

***Report of the Review Panel on Testing
of Blood for Transfusion***

Ireland

September 2002

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Executive Summary

The Working Group A panel of three international transfusion medicine specialists (the Panel) was formed to review issues surrounding the controversy about where the blood donated for transfusion in Ireland should be tested. The Panel met in Ireland in late May and again in early July. Interested parties were interviewed in both Cork and Dublin and the blood centres in each city were visited. Among those interviewed was the Minister of Health and Children. Many documents were reviewed, including, but not limited to, standard operating procedures (SOPs) at both centres, inspection and news reports, and recommendations of several previous groups and individuals charged to evaluate the Irish blood programme.

Background The Panel emphasises that, within the time at its disposal for this review, no imminent danger to the public health was encountered. This general conclusion obtains even though significant management and organizational weaknesses were apparent. The Panel concludes that a competent and dedicated staff operate a functional blood system in Ireland with great skill.

The Panel also emphasises that its effectiveness was partially limited by the paucity of data in several important areas, among them, financial analyses to support major decisions by management and the ability to benchmark the Irish blood system with international best practices. Paramount was the lack of implementation of a National Data Management System as well as a National Quality System. A common updated Quality Manual with a clear statement of what operational standards are approved by the organisation for use during inspections is not in wide use.

The Panel recognises that, on initial reading, this report appears to exceed the scope of the terms of reference of the inquiry. From its inception, the Panel believed that because the various functions of a blood bank are interrelated and thus, difficult to separate from one another, a broad interpretation of the terms of reference was essential to evaluate testing matters appropriately (See Figure 1.) Thus, with the

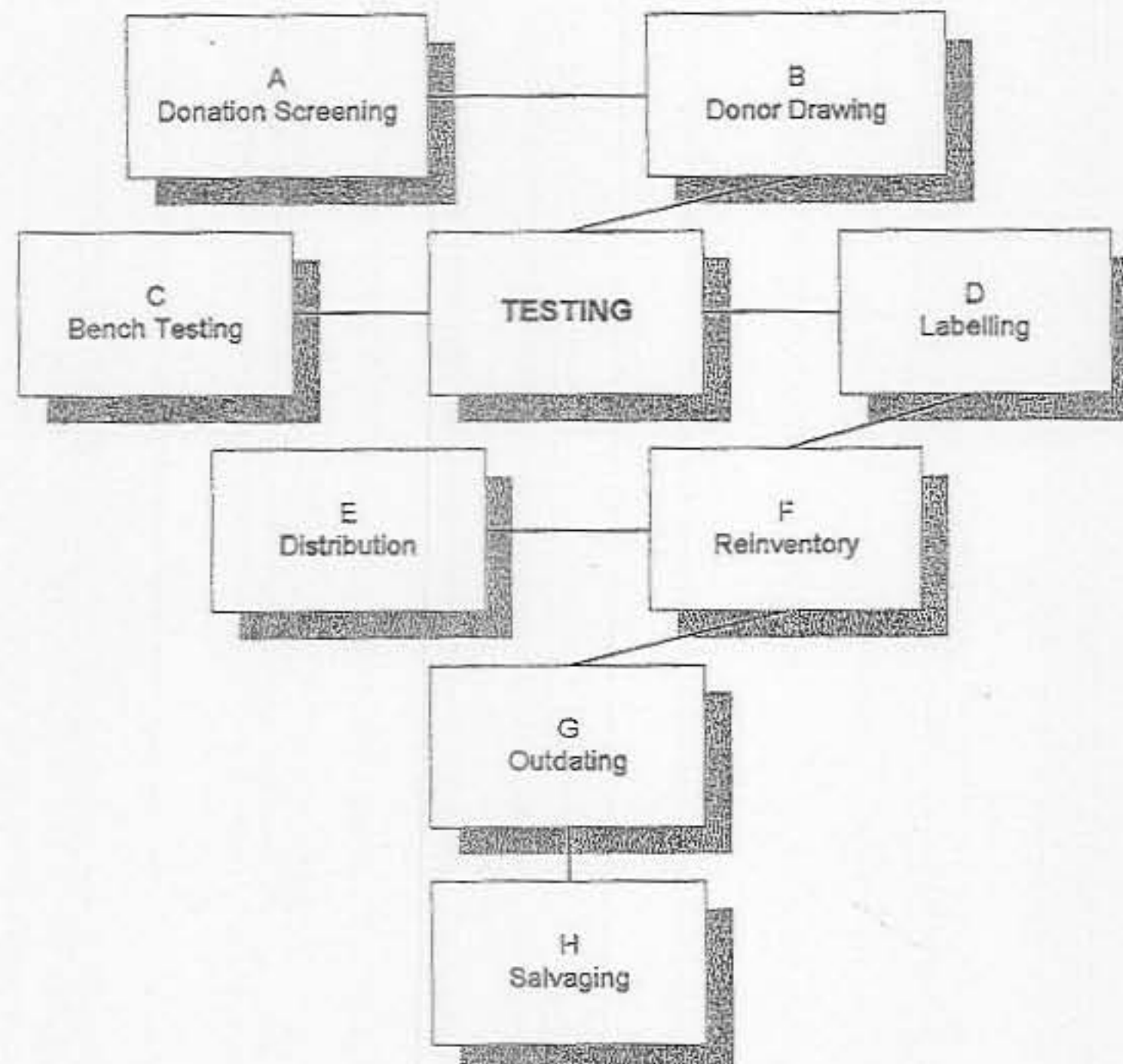


Figure 1. Schematic of Test Result Interaction in a Blood Center

concurrence of representatives of the convening authorities, the terms of reference were interpreted to include functionalities intrinsically related to testing.

The Bain Report This report provided a commonly cited authority to support consolidating blood testing in the laboratory in Dublin in the near term. In fact, the report only recommended testing in a single location at some time in the future. It also outlined three barriers that should be removed prior to such consolidation, chief among them, the lack of a national data management system. None of the barriers has been removed. Further, the 1996 Re-Organization Plan does not mention testing at a single site. Until some systems, most notably information management technology, are integrated into a single national system, consolidating many functions, including testing, is not feasible. Finally, the Panel believes that geographic, cultural, and historical factors may militate against centralisation of the entire Irish blood system.

