

SOUTH AFRICAN LAW COMMISSION

Project 85

ASPECTS OF THE LAW RELATING TO AIDS:

Disposable Syringes, Needles and other Hazardous Material

Universal Work Place Infection Control Measures (Universal Precautions)

National Compulsory Standard for Condoms

Regulations relating to Communicable Diseases and the Notification of Notifiable

Medical Conditions

National Policy on HIV Testing and Informed Consent

INTERIM REPORT

FEBRUARY 1997

To Mr A M Omar, M P, Minister of Justice

I am honoured to submit to you in terms of section 7(1) of the South African Law Commission Act, 1973 (Act 19 of 1973), for consideration the Commission's interim report on **Aspects of the law relating to AIDS.**

I MAHOMED

Chairperson

ACKNOWLEDGEMENT

The Commission is indebted to Mr G Cohen (research assistant to Mr Justice E Cameron, project leader) who, together with Mr Z Achmat and Ms A E Strode (members of the project committee) undertook the research for this report and to Mr G G Smit (former member of the project committee) who assisted in drafting the subordinate legislation recommended in the report.

INTRODUCTION

The South African Law Commission was established by the South African Law Commission Act, 1973 (Act 19 of 1973).

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SUMMARY OF RECOMMENDATIONS

1 DISPOSABLE SYRINGES, NEEDLES AND OTHER HAZARDOUS MATERIAL

(Paragraphs 2.1-2.20)

1.1 Health care providers and hospitals, as employers, are required to take reasonably practicable steps to eliminate (or mitigate) any hazard or potential hazard to the safety or health of their employees. Employers can be held liable for HIV transmission in the workplace that results from their failure to take reasonably practicable precautions (such as providing for the use and easy destruction of disposable syringes).

1.2 Re-use of needles and syringes can lead to patient-to-patient transmission of HIV, hepatitis B and other blood-borne pathogens.

1.3 Health care workers and cleaning staff are at greatest risk of needle-stick injuries (and being exposed to HIV) when they are cleaning or removing unsterile needles from syringes. The costs associated with such exposures - counselling, testing, and prophylaxis - are significant, irrespective of whether HIV transmission occurs.

1.4 The most effective way to prevent HIV exposure in the health care setting through this means is to use disposable syringes and needles, to provide for their safe removal and destruction after use, and to prohibit their re-use. In a limited number of instances, non-disposable (glass) syringes are therapeutically necessary.

1.5 It is recommended that the Minister of Health and the Minister of Labour, under the authority of section 33(1) of the Health Act, 63 of 1977, and section 43(1)(b) of the Occupational Health and Safety Act, 85 of 1993, respectively, adopt regulations that require health care providers to ensure the use of disposable syringes and needles, except where medically otherwise indicated, and to take reasonable steps to provide for the safe disposal of such syringes and needles. Draft regulations to this effect are contained in Annexures A and B.

1.6 The Commission encourages the Department of Health, in conjunction with relevant role-players, further to develop operational guidelines supporting these legislative directives.

2 UNIVERSAL WORK PLACE INFECTION CONTROL MEASURES (UNIVERSAL PRECAUTIONS)

(Paragraphs 3.1-3.25)

2.1 Employers are required to ensure a reasonably safe working environment and are liable for injuries that result from their failure to do so. Current statutory provisions do not explicitly require the implementation of universal precautions to prevent the transmission of blood-borne pathogens during, or due to, work place accidents.

2.2 Because HIV transmission occurs through certain scientifically known and well defined routes which require the exchange of body fluids, the risk of transmission of HIV in the work place is minimal. Through the implementation of universal precautions it is possible to eliminate or substantially reduce the minimal risks of HIV transmission in the work place. To ensure that these precautions are in fact enforced, as well as to enhance public confidence and understanding of genuine transmission risks, the relevant statutory provisions need to be amended.

2.3 Universal precautions are the cheapest and most efficient way to prevent transmission of HIV, hepatitis B and other blood-borne pathogens in the work place.

2.4 The application of universal precautions makes it unnecessary to determine the HIV status of patients, health care workers or other employees for any purpose related to preventing transmission.

2.5 It is recommended that the General Safety Regulations, published under section 43 of the Occupational Health and Safety Act, 85 of 1993, should be amended to ensure the application of universal precautions, and the provision of appropriate training, and thus to reduce

the minimal risk of HIV transmission in the work place. Draft regulations to this effect are contained in Annexure C.

