the "baseline" rather than "worst case" scenario for frequency of abrasion, the differential would be increased by a further 5 logs. That is, each dental procedure would be about 1,000,000,000 times less likely than a tonsillectomy to transmit the disease. Compared to surgery involving the CNS or back of the eye, the differential would be even greater.

3.6.4 These comparisons hold whenever similar assumptions are made about the efficacy of decontamination procedures in the two contexts. If decontamination in dental practice was generally less effective, the risk differential would be eroded. Even so, it is difficult to envisage it not remaining substantial.

3.6.5 The Scenarios set out in Section 3.5 also allow comparisons between potential risk to Pubic Health, taking account of the frequency of procedures. Continuing the comparison with tonsillectomies, it may be of interest that with decontamination inputs set at their most pessimistic values in both models:

- In the "baseline" scenario on tissue abrasion, vCJD infection by this route would be about 1,000,000 times rarer than from tonsillectomies, even after taking into account the much greater frequency of dental procedures

- In the worst case scenario for transmission via tonsillar abrasion, (top left corner of Table 3) the number of infections expected would be about 1/10th of those due to tonsillectomies. That is, there are about 1,000 times more dental procedures (75m compared with 74,000 annually), each of which would carry about 1 / 10,000th of the risk of transmitting vCJD.

3.6.6 Also in the worst-case scenario, tonsillar abrasion during dentistry would contribute about 0.4 expected infections per annum against a background of 6,000 existing

[10] Of this 4-log (10,000 fold) differential, 2 logs allow for the 1 in 100 chance of tonsillar abrasion in this scenario, 1 log for the chance of abrading receptive tissue subsequently, and roughly 1 log for there being 1 rather than 12 instruments assumed to pick up infective material.

infections. Bearing in mind that even this estimate requires pessimistic assumptions about both decontamination and the chances of instruments abrading tissue, this route would have no detectable impact on the outbreak. Its contribution to any feedback from infection to prevalence of the disease would also be a negligible, as would any "amplification" of other routes. So, for example, assessments of vCJD transmission risks through donated blood or via hospital surgery need make no additional allowance for individuals also being exposed to potential risks from tonsillar abrasion during dentistry.

4. ENDODONTIC SURGERY: FILES AND REAMERS

4.1 Introduction

Background

4.1.1 Though we have concentrated so far on the risks posed by instruments abrading the lingual tonsils of infective patients, the possibility of infectivity being present in other tissues cannot be ruled out. This has particular relevance for items such as files and reamers. These are known to be difficult to clean effectively, and have been observed to carry significant residues of material after cleaning[11]. Concerns have also been raised about the efficacy of decontamination in dental practice more generally[12].

4.1.2 This chapter therefore considers the transmission risks that *could* arise from the re-use of files and reamers, if dental tissues were to carry vCJD infectivity. It should be stressed that this is a purely hypothetical situation. (By contrast, the previous analysis dealt with a tissue for which there was evidence of infectivity in humans.) However there is now emerging evidence on the *amount* of material that may adhere to such instruments. Based on this, we can calculate the risks of vCJD transmission in scenarios where this material is *assumed to be* infective. We concentrate on exploring a "worst plausible case" to investigate how great a transmission risk *could* be posed by the re-use of files and reamers.

Dental Files and Reamers

4.1.3 Files and reamers are commonly used to make or enlarge holes in teeth during endodontic (root canal) procedures. **Annex E** defines files and reamers in more detail, and outlines the nature of endodontic surgery. Typically, they are employed following the use of a high-speed drill and burs, in order to gain access to the diseased root canal space. In this process they come into contact with tooth dentine, pulp and possibly the gums.[13]

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[11] Smith, A, Dickson, M, Aitken, J. and Bagg, J. (2002): "Contaminated Dental Instruments" *J. Hospital Infection* **51**, 233-235.

