Joint Trade Union Response to the Department of Health

National Decontamination Strategy

January 2006

The unions AMICUS, GMB and UNISON represent the majority of staff employed in the NHS providing decontamination and sterile services. This is their response to the proposals contained within the Department of Health (DH) National Decontamination Strategy for England. The full DH strategy document can be found on the DH website at *http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy*.

Introduction

The DH decontamination strategy was determined through processes that totally excluded the NHS staff trade unions. The industrial relations issues raised by this failure to consult and by the staffing implications of the strategy recommendations are being dealt with in other forums. This document focuses on the technical aspects of the strategy that are cause for concern.

The strategy was summarised by the DoH in March 2004 as follows:

IMPROVING DECONTAMINATION IN THE NHS IN ENGLAND

1. The Committee advising the Department of Health on vCJD (SEAC) has advised that effective decontamination of surgical instruments is key in preventing the person to person spread of the disease. A survey of sterile supply departments (SSDs) showed that much needed to be done.

2. The Department has already spent some £120m on replacing equipment, improving working conditions in existing SSDs and buying new instruments to facilitate centralisation. In order to sustain the improvement and enable the NHS to meet the requirements of European legislation on the reprocessing of instruments, many of the existing SSDs need to be replaced completely.

3. All health systems in the NHS need to have access to decontamination facilities which:

- comply with the highest current technical standards;
- have in place plans to anticipate changes in demand and react to improvements in technology;
- are subject to rigorous inspection and registration regimes.

4. The strategy for improving decontamination launched last June, set out our plans for moving forward. There will continue to be a mixed economy for providing decontamination services to the NHS. Local needs and facilities will determine the way in which the service is provided locally but all will be provided to the same nationally agreed set of standards.

Services will be provided as a result of:

- Intermediate investment - a small number of developments to meet the national standards may be funded either from central funds or from those available within local health systems. They will require long term capital commitment locally to maintain a sustainable solution.
- Private Finance Initiative - there are a number of major PFI schemes for new hospital developments that include decontamination services within the overall scope of the project.

- Outsourced service - by private contractors through market testing. There are contracts already in place between NHS Trusts and private contractors.
- Contractual Joint Venture - a new style of local partnership between the NHS and private contractors to provide decontamination services.

5. The contractual joint venture is to be preferred to the market testing/outsourcing approach because the nature of the relationship is cooperative rather than adversarial.

6. Those local health systems joining a contractual joint venture will have the continuing benefit of the private sector's resources and expertise. Their benefits will also include:

- no capital cost, either now or in the future
- transfer of risks to the private sector, including those associated with product liability, technology, fluctuations in demand, funding,
- management and compliance with standards
- revenue benefits of scale and efficiency

7. We believe that there might be of the order of 120 centres nationally, instead of over 300 at present. The final number will be determined by the aggregated decisions of SHAs, PCTs and NHS Trusts over how they wish to group their services.

General Points

- These are not PFI projects – it is a support service partnership model, although we are following the PFI guidance with respect to staff.
- They are local projects, managed locally, with local teams taking the decisions
- We do not know where the new centres are to be located, or how many there will be for each project – these are aspects of the bids to be evaluated locally – but they are unlikely to be on NHS sites
- Effective tracking and tracing systems will be introduced as the result of these new developments
- With the help of professional organisations, we have developed a new training package for all staff involved with decontamination. This will lead to recognised qualifications

March 2004

The Trade UNION Response - Technical Issues

The following response was compiled from comments and evidence received from our members working in Sterile Service departments across the UK.

Contractual Joint Ventures.

The favoured joint venture approach given in the DH summary above ignores a number of flaws in the rationale given for arriving at this conclusion. It also fails to highlight risks in the application of decontamination and sterile services through their preferred method, and the ongoing measures that will be used to monitor performance. While some of these risks are identified in the full strategy document numbering some 200 pages it is noted that the scale of these risks are often underscored especially where no meaningful solution has been identified.

The following is an analysis of all the aspects of the strategy in sequence as they appear in the full report.

Introduction, Section 2.1, page 3 - Project Scope:
The Decontamination Organisational Review Information System (DORIS) is a web based software application in support of NHS organisations to enable them to summarise their Process Assessment Tool (PAT) data whilst providing a classification of their current practices. It supposedly allows organisations to model their existing and future service provision for decontamination and allows the production of board reports, automatically inserting data from assessments undertaken.