2.6 The Commission encourages the Department of Health, in conjunction with relevant role-players, further to develop operational guidelines supporting these legislative directives.

3 NATIONAL COMPULSORY STANDARD FOR CONDOMS

(Paragraphs 4.1-4.23)

3.1 Condoms are one of the most effective ways to prevent HIV transmission.

3.2 When used correctly, properly stored and manufactured condoms can dramatically reduce the possibility of HIV transmission.

3.3 Condom breakage or failure increases the risk of HIV transmission.

3.4 Uncertainty about condom reliability has contributed to the difficulty of convincing people to use condoms. Poor manufacturing, packaging, and incorrect storage increase the likelihood of condom failure, and heighten consumer reservations about their use.

3.5 It is recommended that the Minister of Health issue regulations, under the authority of sections 33(1) and 40 of the Health Act, 63 of 1977, requiring all condoms (including female condoms and novelty condoms) manufactured, offered for sale or distributed in South Africa to carry the relevant SABS certification mark. Draft regulations to this effect are contained in Annexure A, including a penal provision.

3.6 It is further recommended that the SABS revise the existing South African specification for condoms to conform more closely with international standards.

3.7 The SABS should, in consultation with relevant role players, develop an SABS

specification for female condoms conforming with international standards.

4 REGULATIONS RELATING TO COMMUNICABLE DISEASES AND THE NOTIFICATION OF NOTIFIABLE MEDICAL CONDITIONS

(Paragraphs 5.1-5.16)

4.1 The Regulations Relating to Communicable Diseases and the Notification of Notifiable Medical Conditions which were issued in 1987 by the Minister of Health under the Health Act, 63 of 1977, include provision for the mandatory application of coercive measures (for example, isolation and quarantine) in response to scheduled communicable diseases and notifiable medical conditions. AIDS (but not HIV infection) is listed as such a disease in these Regulations. (Neither HIV infection nor AIDS are currently declared “notifiable medical conditions” in terms of section 45 of the Health Act, 63 of 1977. The issue of notifiability is not dealt with in this interim report.)

4.2 The 1987 Regulations raise constitutional questions regarding the infringement of (amongst others) the rights to privacy, freedom of association and movement, dignity, and administrative justice.

4.3 Coercive measures that provide for the isolation and detention of persons with HIV infection or AIDS are not successful means of curbing the epidemic. As stated in the Commission’s Working Paper 58, quarantine, isolation and detention create a climate of fear and denial which encourages the spread of the epidemic rather than curbing it.

4.4 It is recommended that the draft Regulations relating to Communicable Diseases and the Notification of Notifiable Medical Conditions, published under Notice 703 of 1993, in Government Gazette No 15011 of 30 July 1993 (and which deschedule AIDS as a communicable disease in respect of which coercive measures apply mandatorily) should be finalised and promulgated, subject to the amendment of draft regulation 15 (which currently places unnecessary restrictions on the conveyance of the body of a person who was known to have been a “carrier of HIV” at the time of his or her death).

5 NATIONAL POLICY ON HIV TESTING AND INFORMED CONSENT

(Paragraphs 6.1-6.15)

5.1 Informed consent in the health care setting refers to the patient's right to self-determination - the right to consent to or refuse any medical procedure after the provision of adequate information to make an informed decision.

5.2 Testing for HIV infection presents serious medical, legal, ethical, economic and psychological implications. Because HIV infection is a life-threatening condition, reasonable persons or health care workers will attach significance to the outcome of an HIV test, especially a positive diagnosis.

5.3 Voluntary testing for HIV infection with informed consent is recognised as indispensable in the care and support of persons with HIV infection and to prevention efforts.

5.4 According to members of the public, health care workers and AIDS organisations, many patients are subjected to HIV tests without proper informed consent at public and private health care facilities.

5.5 Supported by Kirk-Cohen J's decision in *C v Minister of Correctional Services*, 1996 4 SA 292 (T), the Commission proposes that pre-test counselling should be recognised as an integral component of informed consent in the context of HIV testing.

5.6 It is recommended that the Minister of Health should under the authority of section 2 of the National Policy for Health Act, 116 of 1990, adopt a national policy on HIV testing and informed consent. A draft policy to this effect is contained in Annexure D.

5.7 It is further recommended that the Life Offices' Association continue to develop, together with relevant role-players, professional guidelines for the insurance industry that encompass and advance the legal principles contained in the national policy.