[12] Lowe, AJ, Burke, FJT, McHugh, S and Bagg, J (2001a): "A survey of the use of matrix bands and their decontamination in general dental practice" *British Dental Journal* 192, 40-42, & Lowe, AJ, Bagg, J, Burke, FJT, MacKenzie, D and McHugh, S (2001b): "A study of blood contamination of Siqveland matrix bands" *British Dental Journal* 192, 43-45.

[13] Other items such as burs are also difficult to clean, but are considered less likely to encounter pulp.

4.1.4 Unlike many instruments used in hospital surgery, files and reamers have fairly short working lives, typically being used about 8-10 times (say a mean of 9) before being discarded. Typically, 6 files or reamers will be used in the course of one endodontic intervention, files now being the more common instrument of choice. Files and reamers are already single-use items in US dental practice - *not* on infection control grounds, but to minimise the risks of tips breaking off inside patients' teeth - with consequent possible litigation.

4.2 Key Scenario Inputs

4.2.1 We start the analysis by generating scenarios for the risk of vCJD transmission given an operation on an infected patient, following the logic of the Sequential Operations Model discussed in Chapter 2. We assume that files and reamers would necessarily encounter dental pulp during use. So in this context the model can be used in its original form (as in Figure 1) rather than requiring the additional probabilities introduced to consider accidental abrasion of the tonsils (Figure 2). Key inputs to the analysis are then as discussed below.

Material adhering to files / reamers

4.2.2 The key question here is the mass adhering *after* the item has been cleaned. As noted, there is now some evidence on this, which can be used directly in the model (rather than hypothesising a mass adhering initially and then the reduction achieved by cleaning). Ongoing studies by Perrett and Jeffries (reported to DH Decontamination Research Group, 2nd July 2002) report visible residue on dental files and reamers after cleaning (either in General Dental Practice or hospital SSDs). Having used fluoroluminescence methods to measure residual protein, they report an average equivalent to around 10 micrograms (10^{-5} g) dry weight of protein (the researchers noting that "dry weight" is about one-fifth of the equivalent mass of wet tissue, on which estimates of vCJD infectivity are generally based). However this amount adhering was subject to high variability, with instruments from General Dental Practice typically more highly-contaminated than those from hospitals, carrying up to around 50 micrograms dry weight.

4.2.3 As a starting-point for this analysis, we therefore consider a scenario in which files and reamers used in General Practice carry the equivalent of 30 micrograms dry weight of protein after cleaning, i.e. about **150 micrograms (1.5×10^{-4} g) of wet tissue**.[14]

4.2.4 In addition, further material of roughly the same mass was found to be attached to the rubber dam typically placed below the instrument handle. For present purposes, we suppose that this additional material would be unlikely to be deposited into a vCJD-receptive site on re-use. It is therefore disregarded – though this assumption could be revisited if appropriate.

4.2.5 At present the origin of this residual protein is unknown. Given the use to which files and reamers are put, it may be assumed to be some combination of pulp (perhaps of most concern re possible vCJD infectivity), dentine, and other host

[14] For comparison, the existing model for hospital surgery uses a baseline scenario of 10^{-5} g adhering to each instrument after cleaning.

material from the root canal – e.g. from an abscess necessitating treatment. However the proportion of these within the residue are unknown.

Potential Infectivity of Material

4.2.6 As already stressed, the presence of any infectivity in dental tissues is purely hypothetical at this stage. For illustration, however, we will explore what appears to be the worst possible case. It should also be stressed that, though difficult to clean, files and reamers can and should be autoclaved. The question therefore is what *residual* infectivity might be left after autoclaving.

