



**Association of Anaesthetists of Great Britain & Ireland**  
**Needlestick Working Party Report**

Council of the Association of Anaesthetists of Great Britain & Ireland (AAGBI) established a Working Party on Needlestick Injuries in December 2007. Its initial membership was:

Dr Andrew Hartle (Chair)	AAGBI Council
Dr Steve Yentis	AAGBI Council
Dr Stuart White	Consultant Anaesthetist, Brighton
Dr Mark Hearn	GAT Representative
Dr Dominic Bell	Intensive Care Society
Dr Daniel Sokol	Lecturer in Medical Ethics & Law
Ms Kim Sunley	Royal College of Nursing
Dr Andy Lim	Royal College of Anaesthetists
Ms Janette Roberts	Patient Liaison Group

The Working Party was to consider the testing of patients for Blood Borne Viruses (BBV) after needlestick and other occupational injuries, especially in the light of recent legislative change (Human Tissue Act 2004 [HTA] and Mental Capacity Act 2005 [MCA]), and the withdrawal of previous guidance from the General Medical Council (GMC).

The legal 'limbo' surrounding the testing of patients who lacked capacity, and who had been the source of a needlestick or other occupational injury had been described in detail in Stuart White's editorial in *Anaesthesia* (Needlestuck. *Anaesthesia* 2007; **62**: 1199-201). Initial guidance from the GMC had been that testing of such patients could take place in exceptional circumstances. The introduction of HTA and MCA had led to that guidance being withdrawn, and advice from Medical Indemnity organisations was now that such testing without the patient's consent was unlawful. This now meant that Healthcare professionals who sustained occupational exposure were unable to know the viral status of the source when making decisions about the initiation or discontinuation of post exposure prophylaxis (PEP).

At the first meeting held on 9<sup>th</sup> May 2008 it was agreed that there were three strands to the WP's remit:

- Establish what changes were possible to the current legal situation and make recommendations.
- Identify mechanisms by which change could be effected.
- Identify ways by which public support for such change could be achieved, including identifying other stakeholders.

The WP discussed the apparent variability of response to the current situation. In some units patients were never tested after occupational injury, but in others testing may still be performed, either with or without the agreement of next of kin. This creates a 'postcode lottery' in the management of occupational injuries, and also places healthcare workers at risk of legal, disciplinary or regulatory action. Such inconsistency in management is not acceptable.

After some discussion, the following possible changes were agreed, roughly in order of most to least restrictive, and possibly in ascending order of likely public acceptability:

- Blanket testing of all patients.
- Testing of all patients who become the source of a needlestick/infective injury.
- 'Presumed Consent' for testing unless prior evidence of objection.
- The previous *status quo*, i.e. testing only after an individual risk/benefit analysis (to include psychological as well as physical risk).
- Testing with the consent of next of kin.
- No testing without specific consent from the patient.

Members of the WP agreed to analyse each of these options, before making recommendations to Council. Those analyses are attached.

The WP agreed that, before the situation of testing arose, first priorities for all stakeholders should be:

- Prevention/preventative technology
- Improved (confidential) reporting
- De-stigmatisation

Three principle methods of achieving a change in the law were identified:

1. A change in the law (Statutory Instrument, amendment, primary legislation)
2. An elaboration of existing law
3. A test case

In order to establish public support, which will be vital for any change, the following themes were explored:

- Exploring broader benefits and harms to -
  - Individual patients
  - Individual healthcare staff
  - Employers
  - Society
- The virtuous/responsible patient
- Comparisons with zero tolerance to violence
- Reciprocity

Other stakeholders included:

- British Association of Operating Department Practitioners
- Unison
- Unite
- Chartered Society of Physiotherapists
- Association of Occupational Health
- NHSE (including medical Directors)
- Patients Association
- Terrence Higgins Trust
- GMC
- NHSLA
- MPS/MDU/MDDUS
- BMA
- Court of Protection
- Office of Official Solicitor
- Health and Safety Executive
- Department of Health
- Human Tissue Authority

Methods to estimate/establish public support included:

- Properly conducted patient/lay person research
- Public opinion poll
- Letters/editorial in other journals
- Parliamentary spokesmen (especially for Trade Unions)
- BBC Online Poll
- Online Downing Street petition
- The general and medical press

The Working Party met again in June 2008, when initial drafts of the analyses were considered.

