

be extremely interesting in its own right, but not actually necessary to advance disease control and protect public health.

7. CONCLUSION

The approaches to the investigation of the transmission of BSE and scrapie, outlined above, differ only slightly. Those differences are due to the nature of the two diseases. BSE was a novel spongiform encephalopathy, in a hitherto unaffected species, that had characteristics of a point source epidemic, with an agent that could have been incorporated into a wide variety of feedstuffs and iatrogenically administered to naïve populations, and there was early evidence that it was not restricted to bovines. It was vital to establish, albeit experimentally, which other species might be affected, and whether the epidemic could be maintained by natural transmission, if the source was removed. In contrast, scrapie has been endemic throughout Great Britain for centuries, is maintained naturally (even if we don't know exactly how) and has a known host range. The principles, process and integration of evidence from different types of studies, however, are similar for both of these TSE and can be applied to any emerging or suspected spongiform encephalopathy.

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医薬品
医薬部外品 研究報告 調査報告書
化粧品

識別番号・報告回数			報告日	第一報入手日 2008年3月21日	新医薬品等の区分 該当なし	厚生労働省処理欄				
一般的名称	乾燥濃縮人アンチトロンビンⅢ		研究報告の公表状況	56th Annual Meeting of the American-Society-of-Tropical-Medicine-and-Hygiene 1044	公表国 アメリカ					
販売名 (企業名)	①ノイアート(ベネシス) ②ノイアート静注用1500単位(ベネシス)									
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				
<p>ヒト顆粒球アナプラズマ症 [Human Granulocytic Anaplasmosis (HGA)] の発生率は、1999年以来2倍になった。原因病原体の <i>Anaplasma phagocytophilum</i> は、ニューイングランドの風土病であり、主にマダニ <i>Ixodes scapularis</i> の流行によってヒトに感染する。<i>A. phagocytophilum</i> によって引き起こされる疾患は、無症候なものから重篤なものまであり、一様ではない。<i>A. phagocytophilum</i> の輸血感染が1例報告されているが、現在 HGA のスクリーニングは実施されていない。</p> <p>この病原体によって引き起こされる血液の安全リスクを調査するため、我々はコネチカット州及びマサチューセッツ州の血液ドナーの陽性率を測定した。血液サンプルを春の後半から冬の初め(2001-2005年)及び2006年の初めから1年間、採取した。参加ドナーからの血清について、間接蛍光分析(IFA)を使って <i>A. phagocytophilum</i> のヒト IgG 抗体の試験を実施した。IFA 力値が ≥1:64 のときに陽性とした。IFA によって検査した 15,828 名のドナー中、432 名(2.7%) が <i>A. phagocytophilum</i> 抗体陽性であった。力値の分布は以下の通りであった。1:64 が 256 名(59%)、1:128 が 115 名(27%)、1:256 が 42 名(9.7%)、1:512 が 14 名(3.2%)、≥1:1024 が 5 名(1.2%) であった。マサチューセッツ州ドナーの陽性率は 2.2% (30/1,346)、コネチカット州ドナーの陽性率は 2.8% (402/14,482) であった。血清陽性率ピークは、次の月に生じた: 2月(4.7%)、12月(3.7%)と9月(3.4%)。全体的に、年間陽性率は 1.7% (2004年) から 4.1% (2001年) まで変化が見られた。年間血清陽性率で観察された変動は、おそらく <i>A. phagocytophilum</i> の複雑なライフサイクルに影響する気候および環境因子によるものであろう。</p> <p>比較的高い陽性率が持続していることから、<i>A. phagocytophilum</i> の血液安全性に及ぼす影響を調査する必要がある。</p>	代表としてノイアート(献血)の記載を示す。									
<table border="1"> <thead> <tr> <th>報告企業の意見</th> <th>今後の対応</th> </tr> </thead> <tbody> <tr> <td>米国ニューイングランド地方の供血者中の <i>A. phagocytophilum</i> の血清陽性率が比較的高い値を持続しているとの報告である。</td> <td>本報告は本剤の安全性に影響を与えないと考えるので、特段の措置はとらない。</td> </tr> </tbody> </table>						報告企業の意見	今後の対応	米国ニューイングランド地方の供血者中の <i>A. phagocytophilum</i> の血清陽性率が比較的高い値を持続しているとの報告である。	本報告は本剤の安全性に影響を与えないと考えるので、特段の措置はとらない。	2. 重要な基本的注意 (1) 本剤の原材料となる献血者の血液については、HBs 抗原、抗 HCV 抗体、抗 HIV-1 抗体、抗 HIV-2 抗体、抗 HTLV-1 抗体陰性で、かつ ALT(GPT) 値でスクリーニングを実施している。更に、プールした試験血漿については、HIV-1、HBV 及び HCV について核酸増幅検査(NAT)を実施し、適合した血漿を本剤の製造に使用しているが、当該 NAT の検出限界以下のウイルスが混入している可能性が常に存在する。本剤は、以上の検査に適合した血漿を原料として、Cohn の低温エタノール分画で得た画分から人アンチトロンビン III を濃縮・精製した製剤であり、ウイルス不活化・除去を目的として、製造工程において 60℃、10 時間の液状加熱処理及びろ過膜処理(ナノフィルターション)を施しているが、投与に際しては、次の点に十分注意すること。
報告企業の意見	今後の対応									
米国ニューイングランド地方の供血者中の <i>A. phagocytophilum</i> の血清陽性率が比較的高い値を持続しているとの報告である。	本報告は本剤の安全性に影響を与えないと考えるので、特段の措置はとらない。									



