

MDA DB 9601
APRIL 1996

*Latex Sensitisation in
the Health Care Setting*

(Use of Latex Gloves)

DEVICE BULLETIN 9601 APRIL 1996

ACKNOWLEDGEMENTS

This Device Bulletin was produced by Miss Wendy O'Gilvie.

The Medical Devices Agency (MDA) of the Department of Health would like to thank all those who have contributed to this document, in particular.

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APPENDIX A

This Device Bulletin is designed to increase awareness of the potential problems posed by latex sensitisation within the health care setting, with particular emphasis on the use of latex gloves.

It aims to:-

- advise health care personnel of the increase in reports of the incidence of latex allergy.

see: Reactions to latex (Section 3)

Prevalence of latex allergy (Section 4)

- emphasise the importance of identification of latex sensitisation in staff and in patients.

see: Diagnosis of Latex and Rubber Allergies (Section 6)
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- highlight the importance of incorporating questions regarding latex reactions into all admission records as part of the patients' allergic history.

see: Management of Sensitised Patients (Section 8)

- provide information on which to base specifications for latex and other gloves used in the health care setting.

see: Glove Quality and Selection (Section 9)

- advise purchasers of the importance of obtaining information on maximum extractable protein levels, in order to make rational choices when buying gloves.

see: Glove Quality and Selection (Section 9)

- emphasise the importance of making adequate provision for a safe working environment, by suggesting alternatives to latex.

see: Management of Sensitised Health Care Workers (Section 7)

1. INTRODUCTION

Many countries, including the UK, have experienced an increase in latex sensitisation due to general exposure to latex, in the form of medical and non-medical products.

However, there is no current evidence which indicates that there is an increase in prevalence within exposed populations.

In recent years concern among health care workers and the general public, with regard to the hazards and modes of transmission of various pathogens, has led to the increased use of barriers against infection, with gloves forming a primary method of protection.

Most medical gloves are made of natural rubber latex. It is a durable, flexible material which affords a high degree of protection from many microorganisms.

The use of natural rubber latex is not confined to the manufacture of gloves but is also used to produce a range of medical devices including catheters, condoms, elasticated bandages and wound drains. It should be noted that the presence of latex as a constituent of a device may not always be readily obvious.

As the frequency and duration of the use of latex products has increased, the emergence of latex sensitisation has been identified as a problem for some individuals, leading to a variety of allergic reactions ranging from urticaria to rare occurrences of anaphylactic shock.

2. WHAT IS NATURAL RUBBER LATEX?

Natural latex is produced by the *Hevea brasiliensis* tree. The cloudy white liquid latex is collected by 'tapping' the tree, it then undergoes a complex coagulation process, involving the addition of sulphur and organic chemicals (e.g. accelerators). This process provides the strength, elasticity and dimensional stability characteristic of many rubber products.

Natural rubber latex is composed therefore, of *natural proteins* and *added chemicals* some of which will be removed during washing procedures conducted during the latter stages of production.

3. REACTIONS TO LATEX

Latex allergy is an allergic reaction to one or more of the components of natural rubber latex products. There are three recognised types of reactions:

- Irritation
- Delayed Hypersensitivity (type IV)
- Immediate Hypersensitivity (type I)

◆ IRRITATION

This is a non-allergic condition, the effects of which are usually reversible. When latex gloves are used, a rash may occur on the back of the hands which is characteristically dry and itchy. These symptoms usually resolve once contact with the latex product is discontinued.

It is important to note however that skin irritation may be caused by a wide range of substances. For example skin cleansing and disinfecting agents may induce skin reactions which may be confused with latex sensitisation. Where necessary, advice should be sought on a differential diagnosis, precautions or treatment from an occupational physician.

◆ DELAYED HYPERSENSITIVITY (TYPE IV)

This reaction is predominantly caused by an allergy to the residues of *accelerating agents* used in the manufacturing process of gloves.

Also known as allergic contact dermatitis, the severity of this type of allergy varies greatly. It is often characterised by a red rash on the back of the hands and between the fingers. The skin may become leathery and express papules or blisters.

The reaction is delayed, occurring several hours after contact, reaching a maximum after 24-48 hours and then subsides.

Repeated exposure to rubber latex may cause the skin condition to extend beyond the area of contact with the gloves or other medical device.

