estimate that the exposure is reduced by only 93% under the assumption that these sheep are marginally more resistant than ARR/Axx sheep and have an average incubation period of 4 years.

If genotype testing were imperfect (so that a percentage of sheep of other genotypes were mistakenly allowed into the human food chain), then these strategies become significantly less effective (strategies 7 and 8).

Eat ARR/ARR under 18 months and ARR/— under six months (strategy 9). A tighter genotyping strategy could also include an age restriction of, say, 18 months on ARR homozygotes and six months on ARR heterozygotes. This would be more effective, reducing the exposure by 99.9 and 99.6%, to 0.01 and 0.10 million murine ic ID50s, if homozygous sheep are resistant and susceptible, respectively. These figures lie within the estimated range for the total exposure from cattle in 2006, 0.005–0.5 million murine ic ID50s.

(v) *Combination strategies (strategies 10–13)*

Not surprisingly, combination strategies are more effective than single strategies. We considered four strategies that combined maximum SRM removal with age and genotype restrictions. The tightest of these (strategy 13) allows only ARR homozygotes under 18 months and ARR heterozygotes under six months into the food chain and further imposes a maximum realistic SRM removal scheme. If ARR homozygotes are completely resistant to BSE infection, then this strategy reduces infectivity in the human food chain by four orders of magnitude. The strategy has 10-fold less impact if ARR homozygotes are somewhat susceptible.

4. DISCUSSION

We estimate that there are at most only four flocks currently harbouring a BSE epidemic in Britain, but that even a single BSE-infected sheep could pose a considerable risk to consumers, contributing 10–1000 times as much infectivity in the human food chain as a fully infectious cow. Furthermore, 30% of the exposure from sheep comes from infectivity residing in lymph nodes and the PNS—tissues that cannot feasibly be entirely removed from a carcass.

The exposure from four 'typical' BSE-infected sheep flocks each year could be considerable. Our models predict that only a small reduction in exposure could be achieved by a PrP^{Sc}-testing based strategy, a 12-month age restriction or a tightened tissue-based strategy. A six-month age restriction is likely to be more effective and genotype-based strategies, which allow only the most resistant genotypes to enter the food chain, will achieve the greatest reduction in risk to consumers.

All the options discussed here are currently under consideration by the authorities in contingency planning for the event that ovine BSE is discovered. Such decisions, however, must also take into account the predicted cost and feasibility of different plans. Genotyping all sheep in the UK would be extremely expensive, if at all possible or accurate, on such a large scale. Furthermore, it would remove a high proportion of sheep from the food chain, which would also be the disadvantage of having a strict age-based cut-off. Testing sheep for PrP^{Sc} would be less expensive overall as it would not waste vast numbers of uninfected sheep. Tighter SRM-based strategies are also likely to be relatively cheap since only an extension of the existing SRM procedure would be required.

Our calculations rest upon a straightforward mathematical model, but are necessarily data hungry in a situation where not all the relevant data have yet been gathered. The modelling exercise usefully highlights the most glaring gaps in our knowledge. For calculating the infectious load produced by a BSE-infected sheep flock, the most important new data would be quantified BSE infectivity in different tissues in sheep of different genotypes at 6 and 12 months of age (after infection very close to birth). For comparisons of the impact of different risk reduction strategies, information on the sensitivity of proposed tests by genotype, tissue and time since infection would be particularly useful. The comparative risk of ovine and bovine BSE requires further analysis of the conversion rate from bovine oral ID50s to murine ic ID50s. The range used here of 2–4 orders of magnitude probably does not reflect all of the uncertainty surrounding this estimate. Furthermore, comparisons between the exposure from bovine and ovine BSE must be viewed in the light of the uncertainties surrounding estimates of the exposure from cattle.

Although gaps exist in our detailed knowledge of the dynamics of BSE infectious load in infected sheep, our conclusions are robust to the uncertainties that remain and provide best estimates of the exposure from ovine BSE and the effectiveness of control options which can be used in contingency planning. This is the only study that assesses the impact of genotype-based strategies and compares them with other options.

Our main conclusion is that we should remain vigilant of ovine BSE, simply because even a single recently infected sheep is likely to harbour considerable infectivity throughout the carcass, including in tissues that could not feasibly be removed at the abattoir. Furthermore, despite much positive news in recent years, a slowly developing ovine BSE epidemic is not inconceivable and the genotype of sheep that would most easily be infected and in which disease progresses most quickly is very common in our sheep flocks.