4.2.7 We have already referred to the possibility that autoclaving infective material may leave a "plateau" of infectivity of around 10^{2-3} i/c ID_{50} per gram, largely independent of the initial infectivity. To generate a pessimistic scenario, we take the higher value of **10^3 i/c ID_{50} per gram** as a starting-point. It may be noted that residual infectivity of this order could represent either of two scenarios:

- high levels of initial infectivity (e.g. as in the Ingrosso *et al* hamster / scrapie model), despite the negative findings of Ironside *et al* in human tissue – implying that the latter experiments were in some way flawed, or the samples atypical, or
- lower levels of initial infectivity - i.e. below about 10^4 i/c ID_{50} per gram, which might not have been detected by the Ironside tests - combined with autoclaving achieving only a modest (10-fold) reduction.

4.2.8 A further question is the potential efficacy of the dental route as a path for inward transmission of the disease. While there is no human data on this, the Ingrosso *et al* model suggests that this may be a fairly efficient route.[15] For illustration, we consider a scenario in which the dental route is 5 times less efficient than direct intercerebral innoculation. This reflects assumptions made in risk assessments of surgical and blood-borne transmission of a 5 – 10-fold differential between intercerebral and inter-peripheral transmission.[16]

4.2.9 To summarise, we take material such as dental pulp on files and reamers to have a maximum infectivity *after autoclaving* of 2×10^2 ID_{50} per gram for peripheral transmission. Combined with the previous assumption about the mass adhering after cleaning, this implies that each item could carry a maximum potential dose of:

$1.5 \times 10^{-4} \times 2 \times 10^2 =$ **0.03 ID_{50}** immediately prior to re-use.

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[15] Files and reamers are believed to pierce the apex at the end of the tooth root on about 50% of uses: if this is regarded as a necessary condition for inward transmission, any potential risks would be reduced proportionately from those calculated here.

[16] For discussions, see e.g. Brown, P *et al* (1999): Further Studies of Blood Infectivity in an Experimental Model of Transmissible Spongiform Encephalopathy *Transfusion*, Vol 39, Nov/Dec 1999; Taylor, DM and Fraser, JR (2000); The potential risk of transmitting vCJD through surgery *J. Hospital Infection* 44, 318-321

Deposit of material on re-use

4.2.10 Using the simple linear dose-response model, a dose of 0.03 ID_{50} would in principle be sufficient to cause 0.015 expected infections. However, the presence of a given infective load on an instrument obviously does not imply that all of this infectivity would be transmitted to subsequent patients. This depends on how much material becomes detached on re-use. A theoretical worst case would be that in which all of the material is deposited into the first patient on which the item is re-used. However this appears implausible, given that the residual material must have already remained attached through at least one cleaning cycle, and would then have been baked-on during autoclaving.

4.2.11 A more plausible assumption is that a smaller proportion of the residual material (say 1-10%) would become detached on each re-use. The eventual number of infections to be expected would then depend on the effectiveness of second and subsequent decontamination cycles in removing or deactivating infectivity. As noted before, these cycles may each have much less effect than the first.

4.3 Scenarios and their implications

Potential risks per operation

4.3.1 The Sequential Operations Model originally considered indefinite re-use of instruments, but can readily be adapted to allow for the comparatively short life of files and reamers. If these are currently used 8-10 times before being discarded, one would expect an average of 4-5 re-uses after contamination with vCJD, if this occurs at random during the item's lifespan.

4.3.2 Table 5 below sets out four alternative scenarios for the expected number of infections caused by 6 files / reamers over 5 re-uses following initial contamination. The proportion of residue coming off during each re-use is set at 10% or 1%, and the effectiveness of each second and subsequent decontamination cycle at 0 or 1 log (i.e. a further10-fold reduction in infective load each time). Note that increasing the effectiveness beyond 1 log has very little further effect.[17]

[17] Also, because the analysis deals with infective loads that are relatively low – as compared with the risk analysis for CNS surgery – results do not depend on whether instruments are split up or kept in the same sets for successive uses.

Table 5: Expected vCJD infections from 5 re-uses of 6 contaminated files/reamers, varying decontamination and material detached.