In some cases of latex sensitisation this may result in the individual becoming sensitised to unrelated latex containing devices.

◆ IMMEDIATE HYPERSENSITIVITY (TYPE I)

This reaction is predominantly a response to the *natural protein* residue found in natural rubber latex.

This type of reaction, sometimes referred to as an Immunoglobulin E (IgE) response, generally produces symptoms within 5-30 minutes of latex exposure. Such a reaction is almost immediate in effect but usually diminishes rapidly once contact with the rubber material has ceased. The symptoms are characterised by local or generalised urticaria and oedema. If mucous membranes are affected, rhinitis, conjunctivitis or asthma may result. Respiratory difficulties and anaphylaxis may occur in extreme cases.

Anaphylactic shock, characterised by generalised hives, respiratory distress and low blood pressure can occur within minutes of exposure. It is most likely to occur when the skin barrier is broken or the rubber latex device comes into contact with mucous membranes.

The potential allergens which produce type I or IV reactions exist in the finished product as protein or process residues. These are water soluble and readily leach out of the latex. The washing process used in glove manufacture often removes substantial amounts of proteins and process residues. Some will remain, to a greater or lesser extent, depending on the frequency of washes and the chemical processes used.

Repetitive skin or mucous membrane contact with any rubber latex product containing high protein residues may cause sensitisation. Once this has occurred future allergic reactions may be caused through contact with rubber latex products containing lower residue levels.

4. PREVALENCE OF LATEX ALLERGY

The occurrence of allergic reactions to rubber latex was documented as early as 1927 and appeared to be a relatively rare event.⁽¹⁾ Further documentation occurred in 1979, describing the existence of type I allergy to latex.⁽²⁾ The belief that such events are rare has changed over time and some countries now recognise and report latex allergy as a growing problem, particularly in the health care setting.

Type IV allergies to latex have been identified as the most common reaction but, increasingly, type I reactions are now being reported. This has coincided with the increased use of latex rubber gloves in the health care environment over the past few years.

◆ SITUATION IN THE USA

During the 1980's, an increase in the demand for examination gloves occurred in the USA, which led to a corresponding increase in their importation. Many of the imported gloves were produced by manufacturers inexperienced in the production of latex products for health care use. Some of these products were not subject to quality assurance procedures appropriate for medical devices. As a measure of the increasing demand, between 1987 and 1989 the Malaysian Rubber Development Board received over 400 applications to form glove companies where only 25 previously existed.

The issue of reactions to rubber latex was highlighted in the USA in 1989/90 when a number of fatalities were linked with the use of a particular latex-tipped barium enema kit.

As a result the American authorities issued medical alerts to warn about possible reactions to rubber latex products.⁽³⁾

Reports to the Food and Drug Administration (FDA) of allergies caused by medical devices have continued to increase, with surgical and examination gloves frequently identified as the causative device.

◆ SITUATION IN THE UK

The Medical Devices Agency (MDA) has been monitoring the subject of latex allergy for several years because of the concerns raised by American reports of increased incidence among health care workers and certain groups of patients. An investigation in 1992 revealed that no corresponding rise had occurred in the UK. As part of that investigation MDA surveyed various glove manufacturers to establish the incidence of allergic responses to their latex products. In spite of the fact that 117 million pairs of gloves were supplied to the National Health Service (NHS) annually, very few reports of latex sensitivity had been received. It was therefore concluded that there was no need for specific action in the UK at that time.

There are a number of possible reasons for the apparent differences between the UK and the USA:-

- the Department of Health (DH) operated an approval scheme for surgeons' gloves, which ensured that the NHS purchased only those gloves that met a defined specification and were manufactured to agreed standards of quality assurance.
- a toxicological assessment of surgical gloves, by the MDA, formed part of the product approval process.
- the majority of examination gloves, while not subject to the same degree of regulatory control as surgeons' gloves, were purchased from the same suppliers and were usually manufactured to the same quality assurance standards.
- existing suppliers were able to meet increases in demand.
- different user practices existed between the two countries.

At present there are no authoritative statistics which indicate the extent of the problem in the UK health care setting or in the general population. As part of the continuing evaluation of this subject, MDA recently consulted relevant professionals to ascertain whether there had indeed been a significant rise in the incidence of latex sensitisation. Despite anecdotal evidence of an increase in reports, MDA has been unable to find any conclusive evidence that the prevalence in the UK has significantly increased. This is contrary to trends in other countries, such as the USA and Finland.