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医薬品 研究報告 調査報告書

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研究報告の概要

○海綿状脳症諮問委員会(SEAC)、vCJDと歯科治療に関する意見書
英国保健省はSEACに歯科治療処置を介したvCJD伝播のリスク算出を目的とした初期研究の成果についての助言を求めた。
歯組織にプリオン伝播性、感受性がある場合、歯科治療器具によるvCJDの二次伝播が起こりうる。輸血や脳外科手術と異なり、歯科治療は実施数が多く、通常の健康状態の人も受けている。また、記録も不完全なため伝播が起こった場合の追跡と感染防御が困難である。
現時点で歯科処置によるvCJD伝播は起こっていない。歯科治療器具を介したvCJD伝播は、舌扁桃を偶然切った場合と歯髄に接触する処置を行う場合とがあり、後者の方がリスクは高いとみられる。このため、SEACは歯髄治療用器具の使い捨てを勧告した。これが順守されれば、ヒト―ヒト間の持続的感染拡大を防止することが出来るだろう。
初期研究では、歯科処置によるvCJD伝播のリスクがこれまで考えられていたよりも高いことが示唆された。この研究は高用量の感染性物質に暴露された動物モデルを使用した不完全なものであり、またヒトの歯組織の感染性を示すデータはないものの、これらの知見はvCJDが歯科処置によって効率的に伝播されうることを示している。ヒトの歯組織を用いた感染性試験が現在行われており、より正確なリスク算定が可能になるだろう。
公衆衛生上の影響についてのより綿密な考察と、さらなるリスク減少手段の特定のため、全ての歯科治療のリスクについて詳細で包括的な評価を早急に行うことも重要である。評価を迅速に行うために専門家のグループを招集するという保健省の提案は歓迎される。また、伝播のリスクを減少できる新しい除染技術について早急な評価を行うことを考慮すべきである。

報告企業の意見	今後の対応
英国海綿状脳症諮問委員会が、英国保健省の要請に応じてvCJDと歯科治療に関する意見書を発表し、歯科治療のリスク評価、新たな除染技術の評価を求めた。	日本赤十字社は、輸血感染症防止のため輸血歴のあるドナーを無期限に献血延期としている。vCJDの血液を介する感染防止の目的から、献血時に過去の海外渡航歴(旅行及び居住)を確認し、欧州36ヶ国に一定期間滞在したドナーを無期限に献血延期としている。また、英国滞在歴を有するvCJD患者が国内で発生したことから、平成17年6月1日より英国滞在歴1日以上の方からの献血を制限している。さらに、血液製剤の保存前白血球除去を導入し、平成19年1月16日には全ての輸血用血液への保存前白血球除去の導入が完了した。今後もCJD等プリオン病に関する新たな知見及び情報の収集に努める。

使用上の注意記載状況・その他参考事項等

合成血「日赤」
照射合成血「日赤」
合成血-LR「日赤」
照射合成血-LR「日赤」

血液を介するウイルス、細菌、原虫等の感染
vCJD等の伝播のリスク

SEAC

Position Statement

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vCJD and Dentistry

Issue

1. The Department of Health (DH) asked SEAC to advise on the findings of preliminary research aimed at informing estimates of the risk of variant Creutzfeldt-Jakob Disease (vCJD) transmission via dentistry.

Background

2. Prions are more resistant than other types of infectious agent to the conventional cleaning and sterilisation practices used to decontaminate dental instruments[1]. Appreciable quantities of residual material may remain adherent to the surface after normal cleaning and sterilisation[2]. Therefore, if dental tissues are both infectious and susceptible to infection, then dental instruments are a potential mechanism for the secondary transmission of vCJD. Dentistry could be a particularly significant route of transmission for the population as a whole, due to the large number of routine procedures undertaken and also because dental patients have a normal life expectancy. This is in contrast with other transmission routes, such as blood transfusion and neurosurgery, where procedures are often carried out in response to some life-threatening condition. Additionally, the ubiquity of dental procedures and the lack of central records on dental procedures means that should such transmission occur, then it would be difficult to detect and control.