Unfortunately, the intense controversy about where testing should be performed has diverted IBTS staff energy and resources from more compelling unresolved operational issues facing the Irish blood system. Several of these issues will become apparent in this report.

Recommendations

One. It is recommended that IBTS develop and maintain donation testing programmes, including nucleic acid testing, at both the Cork and Dublin Centres.

Two. That to assure uniform national quality and effective operational management of donation testing, the activities of both Cork and Dublin be integrated meaningfully into a single national blood system, but with separate management structures in place at two centres within the national service. It is recommended that a management structure of the Cork Centre be reestablished such that each Centre Director clearly be in charge of their Centre. It follows that the current system of centralised/functional management requires major revisions. It is further recommended that the IBTS headquarters should not be located at either regional Centre, thus dispelling any impression that either is the "National Centre."

Three. It is recommended that representatives from both Cork and Dublin Centres participate in IBTS governance and senior management decision-making meaningfully and in proportion to the blood components and blood products each produces.

Four. It is recommended that future replacements of IBTS Board members reflect balanced geographic representation, the interests of Health Boards and individuals with transfusion medicine expertise (medical, technical or managerial), as well as individuals with expertise in financial and general management of complex commercial medical enterprises. There would be considerable advantage were an international transfusion medicine expert to serve as a Board Member for the next 5 years.

Five. It is recommended that the physical facilities for Dublin and Cork should be of similar quality with space appropriate for their missions. The new Cork facility should be designed to support academic educational and research activities and preferably be located in an academic environment. This recommendation should be given the highest priority by the IBTS.

Six. A national quality system, with clearly stated operational standards, should be implemented throughout the organisation by IBTS. The operational standards should be selected for their rigor. It is recommended that, to gain mutual and public trust, the IBTS operating elements be ISO certified and audited by the accreditation Institute in addition to the IMB inspections according to cGMP and established operational standards.

Seven. It is recommended that a computer system, with Progres serving initially, integrating Cork and Dublin operations nationwide be implemented as a matter of urgency. The highest operational priority should be given to functions related to safety, such as national deferral registries, integration of donation testing results, bag/product labelling and lot release.

Eight. It is recommended that the IBTS nurture research and development programmes at both Centres.

Nine. The number of physicians trained in Transfusion Medicine should be increased with encouragement and financial support from the Irish government.

Ten. It is recommended that upon receipt of Inspection Reports, without regard from which inspecting authority, an action team be appointed by the CEO to respond, item by item, to any recommendations or adverse findings of the Reports. This action team should be charged to report in writing to and through the CEO and/or the Board every 90 days regarding progress in corrective actions until correction of all deficiencies has been documented.

Eleven. At 36 months, a review team should be engaged to determine the responses of the IBTS to the recommendations of this Report. This review team should report to the IBTS Board. It is further recommended that during this period information about costs and productivity be collected prospectively to allow scientifically based cost-efficacy benchmarking of the IBTS.

Body of the Report

Background In 1994, the Blood Transfusion Services Board (BTSB), now the Board of the Irish Blood Transfusion Service (IBTS), anticipated serious public criticism of the management of the service following investigations into the most grave disaster in the history of the Irish Health Service: virus contamination of anti-D immunoglobulin. Thus, it contracted with a consultant (Bain UK, Inc.) to review the management of the service and make recommendations for change. This contract had the support of the Department of Health and Children (DOH&C).

Bain UK, Inc. published their report in May 1995 and recommended fundamental changes.¹ In short, they advised the BTSB and the DOH&C that the blood system should put a centralised management structure in place and, by inference, indicated that this structure should be located in the Dublin Centre. Included in this report was advice on the future shape of programmes for testing blood donations. It was proposed, in line with Bain's overall management philosophy, that all blood donation in Ireland be tested in a single centre at some time in the future, again by inference, this should be in Dublin.

The recommendations in the Bain Report were approved by the BTSB and had the support of the DOH&C. These remain their positions today. The Bain report formed the basis of their Re-Organization Plan for the service, which was approved by the BTSB in the summer of 1996.² An essential theme of this Re-Organization Plan focused on the development of a centralised line management system with the consequent diminution of operational responsibilities within both the Dublin and Cork Centres.

In February 1998, the BTSB approved the introduction of a highly sensitive test for infectious diseases termed the polymerase chain reaction (PCR) for all blood donated in Ireland. It further approved that this technology be outsourced for two years and thereafter be performed for the whole of Ireland in the Dublin Centre. It is reasonable to conclude that this decision encouraged senior service managers to advise the BTSB that the time was appropriate to consider implementing that part of the Bain Report which recommended performing all infectious disease testing in Dublin. Senior managers have emphasized that this proposal was contained in a wide ranging policy paper presented to the BTSB in March 1999,³ although there is evidence within the Health Service that it was common knowledge before this date.⁴ It is noteworthy that, as of this writing, no PCR testing capability has been developed in the Dublin facility.

In 1999, the BTSB requested that senior Irish blood transfusion service managers consult with colleagues outside Ireland and report back to the Board. Senior staff complied by travelling to Finland and England, and in July 1999, advised the BTSB that steps should be taken to transfer all donation testing (blood grouping and infectious diseases) from Cork to Dublin (Murphy and Hynes Report⁵). The Board and the DOH&C approved this proposal.

In July 1999, just prior to the ISBT Board's deliberations on the Murphy and Hynes Report, a group of Munster clinicians, along with several Southern Health Board (SHB) members, met with IBTS Board members. This Munster group expressed deep concerns about the decision to transfer donation testing from Cork to Dublin and equal

concerns about the decision-making processes by which this policy had been reached.⁶ These concerns were subsequently committed to paper and conveyed to the IBTS Chairman.⁷

The response of the IBTS Chairman⁸ was deemed by the Munster clinicians to be unsatisfactory and steps were taken to refer the matter to the Oireachtas Joint Committee on Health and Children.