At a subsequent meeting in February 2009, the WP was joined by Veronica English of the BMA Ethics Department. The RCN was represented on that occasion by Janice Gabriel, and David Whitaker (Immediate Past President, AAGBI) was also present.

VE explained that the BMA had met with Lord Warner at the Department of Health.

Amendment(s) of the Human Tissue Act would probably not help clarify the current legal limbo, as serum (ie not containing cells) was stored and tested for blood borne viruses (BBV), so the HTA was not engaged.

The BMA would prefer not to stretch a best interests argument, although this might be possible by changes to the Mental Capacity Act's code of conduct.

After much discussion the WP narrowed its recommended options to Council as being:

1. All patients who were the source of an occupational injury should be tested for BBV. This would be the greatest infringement of Human Rights and would need primary legislation, but would be fair as **all patients** would be treated the same. An analogy might be drawn with compulsory testing for alcohol and drugs following a Road Traffic Accident. There was an impression that this was what lay people thought happened anyway.
2. The restoration of the previous position whereby the merits of a particular case were assessed and the decision to test or not could then be justified. This was the BMA's preferred option. Trusts could produce policies to ensure fairness, transparency and accountability.

3. Testing could take place with the consent of next-of-kin or other delegated decision makers.

Recommendations as to how the necessary legal change could be effected would depend on meetings between the BMA and the DoH.

AH met with officials from the Department of Health on 15<sup>th</sup> May 2009. They were very interested in the WP's work, particularly the bringing together of a 'coalition' involving such a wide range of Health Care Workers, and the ethical analyses done by the WP. The designation of an affected Health Care Worker as 'patient 2' was particularly compelling. There was no doubt that DoH supports some change in the legal position, but was similarly unsure of which proposal to advocate, or how best to bring this about. Legislation runs serious risks of having unforeseen consequences, and is dependent on the political cycle.

AH was invited to join the DoH Stakeholder Group, which met in July 2009. DoH legal advice was Option 1 would be unlikely to be helpful, as individuals who had had blood taken without consent after road traffic accidents could still withhold consent for its testing, although they would then be guilty of the offence of "refusing to give a sample".

In November 2009 the Department of Health published *Legal issues relevant to non-heartbeating organ donation*, which clearly endorses an expanded interpretation of best interests with specific regard to virological testing using the assent of the next of kin. This interpretation of legislation may be a basis on which to move forward.

[\[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_108825\]](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_108825)

#### Current position

The WP has now fulfilled its first two objectives (determining whether the legal situation should be changed, recommending what that change should be). The legal position remains complicated and will need amendments to the Mental Capacity Act and/or its Code of Conduct. This will require parliamentary time and political will.

## Recommendations

The WP recommends:

1. That AAGBI Council should adopt as policy that the necessary legislative change is effected at least to restore the previous position to allow individual cases to be judged on their merits and testing of patients for Blood Borne Viruses performed after occupational exposure when justified.
2. Council should consider whether to pursue legislative change that would allow
  - a. Processing of a blood sample taken for any other purpose in the event of a patient refusal, and
  - b. presumed consent for testing where the patient lacks capacity and is unlikely to regain this within a set timeframe, (e.g. 6-12 hours)
3. Pending such legislative change, Council should support the model of next of kin assent pending the above resolution and for presumed consent where no next of kin have been identified within the above timeframe of 6-12 hours.
4. Any legislative/policy change should accommodate the principle of reciprocity. The decision to test should be based on defined, objective principles and avoid arbitrary or varying decision-making. Logical and defensible solutions already exist and are currently being applied in some units.
5. Council should approve a revision of its current guidance on 'Blood Borne Viruses and the Anaesthetist'. In particular this should focus on the implications of an occupational injury, post exposure prophylaxis and follow and the subsequent employment. [Note: a WP on 'Occupational Health and the Anaesthetist' has been established with Dr Paul Clyburn as chair.]
6. Council should consider a survey of members to establish the frequency of occupational exposure, particularly when the source patient is unable or refuses to consent to testing [Note: a paper has been accepted for the September 2010 edition of *Anaesthesia* which describes an anonymised postal survey of current practice in ICUs in England. This has an accompanying editorial by AH]