5. RISK OF LATEX ALLERGY

The prevalence and incidence of natural rubber latex allergy still remain unquantified. However, one estimate suggests that the incidence in the general population is less than 1% but may be higher within certain risk groups.⁽⁴⁾

Particular groups of people who experience frequent, prolonged or intimate contact with latex devices are more likely to exhibit hypersensitivity to such products. Users should also be aware of the possibility of natural rubber latex sensitivity being transmitted via the powder used to dust some latex gloves, through direct contact or inhalation.

◆ HEALTH CARE WORKERS

Whilst attention has mainly been directed towards gloves, the risk of allergic reaction within the hospital or health care setting also exists with other medical devices which are latex based. A thorough understanding of personal allergic history is important in order to manage this risk.

In some countries an increasing number of hypersensitivity reactions to latex have been reported by personnel who experience occupational exposure, especially those who are required to wear latex gloves (surgical or examination) as part of their daily routine.^(5,6)

Data from several studies revealed the following:

- One study screened 512 hospital staff in Finland, using a scratch chamber test, and reported an overall incidence of 3% latex allergy. The highest prevalence (6.2%) occurred in operating unit staff, while the control group exhibited a prevalence of only 0.8%.⁽⁶⁾
- A study in the USA interviewed 224 self-selected hospital employees and performed skin prick tests with various latex samples and one non-latex sample. All 224 subjects tested negative for the non-latex glove extract, but 17% tested positive for latex sensitivity. Of the subjects that had tested positive, all reported some symptoms, 84% experienced itching on exposure to latex, 68% developed rashes and 55% reported urticaria. 38% of those with negative skin tests had reported symptoms. In an earlier, non-selective study within the same hospital, only 49% of positive skin test subjects were symptomatic.⁽⁷⁾
- In a study carried out in France, 2.65% of 907 hospital employees were diagnosed as allergic to natural rubber latex by skin prick tests. The incidence of sensitisation was higher among nursing staff than administrative staff.⁽⁸⁾
- A Swedish study reported that 7 out of 202 (3.5%) hospital and dental workers were diagnosed, by either a skin prick test or RAST as allergic to natural rubber latex. This represented less than 10% of subjects reporting glove-related skin complaints.⁽¹⁰⁾
- One of the highest incidence of allergic reactions reported in Europe was in Marseilles. Of a total population of 268 operating room nurses, 248 responded to a questionnaire and

197 of these subjects had diagnostic tests for latex sensitivity performed. Prick tests were positive for 10.7% of the subject group.⁽¹⁰⁾

◆ SPINA BIFIDA AND OTHER CONGENITAL DISABILITIES

The apparently high occurrence of latex allergy in people with Spina Bifida or related syndromes noted in the USA may be a reflection of exposure to latex during the large number of surgical procedures which they undergo. A history of continued use of latex containing catheters, rectal tubes and stoma bags will also contribute to the possibility of reactions to rubber latex. Intraoperative collapse has been reported in the past and deaths have been attributed to latex hypersensitivity in this group.^(11,12,13,14,15) The FDA reported an incidence of 18-40% latex sensitivity in spina bifida patients in 1991.⁽³⁾

Children appear to be particularly at risk of hypersensitivity.^(16,17)

◆ ATOPIC INDIVIDUALS

Atopic individuals are predisposed to allergies in general. They tend to experience hypersensitivities in the form of asthma, hay fever or atopic dermatitis and are more likely to become latex sensitised than non-atopic individuals.^(18,19) Scandinavian countries, in particular, are described as having large populations of atopic individuals.⁽²⁰⁾

In some of the studies on health care workers, reported above, latex allergy was much more common in atopic individuals than in others. In the Finnish study, two thirds of employees that were allergic to latex were atopic, as was the single allergic control. This corresponds to a response rate in the scratch chamber test of 9% for atopic and 3% for non-atopic subjects.⁽⁶⁾ Comparative figures for operating room nurses in Marseilles were 21 % and 5% respectively.⁽¹⁰⁾ In the Swedish study, 43% of the positive subjects were atopic.⁽⁹⁾

In a further study, investigating 569 patients attending a French allergy clinic during 1990/91 9% of atopic subjects with minimal previous exposure to latex were sensitised, compared to 0.4% of non-atopic unexposed subjects. Previous exposure to latex increased the response rates to 36% of atopic and 7% of non-atopic patients. This study included a group of 13 patients who had developed intraoperative anaphylaxis, 62% of whom were atopic.⁽¹⁸⁾ A predisposition to allergic reactions in general thus appears to be a significant risk factor for latex sensitisation.