The relevant hearings of the Joint Committee took place in March, 2000, and the findings in favour of maintaining two donation testing sites were published in April, 2000. At the time of this writing, it is not certain whether the IBTS Board considered formulating a response to the outcomes of these parliamentary deliberations, but it is clear that the IBTS Board has not communicated its views to the SHB. This state of affairs led the SHB to declare a formal vote of no confidence in the IBTS Board.⁹ The IBTS Board responded by proposing that the two Boards work together to establish and support a three-person international panel (the Panel) to advise the IBTS on the most appropriate way to go forward with the single versus the dual site testing options. The respective Boards agreed that each would select one person and the two selected by the Boards would appoint the third member of the team who would also serve as its Chairperson.

The Panel was put in place in March, 2002 and it invited both Boards to supply preliminary background papers related to the issues at hand. Through the good offices of the respective CEOs, these documents¹⁰ were delivered in a timely manner, along with video tapes of the proceedings of the Oireachtas Joint Committee on Health and Children.

Terms of Reference In December 2001, the IBTS Board approved the Terms of References (see Appendix 1) for the Panel's review of the single-site donation testing issues, that had been developed by the SHB.¹¹ The IBTS Board recorded its views on the context in which a number of assessments in the Panel's Report would be considered.¹² These included:

- examine the implications, positive or negative, of maintaining dual-site testing;
- assessing the impact of movement to single-site testing on the quality and timeliness of the service provided nationally; and,
- examining the impact of single-site testing in terms of the removal of an independent back-up system, and the provision of appropriate replacement facilities or arrangements.

In reviewing the preliminary material supplied by the CEOs and after preliminary communications with senior IBTS managers, the Panel concluded there was a need for further clarification of the Terms of Reference of the Review. Specifically, the Panel believed it was important that it be able to acquire further information on the historical aspects of the donation testing issue, that it have access and collaboration from the

officials of the DOH&C, and that it could explore those aspects of the governance/management and quality assurance of the IBTS which affected blood donation testing.

Blood donation testing sits within a complex interacting network of activities within and between Blood Centres (see Figure 1). The Panel believed it was vital that it be able to examine all essential aspects of this network. On Sunday, 19 May 2002, the Panel met with the Chairmen of the IBTS and SHB, Mr. McCloone and Cllr. O'Keeffe, respectively, and with members of their staffs and it was agreed the Panel could examine those aspects of IBTS's governance/management and quality assurance which were deemed by the Panel to be essential for an effective review of testing issues. On Wednesday, 22 May, the Panel briefed the Minister of Health and was advised they would have full access to and the collaboration of government officials. The Panel was requested to make its report simultaneously to the two appointing authorities, IBTS and SHB.

Methodology/Review Process The basic background documents and videos provided by representatives of the respective Boards¹⁰ proved to be invaluable in focusing interviews. The Panel regrets it was not possible to have access to the Flynn Report¹³ and other additional information until its interviews had been completed; however, the Panel believes it was sufficiently informed that this delay did not hamper its ability to render a fair report.

The Panel discussed transfusion medicine in Ireland with numerous interviewees at all levels from technicians to Board members. The Panel believes it was able to meet with all interested parties that were available when the Panel was in Cork and Dublin. The structures of the interviews were intentionally informal in order to encourage free and frank discussions. The Panel, with the support of the IBTS Chairman, put in place arrangements intended to give all members of the IBTS staff an assurance that their interviews would remain confidential (see Appendix 2). In light of comments made in the Flynn Report regarding staff fears of retribution, the Panel believed that this was an important and constructive approach.

Soon after the International Panel was established, it requested that an independent Administrator be appointed to co-ordinate and service the review programme. Preference was given in this request for a civil servant who was not in the DOH&C, or a senior but retired, public service administrative manager. The Panel is aware that considerable efforts were made to support this request and regrets they were unsuccessful. However, the Panel was afforded the extraordinarily helpful assistance of Ms. O'Mahoney (SHB) and Ms. McGuire (IBTS) on its behalf.

The Panel recognises that in establishing a three-person international panel, timing problems were inevitable, especially related to concurrent availability of both the Panel members and desired persons to interview. This difficulty has affected the timeliness of the report of the Panel, but not its substance. The Panel believes that its extensive review of documents and the interviews it conducted have given it an

accurate, although necessarily incomplete in every detail, view of the Irish Blood Transfusion System. We firmly believe this Report is provided by an informed Panel and are grateful to the many people who have made it possible.

Findings and Recommendations

General Comments The Panel believes it is important to emphasize that, although serious management and organizational weaknesses were found during the review, no generalized lack of safety of the current Irish blood supply was detected. The Panel did perceive that many employees felt alienated and insecure and morale was stated to be low. These perceptions suggest that leadership should work on confidence at all levels in efforts to restore employee co-operation, partnership and trust. However, we found, as have others previously,¹⁸ a highly skilled staff in both the Cork and Dublin Centres operate a functionally safe blood system with great dedication despite significant management difficulties.

We caution that the Panel's effectiveness was partially limited by the paucity of available data in several important areas, especially financial analyses to support major decisions by management (including donation testing options) and whether IBTS effectively benchmarks its operational management practices with those of other national Services.

The Panel has concluded that best international practices for donation testing which formed much of the rationale of the Murphy and Hynes Report have not been

established. Having looked at the experiences in several countries, the Panel found there are no best international practices for testing. Each country with a national blood transfusion service must look carefully at what policies best suit its circumstances, including financial considerations, academic and political sensitivities, and nation-specific and cultural aspects related to centralisation of its management. The provision of appropriate back-up facilities (with acceptable management and quality assurance control), and the interests of customers, in particular, Health Boards and prescribing physicians, must be included in decision making. The Panel found little evidence that these considerations had been included appropriately in the decision processes regarding future donation testing programmes for the IBTS (either at the Officer, DOH&C or Board levels).

The Panel frequently encountered strongly held views on various matters but without objective supporting data. Although in many cases differences in approach appeared to be regional (i.e. Dublin versus Cork) this was by no means always the case. Parochial viewpoints frequently complicated the evaluation of evidence presented by several of those interviewed.