June 2010

## **Appendices:**

1. Needlestick
2. Analysis of benefits and harms of blanket testing
3. Analysis of Presumed Consent
4. Analysis of non-consensual testing
5. Analysis of Status Quo
6. Analysis of Next of Kin Assent/Consent
7. Patient perspectives

## Editorial

### Needlestuck

Enacted on the 15th November, 2004, and fully enforced on the 1st September, 2006, the Human Tissue Act 2004 (HTA) [1] is the UK government's woefully impenetrable attempt to clarify the statutory law in England and Wales with regard to the use and storage of human tissue, organs and bodies. The HTA repeals the Human Tissue Act 1961, the Anatomy Act 1984, and the Human Organ Transplants Act 1989.

In response to public concern over the organ retention scandals at Alder Hey Hospital [2] and the Bristol Royal Infirmary [3], and the findings of the Isaacs Inquiry [4], the government hurriedly introduced a consultation document, *Human Bodies, Human Voices* [5], in July 2002, leading to the introduction of the Human Tissue Bill, in December 2003.

In line with much recent legislation, consent was proposed as a fundamental protection for patients, such that virtually all tissue taken from humans could only be used or stored having obtained appropriate consent (from the patient if alive, from the parents of children, or premortem if the patient was now dead), under penalty of fine or imprisonment. Some ramifications of the Bill were immediately apparent, and elicited considerable debate among, and opposition from, the research, legal [6–8] and transplant communities, especially pertaining to anatomy demonstration, research using human tissue [9, 10], tissue databanking [11], genetic research [12] and organ transplantation [13, 14].

Less apparent, unfortunately, were some of the ramifications relating to everyday clinical practice. One scenario in particular has given rise to concern about the protection of healthcare professionals in the event of a needlestick injury.

Accidental blood and body fluid exposure is a daily risk for health care workers, with an incidence of approx-

imately 1–5 per 100 person-years [15]. Up to 40% of patients with HIV are unaware of their status when they are admitted to intensive care [16]. Needlestick injuries account for approximately 80% of exposures, are more common with more complex procedures, and can lead to infection with HIV, and hepatitis B, C and/or D [17]. Seroconversion rates are low for HIV (0.3%) and HCV (0.5%), but much higher for HBV (18–30%) [18]. A number of postexposure prophylaxis (PEP) guidelines are available for HIV [19], HBV and HCV [20]. In the case of HIV, PEP should ideally be commenced within an hour of exposure, and continued at least until the HIV status of the source patient is confirmed. Delays in source patient HIV testing can expose health care workers to inappropriate continuation of PEP administration of drugs with significant side-effect profiles.

However, there is considerable confusion surrounding the issue of consent when testing a source patient for HIV (or other blood-borne viruses). No specific statute exists, and so the legality of testing lies in the common law. Testing involves physical contact with a patient, and therefore the patient's consent is required. Their consent is legally valid if they are appropriately informed (about the nature and purpose of the test, and the risks and consequences of testing), competent to decide (that is, they understand the information presented to them, remember it, and use it to decide whether or not to have the test), and give consent voluntarily [21]. Competent adult patients can consent to, or refuse, testing for any reason, or for no reason at all. At present, no-one may give consent on behalf of an incompetent patient (for example, an unconscious patient in the intensive care unit). Under the common law in England and Wales, the HIV testing of an unconscious patient is legal if it is necessary and in the patient's

best interests (for example, to establish their HIV status for the purposes of treatment).

Therefore, in theory at least, a doctor may not test a source patient for HIV for the benefit of an injured healthcare worker either if the patient refuses a test, or if the patient is incompetent/unconscious.

However, this is not the advice offered in professional guidelines, namely the General Medical Council's *Serious Communicable Diseases* guidelines of 1997 [22] (the British Medical Association and Department of Health defer to the GMC in their own advice). The GMC advises that 'You must obtain consent from patients before testing for a serious communicable disease' (s.4), and 'you may test unconscious patients for serious communicable diseases, without their prior consent, where testing would be in their immediate clinical interests' (s.7), in line with the common law. However, the GMC then advise that 'you may test an existing blood sample, taken for other purposes' if the patient has refused testing or is unable to consent, and the doctor has good reason to believe the patient may have a communicable disease for which prophylaxis is available, and an experienced colleague has been consulted, and the patient is unlikely to regain capacity within 48 h (s.8 + s.9), which course of action may not be in line with the common law, even if the patient is informed of the non-consensual test at the earliest opportunity (s.10).

