Worcestershire Acute Hospitals NHS Trust NHS Pathology

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1 PURPOSE AND SCOPE

This policy details the procedures to be employed for the packaging, handling and transport of dangerous goods, including specimens, to and from WAH NHS Trust Pathology Departments. This is to ensure compliance with current legislation for the Transport of dangerous goods by road and rail

The UK Regulations covering the carriage of dangerous goods by road and rail are derived from European Directives (ADR (road) and RID (rail)), which in turn implement international model agreements governing the transport of dangerous goods.

The requirements for air transport are not covered in this document.

2 RESPONSIBILITY

All laboratory staff must comply with the regulations when sending specimens or cultures on the road.

When transporting specimens, senders must ensure that the specimens arrive within a timeframe appropriate to the nature of the requested examinations and that the specimens are protected from deterioration.

3 HAZARDS AND SAFETY PRECAUTIONS

Biological agents, or materials that contain or may contain them, are allocated to UN Division 6.2- Infectious substances. This Division includes biological products, cultures, genetically modified organisms and medical/clinical waste

Laboratories that accept specimens from outside their own site must ensure that anyone intending to send specimens knows where to get the standard containers, labels and transport boxes. They should also provide written instructions on when and how to use them. It should be noted that the sender is responsible for the specimen/s until it arrives at the recipient centre.

The hospital laboratory is likely to receive specimens and cultures from two broad groups.

- Diagnostic specimens from GP surgeries and Local Authority Environmental Health Departments.
- Diagnostic specimens sent from or via another hospital laboratory, hospital or commercial organisation.

Specimens that are known to present or are suspected of presenting a danger of infection to laboratory staff **(or Emergency workers in an accident situation)** must be identified so that they can be processed separately from other work, using special precautions. Consequently, it is necessary to have a system of hazard labelling to enable staff to take the appropriate precautions.

The principle of matching safety precautions to the level of hazard of the pathogen being handled is fundamental in the Advisory Committee on Dangerous Pathogens (ACDP) report Categorisation of pathogens according to hazard and categories of containment (ACDP HMSO 1995).

It is important to note that in diagnostic pathology there will be a number of specimens that present a risk of infection but cannot be identified, either because a diagnosis has yet to be determined or because such a hazard (eg Hepatitis B) is present in the carrier state. It is therefore essential to ensure that universal safety precautions are applied in the collection, packaging, handling and transport of specimens.

If a specimen is known or is suspected of presenting an infection hazard it is important to ensure that staff can identify the specimen and are given sufficient information to enable them to take appropriate precautions. Consequently it is necessary to employ a system of hazard labelling which meets both those needs. Specimens from the following patient groups should be identified as a “DANGER OF INFECTION”.

- Hepatitis B and C, HIV
- Anthrax*
- Intravenous drug abuser
- Known/suspected “Prion” disease*
- Cryptococcosis*
- Diphtheria*
- Tuberculosis
- Typhoid*

- SARS*

In addition there are a number of imported diseases, which may occasionally be suspected, including:

- Histoplasmosis*
- Plague*
- Rabies*

*Where patients are suspected of being infected with an organism marked with an asterix from the above list then the users have been asked to contact the Consultant Microbiologist before sending any specimens.

If viral haemorrhagic fever eg Lassa, Ebola, Marburg is suspected, patients are not normally admitted to hospital without prior discussion with a Consultant Microbiologist.

Incidents during transportation that may affect the quality of the specimen or the safety of personnel must be reported using the Trust incident reporting procedure.

4 TRAINING

All personnel involved in the packaging, handling and dispatch of specimens will receive comprehensive training and appropriate records maintained.

5 SPECIMEN CONTAINERS

Only CE marked containers supplied by the Worcestershire Acute Hospitals NHS Trust Pathology Departments should be used, except in those circumstances where specimens are to be sent to another laboratory outside the Trust and the receiving laboratory has provided a container suitable for their use.
The person who sends the specimen must ensure that the container used is CE marked, properly closed and not externally contaminated by the contents.

Risk management necessitates that all breakages and leakages are monitored, and a record kept, to remove or reduce the risk of infection such events would present.

6 SPECIMEN TRANSPORT BAGS

Specimen containers (except when being packaged in accordance with PI650) should be placed in the transparent plastic transport bags which are either an integral part of the request form or can be sealed and attached to the order communications printed forms. The bags contain absorbent material for absorbing any specimen leakage.