Historical Perspective The Panel has no doubt that much of the current donation testing controversies have their roots in the hepatitis C scandal, which has left significant and lasting scars on the IBTS. These have been further enhanced by the recent return of yet further inquiries surrounding those hepatitis events. Previous attempts to leave this history behind, by a complete change of top management and

efforts to gain more central control, have both failed. Although the hepatitis C contamination of anti-D immunoglobulin was a most tragic circumstance for the Irish Health Service, it should be emphasized that patients have been unintentionally infected with the hepatitis C virus in other countries and their governments are still struggling to find acceptable ways to compensate these patients. Further, in some countries testing strategies have been or are being initiated to detect or avoid what some regard as only theoretical risks (testing for nvCJD, for example).

The Bain Report¹ provides a commonly cited authority to support consolidating donation testing in the laboratory in the Dublin Centre. It is noteworthy that the Bain Report actually recommended that "... BTSB develop a strategy to consolidate donor testing in a single location at some point in the future." (emphasis added)¹ and identified the lack of a system-wide information technology (IT) capability as one of the barriers to such a consolidation. System-wide information management capability still remains a recognised, but unmet need throughout the ISBT. Moreover, at the time of the Panel's visits, no satisfactory information was available as to when a validated IT system would be operational. Further, the 1996 Re-Organisation Plan does not mention single-site donation testing.² Thus, moving donation testing from Cork to Dublin in the near term was not mandated by any study of the IBTS until the report of Murphy and Hynes.⁵ By contrast, the more recent management report prepared by Flynn and Lynott¹³ stated that the single-site testing decision was "ill-timed and taken precipitously." It should be noted that the Re-Organization Plan did recommend developing a "...national centre for transfusion medicine and (to) act as the World Health Organisation appointed National Reference Laboratory for Blood Group

Serology"² This language relates to providing reference laboratory services rather than centralised routine infectious disease testing or management.

Unfortunately, much of the controversy that the Panel was convened to address was created by a misinterpretation of the Bain Report. The Panel concludes that international evidence suggests that geographic, cultural and historical factors militate against Bain's recommendations for centralisation of both donation testing and site management of the blood transfusion Centres in Ireland.

The the deliberations of the Panel are presented as "the issue examined" and the "recommendations" based on the findings during examination of the issues.

Issue One - Testing Site. The Panel understands that donation testing issues, especially where nucleic acid testing (NAT) should be performed, initially triggered its engagement to perform this limited review of the IBTS. NAT, by a method known as the polymerase chain reaction (PCR), is a highly sensitive laboratory method for detecting infectious agents in blood. Currently NAT of the Irish blood drawn for transfusion in Ireland is performed in Edinburgh, Scotland. Because of the high sensitivity of PCR, most laboratories will experience occasional down-time due to contamination or other operational difficulties. Thus, backup NAT capability is critical to maintain an uninterrupted supply of blood. The strategy of Dublin and Cork providing mutual back-up would be both practical and managerially attractive. The currently envisaged long-term IBTS NAT back-up options of transporting samples to a foreign country are not soundly based.

Notwithstanding the Murphy and Hynes Report⁵ the Panel could find no convincing financial, scientific, medical or operational analyses from the IBTS that supported establishing donation testing at a single site. Further, the Panel determined that both sites appear capable and well run.

In the Murphy and Hynes Report⁶ it is suggested that a labour savings of 252,555 pounds would be realised by consolidating donation testing in one laboratory. Yet, when discussing the transfer of testing from Cork to Dublin at a meeting of the Blood Product Advisory Group in Cork, an IBTS senior manager stated "(t)hat when this transfer (testing from Cork to Dublin) is finished there will be the same number of staff or more employed there," meaning at Cork.¹⁴ Further, the specimen transportation and data transfer costs, especially without an integrated computer system, for testing in a single centre have not been addressed. As already noted, one of the serious management deficiencies the Panel encountered was the paucity of financial data within the IBTS. The Panel bench-marked internationally with other systems and estimate that the additional capital costs of physically fitting out two duplicate testing facilities (Cork and Dublin) rather than one would be rather modest. These costs would be partly offset by avoiding recurring costs of shipping and communicating to and from a single testing site and the quality control of a foreign back-up laboratory to provide emergency testing. Finally, international benchmarking suggests the IBTS estimate of six to nine additional staff to perform NAT testing in both centres is excessive.

The Panel believes that the IBTS Board should consider at some time in the future whether current NAT of donated blood should be continued. As further

experience with the results of NAT in other countries is being evaluated, it is becoming clear that the benefits are not as great as predicted. First, it is not fail safe. In a recent report from Singapore, HIV was transmitted to recipients by a recently infected donor negative on minipool NAT.¹⁵ Further, it was calculated in a recent UK study that the cost per year of recipient quality adjusted life year by detecting a single unit infected with the hepatitis C virus was 7,900,000 British pounds to rise to 31,500,00 pounds in the near future.¹⁶ The authors suggest that, when compared with other medical interventions, NAT of blood for transfusion is not cost-effective. In Sweden and Denmark, NAT is not performed on blood for transfusion. In Scotland, NAT for human immunodeficiency virus (HIV) was recently abandoned due to lack of efficacy at a savings estimated to be 1,211,788 Euro annually.

Any decision not to perform NAT testing based on cost-effectiveness must be discussed in light of potential legal repercussions. In UK, a recent ruling under the terms of the Consumer Protection Act is cause for concern.¹⁷ The failure of transfusion services to adopt all reasonable measures to increase safety of the blood could leave such Services legally at fault and liable for damages.¹⁷

Recommendation One - Testing Site. It is recommended that IBTS develop and maintain donation testing programmes, including nucleic acid testing, at both the Cork and Dublin Centres. This development would have the following advantages:

- a. A national back-up system for testing would be automatically maintained.
- b. Such a structure would be operationally cost-effective.

- c. The morale and involvement of the Munster medical community, as well as the Centre staff, would be enhanced.
- d. The contribution to further expanding the biomedical research programmes within the University of Cork, with the potential for local commercial spin-off could be substantial.
- e. An opportunity would arise to manage deep seated conflicts between Munster and Dublin more effectively by the development of productive partnerships.