◆ INDIVIDUALS WITH CERTAIN FOOD ALLERGIES

Several case reports have indicated the possibility that those individuals sensitive to avocado, chestnut or banana demonstrate an increased likelihood of sensitisation to rubber latex. A cross reacting agent may be the cause.^(21,22,23,24)

◆ POWDERED GLOVES

The risk of latex allergy is exacerbated by the use of powdered gloves which increase exposure to latex allergens, not only to the user but to sensitised individuals in the vicinity. Most powdered gloves have higher extractable protein levels than powder free gloves. Where powdered gloves are used in procedures, powder may be introduced into the patients body or come into contact with mucosal surfaces. This may cause sensitisation and subsequent allergic reaction. Post-operative complications may also occur, such as starch granuloma, which is a well documented complication observed following abdominal surgery, where glove powder has caused an inflammatory condition resulting in intra-abdominal adhesions.^(25,26,27,28,29)

Modified starch powder is used, in some gloves, as a form of lubrication to facilitate their donning. Although the modified starch powder used is not an allergen itself, the protein residue present in latex readily attaches to the starch which acts as a carrier, allowing airborne transmission and absorption into the body via the respiratory tract. This may cause reactions such as asthma and rhinoconjunctivitis and may once again be a particular problem in areas of the health care setting (where many powdered gloves are used).

- In a survey of Canadian glove factory workers, there was an estimated 3.7% prevalence of occupational asthma in response to latex. None of the subjects had skin manifestations although 11% of those tested responded positively to prick tests with natural latex and this, in conjunction with the respiratory symptoms, suggested that exposure to the latex allergen was by inhalation via the glove powder.⁽³⁰⁾
- A case series, mainly comprising German hospital staff, showed that latex sensitive individuals could handle powdered vinyl gloves without significant effect. However, a similar challenge where the subjects handled powdered latex gloves, whilst wearing latex free gloves, immediately produced sneezing and rhinorrhoea in all cases.⁽²⁵⁾

Thus the use of powdered latex gloves increases the likelihood of sensitisation to both health professionals and patients, as well as adding to the risk of procedural complications.

◆ FEMALES

Many studies have reported a greater incidence of hypersensitivity to rubber latex in women.⁽³¹⁾ The possibility of selection bias due to a higher proportion of women in the exposed population precludes any conclusions about prevalence. However, such studies have suggested that additional risks may arise from:

- certain female dominated professions, such as nursing, which carry an increased risk of occupational exposure⁽³²⁾
- obstetric procedures^(33,34)
- gynaecological examinations⁽³⁵⁾
- contact with contraceptives^(4,36)

6. DIAGNOSIS OF LATEX AND RUBBER ALLERGIES

Whenever latex sensitisation is suspected, diagnostic testing should be encouraged in order to identify the allergen. Appropriate advice can then be provided on allergy avoidance and alleviation of symptoms.

Health care workers who regularly use gloves and show any characteristic symptoms of latex allergy, particularly those who have a history of allergies, should seek advice from occupational health departments. Patients with symptoms of possible latex allergy should also be tested.

A risk assessment should be undertaken to determine the need for carrying out diagnostic tests in other high risk groups. The Control of Substances Hazardous to Health (COSHH) Regulations (1994) impose a statutory obligation on employers, including the health sector, to carry out risk assessments for hazardous substances, implement suitable control measures and carry out any necessary health surveillance.⁽³⁷⁾

The following methods may be used in diagnosis:

◆ SKIN PRICK TEST

This tends to be the preferred test method as it is a sensitive and safe means of diagnosis. An aqueous extract of rubber latex protein is introduced at an epidermal puncture site. A positive result is graded according to the diameter of erythema at the test site, compared with a positive (histamine) and a negative (saline) control.

◆ PATCH TEST

This is used to identify specific contact antigens involved in delayed reactions, causing allergic dermatitis. It involves a two day occlusive application of the test material to intact skin. Positive responses are looked for on day two and then day four.