However DORIS returns are unlikely to enable accurate performance management of the service, as DORIS was not designed or intended for such a purpose. No alternative or additional system has been proposed.

It is stated (3rd Bullet point) that best practice will be encouraged through a payment and performance mechanism. There are concerns that where the Service Provider has a vested interest in a particular brand/make of instrument or equipment, that decontamination matters, related to whether or not the design will permit safe decontamination, may be set aside for commercial reasons. No mechanism has been proposed to monitor and if necessary address this.

2.1 page 4 – Primary Care & Private Sector

Whilst it is recognised that the Primary Care Sector must comply with the same Standards as the Acute Sector, no details are given of how the allowance has been calculated for migration of decontamination currently carried out in Primary Care facilities to the reconfigured centralised facilities. (Refer to 6.3.6).

To exclude the private sector from the scope of the strategy is a major flaw, especially bearing in mind recent worrying pronouncements made by the new secretary of state for Health of increasing private sector involvement in the NHS. The statement in **section 2.2.3, page 5 Decontamination Process** that an "*holistic view needs to be taken*" seems somewhat at odds with such an exclusion.

2.2.7, page 10 – NHS Decontamination Business Case

The introduction of single-use tonsillectomy instruments was a response by government to mitigate the "*theoretical*" risk of transmission of vCJD by iatrogenic means during tonsillectomy (See Press release 2001/0623); not as an interim measure whilst decontamination standards were improved. The single-use policy was reversed because actual harm occurred through use of allegedly poor quality single-use instruments, and not because improved decontamination facilities had negated the previously described theoretical risk.

Certain reusable instruments used in tonsillectomy, and indeed many other procedures, are not easily decontaminated due to their complex construction. Even with state-of-the-art decontamination facilities and equipment this will not change significantly and still leaves the door open for potential risks of cross infection. The matter requires manufacturers to re-engineer these difficult to clean devices to render then easier to clean and inspect. Or indeed design the complex features as "bolt-on" single-use components.

This matter demonstrates that decisions on decontamination risk management, taken at macro level, do not always consider lateral issues from an operational perspective.

Page 11 - The Scottish Experience:

The Scottish Experience does provide a useful source of intelligence. However there has been a great deal of adverse publicity in the Scottish press focusing on service failures. The root causes of non-conformance, for example large back-logs of equipment (3/4 days), insufficient equipment to deal with waiting list initiatives and premature merging/centralisation of services, do not appear to have been considered as lessons to be learnt. This is especially relevant in determining the strategic solution for England, bearing in mind that "*the NHS in England is a more complex entity"*

There is currently no national model or suggested framework proposed by the strategy for systematic planning, control and management of theatre throughput. Without this it is difficult to be confident of any consistent, let alone successful application of any such national strategy.

The Scottish Experience tells us how vital it is to test and trial such fundamental changes before any widespread implementation. It begs the question as to why the strategy is not being piloted first.

3.2, page 17 - The New Technical Environment:

It is stated in the bottom paragraph that:

The service provider will be required as part of his responsibilities to segregate out of the process any modified and/or non-CE compliant instruments."

The current haste with which the strategy is being pursued, without any proper prior assessment of the potential financial impact of such a process is an unnecessary risk. The cost implications to the NHS will be difficult to determine but it will be committed to pay for it. In any event there should be some form of national external verification to determine the legitimacy and probity of any segregation.

3.2, page 18 - The New Technical Environment:
Whilst a standard maximum turnaround time of 24 hours is quoted, such is the lack of detail provided by the strategy that it has to be presumed that this is timed commencing from receipt of contaminated product into the decontamination facility. It also assumes optimum resources are in place, including adequate instrumentation. Experience would suggest however that there is insufficient detail in the process (and thus plenty of ready-made loopholes) to make these turn around target times meaningless. One only has to look at the practice employed in some struggling A&E's of keeping non-critical patients waiting outside casualty departments in ambulances to delay official admission and thus stop the clock ticking to envisage how even such a generous time period as 24 hours could be stretched.

A key factor in contract control at local level will be the robust management of Trust Waiting List Initiatives. Historically, government and senior hospital management has little concept of the consequences to safe reprocessing caused by sudden upturns in complex surgery. This manifests in demands to reduce instrument turnaround times, which not surprisingly increases the likelihood of non-conformances and the consequential risks.