The advice states that 'you must therefore be prepared to justify your decision (to test non-consensually)' if a complaint is made to the doctor's employer or the GMC, or if challenged in court, but justification could prove difficult. Several arguments might be used. Firstly, the 'best interests' argument: the patient was tested because his/her symptoms were unexplained and possibly attributable to HIV/HBV/HCV, requiring diagnosis and



treatment. This would require a high standard of circumstantial medical evidence suggesting this to be the case. Second, the 'good egg' argument: the unconscious patient is assumed to be a kind person, who would consent to testing if s/he were competent, and therefore, have his best interests served through not subjecting the injured healthcare worker to either the anxiety of not knowing the patient's HIV status, or the side-effects of PEP. Finally, the 'rights' argument: that the healthcare worker's right to discover the patient's HIV status (possibly with reference to Articles 2 and 3 of the Human Rights Act 1998 (HRA) [23]) is more pressing than the patient's right to not be tested (possibly protected by Articles 2, 3 and 8 of the HRA).

In practice, such justification is yet to be tested in a UK court [24], and is now unlikely to be, as the GMC has recently rescinded paragraphs 8–11 of *Serious communicable diseases*, in light of the Human Tissue Act 2004 and the Mental Capacity Act 2005.

According to the HTA, appropriate consent from living patients is legally required [1(1)(d) + (f)] for storage and use of human tissue (which includes blood for HIV testing) for the purpose inter alia of obtaining scientific or medical information about a living or deceased person which may be relevant to any other person [Schedule 1, s.1(4)]. Storage and use of tissue from patients who lack capacity (i.e. many intensive care patients) is unlawful (s.6), unless allowed by the Secretary of State, in this instance according to the Human Tissue Act 2004 (Persons Who Lack Capacity to Consent and Transplants) Regulations 2006 [25]. The Regulations allow for non-consensual storage and use of tissue to 'obtain scientific or medical information about a living ... person which may be relevant to another' (i.e. an HIV test after needlestick injury), provided inter alia that the nominated doctor taking the blood does so in 'what s/he reasonably believes to be in the best interests of the person lacking capacity from whose body the material came'. So again, blood may only be taken if the intent is to benefit the *patient*, and not the healthcare worker.

The Mental Capacity Act 2005 [26] (MCA) is no more helpful in terms of the non-consensual testing of patients who lack legal capacity. From October 2007, patients over 16 years of age must be assumed to have capacity unless they are found to lack capacity. Any decision to test a patient without capacity for HIV must continue to be made in the patient's best interests, if there is no other way to establish his/her HIV status. Although it will remain the case that the doctor will usually decide (s/he must be able to justify that decision in court), any decision must be made in the *patient's* best interests (i.e. not the interests of the healthcare worker sustaining a needlestick injury). Interestingly, a properly appointed donee of an Lasting Power of Attorney, or a court-appointed deputy, may give proxy consent for blood testing, but again they must do so in the *patient's* best interests. In addition, a patient may, in theory, consent to or refuse HIV testing by means of an advanced directive.

Effectively, therefore, the combined effects of the HTA and MCA have firmly closed the backdoor to testing afforded by the GMC's previous guidelines, and threatened doctors with imprisonment if they test patients for HIV non-consensually.

This problem was foreseen during the passage of the Mental Capacity Bill, but an attempt by the British Medical Association to amend the Bill to allow non-consensual HIV testing to 'avert the death of, or serious illness in, another person' was withdrawn, after assurances from the government that this circumstance would be clarified in the Code of Practice accompanying the Act [27]. Predictably it wasn't – there is no reference to HIV testing in all 302 pages of the Code of Practice [28]. Section 6 of the Code deals with the protections that the Act offers for healthcare workers (amongst others), but repeats the maxim that any intervention must be in the patient's best interests.