◆ THE USE TEST

This is conducted over 15-20 minutes, or less if the subject experiences distress. It has been recommended that only one finger of a glove be used initially, in order to minimise the risk to highly sensitised individuals. The inner surface of the glove or the hand of the subject are dampened prior to administration of the allergen, only the source material is identified not the specific allergen.

◆ IN VITRO TESTING

The advantage of methods such as RAST (radioallergosorbent) and ELISA (enzyme linked immunosorbent assay) testing is that the reaction and determination is made *in vitro* rather than on the surface of the subject's skin. The reaction between patients' serum and test material identifies latex specific IgE. However, sensitivity of these tests is such that allergic individuals may go undetected if tests are used in isolation. They are also expensive.

7. MANAGEMENT OF SENSITISED HEALTH CARE WORKERS

It is important for all health care staff to be made aware of the hazards posed by latex sensitivity.

Staff working in high latex exposure areas who are known to be atopic or who have food allergies associated with latex allergy (e.g. avocado, chestnut and bananas) should be particularly cautious when contact is made with latex gloves or other devices. If signs of reaction, such as localised itching, oedema, erythema or shortness of breath occur, latex contact should be discontinued and the advice of the occupational health department should be sought. If in-house occupational health provision is not available, suitable referral arrangements should be made as advised in 'Occupational Health Services for NHS Staff' (1994).⁽³⁸⁾

Any member of staff who experiences latex exposure and displays allergic symptoms should seek specialist advice, in order that a diagnosis can be made and treatment of symptoms undertaken. Where latex sensitivity is diagnosed, alleviation or avoidance strategies should be advised.

◆ AVOIDANCE OF LATEX

Depending on the severity of allergy, staff are advised initially to switch to powder-free gloves with low extractable protein levels, and to monitor their symptoms and observe if they subside or disappear. If this is not effective, switching to non-latex gloves, or use of a non-latex glove between the skin and a normal latex glove is recommended. However, such techniques may still prove inadequate for a small minority of individuals who are highly sensitised. In such cases, non-latex substitutes are available for most commonly used natural rubber latex products, including gloves.

◆ GUIDANCE WITHIN THE WORK PLACE

Specific information should be available in the work place for health care workers. This may involve occupational health departments and specialist work areas devising local policies on latex sensitisation and ensuring that such information is promoted widely within the establishment.

Supplies departments now have access to information regarding protein levels in medical gloves and can therefore provide feedback about different glove types and brands to those responsible for glove purchasing. Staff should be encouraged to report reactions through their locally established procedure, so that prevalence can be monitored centrally. Reports of allergic reactions should also be reported to the Adverse Incident Centre (AIC) at MDA where national monitoring may provide future statistics and an indication of the extent of latex sensitisation in the health care setting. See Appendix A: 'Adverse Incident Report Form'.

8. MANAGEMENT OF SENSITISED PATIENTS

Staff must be aware of the potential dangers posed by natural rubber latex devices to the delivery of care to patients in the health setting. This is particularly pertinent to patients in the identified high risk groups. Increased awareness may aid the prevention of allergic reactions and, in rare instances, occurrence of intra-operative collapse.

◆ PATIENT HISTORY

Routine patient admission already involves information gathering about a patient's known allergies and should be extended to include specific questions which may detect known or possible occurrence of latex allergy. This requires relevant personnel to ask pertinent questions when patients are seen in outpatient departments and on pre-operative admissions as well as during routine admissions.

A history suggestive of reactivity to latex may be gained by anecdotal accounts of swelling or itching of lips after blowing up balloons, or following dental or internal examinations. Swelling or itching of hands following contact with household gloves is also suggestive of possible sensitisation, as are reactions following the use of condoms or diaphragms. Other historical evidence includes hand eczema, food allergies or previous unexplained anaphylaxis.

Where type I allergy to latex is suspected, the implications for clinical management should be considered. Confirmation by a dermatologist using an appropriate method of diagnosis may be appropriate, particularly if a surgical procedure or mucus membrane contact is implicated.

◆ SURGERY AND MEDICAL PROCEDURES

Where type I allergy is confirmed and surgery or other medical procedures are necessary, patients should be scheduled first on the theatre list in order to minimise their exposure to airborne latex allergens and non-latex gloves should be used. A latex-free operating room environment may be possible in some circumstances.