Finally, the need to perform NAT of donated blood for known infectious agents should be reevaluated.

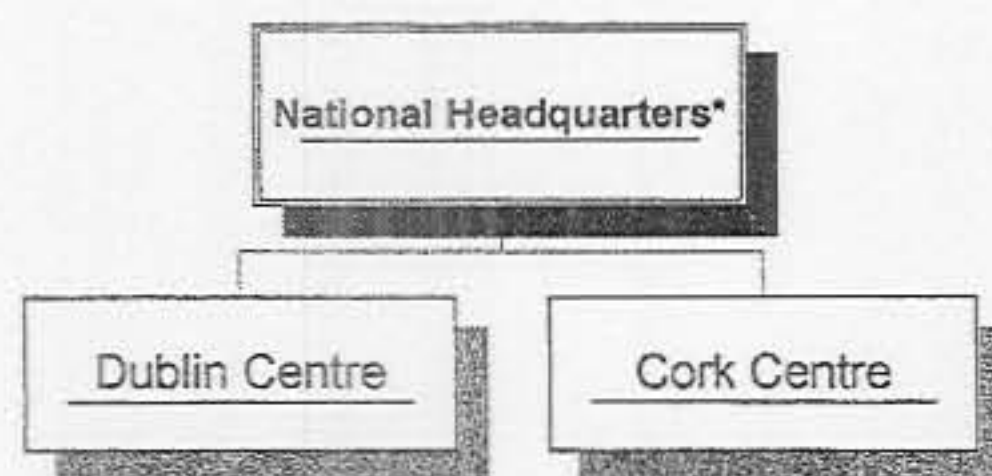
Issue Two - IBTS Operational Management Structure and Functions. It became clear during this review that, until very recently, Cork and Dublin essentially maintained separate, non-integrated management systems. Among the more obvious indicators, common standards are not in place, personnel policies are not uniform and donor deferral registries are not shared. The latter is an important safety issue because a donor could be on the deferral registry in Cork but that deferral be unknown to Dublin. Should such a donor present in Dublin, seeking HIV testing for example, he or she would be permitted to donate.

At the time of the Bain Report, the senior management of the BTSB strongly believed that the organisational structure of BTSB was ineffective. The management

structure and functions that were introduced as a consequence of the Bain Report and the 1996 Re-Organisation Plan have made a significant contribution to the current donation testing controversy. This difficulty was recognized in the Flynn report in stating " (t)he concept of a national organization with national structures and standards . . . ha(s) become confused with centralisation of functions and management."¹³ The Panel believes this statement is soundly based and the resulting management weaknesses are still apparent.

The IBTS would benefit from an operational governance system in which the Blood Centres and a national management team the size and functions of which should be reviewed, were physically separated and the latter not involved in the day-to-day operational management of either Centre. The Cork Centre requires management co-equal in authority, experience and expertise as similarly placed staff in Dublin.

Recommendation Two - IBTS Operational Management Structure and Function. That to assure uniform national quality and effective operational management of donation testing, the activities of both Cork and Dublin be integrated meaningfully into a single national blood system, but with separate management structures in place for the two Centres within the national service (Figure 2). It is recommended that a



*Preferably not co-located with either center

Figure 2. Recommended Management Structure of a National System

management structure of the Cork Centre should be reestablished such that each Centre Director clearly be in charge of their Centre. It follows that the current centralised/functional model requires major revisions. It is further recommended that the IBTS national headquarters team not be physically located at either Centre, thus dispelling any impression that either is the "National Centre."

Issue Three - A More Balanced IBTS Governance Representatives, particularly the Centre Directors, from both the Cork and Dublin Centres do not participate equally in the IBTS governance and particularly in all national policy making and strategy development. It would be desirable that the leadership in Cork be included in decision making at the national level, and that staff at Cork should be appropriately consulted in relation to planning the Cork Centre. Many of the recommendations of this report would benefit greatly from a more balanced governance.

Recommendation Three - A More Balanced IBTS Governance It is recommended that Representatives from both Cork and Dublin Centres participate in IBTS governance and senior management decision-making meaningfully and in proportion to the blood components and blood products each produces.

Issue Four - External IBTS Governance The IBTS Board historically has not included independent members with transfusion medicine (medical or technical) expertise. The Board has relied upon consultants, advisors, and especially staff, when acting on technical issues. It was determined that there is a risk under the circumstances described in this report, that proposals made by senior staff will not be

subjected to searching scrutiny and that members of the Board may tend to defer to senior staff. This determination prompted the recommendation of the Panel that an international transfusion medicine expert be a member of the Board.

There is, in the context of the decision making process regarding donation testing and the centralisation of management, a widespread view among IBTS senior and middle management staff that the DOH&C officials have been very closely involved. The Panel has acquired sufficient evidence to conclude that this perception is valid and it endorses recent moves by the DOH&C to withdraw its officials from membership of the IBTS Board.

Recommendation Four - External IBTS Governance It is recommended that future replacements of IBTS Board Members reflect balanced geographic representation, the interests of Health Boards, and individuals with transfusion medicine expertise (medical, technical or managerial), as well as individuals with expertise in financial and general management of complex commercial medical enterprises. There would be considerable advantage were an international transfusion medicine expert to serve as a Board member for the next 5 years.

Issue Five - Physical Facility Comparability As stated, the Panel believes strongly that two separate regional centres, both managed as parts of an all-Irish organisation, should be maintained. The concept of a National Blood Centre (NBC) for either of the centres is counterproductive and inhibits collaboration.

Comparisons between the Dublin and Cork Centre facilities are a matter of concern. The Cork Centre is in urgent need of complete replacement. The working areas are crowded, the staff cramped, and the buildings in marginal condition. These deficiencies of the Cork physical facilities have been noted in inspection reports of the IMB since 1999,¹⁸ the earliest reports provided to the Panel. Relocation of the Cork Centre, preferably to an academic environment, is urgently needed. Such a site has been offered to the IBTS by the SHB. The Dublin centre is an architectural masterpiece and the Panel recommends any new Cork facility be of comparable quality.