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1 BACKGROUND

1.1 The South African Law Commission has been investigating aspects of law reform relating to HIV/AIDS since 1993.

1.2 Since then extensive research has been done. Evidence was heard from interest groups and a discussion document (Working Paper 58) was published for general information and comment during 1995.

1.3 The comments on the Working Paper reflected differences of opinion between interest groups **inter alia** on the Commission's basic preliminary conclusion that an AIDS-specific statute (containing a general prohibition on unfair discrimination on the grounds of HIV infection) was warranted.

1.4 After the appointment of members of the Commission's Project Committee on HIV/AIDS ("the Project Committee") had expired, and the appointment of a new representative Law Commission at the beginning of 1996, new appointments were made to the Project Committee. The Project Committee's mandate is to assist in resolving the differences of opinion between interest groups and in developing a draft report for submission to the Minister of Justice.

1.5 The Project Committee is pursuing a consultative process in an attempt to resolve the differences. It is also following an adapted approach of dealing with issues incrementally in an attempt to finalise them more swiftly. In doing so, it has identified certain aspects concerning HIV/AIDS which warrant urgent intervention, and which from a scientific, medical and legal viewpoint appear to be relatively uncontroversial. These include:

1.5.1 A prohibition on the use of non-disposable syringes, needles, and other hazardous material.

1.5.2 The implementation, in relevant occupational legislation, of universal work place infection control measures (universal precautions).

1.5.3 The statutory implementation of a national compulsory standard for condoms

according with international standards.

1.5.4 The amendment, finalisation and promulgation of the draft Regulations relating to Communicable Diseases and the Notification of Notifiable Medical Conditions, 1993 (which deschedule AIDS as a communicable disease in respect of which certain coercive measures apply).

1.5.5 The promulgation of a national policy on testing for HIV infection.

1.6 Preliminary proposals regarding the above were substantiated in a discussion paper (Discussion Paper 68) which was widely distributed for comment among role-players on 2 October 1996. Comments were received from 60 respondents. (A list is attached as Annexure E.) In general, the comments supported the preliminary proposals. On the whole the Project Committee's view, that the matters dealt with warrant urgent intervention and are relatively non-controversial, was confirmed.

1.7 Discussion Paper 68 also included preliminary proposals regarding the amendment of the regulations governing death certificates in terms of the Births and Deaths Registration Act, 1992, so as to protect privacy in relation to HIV/AIDS while at the same time establishing a reliable mechanism for the collation of essential epidemiological information. In view of comments which indicated that this issue needed more debate and consideration, it is not included in this report but will be held over for inclusion in a further interim report or in the Commission's later comprehensive report. The Project Committee proposes to convene a workshop early in 1997 to seek consensus on this issue.

1.8 It is to be noted that this interim report deals only with the matters indicated in paragraph 1.5 above. Subsequent interim reports will deal with other matters identified for reform.

2 DISPOSABLE SYRINGES, NEEDLES AND OTHER HAZARDOUS MATERIAL

* Present position

2.1 There are currently no statutory provisions requiring the use of disposable syringes to prevent the transmission of HIV, hepatitis B and other blood-borne pathogens.

2.2 Under the authority of the Health Act, 63 of 1977 (“the Health Act”), section 33, the Minister of Health is empowered to make regulations, **inter alia** relating to measures aimed at preventing the occurrence or the spread of communicable diseases or controlling or restricting such diseases. Section 1 of the Health Act defines communicable disease as “any disease which can be communicated directly or indirectly ... through any agent to any person or from any person suffering therefrom or who is a carrier thereof to any other person”. In terms of this definition HIV infection is a communicable disease. The Minister is accordingly empowered to make regulations to prevent its occurrence or spread. Measures aimed at preventing the spread of HIV infection would at the same time contribute to the prevention of the occurrence or the spread of AIDS.¹

2.3 Under the Occupational Health and Safety Act, 85 of 1993 (“OHSA”), section 43(1)(b), the Minister of Labour may, moreover, make regulations “which in the opinion of the Minister are necessary or expedient in the interest of the health and safety of persons at work ... or the protection of persons other than persons at work against risks to health and safety arising from or connected with the activities of persons at work ...”.