In an attempt to clarify the law in relation to HIV testing, I contacted both the HTA and the Court of Protection (the latter via the Public Guardianship Office). Both agencies

were very helpful. After consultation, the HTA sent me the following statement for publication:

'The HTA are aware of the complex issues this situation generates. The HTA are currently part of discussions on this issue being led by the Department of Health, BMA and other organisations in relevant sectors. The general status of the situation is that this issue is still under discussion and the regulations are still being drafted. Therefore, at present it is difficult for the HTA to comment further on this area. We are waiting further clarification from the Department of Health at which point we will be in a position to move forward on this area of work. Please keep checking the HTA and relevant websites in the sector for any news on this issue'.

The Public Guardianship Office referred me to the Human Tissue Branch of the Department of Health, who concurred with the above analysis of the problem, and stated by letter: 'We are actively considering this complex issue and have – as the HTA advised you – been in discussion with a number of interested bodies. We hope to be in a position during the summer to consult on new proposals for addressing some of the concerns expressed'.

To summarise, anaesthetists must beware: in the event of a needlestick injury to a healthworker, blood may only be drawn from an unconscious patient for the purposes of communicable virus detection, provided that to do so would be in the best interests of the *patient*.

The medical and nursing professions, in partnership with the Department of Health and the Courts, would be well advised to strenuously seek an expeditious solution to this impasse to optimise the postexposure treatment of healthcare workers after needlestick injuries.

### Acknowledgements

I would like to thank the Human Tissue Authority, Public Guardianship Office and Department of Health for their prompt assistance, as well as Dr Steve Yentis for initially raising the issue. An interesting discussion of the ethics surrounding these issues can be found on

Radio 4's *Inside the Ethics Committee*, broadcast 12th September, 2007 [29].

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**Analysis of Benefits and Harms of Compulsory testing**

	<b>Patient</b>	<b>Practitioner</b>	<b>Team</b>	<b>Trust</b>	<b>Public</b>
<b>Benefits</b>	Fair – all patients treated the same Possible early diagnosis and Rx	Certainty of need for Rx Better informed decision Feels “valued” More likely to report?	Team morale Feel “valued” Less likely to have absence due to stress May be less risk averse More likely to report	Better Staff Morale More focused Rx may reduce costs Reduced absence Senior Mgt do not have to spend time on individual cases Legal clarity Improved Occupational Health	Happier valued workforce Enhance Recruitment retention Better prevalence information “right Thing to do” HCPs may less risk averse
<b>Harms</b>	Autonomy overridden - coercion Small risk from procedure False positives/negatives	Uncertainty of –ve result False -ve	Additional procedure - > additional exposure May become less careful	Resistance from GUM/Virology	Potential Distrust of doctors/NHS Costs of testing/treatment Potential Compensation to patient/practitioner
<b>Practicality</b>	Additional storage of samples Cost of testing, staff time How to deal with results – confidentiality for patient and practitioner Simplified Process Primary medical/dental care?				

## OPTION 3 – PRESUMED CONSENT.

‘Presumed consent’, in the context of blood borne virus testing, assumes that consent has been given for blood testing unless the patient has specifically refused testing. There is no legal precedent for presumed consent in the United Kingdom.

Several commentators have decried the very notion of presumption, declaring that ‘presumed consent’ is equivalent to ‘no consent at all’ and that the presumption of consent affords the patient little protection against what would otherwise be legally considered a battery. Presumption places no duty on the doctor to ascertain whether the patient might indeed be capable of giving consent (as should happen according to the Mental Capacity Act 2005), or to provide information to the patient about the risks and benefits of BBV testing, or to assess whether there is any voluntariness on the part of the patient to agree to what is proposed. In addition, vulnerable groups (children, mentally incompetent adults) may not be in a position to raise an objection. As such, presumed consent is contrary to the increasing emphasis placed on patient autonomy by UK legislators, through consent.

Nevertheless, 4 arguments might be used to support the introduction of presumed consent for BBV testing:

- 1) Public support. Overwhelming public support, through informed public debate, could consolidate an ethical mandate for presumed consent in this specific instance.
- 2) Social contract. Doctors and nurses will continue to provide healthcare for patients, on the understanding that consent will be presumed for BBV testing should a needlestick injury occur and there is a genuine risk of inoculation (with safeguards similar to the GMC’s withdrawn advice).
- 3) ‘Soft’ presumed consent ie presumed consent only with the confirmative assent of relatives or close acquaintances.
- 4) Organ donation. The government have recently indicated at least an interest in presumed consent with regards organ donation. Applied to BBV testing, this would mean that individuals would have to specifically ‘opt out’ of testing, probably by indicating in written form that they would not want to be tested. There is a danger that by setting a new legal context in the case of BBVs, that a precedent of presumed consent could be extended to organ donation.