Specimen transport bags, marsupial or attached to form must be sealed by means of the integral sealing strip.

7 LEAKING SPECIMENS

See local procedures for dealing with biological spillages

8 TRANSPORT OF SPECIMENS BY ROAD OR RAIL

8.1 DEFINITIONS (from ADR)

8.1.1 Infectious substance

Infectious substances are substances that are known or are reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria,

viruses, ricketsia, parasites, fungi) and other agents such as prions which can cause disease in humans or animals.

8.1.2 Biological Products

Biological products are those products derived from living organisms which are manufactured in accordance with the requirements of appropriate national authorities (in the UK: the Department of Health and the Medicines and Healthcare Regulatory Authority), which may have special licensing requirements, and are used in either prevention, treatment or diagnosis of disease in humans or animals or for related development, experimental or investigational purposes. They include (but are not limited to) finished or unfinished products such as vaccines.

8.1.3 Cultures

Cultures (laboratory stocks) are the result of processes by which pathogens are amplified or propagated in order to generate high concentrations; thereby increasing the risk of infection should exposure occur.

8.2 TRANSPORT OF INFECTIOUS MATERIAL

There are 4 steps involved in the safe transport of infectious material. These are:

- classification;
- packaging;
- labelling; and
- transporting.

8.2.1 CLASSIFICATION

Infectious substances are divided into the following categories:

- Category A: an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life threatening or fatal disease to humans or animals. This includes all agents classified as HG4 in the Approved List of biological agents, many HG3 agents and two HG2 agents (Clostridium botulinum and poliovirus). Those that can cause disease in humans or animals are assigned to UN 2814. Exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.
- Category B: any infectious substance that does not meet the criteria for inclusion in Category A. These are assigned to UN 3373, with the exception of cultures, which are assigned UN 2814. Currently cultures of *Mycobacterium tuberculosis, Escherichia coli* 0157 and *Shigella dysenteriae type 1* that are intended for diagnostic or clinical purposes can be transported as Category B UN 3373.

Specimens such as blood, tissue, excreta, secreta etc collected from humans or animals are considered, as a minimum, Category B infectious substances. For example, samples from patients where there is no reason to suspect that they are suffering from a severe infectious disease. However, if there is evidence to suggest otherwise, e.g. on the basis of known medical history, local endemic conditions or professional judgement concerning the circumstances of the source material, then such material should be assigned to Category A.

The following substances are not subject to the provisions of the regulations:

- non-pathogenic micro-organisms (for either humans or animals);
- blood and blood components for transfusion or transplant and tissues or organs for use in transplants;

- samples (non-human/animal derived) where there is only a low probability of infectious substances being present, e.g. food screening samples, environmental samples (water, soil etc) or else material (including material derived from human or animal sources) that has been treated to inactivate any infectious substances;
- biological products that have been manufactured and packaged in accordance with MHRA/DH requirements, and are carried for the purposes of final packaging and distribution;

8.2.2 PACKAGING

Category A infectious substances (UN 2814) should be packed using Packaging Instruction 620 (PI620). This packaging must meet UN performance requirements as shown by design type testing. These are known as UN-type approved packaging for Class 6.2 substances and they are certified and marked accordingly. Dimensions of outer package must be at least 100 mm on two dimensions; minimum size of diamond must be 50 mm on each side.

Substances assigned to UN 3373 should be packaged in accordance with PI650. Packaging for Category B infectious substances, packed using PI650, must be capable of passing a 1.2 m drop test. Trust Courier transport boxes have been tested and comply with this test
If you send infectious substances packaged and labelled in accordance with PI650, no other requirements of the legislation apply-(with the exception of the appropriate labels below)

8.2.3 LABELLING

Packages containing infectious substances should be marked with:

- The proper shipping name, e.g. “Biological Substance Category A”. (UN2814) or Biological Substance Category B (UN3373) (It is no longer necessary to show the technical name, i.e. the name of the micro-organism, on the package but the proper shipping name should be supplemented with the technical name in the accompanying transport documentation); with the appropriate UN number (e.g. for “Biological Substances Category A” this would be UN 2814); and
- The appropriate warning label. A Transport Document is NOT required for UN3373 items.

UN3373 Biological Substance Category B

UN2814 Infectious substance affecting humans

- For frozen specimens being transported in an overpack, any certificated markings must be visible through the overpack or repeated on the overpack itself. The packaging should also be marked to indicate any subsidiary hazards.