* Motivation for change

¹ The recommendation in paragraph 5.15 below that AIDS be removed from Annexure I to the Regulations relating to Communicable Diseases and the Notification of Notifiable Medical Conditions, 1987 (GN 2438 of 1987 in GG 11014 of 30 October 1987), does not detract from the fact that HIV infection broadly falls within the definition of “communicable disease”. The Annexure contains a list of certain communicable diseases in respect of which specific coercive measures apply mandatorily. As is indicated below, AIDS does not correspond with the highly contagious diseases so listed (see paragraph 5.5). It is therefore recommended below that AIDS be removed from the list.

2.4 Re-use of syringes and needles can lead to **patient-to-patient** transmission of HIV, hepatitis B and other blood-borne pathogens. The highest risk of patient-to-patient transmission of blood-borne pathogens occurs during mass immunisation campaigns where unsterilised syringes and needles are re-used or a single, disposable syringe is used to immunise a number of subjects.²

2.5 Moreover **health care workers** and **cleaning staff** are put at risk of exposure to HIV infection, hepatitis B and other blood-borne pathogens by the use of non-disposable syringes and needles.³ Risk of HIV transmission in the work place or health care settings occurs when **health care workers** recap, re-use, or attempt to sterilise syringes and needles.⁴ Lack of adequate provision of appropriate receptacles for the safe disposal of sharps (eg needles, canulas, scalpel blades and knives) is associated with further increased risk of injuries to health care workers and **cleaning staff**.⁵ Health care workers and cleaning staff are at greatest risk of needle-stick injuries (and exposure to HIV infection) when they are cleaning or removing unsterile needles from syringes. The costs associated with such exposures - counselling, testing, and prophylaxis - are significant, irrespective of whether HIV transmission occurs.⁶

2.6 The most effective way to prevent exposure to HIV infection in the health care setting through this means is to use disposable syringes and needles, to provide for their safe removal and destruction after use, and to prohibit their re-use.

² Aylward et al 1995 **Bulletin of the WHO** 531; Wyatt **The Impact of Injections on Daily Medical Practices** 15-30 .

³ Fowler 1996 **Occupational Safety & Health Reporter** 315.

⁴ Aylward et al 1995 **Bulletin of the WHO** 531.

⁵ Mayfield 1993 **US FDA Consumer** 9. This observation was confirmed by members of the Project Committee involved in the health care profession.

⁶ Bleicher 1991 **Journal of Health and Hospital Law** 41.

2.7 Health care providers and hospitals, as employers, are required to take reasonably practicable steps to eliminate (or mitigate) any hazard or potential hazard to the safety or health of their employees.⁷ Employers can be held liable for HIV transmission in the workplace that results from their failure to take reasonably practicable precautions (such as providing for the use and easy destruction of disposable syringes).⁸

* **Preliminary recommendations contained in Discussion Paper 68**

2.8 The Project Committee recommended statutory provision for the compulsory safe disposal of all syringes and needles after use. The Project Committee proposed that the Ministers of Health and of Labour should, under the authority of the Health Act and of OHS Act respectively, by regulation prohibit the use of non-disposable syringes and needles and the re-use of disposable syringes and needles, and also provide for the safe disposal of syringes, needles and sharps.

* **Comments received**

2.9 Nearly all of the respondents, including the Medical Association of South Africa (“MASA”) and the Departments of Health and Labour, supported the idea that syringes and needles should not be re-used. However, concern was expressed about the enforceability of such a proposal. Some respondents further suggested that provision should be made for the safe disposal of all medical waste.

2.10 The Democratic Nursing Organisation of South Africa supported the proposal but wanted assurance that health staff would be enabled to comply with such regulation by the supply of adequate equipment. The South African Nursing Council was in favour of the proposal, but likewise found it essential that legislation requiring the proper use and destruction of disposable syringes and needles be supported by adequate funding and supplies to ensure that re-use is not considered. The Department of Health observed that if the re-use of disposable syringes was to be prohibited, the Minister should have the capacity to enforce this.

⁷ The Occupational Health and Safety Act, 1993 sec 8.

2.11 The Interim National South African Medical and Dental Council (“the Interim SAMDC”), the South African Society of Occupational Health, the Infection Control Association of Southern Africa, and Dr P W W Coetzer supported the introduction of statutory provision for the destruction of disposable syringes, but drew attention to the fact that certain medical procedures could not be performed with disposable syringes and needles, and that it might be necessary to provide for the use of non-disposable (glass) syringes and needles in very specific circumstances.