## AAGBI Needlestick Injuries Working Party

Daniel K. Sokol

*Option: non-consensual testing of patients (on an existing or specifically taken sample) in the event of a needlestick injury for the benefit of the injured healthcare professional.*

This option is currently unlawful in England and Wales if the testing is not in the *patient's* best interests.

Several arguments can be presented in favour of the option:

1. The clinical, social and psychological benefits to the healthcare professional outweigh the relatively minor infringement of autonomy associated with testing a sample.
2. In the case of unconscious patients, it is probable that the vast majority would not object to the test, given the absence of pain, the virtually non-existent clinical risks of the testing and the obvious benefits to the healthcare professional.
3. The injured worker's colleagues who form part of the medical team may be reassured by a) knowing their colleague's state of infection, b) knowing that their colleague is aware of his or her state of infection and c) knowing that testing is a lawful option in the eventuality of sustaining a needlestick injury themselves.
4. In light of the incidence of needlestick injuries and the distress potentially caused by ignorance of one's disease status, allowing such testing is likely to boost staff morale, reduce 'burnout' in the profession generally and may help retain staff. This should benefit patients generally.
5. This option, which emphasises the autonomy and welfare of the healthcare professional, may aid recruitment into high-risk specialties or, at least, will not contribute to a fall in recruitment.
6. Reciprocity – one may argue that patients have certain duties towards the healthcare professionals who are putting themselves at risk to help them (e.g. the duty not to be physically or verbally abusive), as long as these duties are not too onerous. Allowing oneself to be tested for HIV and hepatitis, even if only for the benefit of the healthcare workers, may constitute a patient's duty and should be enforced.

There are also arguments against the option:

1. Non-consensual testing may violate the autonomy of those who either explicitly refuse to be tested or, if unconscious, who *would have* refused to be tested.
2. Is it really practicable or indeed desirable to obtain a sample from a conscious patient who does not wish to be tested? One less coercive option, then, would be to permit non-consensual testing on unconscious patients only (except when it is known that the patient would not have wanted to be tested, e.g. in an advance directive or through a Lasting

Power of Attorney) while requiring some form of consent for conscious patients. If the patient is conscious but incapacitous, we could suggest that testing is permitted on an existing sample only.

3. If testing is compulsory, patients in need of medical treatment may be reluctant to seek treatment for fear of being tested against their will (albeit only in the rare eventuality of a needlestick injury). This could have adverse effects on the patients' health and have negative cost implications to the National Health Service. This represents another reason for preferring the non-mandatory option mentioned above.

A number of questions remain. If the test is performed against a competent patient's will, should the information obtained be offered to the patient? Should it be recorded in the patient's notes? If the patient was unconscious when the test was performed, when, how and what should he or she be told?

## AAGBI NEEDLESTICK INJURIES WORKING PARTY

## OPTIONS FOR CHANGE

## OPTION 5 – MAINTAIN STATUS QUO.

A competently made refusal of BBV testing by a patient prohibits a doctor from testing that patient's blood for BBVs in the event of a needlestick injury to a third party.

The effect of Mental Capacity Act 2005 and the Human Tissue Act 2004 on the non-consensual testing for BBVs after needlestick injuries involving patients without capacity has been to countermand the advice (now withdrawn) of the GMC (*Serious Communicable Diseases* guidelines, 1997) with regard to this eventuality. Statute now demands that in the event of a needlestick injury to a healthworker, blood may only be drawn from a patient who lacks legal capacity for the purposes of BBV detection, provided that to do so would be in the best interests of the *patient*.

If BBV testing is prohibited, the injured third party must wait for 3-6 months before secondary testing to confirm seroconversion, taking appropriate post-exposure prophylaxis (PEP) in the interim exposing themselves to both the side-effects of PEP drugs, and associated psychological stress.

The prevention of needlestick injuries remains of primary importance. Nevertheless, injuries are likely to still occur. Pragmatically, such injuries are rare; furthermore, needlestick injuries from a known patient who is permanently unable to consent are likely to be extremely rare. Nevertheless, a situation involving an untestable patient is likely to arise, and it is morally untenable that the 'right' to treatment of the injured party should defer to any 'right' of an incompetent patient not to have a BBV test, particularly if a more minimally invasive test can be used and appropriate safeguards regarding confidentiality are observed.