Recommendation Five - Physical Facility Comparability It is recommended that the physical facilities for Dublin and Cork should be of similar quality with space appropriate for their missions. The new Cork facility should be designed to support academic educational and research activities and preferably be located in an academic environment. This recommendation should be given the highest priority by the IBTS.

Issue Six - Adoption of Standards and Certification The Panel repeatedly heard interviewees mention the lack of public confidence in the IBTS. One strategy to overcome this, at least in part, would be formal compliance with international and independent quality standards. It is unclear currently to what generally accepted standards the IBTS internally benchmarks itself. ISO 9000 certification, in its most current iteration, of both centres would be an important initiative in this direction. Even though there were several findings of "partial compliance" of standards in Cork during its ISO 9000 inspection, the paradox of Cork having ISO certification, while Dublin does not, is striking. This has added fuel to the public controversy surrounding

the donation testing issue. The IMB plays a significant role in promoting and maintaining comparable quality assurance throughout the IBTS through its role in licensing of blood and blood products.

In the Hederman O'Brien Report¹⁹ a number of points were made with regard to ways of improving the service provided by the predecessors of the current IMB and the IBTS. These included:

- closer liaison with sister regulatory agencies in other countries;
- a increase in the resources for the IMB to meet increased regulatory activity; and,
- clarification of the relationships between the IMB and the Department of Health such that the responsibility for enforcing licensing requirements is clear.

In examining the current donation testing controversy, in the context of the Terms of Reference of this Review, the Panel believes that the Hederman O'Brien points referred to above still require further attention, and that this would bring significant benefit to the future operations of the IBTS.

Recommendation Six - Adoption of Standards and Certification A national quality system, with clearly stated operational standards, should be implemented throughout the organisation by IBTS. The operational standards should be selected for their rigor. It is further recommended that, to gain mutual and public trust, the ISBT

operating elements be ISO certified and audited by the accreditation Institute, in addition to the IMB inspections, according to cGMP and established operational standards.

Issue Seven - System-wide Computer System As currently configured, the computer systems used within the IBTS, are not compatible with one another. Thus, it is possible that a donor permanently deferred by one centre could be drawn unknowingly and the unit entered into inventory at the other. Correction of this deficiency is vital to the safety of the Irish blood system. A contemporary computer system is of critical importance for tracking positive test results to block labeling and hence prevent the release of an unsuitable unit. Further, a national computer system is only complete when the application of test results of one Centre are available to evaluate future donations at the other Centre. This is particularly important for the results of tests for infectious diseases; truly infected donors with borderline reactivity in one donor centre could be negative at the second. Were prior positive test result not available at the second Centre, a potentially infected unit could enter the blood supply. The Panel was informed that such a unified system is ready, but its implementation has delayed over one year by unresolved industrial relations difficulties. These difficulties should be resolved as soon as is practical.

Recommendation Seven - System-wide Computer System It is recommended that a computer system, with Progres a serving initially, integrating Cork and Dublin operations nationwide be implemented as a matter of urgency. The highest operational priority should be given to functions related to safety, such as national

donor deferral registries, integration of donation testing results, bag/product labelling and lot release.

Issue Eight - Research and Development One of the most striking changes in transfusion medicine practice over the last decade is the recognition that, as a discipline, it generally has moved from a laboratory-based model to a pharmaceutical manufacturing model with a close working clinical interface.³ The manufacturing and clinical models thrive on research. The IBTS has not benefitted by responding to this paradigm shift and this lack of a research and development culture is a cause for concern. IBTS management appears driven primarily by business and technology needs, rather than research.

The locations of the Dublin and Cork Centres on medical academic campuses provide ideal opportunities for both to augment their research programmes. The Panel does not share the view that the research opportunities may be more limited in Cork due to its modest size. Rather, at the present time, because of the attitudes of the various associated Universities the medium and long-term research opportunities in Cork look particularly attractive.

Recommendation Eight - Research and Development It is recommended that the IBTS nurture research and development programmes at both Centres.

Issue Nine - Increase the Number of Transfusion Medicine Specialists The number of Transfusion Medicine specialists in Ireland, currently five, is insufficient. It

would seem unlikely that their numbers will increase without influence from the Irish government. The Panel understands that this issue may be complicated by the absence of facilities in Ireland possessing the ability to train transfusion medicine specialists. However, such capability could be developed and, while it is, arrangements should be made to obtain assistance from abroad. The availability and presence of additional transfusion medicine specialists might exert the dual effect of improving transfusion practices and increasing the confidence of the Irish public in blood transfusion medicine in general, and the strength of the IBTS/clinical interface in particular. The Panel applauds the reported recent developments to increase the number of haematologists and blood transfusion medicine service medical personnel. It strongly advises the IBTS Board to promote training programmes for these doctors, many of which, in the short term, would have to be trained outside of Ireland.

Recommendation Nine - Increase the Number of Transfusion Medicine Specialists

The number of physicians trained in Transfusion Medicine should be increased with the encouragement and financial support from the Irish government.

Issue Ten - Inspection Responses Reviews of IMB inspection reports of both the Cork and Dublin Centres filed since 1998, indicate in many cases the same adverse findings appear year after year. It appears clear that the IBTS does not have an integrated approach to correcting deficiencies identified during inspections. Although not all findings can be resolved or corrected in 12 months, such as the physical facility in Cork, progress should have been made correcting any adverse finding and a status report available to the inspectors outlining such progress. Such a programme of

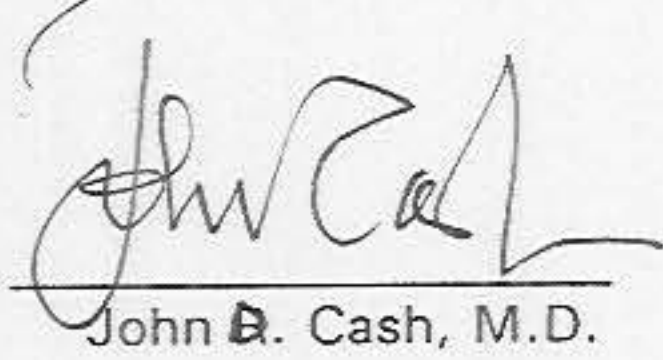
corrective action is generally regarded as a key element of any continuous improvement initiative.