(*Assumes* residue of 1.5 x 10^{-4} g tissue per instrument after first decontamination, of hypothetical infectivity 2 x 10^{2} ID_{50} per gram)

	Effect of each 2nd and subsequent decontamination cycle on infective load	
Proportion of mass detached on each re-use	No effect	1 log reduction
10%	3.7 x 10^{-2}	1 x 10^{-2}
1%	4.4 x 10^{-3}	x 10^{-3}

4.3.3 Given this pessimistic scenario for the level of infectivity that could be present, the number of onward infections caused each time a set of 6 files or reamers is used on an infective patient might thus be *up to* roughly 4 x 10^{-2}.

Maximum Potential Risks to Individual Patients

4.3.4 A question of concern in its own right is the maximum risk that could be faced by any single individual, as the previous calculations take no account of the distribution of risks as instruments are successively re-used. Questions of individual risk are of particular importance in the context of vCJD "incidents" in which a patient is subsequently diagnosed with vCJD. In that circumstance, the maximum transmission risk would fall on the next patient on whom an instrument (or instruments) were used.

4.3.5 Even leaving aside the question of whether this individual could actually be identified, risks to each patient are subject to much more uncertainty than the expected total of expected infections as instruments are re-used. In particular, files and reamers are not generally re-used in the same sets, so it is not known how many of those used on an infective patient would have been used on any individual subsequent patient.

4.3.6 Nevertheless, "what-if" calculations can establish an *upper limit* for the risk to any individual. This is done by considering the (hypothetical) case in which *all six* contaminated files and/or reamers are re-used on the *same* patient. It can be shown that even then, that patient would have a less than 1% chance of being infected with vCJD in the scenarios considered here. (More detailed calculations for risks down the "chain" of re-use are shown in **Annex F**). This compares with estimated risks of infection from "first re-use" of instruments as high as 100% for CNS and Posterior Eye surgery, and 10% for LRS operations, when calculations are done on a similar basis.[18] In making such comparisons, it should also be noted that there is direct

[18] These calculations were provided by EOR and are cited in the CJD Incidents Panel Consultation Document *Management of Possible Exposure to CJD Through Medical Procedures* (Dept of Health, October 2001)

evidence for infectivity in these latter tissues, whereas infectivity of dental pulp remains speculative.

Risks to Public Health: Snapshot infection rates

4.3.7 As for tonsillar abrasion, the number of infections that might be caused within the whole population depends on how many operations are liable to be carried out on infective patients – and hence on the frequency of operations and the prevalence of the disease.

4.3.8 On the first point, up to about 1.5m endodontic procedures are carried out annually for the NHS (Dental Practice Board returns for England in 2001-2002 total about 1.1m), and a substantial additional number in private practice. We therefore use a rough estimate of 2 m per year (this estimate may appear somewhat high, but should also allow for the point that about 20% of recorded procedures involve the patient visiting the dentist more than once.)

4.3.9 On the second point, we can again take an illustrative scenario for the prevalence of the disease. Suppose that 6,000 people in the UK were carrying the disease – i.e. a prevalence of about10^{-4}, or 1 in 10,000 patients – all of them currently infective. Then the expected numbers of infections within in the population per year would be:

Number of operations * prevalence * infections per operation

= $2 \times 10^{6} * 10^{-4} * 4 \times 10^{-2}$ = **8** expected infections per annum.

4.3.10 This is significantly greater than the "worst case" scenario for tonsillar abrasion (with about 0.4 expected infections per annum), reinforcing the need for further research into the possible infectivity of dental tissues. It also compares with about 4 infections that would be expected to arise each year from tonsillectomies in a similarly-pessimistic scenario. Nevertheless, all these are maximum numbers. Set against the hypothetical number of 6,000 existing infections, none of these secondary routes would have any significant impact on the course of the outbreak.