3.2 page 19 - Primary Care:
It is agreed that there is significant need to mitigate risks of Healthcare Associated Infection in Primary Care through improved decontamination. However there are serious concerns that if decontamination equipment e.g. bench-top sterilisers or washer disinfectors are purchased and placed in PCT's (Primary Care Trusts), that without adequate training programmes and policing current poor practice may not only continue but be exacerbated. As of yet no detailed national processes to ensure safe implementation, ongoing training and external auditing of primary care facilities has been proposed.

Further, the impact of recent proposals for reconfiguration of PCT's needs to be taken into proper consideration. It is suggested that the strategy is not applied to PCT's until this whole area has been thoroughly re-examined.

4.2.2, page 27 - Health and Safety:
The strategy documents fails to explain how manual washing processes will be nationally validated and monitored.

4.2.4 page 29 - Environment:
Pooling and sharing of instrument sets may be required to mitigate spiraling instrument costs. However sets must not be split up otherwise traceability will be lost, which could lead to adverse consequences. If this aspect has been considered in the model for predicting the uplift in instrumentation how was it calculated? (5.2.2, Constraints, Page 37, also refers)

5.0, page 33 - Options Appraisal:
We understand that the 120 centres quoted comprise the existing seventy (70) MDD Compliant facilities plus fifty (50) "super-centres". How was this figure arrived at with such poor data available nationally on product throughput? (See Risk Assessment, Item G, Page 199).

5.2.2 page 37 - Constraints:

Current instrument stocks plus 20% (max). It is difficult to see how this conclusion was reached considering 6.3.6, Scalability, quotes a potential 122% increase in activity.

Current staff levels (as a maximum). This is a potentially flawed assumption, as it appears to assume current levels are adequate and not to take into consideration uplift in throughput from local decontamination.

5.2.3, page 38 - Constraints

Why were options 8 and 9 not rejected on the grounds of:

- Likely clinical need for instruments within flexible, including immediate return times;
- Likely inability of current process to create step change in numbers, types and procurement process of instruments;
- Likely inability of current process to affect number, types and procurement of staff significantly.

Section 5.3.1, page 41 - Key Revenue Effects:

Point 2 – If this item identifies that additional staff are required, why is this not acknowledge at 5.2.2?

Section 6.2.2, page 50 - Activity Projections:

It is a source of concern that the final number of facilities is structured around such large activity assumptions. It is not detailed what capacity has been included to allow for error in these assumptions.

6.2.3, page 50 - Other Generic Assumptions:

For certain types of instrumentation, such as Lap.Chole. and Arthroscopic, this needs to be three to five years, not ten.

If the option of 50 centres is applied there may well be high levels of redundancy as it is unlikely that redundant technicians will be easily absorbed into other hospital departments without a structured retraining programme.

6.2.4 page 51 - Summary of Option Specific Assumptions:

Once again there are concerns about the magnitude of these assumptions and adequate provision for margin of error in the linkages.

6.2.9, page 54 - Analysis of ERIC (Estates Returns Information Collection) Data:

In order to adequately analyse data on trays; it would be useful if criteria could be published which would form the national definition of what constitutes a tray e.g. minimum number of instruments.

6.3.1, page 56 - The Consequent HR Issues:

It is believed that the proportion of technicians who will transfer into enlarged departments may be small. This has been raised in the Risk Assessment, Item E, Page 199 and given a Low probability. We would suggest that this should be at least Medium and consideration is given to consequences of drift to High. No

contingency plan has been developed to mitigate the consequences of insufficient skilled technicians being available, and the consequent impact on service availability.

6.3.3, page 57 - Nature of the Service:

Increasingly complex technology and the supporting I.T. infrastructure employed to sustain the evolving science of decontamination need not necessarily correlate with the view that such advances mean a hospital should regard this progression as “non core activity”. Any more than advances in diagnostic technologies should be viewed in this way. Indeed moving services off-site could trigger consequences previously alluded to in our response to 6.3.1.

As medicine and the delivery of healthcare become more technically dependent, then surely the healthcare provider has a vested interest in retaining control.

6.3.6, page 58 - Scalability:

It is recognised in the Risk Assessment, Page 199, Item G, that the continued use of inaccurate information is a High Risk. This does not support the conclusion that Options 8 and 9 should be preferred.

6.4.1, page 59 - Do Minimum Capital Modelling:

Instrumentation for Red, Amber and Green sites is quoted at 100% requirement. Assuming the criteria are similar, why is it believed that only a 20% requirement is needed at 5.2.2?