3. Cases of vCJD transmission arising from dental procedures have been reported to date [3] . Previous DH risk assessments[4,5] have focused on two possible mechanisms for the transfer of vCJD infectivity via dental instruments; accidental abrasion of the lingual tonsil and endodontic procedures that involve contact with dental pulp. In considering these assessments, SEAC agreed that the risk of transmission via accidental abrasion of the lingual tonsil appears very low. However, the risk of transmission via endodontic procedures may be higher and give rise to a self sustaining vCJD epidemic under circumstances where (i) dental pulp is infective, (ii) transmission via endodontic instruments is efficient and (iii) a large proportion of vCJD infections remain in a subclinical carrier state (SEAC 91, February 2006). In light of this, SEAC advised that restricting endodontic files and reamers to single use be considered [6]. SEAC recommended reassessment of these issues as new data emerge.

New research

4. Preliminary, unpublished results of research from the Health Protection Agency, aimed at addressing some of the uncertainties in

otection Agency, aimed at addressing some of the uncertainties in e risk assessments, were reviewed by SEAC (SEAC 97, May 2007). e prion agent used in these studies is closely related to the vCJD ent. This research, using a mouse model, shows that following oculation of mouse-adapted bovine spongiform encephalopathy SE) directly into the gut, infectivity subsequently becomes despread in tissues of the oral cavity, including dental pulp, salivary ands and gingiva, during the preclinical as well as clinical stage of sease.

It is not known how closely the level and distribution of infectivity in e oral cavity of infected mice reflects those of humans infected with JD, as there are no comparable data from oral tissues, in particular ntal pulp and gingiva, from human subclinical or clinical vCJD ses[7]. Although no abnormal prion protein was found in a study of man dental tissues, including dental pulp, salivary glands and ngiva from vCJD cases , the relationship between levels of infectivity d abnormal prion protein is unclear[8]. Infectivity studies underway ing the mouse model and oral tissues that are presently available om human vCJD cases will provide some comparable data. On the sis of what is currently known, there is no reason to suppose that e mouse is not a good model for humans in respect to the stribution of infectivity in oral tissues. Furthermore, the new data are nsistent with published results from experiments using a hamster rapie model[9] .

A second set of experiments using the same mouse model showed at non-invasive and transient contact between gingival tissue and e dental files contaminated with mouse-adapted BSE brain mogenate transmits infection very efficiently. It is not known how ficient gingival transmission would be if dental files were ntaminated with infectious oral tissues and then subsequently eaned and sterilised, a situation which would more closely model man dental practice. Further studies using the mouse model that ould be more representative of the human situation, comparing oral sues with a range of doses of infectivity, cleaned and sterilised files d the kind of tissue contact with instruments that occurs during ntistry, should be considered.

SEAC considered that the experiments appear well designed and the nclusions justified and reliable, while recognising that the research is complete and confirmatory experiments have yet to be completed. It recommended that the research be completed, submitted for peer-view and widely disseminated as soon as possible so others can nsider the implications. Nevertheless, these preliminary data crease the possibility that some oral tissues of humans infected with JD may potentially become infective during the preclinical stage of e disease. In addition, they increase the possibility that infection uld potentially be transmitted not only via accidental abrasion of the gual tonsil or endodontic procedures but a variety of routine dental ocedures. Implications for transmission risks

The new findings help refine assumptions made about the level of fectivity of dental pulp and the stage of incubation period when it comes infective in the risk assessment of vCJD transmission from [10]

the reuse of endodontic files and reamers[10]. For example, if one patient in 10 000 were to be carrying infection (equivalent to about 6 000 people across the UK – the best current estimate[11]), the data suggest that in the worst case scenario envisaged in the risk assessment, re-use of endodontic files and reamers might lead to up to 150 new infections per annum. It is not known how many of those infected would go on to develop clinical vCJD. In addition, transmission via the re-use of endodontic files and reamers could be sufficiently efficient to cause a self-sustaining vCJD epidemic arising via this route.

9. These results increase the importance of obtaining reliable estimates of vCJD infection prevalence. Data that will soon be available from the National Anonymous Tonsil Archive may help refine this assessment and provide evidence of the existence and extent of subclinical vCJD infection in tonsillectomy patients. Further data, such as from post mortem tissue or blood donations, will be required to assess prevalence in the general UK population[12].

10. Recent guidance issued by DH to dentists to ensure that endodontic files and reamers are treated as single use[13] is welcomed and should, as long as it is effectively and quickly implemented, prevent transmission and a self-sustaining epidemic arising via this route. However, the extent and monitoring of compliance with this guidance in private and National Health Service dental practice is unclear.