2.12 Some respondents, including the National Association of People Living with HIV Infection or AIDS (“NAPWA”) and the Department of Community Health, University of Cape Town, emphasised that the incorrect disposal of bio-hazardous material also presented risks of HIV transmission to parties who might come into contact with improperly discarded material. Both envisaged supportive legislation to address this problem.

2.13 The Department of Health further asserted that comprehensive guidelines should be developed by role-players in conjunction with the Department to support the principles enunciated in the proposal. The Department observed that it was policy throughout the government health services that disposable syringes were to be used once only and that adequate supply and ongoing quality control might be more important than legislation.

* **Evaluation of comments**

2.14 The Commission concluded that the broad support for the proposed measures indicated that they were virtually uncontroversial and urgently necessary, subject to certain concerns about implementation and supply.

2.15 In view of the comments received, the initial proposal was amended to provide for the use of non-disposable syringes and needles where medically indicated.

⁸ Ibid, sec 8 and 35.

2.16 The Commission took note of recent media reports that bio-hazardous disposable materials, used in patient-care in health care facilities, have been found dumped in municipal and other uncontrolled waste disposal sites. It was clear from the comments of the Department of Labour and the South African Bureau of Standards (“the SABS”) that these concerns, and similar ones raised by NAPWA and the Department of Community Health, University of Cape Town, were currently being addressed by the SABS and the Department of Labour.⁹

2.17 In response to concerns about the cost of supplying disposable syringes and needles, the Commission observes that the cost of providing disposable syringes and needles is not necessarily more than that of effectively sterilising non-disposable syringes and needles.¹⁰ The social, human and economic costs incurred as a result of ineffective sterilisation must also be taken into account.

* **Recommendation**

2.18 It is recommended that the Minister of Health and the Minister of Labour should, under the authority of section 33(1) of the Health Act and section 43(1)(b) of the Occupational Health and Safety Act respectively, adopt regulations to the following effect:

- 1) In order to prevent the transmission of HIV, hepatitis B and other blood-borne pathogens - from patient to patient, and from patient to health care worker - all health care providers, whether public or private, shall take reasonable steps to provide disposable syringes and needles for use by their employees in all medical procedures.
- 2) Every such health care facility shall -
 - a) ensure the use of disposable syringes and needles, except where medically otherwise indicated; and

⁹ Both the SABS and the Department of Labour, in their responses to Discussion Paper 68, indicated that the disposal of syringes, needles and other hazardous wastes should be regulated by SABS Code. The SABS specifically referred the Project Committee to the code of practice SABS 0229 (Packaging of Dangerous Goods for Road and Rail Transportation in South Africa), covering clinical and (bio-)medical waste, which is currently being revised by the SABS.

- b) take reasonable steps to provide for the safe disposal of hazardous material.

2.19 The Commission encourages the Department of Health, in conjunction with relevant role-players, further to develop operational guidelines supporting these legislative directives.

2.20 Draft regulations as recommended are contained in Annexures A and B.

¹⁰ Wyatt in **The Impact of Injections on Daily Medical Practices** 15-30 .

3 UNIVERSAL WORK PLACE INFECTION CONTROL MEASURES (UNIVERSAL PRECAUTIONS¹¹)

* Present position

3.1 OHSA presently requires employers to provide and maintain, as far as is reasonably practicable, a safe working environment. Employers, including health care providers, may be liable for injuries that result from their failure to provide a reasonably safe working environment.¹² In addition, employers have a common law duty to take all reasonable steps to provide a safe work place for their employees.¹³

3.2 The Compensation for Occupational Injuries and Diseases Act, 130 of 1993, section 71, requires employers to furnish and maintain the prescribed equipment and services for first aid to employees.

3.3 The General Safety Regulations,¹⁴ promulgated under OHSA, require employers to provide access to prompt first aid, to train personnel on its appropriate use, and to promote a safe working environment.¹⁵ The Annexure to regulation 3 of the General Safety Regulations lists 18 items that first-aid boxes are presently required to contain.¹⁶

¹¹ The concept of “universal precautions” is used worldwide in the context of HIV/AIDS to indicate control measures in the health care setting aimed at the prevention of HIV transmission. Such measures are intended to prevent the transmission of infection from one person to another and include: instructions concerning basic hygiene, the wearing of protective clothing and instructions concerning the administration of injections and the performance of certain surgical procedures (Van Wyk A C **AIDS: The Health Care Challenge** 129-134).