Possible solutions include:

- 1) Covert, non-consensual testing – which is against the law;
- 2) Testing secondary to reassessment of a patient's BBV risk, in which case testing would (probably) be in the patient's best interests
- 3) Non-consensual testing to provoke a legal test case. This is a high-risk strategy that could lead to imprisonment, but could stimulate a thus far intransigent government into introducing secondary legislation
- 4) Lobbying government to introduce secondary legislation, or MPs to introduce a Private Member's Bill
- 5) Increasing awareness among patients of how to assert their choice under existing legislation, for example, via a Lasting Power of Attorney or Advance Decision.

**Needle-stick injury and HIV testing of the incompetent adult****– the status of assent of the next-of-kin****MD Dominic Bell**

The precise status of the next-of-kin in the healthcare management of the incompetent adult remains ill-defined within the UK or indeed any jurisdiction. The Mental Health Act 1959 removed any authority under English law and although the Mental Capacity Act has extended ‘power-of-attorney’ to medical and personal welfare matters, this will predictably be limited numerically and in the nature of the undertakings. Responsibility continues to rest therefore with medical staff acting in the ‘best interests’ of the patient,<sup>1</sup> but directives from both government and the professional bodies specify the involvement of the next-of-kin in decision-making.<sup>2 3</sup> Furthermore, since ‘best interests’ are not limited to ‘best medical interests’, but incorporate *‘the patient’s wishes and beliefs when competent, their general well-being and their spiritual and religious welfare’*,<sup>2 3</sup> it appears essential to consult the next-of-kin to determine their interpretation of these factors.

Despite this somewhat ambivalent position and additional conflict with the duty of confidentiality, it is routine practice therefore within critical care to engage the next of kin not only to update them on condition, prognosis and plans, but to ensure their understanding of and assent to interventions such as surgery, tracheostomy, or blood transfusion, using Consent Form 4 in certain circumstances.

The responsibility of the next of kin is particularly increased in decision-making on maintenance, escalation, or withdrawal of life-sustaining medical treatment [LSMT] when the prognosis and longer-term benefits are doubtful, and the next of kin are asked to express a view on what they believe the patient would have wanted in such circumstances, knowing their values and beliefs. This principle is extended further



when asking for the family's position as to whether the patient would have favoured organ donation when active support is to be withdrawn following a consensus on futility. The overwhelming benefit of organ donation falls to a third party and it can be seen that with reference to non heart beating donation, further undertakings are necessary to ensure that the transplanted organs are at optimal viability and safety, including serological testing for HIV and other transmissible diseases prior to death, an intervention endorsed by the Intensive Care Society.<sup>4</sup> The arguments for this approach are that it is in no one's interests to embark on the process of retrieval and to subsequently discover the presence of transmissible disease, or to delay the transplantation of vulnerable organs whilst awaiting the results of such tests or indeed tissue typing, taken after death.<sup>5</sup>

In this scenario the next of kin are provided with full information as to all the facets of organ donation, including the above aspects, in line with previous government directives on provision of information for valid consent,<sup>6</sup> and give assent on that basis.

The proposal to adopt this approach for serological testing after needlestick injury is not therefore radical. The historical stigmata associated either with testing or a positive result have been largely eliminated through legislation and government directives, as well as the advances in medical therapy such as HAART. The key principles essential to make this approach ethically defensible would be provision of full information on what the test involves and the implications of a positive result, full information on the physical and mental health implications for the relevant healthcare practitioner of either knowing or not knowing a test result, choice as to how the test result is recorded and ultimately provided to the patient if and when they should

regain capacity, and the absence of coercion. By considering standards in other settings, it would appear essential to provide a written booklet on the above aspects and for the interview to be carried out jointly by senior practitioners from intensive care and genitourinary medicine. [This strategy has been defined and carried out within the critical care environment of the General Infirmary at Leeds over the last 18 months].