Recommendation Ten - Inspection Responses It is recommended that upon receipt of Inspection Reports, without regard from which inspecting authority, an action team be appointed by the CEO to respond, item by item, to any recommendations or adverse findings of the Reports. This action team should be charged to report in writing to and through the CEO and/or the Board every 90 days regarding progress in corrective actions until correction of all deficiencies have been documented.

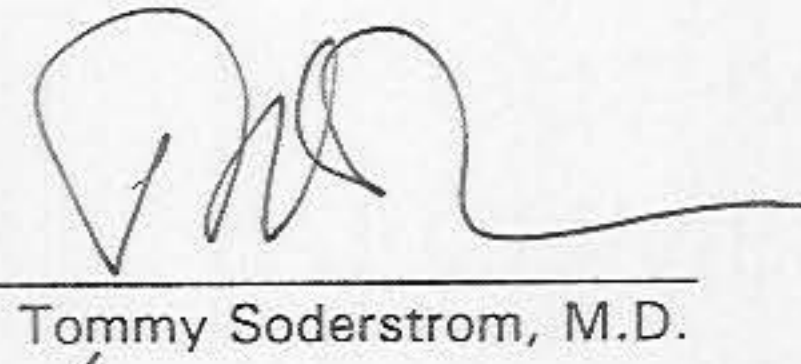
Issue Eleven - Implementation and Follow-up Many reviews of the Irish blood banking system have been undertaken over the past 10 years. Follow-up of the various reports and recommendations can, at best, be described as incomplete. The Panel believes that a group of reviewers should be empaneled to determine the impact of the Panel's recommendations on the practices of the IBTS. It is also important that the Board establish improved general monitoring programmes.

Recommendation Eleven - Implementation and Follow-up At 36 months, a review team should be engaged to evaluate the responses of the IBTS to the recommendations of this Report. This review team should report to the IBTS Board. It is further recommended that during this period, information about costs and productivity be collected prospectively to allow scientifically based cost-efficacy benchmarking of the IBTS.

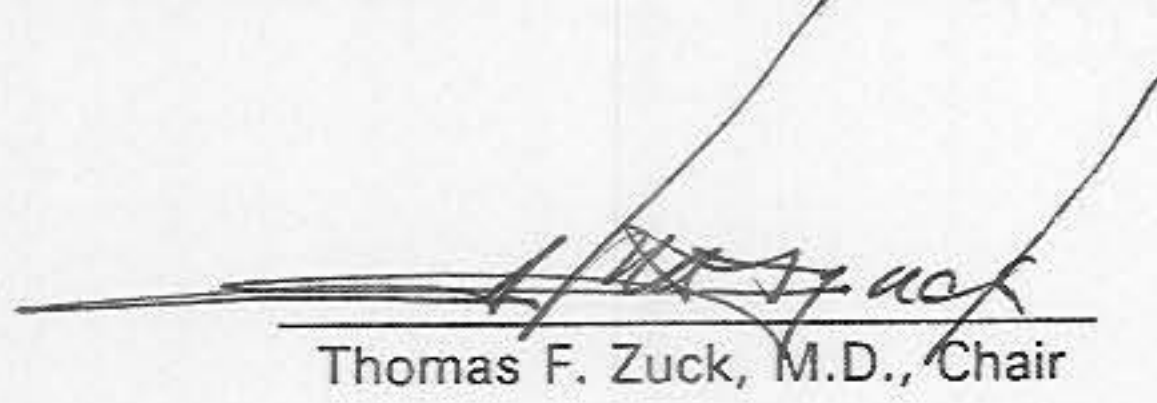
This unanimous report is respectfully submitted by the Panel.



John D. Cash, M.D.



Tommy Soderstrom, M.D.



Thomas F. Zuck, M.D., Chair

REFERENCES

1. Bain Report: Fact finding and analysis; Recommendations, 1995.
2. Re-Organization Plan, Blood Transfusion Board, 1996.
3. Murphy W. Medical and Technical Factors that will impact the way the Blood Transfusion Board performs its functions in the short to medium term. Presented to the BTSB, 1995.
4. McNamara Report. Presented to the Southern Health Board, 1999.
5. Murphy W, Hynes M. Report presented to the IBTS Board, 1999.
6. Report presented to the IBTS Board on a meeting held in the Cork University Hospital with members of the Southern Health Board and Munster clinicians, 1999.
7. Report prepared by the Munster Regional Representative Group. The proposal to discontinue blood testing at the Munster Centre of the IBTS---an assessment, 1999.
8. Letter from IBTS Chairman (Dr. Barker) to Southern Health Board Vice Chairman (Dr. Molloy, November 1999.
9. Press Release from the Southern Health Board, December 2000.
10. List of preliminary material supplied to International Panel members from IBTS and SHB, March 2002.
11. Terms of Reference for the Review, approved by IBTS Board and SHB, December 2001.
12. Letter from IBTS Chairman (Mr. McCloone) to SHB Chairman (Deputy O'Keefe), December 2001.
13. Flynn P, Lynott MP. Evaluation of the recommendations to the Board of the Irish blood transfusion service, 2001.
14. Murphy W. Statement at Blood Product Advisory Group, 2000.
15. Ling AE, Robbins KR, Brown TM, et al. Failure of routine HIV-1 tests in a case involving transmission with the preseroconversion blood components during the infectious window period. JAMA 2000;284:210-214
16. Simmonds P, Kurtz J, Tedder RS. The UK blood transfusion service: over a (patient) barrel? Lancet 2002;359:749-750.