6.4.2 page 61 - National Capital Investment Requirements:

The accuracy of information that is held by each Trust on the circulating capital value of instrumentation is assumed to be poor. In such circumstances it is essential that the formula detailing how the figure of £74.7 million for instruments against each option was calculated including margin for error.

6.5.1, page 64 - Supporting Evidence:

It is inappropriate to list these three “*factors*” as justification for stand-alone specialist services. Firstly they are not based on facts at all but on the biased, unsubstantiated and financially motivated “feedback” of leading private sector providers.

The statement at the bottom of page 64 states that:

*“This all reflects the **fact** that involvement of the private sector ensures that the profile of the service is significantly enhanced as a stand alone specialist service as compared with a support service within Trusts.”*

It is astonishing that a subjective opinion, which is not supported by any empirical or other evidence, is quoted as a fact. It calls into question the probity and integrity of the document and it’s authors.

Further, it is an insult to the many staff who over the years have striven, with little support locally or centrally, to provide and maintain safe decontamination services within the NHS.

Sterile Service managers and technicians take immense pride in belonging to and being part of the wider hospital team and the NHS. This statement

illustrates how such an important asset of in-house sterile service provision is completely ignored in a somewhat desperate and amateurish attempt to provide clinical justification for outsourcing sterile services when none exists.

6.6.1 page 66 - Performance Related System:

PAT (Process Assessment Tool) 16 refers to reducing items in the system requiring fast tracking in four hours or less. Fast tracking should not even be considered within the context of the strategic objectives other than in exceptional circumstances to mitigate potentially life-threatening situations.

What is meant by "migration between trays" should be clarified. (Should this relate to instrument movement, please refer to our response to 4.2.4).

Basis of termination – This could be a potentially difficult area. Admissions departments when booking patients for surgery do not always take account of instrument supplies or turnaround times. It is recognised that there will be a requirement for some fast tracking due to instrument levels and available investment capital. Fast Tracking must still be undertaken to the required standards, and will be defined in local output specifications based upon reprocessing time and logistics currently assumed to be approx. 5 hours.

7.1.2 page 69 – Critical Objectives

5. *The final solution must demonstrate VFM and be able to compete on "lowest price" basis – being cheaper than other solutions.*

We fear that this is a potentially dangerous premise to award contracts of such complexity and patient care criticality. Value for money is always desirable but achieving quality is dependent on many factors. We would suggest that the final solution must demonstrate achievement against quality indicators as a priority before VFM.

7.4.8 page 80 - Interface with the Pathfinder Project:

It is believed that there is not sufficient time available to learn from this project. The timing of the following waves is too soon; therefore operational problems that will only be apparent after the contract is up and running, and the solutions deployed may be lost or too late to prevent adverse outcomes in facilities that open later. Again this clearly illustrates the need for a pilot.

7.5.1 page 81 - Future Work - National/Local:

Cluster Groups and local opinion was sought originally. However, it seems if this was unhelpful in arriving at what looks like a pre-determined outcome it was ignored and those responsible marginalised. Proper, ongoing consultation with all the technical interest groups has not taken place, perhaps in an attempt to sweep the most fundamental and obvious flaws under the carpet.

7.5.2 – page 81 - Procurement Responsibilities:

1st Point – A weighting of priorities of defined areas was mentioned as the basis for determining the number of procurements per wave, but no detail was given as to weighting composition or order priority. A copy of the weighting structure should be provided for analysis.

7.6 page 82 – Conclusions:

1st Point – It is assumed that this comment refers to local contracts, as and when tender requirements are being collated. Again we wish it to be made known that local opinion from interested parties were excluded from participation in developing area strategies as part of informing the national solution.

2nd Point – There is no reason properly funded in-house provision cannot deliver MDD standards across the NHS on a long term sustainable basis – indeed they have already being doing this for many years.

3rd Point – There is little evidence to suggest the "competitive market" will provide the best VFM case apart from the unsubstantiated and obviously biased opinion. See also our comments on 6.5.1 page 8 above.

4th Point – This is an extremely brave statement when considering the diversity of the existing structures and the potential difficulties when merging not only equipment but cultures. Successful replication may take longer than perhaps envisaged. No slippage to cover these issues appears to have been factored into the deadline for completion of the strategy.