### **Legal, political and professional implications of these proposals**

The above strategy would arguably not require any change in legislation since the Human Tissue Act does not specifically prohibit serological testing but simply dictates that any intervention be in the patient's 'best interests'. For the protection of the involved health care practitioners, it would however clearly be helpful for government to endorse an expanded interpretation of 'best interests' to include 'values and beliefs' as well as purely medical best interests, and the role of the next of kin in determining those best interests for the individual patient. If such endorsement were not to be forthcoming, it should be apparent that non heart beating organ donation could no longer be considered viable, since the process is critically dependent on a parallel expanded interpretation of best interests and the assent of the next of kin. With such endorsement however, it would then fall to the health-care professions to explicitly define process as above to ensure provision of all essential information and avoid any consideration of coercion.

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<sup>1</sup> *Re F (Mental Patient: Sterilisation)* [1990] 2 AC 1 (HL)

<sup>2</sup> Department of Health. Good Practice in Consent. HSC 2001/023

<sup>3</sup> GMC. *Seeking patients' consent: the ethical considerations*. GMC November 1998

<sup>4</sup> Ridley S, Bonner S, Bray K, *et al*. UK guidance for non-heart beating donation. *Br J Anaesth* 2005; **95**:592-595

<sup>5</sup> Bell MDD. Non-heartbeating organ donation – clinical process and fundamental issues *Br J Anaesth* 2005; **94**: 474-78

<sup>6</sup> Isaacs Report. Department of Health. London May 2003

## Needle-stick Injuries from a Patients Perspective

The options considered at the meeting of /May 9<sup>th</sup> with regard to the testing of patients who have been the source of needle stick injuries were discussed with a broad range of people i.e.: Yorkshire Cancer Network, Members of the Membership Council of the local Trust, Members of Cancer Connections, general members of the public with the ages ranging from late teens to 70s.

There was a general concern that NHS staff (considered in the widest terms) could be left in a vulnerable situation, emotionally and psychologically should there be a needle stick injury, with no recourse to testing if there is no permission given by the source of the possible infection. They did not believe that it should be an occupational hazard that should be accepted. The general opinion was that all staff had the right to work in a safe environment and that their rights were every bit as important as the patients.

There was an overwhelming belief that there should be effective training in place for all staff on how to deal with equipment that could cause a needle-stick injury and how to dispose of it correctly; also that the correct equipment for disposal should be a top priority for all Trusts regardless of costs. There was also a belief that the training should be updated regularly so that standards of care were maintained. It was also felt that all Trust should be aware of the safest equipment on the market and encourage staff to use it, thereby having an environment of good practice. There was a wish expresses that an environment of openness operates within the NHS so that staff felt that they would be well supported if a needle-stick injury occurred.

All six options were presented to the individuals questioned. There was a range of responses as to how the case for needle stick testing should take place,

- A) Probably most felt that there should that there should be blanket testing, that a form should be signed when admitted to hospital for any procedure. Even when it was pointed out that certain patients might not present them-selves for

treatment if it was understood that a sample of body fluids needed to be taken (for fear of needles). The question was asked if a mouth swab would allow the range of tests needed to confirm a blood borne disease thereby circumventing the need to take blood.

- B) The next most made response was, all patients should sign a form that should they be the source of a needle-stick injury they would be prepared to be tested. It was stressed in both response a / b that the consent forms should be explained very clearly to all. Not one person spoken to said that they would refuse consent for testing for them selves or for a relative should that relative be unable to give permission due to their medical condition.
- C) When asked what should happen if an accident occurred when a patient was unconscious with no person present to give permission for testing to take place, the general response was that a test should go ahead with a full explanation given, either to the relatives when they arrive or the patient when conscious again. Should the relatives be present then they should have a clear picture drawn of the situation and be asked for permission to test.
- D) There was a general resistance to the idea of presumed consent for both competent and incompetent patients. What was strongly expressed was the feeling that the treatment throughout a needle-stick injury incident should be sensitively managed for patient and professional so that it would have the best outcome for all concerned.

It should be appreciated the general public do not have the detailed knowledge of the medical ethics that are being considered by the committee. The responses recorded are their reactions to the six changes to be considered.

Everyone without exception was concerned for the safety of NHS staff, they were concerned for the cost implications if staff were off sick and if other NHS personnel did not declare a possible infection and go on to infect other colleagues or patients. It was recognised by all that there will always be unreasonable people what ever changes take place and some felt that if they did not co-operate with NHS personnel then treatment could be refused.