17. Ruling by Justice Burton as cited in Simmonds P, et al.¹⁶
18. Irish Medicines Board. Inspection Report, Blood Transfusion Service Board, Cork, 1999.
19. Hederman O'Brien M, Bellingham A, Hussey C. Report of the expert group on the blood transfusion service board. 1995

Appendices

SPECIFIC TERMS OF REFERENCE

To assess the advantages and disadvantages associated with:

- (a) Dual site testing and
- (b) Single site testing Irish Blood Transfusion Service (IBTS) organisation, key issues for consideration may include –

- Assessing the impact of movement to single site testing on the quality and timeliness of service provided nationally and in the Munster region. In particular evaluating the impact of such change on (a) user confidence, and (b) donor participation in the area;
- An assessment and comparison of standards, backup centre roles, and reportage systems of both centres to date;
- Examining the impact of single site testing in terms of the removal of a backup system, and the provision of appropriate replacement facilities or arrangements;
- Examining the impact of such a change on the ability of the organisation to cater for other possible (demand) emergencies throughout the country, and
- Estimating the cost implications, positive and negative, of maintaining dual site testing;
- All relevant documents of the IBTS organisation, the Southern Health Board, and other bodies necessary as agreed between the two Boards, should be made available to the review group. Also, access should be provided to all relevant personnel;
- The International Expert Group should complete its report within two months of its initial convening and should submit it simultaneously to the Chairpersons of the IBTS and the SHB.

CONFIDENTIALITY AGREEMENT

(On plain notepaper with the names and addresses of three experts)

| | | |
|--|---|---|
| Professor Thomas Zuck 2861 Patterson Farms Lane Cincinnati Ohio 45244 USA | Professor John Cash 1 Otterburn Park Edinburgh E114 UJX Scotland | Professor Tommy Söderström Karlinska Hospital 17176 Stockholm Sweden |
|--|---|---|

Dear [Insert name of interviewee]

As you know we have been appointed by agreement between the Irish Blood Transfusion Service and the Southern Health Board to prepare an independent report with the attached terms of reference on the issue of single/dual site testing.

We are anxious that every IBTS staff member with whom we speak in the course of our work on this assignment can speak with full candour and give us the benefit of his/her knowledge and views relevant to the issues in the terms of reference. We are anxious also that we can discuss with such persons these issues in a similar manner.

We will treat your communications with us and our communications with you in confidence and not divulge these communications to any third party save in accordance with a lawful requirement such as a court order or in so far as it may be necessary for us to do so in furtherance of this assignment. We will be grateful if you would confirm likewise (by signing where indicated below) that you will treat such communications in confidence.

Yours sincerely

Thomas Zuck

John Cash

Tommy Söderström

[IBTS staff member]

Date:

IBTS/SHB (international) Inquiry

DOCUMENTS REQUIRED BY JDC BEFORE JULY 2002 VISIT

(Note on possible sources of information: * signifies Chairman of IBTS, + the SHB CEO's Office and # the DOH&C)

1. The Flynn Report (2002)(*)
2. Tissue Banking Report (Dr Eastland, 1997) (*)
3. List of most senior Officials of the DOH&C Blood Policy Division/Unit since it was established (#)
4. Summary of BTSS/IBTS Board's formal responses to the Hederman/O'Brien Report (1995), the Bain Report (1995), the Re-Organisation Plan (1996), the Finlay Report (1997), Ernst and Young Report (1998), and the Murphy and Hynes Report (1999). Our specific interest is to see the recommendations of each Report/Plan listed, which were approved by the Board and what stage implementation has been reached with regard to those which received Board approval. (*)
5. The McNamara Report (1999) (+)
6. Information on meetings between IBTS and the SHB since January 1999 in terms of who initiated them (*+)
7. Copies of letters written to IBTS in 1999 2000 from Munster clinicians (+)
8. Detailed information sufficient to enable the international team to understand how the original estimated cost of the new Cork Centre was calculated to be £3.5million in January 1998 and how it rose to £12.0million in July 1999. (*)
9. Dublin Centre annual blood collection figures (per 1000 population served) from 1992-2001 (*)
10. Cork Centre annual blood collection figures (per 1000 population served) from 1992 -2001(*)
11. Dublin Centre annual issue of platelet concentrates (per 1000 population served) from 1992-2001 (*)
12. Cork Centre annual issue of platelet concentrates (per 1000 population served) from 1992-2001 (*)
13. Annual IBTS Reports from 1994 (*)
14. CVs and Job Descriptions of CEO, Deputy CEO, NMD, Deputy NMD, Quality Assurance Manager, Donation Testing Manager, Personnel Manager Finance Manager and IT Manager in Dublin (*)
15. As above (14) but where relevant for the Cork Centre (*)

16. List of all the BTTB/IBTS CEOs, and NMDs since 1992, with periods in office. (*)
17. List of BTTB/IBTS Chairmen and Board Members since 1992, with periods in office. (*). (Please also provide information of those Chairmen and Board Members who resigned).
18. List of names of DOH&C officials on BTTB/IBTS Board since 1992, with periods in office (*)
19. Information on meetings between senior officials of the Irish Medicines Board and senior IBTS managers and/or Board Chairmen. (*)
20. List of IBTS medical consultants and their membership of IBTS committees and as observers on committees outside Ireland (and periods served since 1992) (*)
21. Terms of reference and current membership (include place or work) of all IBTS committees (including, PCR Implementation Committee, Consultants' Committee, Haemovigilance Committee, Business Continuity Planning Committee, Hospital Liaison Committee, Human Resources Management Committee, Finance Committee, Purchasing and Inventory Committee, IT Committee, National HCV Expert Committee, National Users Group, Executive Management Group, and Management group (*)
22. Copies of all IMB inspection reports from the Dublin and Cork Centres (*)
23. Copies of all UK Medicines Control Agency Reports on the Dublin and Cork Centres (*)
24. Copies of relevant (to this Review) of IBTS Board Minutes (and papers submitted to the Board) in 1999 (*)
25. Copy of IBTS Board's response to the conclusions of the Oireachtas Committee's proceedings of 2000 (*)
26. DOH and C's Blood Policy Unit's response to the conclusions of the Oireachtas Committee's proceedings of 2000 (#)
27. List of Secretaries to the BTTB/IBTS Board since 1992
28. Information on any regulations/code of practice with regard to the appointment public sector staff in Ireland and comments on these with regard to the IBTS.
29. Information on the current research work throughout the IBTS, including a list of peer reviewed published papers in the period 1996 – 2001 and the number and grade of FTE staff currently engaged in research

John Cash

June 2002