8.2.2 page 85 - Options for Implementation:

2nd Paragraph – If this refers to the Registration Scheme, then the statement should have included that ISSM, ICNA and NATN representatives have played and are playing a role in the formulation of the document.

8.2.5 page 92 - Procurement Process:

It is a concern that the Secretary of State could be deprived of a more fulsome report as key stakeholders have not been given a fair hearing as to their concerns around safeguarding public health whilst maintaining government targets.

Cross-refers to:

- 7.5.1, Page 81, Future Work, National/Local
- 7.6, Page 82, Conclusions
- Roll Out Programme, Page 97, 6th Point.

9.1 page 99 - National Decontamination Resource Plan - Bradford/Leeds Decontamination – Service Procurement

- Sterile services input should be at strategic level. The present national situation is a consequence of the failure to understand the significance of poor decontamination facilities and services at a sufficiently high level.
- From the diagram, it is not clear at which stage the clinicians and theatre managers are included within the procurement process.
- Again, it is not clear where local risk management is represented within this structure.

10.0 page 107 - Conclusions and Recommendations:

The risk rating referred to in this paragraph as “low” is not compatible with the risk assessment on page 198.

Whilst consultation took place on technical matters associated with the Output Specification for Decontamination Services, there is no reference to technical consultation taking place on the impact of reducing the current number of decontamination facilities to those of the proposed strategic solution. No data or methodology is given to justify assigning it’s low risk rating.

Appendix 3 page 161 - Contingency and Disaster Management:

Whilst emphasis has been placed on these aspects from the perspective of local contracts, there is no mention of a strategic analysis carried out to validate the national strategy. In other words, where is it stated that the solution proposed will be able to deliver achievable and sustainable contingency and disaster management outcomes, to a suitable and sufficient national standard. This is especially relevant in view of recent events in London.

Summary of Trade Union Concerns

i. Staff trade unions and existing independent technical expertise within the NHS have been excluded from the processes through which the strategy has been determined, including the National Project Team. However over 50% of the members of the National Project Team are from the private sector.
ii. Minimal evidence of existing successful in house services or potential in-house solutions has been sought or considered. The role that specialised in-house sterile services staff also play in identifying damaged or impaired surgical instruments and other equipment has been ignored.
iii. The scoring process and methodology that determines preferred options and will monitor performance is suspect. This includes “***the need to attract private sector providers***” as a fundamental criteria to be met, the playing down or ignoring of known risks of private sector provision and exaggeration of risks relating to in-house provision.
iv. Major problems and risks with the proposed off-site services have been ignored or played down. These include issues around the decontamination and sterilisation of non-portable equipment such as endoscopes and the vulnerability of delicate surgical instruments in transport.
v. Unusually, piloting the strategy is not considered an option. Wholesale implementation across England without the benefit of hindsight a pilot brings is an unnecessary risk from a clinical and methodological perspective. However if the main aim is to privatise, it is desirable to get it done as soon as possible, especially before the harmful effects are apparent and it is too late to undo the damage.
vi. Little consideration has been given to actual evidence from regions / countries where centralised private sector provision of decontamination and sterilisation services is already in place.
vii. Unsubstantiated statements from the private sector are treated as fact and as if there is no ulterior motive behind them.

Trade Union Conclusion

The joint unions believe that the evidence is incontrovertible in proving that privatisation and not patient care is the driving force behind the decontamination strategy. The large number of private sector interests involved in the project board and the exclusion of independent staff representatives and independent technical expertise have fundamentally compromised any objectivity.

We believe that the major potential risks in the strategy and the undue haste with which it is being pursued and implemented across England far outweigh the supposed advantages.

Privatisation of hospital cleaning services has resulted in a 50% cut in cleaning staff and a subsequent massive deterioration in NHS cleaning standards and perhaps unsurprisingly a corresponding increase in MRSA and HAI's. The Government continue to refuse to acknowledge any link or even a potential link. The lessons to be learnt here and in the Scottish experience are being ignored, as they do not fit with the privatisation agenda.

From a technical perspective the joint unions call on the Government to cease further implementation of the Strategy beyond the Pathfinder project to enable proper consideration by an unbiased and impartial body of the many concerns raised above and elsewhere. Failure to do so will run a serious risk of adding to the current MRSA & HAI crisis and will further call into question this Government's stated aim of putting patient care at the top of it's Health policy priorities.

AMICUS, GMB & UNISON

January 2006.