4.3.11 Finally, it is of interest to note the implications of this scenario for the chance of *any single file or reamer* passing on infection during its working life. This will be approximately (6×10^{-3} * prevalence of the disease), or in this case $6 \times 10^{-3} \times 10^{-4} = 6 \times 10^{-7}$. Numerically, this is a small (less than 1 in 1 million) risk.

5. CONCLUDING COMMENTS

5.1 General

5.1.1 Given the many uncertainties about vCJD, it would be rash to dismiss the risk associated with any potential transmission route. It is clearly possible for a patient incubating vCJD to undergo invasive dental procedures. In principle, this may give rise to two potential transmission routes.

- Firstly, his or her tonsils may be abraded, and for infective material picked up. The instrument may then abrade a vCJD-receptive site on re-use
- Secondly, other tissues such as dental pulp *may* carry potential vCJD infectivity, though there is no evidence of this being the case in humans.

In either case, some residual infectivity would be likely to survive the normal processes of decontamination. The analysis presented here has attempted to quantify the resulting risks, given what is known, and in a variety of scenarios.

5.1.2 For the former route, any possible vCJD transmission is dependent both on initial abrasion of tonsillar and then subsequent abrasion of a receptive site. Clarifying how likely this sequence of events might be has necessarily been heavily reliant on expert judgement rather than firm experimental evidence. Subject to this caveat, it appears that transmission should be very unlikely, even given a procedure on an infective patient.

5.1.3 The second route is subject to rather different uncertainties. There is no doubt that instruments will encounter tissues such as pulp during the course of endodontic use, and there is some direct evidence on the amount of material adhering to files and reamers *after* washing. However it is not clear that these tissues pose any specific risk of vCJD transmission. We have therefore generated a range of purely hypothetical scenarios.

5.2 Potential levels of risk

5.2.1 The impact of either of these potential transmission routes appears to be small in comparison with forms of surgery that would routinely disturb tissue known to carry vCJD infectivity. This remains true even allowing for the large number of dental procedures carried out.

5.2.2 We have seen that for a given prevalence of vCJD in the population (and assuming similar decontamination standards):

- Given the majority expert view on the likelihood of tissue abrasion, the risk of transmitting vCJD via tonsillar abrasion during dentistry would be about 1,000,000,000th that for a tonsillectomy. Even allowing for there being about 1,000 times more dental procedures per annum, this transmission route would be about 1,000,000 times less significant than that associated with tonsillectomy.
- Even taking a pessimistic view of the likelihood of abrasion, each individual dental procedure would carry about 10,000th the transmission risk of a

tonsillectomy, and the dental route would be about 1/10th as significant as a potential risk to public health.

- If tissues such as dental pulp were infective, then clearly the transmission risks associated with dentistry would be higher. The analysis has used what-if scenarios, taking account of evidence on the amount of material carried on difficult-to-clean instruments. Even then however, the per-operation risks would remain well below those associated with procedures such as tonsillectomy. (Given the larger number of endodontic procedures, risks to public health from dentistry would be of the same order as from tonsillectomies.)

5.3 Implications of the analysis

5.3.1 At present, it seems justifiable to place procedures carried out during "high street" dentistry well down any ranking of those operations at risk of transmitting vCJD. This does not imply that the dental route should be ignored. The point is rather that dentistry need not be treated as a "special case": the need is to ensure that generic measures to ensure good decontamination apply fully to dental practice. At the same time, use of disposable instruments where possible is to be encouraged. In this, the analysis supports existing advice and policy.

5.3.2 Even though the risk of vCJD transmission appears small on current evidence, the situation needs to be kept under review in the light of any new evidence on infectivity of relevant tissues. In addition, there remains the possibility that a contact-only transmission mechanism could apply, potentially increasing the risks of secondary infection. Finally, the evidence that washing can leave significant levels of contamination on instruments such as files and reamers raises questions about the risks of transmitting other diseases. All these points reinforce the need for a precautionary approach toward instrument decontamination, design and usage, in dentistry as in hospital surgery.