8.2.4 TRANSPORT

The regulatory requirements only apply to transport of infectious material off site, however on-site transport still needs to be carried out in a safe manner.

In general samples sent using UN3373 can normally be sent via the postal service.

UN 2814 will require specialist courier services and must not be sent via Trust transport or postal services.

8.3 SPECIMEN TRANSPORT VIA THE ROYAL MAIL

Packaging Instruction 650 (P650) must be complied with. Packaging Instruction 650 is intended to provide all the information necessary to prepare and transport safely a consignment of diagnostic specimens. Among the requirements are:

- The packaging must be of good quality capable of passing a 1.2.m drop test.
- The package must be marked with "UN3373" this will appear inside a diamond symbol with a minimum size of 50mm sides. This must be clearly visible and legible. The lines of the diamond must be at least 2mm **and** the letters/numbers at least 6mm high.

In addition:

- **For liquid substances**:
  - The primary receptacle(s) shall be leakproof.
  - The secondary packaging shall be leakproof.
  - If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.
  - Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substances will not compromise the integrity of the cushioning material or of the outer packaging.

- **For solid substances**:
  - The primary receptacle(s) shall be siftproof.
  - The secondary packaging shall be siftproof.
  - If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.

- **Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen**:
  - When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations shall be met. When used, ice or dry ice shall be placed outside the secondary packagings or in the outside packaging or an overpack. Interior supports shall be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack shall be leakproof. If carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up pressure that could rupture the packagings and shall be marked "Carbon dioxide, solid" or "Dry ice".
  - The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures that could result if refrigeration were lost.

8.4 TRANSPORT USING A TAXI / COURIERS

Category A (UN2814 Infectious substances affecting humans) must not be sent via Taxi or Courier unless the Courier is approved for the carriage of Category A substances, in which case specimens must be packaged according to PI620 UN 2814 (ADR). Boxes and packing instructions will be provided by the specialist courier company. These packages may be printed "in accordance with IATA Packing Instruction 602"-this is the air-freight equivalent of ADR PI620

Specimens transported by taxi or general courier must be packaged according to PI650 (as above)

Staff employed by the Trusts as courier drivers should be offered Hepatitis B vaccination and trained to deal with spillages and breakages.

8.5 SPECIMEN TRANSPORT TO PATHOLOGY FROM OUTSIDE THE HOSPITAL VIA HOSPITAL TRANSPORT

Laboratories, which accept specimens from off site, must ensure that the person/s intending to send specimens knows where to get the standard containers, labels and transport containers. Written instructions on when and how to use them must also be provided.

Specimens must be transported in dedicated secure transport containers with lids that fasten to close. The seal on the transport boxes must be sufficiently robust to prevent leakage of the contents to the external environment. Each box must bear the UN3373 warning label (see 8.2.3) stating "Biological Substance Category B" UN 3373 - This box must not be opened and/or tampered with'.

8.6 SPECIMEN TRANSPORT TO PATHOLOGY FROM WITHIN THE SAME HOSPITAL SITE AS PATHOLOGY

Specimen containers should be transported in the rigid transport containers provided.

Transport containers must not be used for any purpose other than for carrying specimens.

The transport containers must be made of a smooth impervious material such as plastic or metal, which can be disinfected and cleaned easily, and must retain liquid in the event of leakage of a specimen.

The containers should be disinfected or autoclaved whenever contaminated in accordance with the Microbiology Department biological spills procedure. The transport containers must be able to withstand being autoclaved in the event of gross contamination. Records must be maintained.

Large specimen containers must be deposited in pathology reception the correct way up in order to reduce the risk of leakage.

8.7 SPECIMENS AND CONTAINERS CONTAINING HAZARDOUS SUBSTANCES (other than biological agents)

If there is a hazardous reagent in the container, an appropriate COSHH hazard warning label must be attached.

9 AUDIT

This policy is subject to regular audit as directed by the Pathology Quality and Accreditation Group in order to determine its effectiveness by comparing compliance with the standards.

10 REFERENCES

- Biological Agents: Managing the risks in laboratories and healthcare premises (HSE 2005)
- The Approved List of Biological Agents HSE 2004HSAC: “Safe working and the prevention of infection in clinical laboratories and similar facilities” (second edition 2003)
- HSE Infectious Substances, Clinical Waste and Diagnostic Specimens.