All procedures conducted on patients with acute latex sensitisation should be performed in a setting in which anaphylaxis can be treated.

◆ HEALTH EDUCATION

Patients with confirmed latex allergy should be reminded to inform doctors, dentists or other health professionals of this allergy before any examinations or procedures are conducted.

9. GLOVE QUALITY AND SELECTION

Although research has shown that protein residues in latex are responsible for sensitisation, one of the most difficult tasks to date has been conclusive identification of the causative allergen(s). If such identification were possible the risks posed by latex hypersensitivity would be far easier to manage. Current research is attempting to make such identification possible, but any conclusive findings will not be available for some time. As a result, current standards and specifications do not state safe or acceptable extractable protein residue levels.

Latex gloves used in the health care setting fall into two main categories;

- Surgeons' or Surgical (sterile)
- Examination (sterile or non-sterile).

The NHS Supplies Authority has sought to ensure, through its national and divisional contracts for medical gloves, that gloves fully comply with the DH quality assurance standards, as laid down by the MDA. In September 1994 the Supplies Authority introduced improved commercial purchasing requirements which include information from suppliers on the place of manufacture, extractable levels of protein in the gloves (including identification of the test method used), independent certification of compliance with relevant standards or specifications and a choice of powdered and powder-free gloves, and non-latex alternatives.

By June 1998, all medical gloves will be required by law to carry the CE marking, under the provisions of the Medical Devices Directive (93/42/EEC). This marking indicates that the product complies with Essential Requirements of safety and performance. European standards can be used (by manufacturers and regulatory bodies) to demonstrate that these Essential Requirements have been met.

There are now British Standard implementations of the European Standards for Medical Gloves for Single Use (both surgeons' and examination).^(39,40) These standards cover specifications for physical properties and ensure that the gloves provide, and maintain in use, an adequate level of protection from cross-contamination for both patient and user. These specifications do not cover biological safety aspects but work has begun to develop a European Standard which will deal with this.

The European standard under development will specify a single test method for protein determination which standardises and maximises extraction of protein residues from gloves. This test will be more sensitive than methods currently used either in the UK or the USA.

Because it is not yet possible to determine an extractable protein level that can be defined as non-sensitising, no allowable limit can be set in standards or specifications for medical gloves, and **no definitive guidance can be provided to purchasers on what protein levels can be regarded as safe**. However, recent concerns regarding latex sensitisation have already resulted in a general reduction in extractable protein levels. Most

manufacturing processes, for surgical and powder free examination gloves, will result in extractable protein residues below 100µg/g and many will achieve levels below 50µg/g (draft European Standard method).

Although information concerning protein levels is not required to be included in glove packaging labels, suppliers/manufacturers can provide such information to purchasers, which can then be made available to address enquiries from glove users.

CONCLUSIONS

- latex sensitisation has been recognised for many years but there has been an increase in the number of cases identified in recent years.
- increased exposure to latex devices, particularly those with high allergen contents, may be the leading cause of increases in reports of allergic reactions to latex.
- in order to minimise the occurrence and effect of latex allergy, both individuals and organisations need to be aware of latex sensitisation/allergy and take appropriate measures. This includes regulators, manufacturers, suppliers, purchasers, users of latex gloves and health care managers.
- a policy should be implemented within any health care establishment:
 - (i) to address how best to disseminate information relevant to the existence and management of latex sensitisation/allergy.
 - (ii) to stress the importance of routine questioning of patients about previous reactions to latex based products.
 - (iii) to encourage staff to seek guidance if actual or possible latex allergy presents.
 - (iv) to make adequate occupational health facilities for staff.
 - (v) to make provision for alternatives to latex based devices as necessary.
 - (vi) to produce a compilation of purchasing data, including the maximum extractable protein content of gloves used within the health care environment, so as to enable informed choices to be made when purchasing gloves,
 - (vii) to stress the importance of maintaining records of adverse reactions to latex devices, including the maintenance of patient records.
 - (viii) to stress the importance of reporting incidents involving allergic reactions to latex devices, in order that national data may be analysed. (See Appendix A: Adverse Incident Report Form)

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DISTRIBUTION

This Device Bulletin should be brought to the attention staff in all hospitals and community healthcare departments that use latex gloves/devices, primary healthcare teams and to purchasing officers.

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