11. The new research also suggests that dental procedures involving contact with other oral tissues, including gingiva, may also be capable of transmitting vCJD. In the absence of a detailed risk assessment examining the potential for transmission via all dental procedures, it is not possible to come to firm conclusions about the implications of these findings for transmission of vCJD. However, given the potential for transmission by this route serious consideration should be given to assessing the options for reducing transmission risks such as improving decontamination procedures and practice or the implementation of single use instruments.

12. The size of the potential risk from interactions between the dental and other routes of secondary transmission, such as blood transfusion and hospital surgery, to increase the likelihood of a self-sustaining epidemic is unclear.

13. It is likely to be difficult to distinguish clinical vCJD cases arising from dietary exposure to BSE from secondary transmissions via dental procedures, should they arise, as a large proportion of the population is likely both to have consumed contaminated meat and undergone dentistry. However, an analysis of dental procedures by patient age may provide an indication of the age group in which infections, if they occur, would be most likely to be observed. Should the incidence of clinical vCJD cases in this age group increase significantly, this may provide an indication that secondary transmission via dentistry is occurring. Investigation of the dental work for these cases may provide supporting data. There is no clear evidence, to date, based on surveillance or investigations of clinical vCJD cases, that any vCJD cases have been caused by dental procedures but this possibility cannot be excluded.

nnot be excluded.

onclusions

. Preliminary research findings suggest that the potential risk of ansmission of vCJD via dental procedures may be greater than eviously anticipated. Although this research is incomplete, uses an imal model exposed to relatively high doses of infectivity, and there e no data from infectivity studies on human oral tissues, these idings suggest an increased possibility that vCJD may be relatively ficiently transmitted via a range of dental procedures. Ongoing fectivity studies using human oral tissues and the other studies ggested here will enable more precise assessment of the risks of JD transmission through dental procedures.

. Guidance was issued to dentists earlier this year recommending at endodontic files and reamers be treated as single use which, ovided it is adhered to, will remove any risk of a self-sustaining idemic arising from re-use of these instruments. To minimise risk it critical that appropriate management and audit is in place, both for HS and private dentistry.

. It is also critical that a detailed and comprehensive assessment of e risks of all dental procedures be conducted as a matter of urgency. hile taking into account the continuing scientific uncertainties, this ll allow a more thorough consideration of the possible public health plications of vCJD transmission via dentistry and the identification of ssible additional precautionary risk reduction measures. The sessment will require continued updating as more evidence becomes ailable on the transmissibility of vCJD by dental routes, and on the evalence of infection within the population. A DH proposal to nvene an expert group that includes dental professionals to expedite ch an assessment is welcomed. Given the potential for transmission a dentistry, consideration should be given to the urgent assessment new decontamination technologies which, if proved robust and fective, could significantly reduce transmission risks.

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Page updated: 13 June, 2007

医薬品
医薬部外品　研究報告　調査報告書
化粧品

別紙 3-4

識別番号・報告回数		回	報告日 年　月　日	第一報入手日 2007 年 5 月 17 日	新医薬品等の区分 該当なし	総合機構処理欄
一般的名称			研究報告の公表状況	vCJD and blood transfusion in the United Kingdom Hewitt, P. Transfusion clinique et biologique, 13, 312-316 (2006)	公表国 英国	
販売名（企業名）						

研究報告の概要	使用上の注意記載状況・その他参考事項等
本稿の大部分は，昨年 Vox Sanguinis で発表された同一の著者による総説〔第 8 回感染症定期報告で報告（BYL-2007-0263)〕でも報告されている。追加情報はないが，恐らく，血漿由来製剤による変異型クロイツフェルト・ヤコブ病の感染リスクは血液成分輸血によるリスクよりもはるかに低い，という一般的な概念を支持している。	BYL-2007-0285

報告企業の意見	今後の対応
これまでに，血友病患者及び英国で採取された血漿由来製剤の大量投与を受けた患者での vCJD 症例は 1 例も報告されていないことは，血液製剤による vCJD 伝播のリスクは極めて低いことを示唆している。弊社の血漿分画製剤及びコージネイト FS 又はコージネイト FS バイオセットの製造工程培地に使用されている血漿分画成分は，英国よりもリスクがかなり低い米国で採取された血漿で製造されている。その上，これら血漿分画製剤の製造工程では，大幅にプリオンを除去することが実験的に確認された病原体除去工程を導入している。	現時点で新たな安全対策上の措置を講じる必要はないと考える。