¹² Cf The Occupational Health and Safety Act, 1993 sec 8 and 35.

¹³ Van Wyk 1991 **Codicillus** 335; Strauss 1988 **SAPM** 13.

¹⁴ GN R 1031 of 1986 in **GG** 10252 of 30 May 1986 (originally published under sec 35 of the Machinery and Occupational Safety Act, 6 of 1983, which was repealed by the Occupational Health and Safety Act, 1993).

¹⁵ The General Safety Regulations as amended by GN R 2245 of 1992 in **GG** 14192 of 7 August 1992, reg 3(2), (3) and (4).

¹⁶ Wound cleanser/antiseptic (100 ml); swabs for cleaning wounds; cotton wool for padding (100 g); sterile gauze (minimum quantity 10); 1 pair of forceps (for splinters); 1 pair of scissors (minimum size 100 mm); 1 set of safety pins; 4 triangular bandages; 4 roller bandages (75 mm x 5 m); 4 roller bandages (100mm x 5m); 1 roll of elastic adhesive (25mm by 3 m); 1 non-allergic adhesive strip (25 mm by 3m); 1 packet of adhesive dressing strips (minimum quantity, 10 assorted sizes); 4 first-aid dressings (75 mm x 100mm); 4 first-aid dressings (150mm x 200mm); 2 straight splints; 2 pairs large and 2 pairs medium disposable latex gloves; 2 CPR mouth pieces or similar devices.

3.4 Current statutory provisions do not explicitly require the application of universal precautions to prevent the transmission of HIV, hepatitis B¹⁷ or other blood-borne pathogens during, or as a result of, work place accidents. However, in guidelines relating to HIV/AIDS, the Interim SAMDC and MASA include instructions emphasising the employer's responsibility to ensure a safe work place for health care workers which includes the endorsement of universal infection control.¹⁸

* **Motivation for change**

3.5 Universal precautions means treating all body fluids as potentially infectious. Because HIV transmission occurs through certain scientifically known and well defined routes which require the exchange of body fluids, the risk of transmission of HIV in the work place is minimal.¹⁹ However, the scale of the HIV/AIDS epidemic suggests that all work places already have or will have employees with HIV infection, including those in the health care setting. Universal precautions will help reduce the minimal risk of HIV transmission. Application of universal precautions makes it unnecessary, for reasons relating to transmission, to determine the HIV status of health care workers, other employees, and patients. Furthermore, insistence on universal precautions conveys the correct information regarding the limitation and avoidance of transmission risks.

3.6 Within the work environment, where a range of accidents may occur, it is impossible to determine which blood or body fluids are infectious.²⁰ In any event, treating all blood as potentially infectious is cheaper than testing all blood for pathogens. Universal precautions are the cheapest, most efficient way to prevent the transmission of HIV, hepatitis B and other blood-borne pathogens in the work place.²¹

¹⁷ In the USA universal precautions include inoculation against hepatitis B (Synopsis 1991 **Occupational Safety & Health Reporter** 1676).

¹⁸ **SAMDC Guidelines** 3, 6; **MASA Guidelines** 4, 6, 7, 11 et seq.

¹⁹ Albertyn & Rosengarten 1993 **SAJHR** 77; **Australia Discussion Paper Employment Law** 9, 32; Isaacman 1990 **St Louis University PLR** 445-454.

²⁰ Fowler 1996 **Occupational Safety & Health Reporter** 315.

²¹ Synopsis 1989 **Occupational Safety & Health Reporter** 149. *Jansen Van Vuuren v Kruger* 1993 4 SA

3.7 To comply with international and national guidelines on universal precautions, a few simple steps can be included in general work place safety measures to prevent the transmission of blood-borne pathogens in the work place: paper or other material should be used to absorb spilt blood; gloves should be used to handle blood or potentially bloody objects; syringes should be disposed of after use; and a freshly diluted bleach solution should be used as a disinfectant.²² All such hazardous material should be safely disposed of. To best ensure the implementation of universal precautions, a few inexpensive items could be added to the other items presently required in the first-aid boxes provided for by the General Safety Regulations.

3.8 In its guidelines the Interim SAMDC expressed the unequivocal view “that adherence to universal precautions is the most important, and possibly only action, that will significantly protect health care workers against infection by HIV and other blood-borne pathogens”.²³ In spite of these guidelines, evidence suggests that universal precautions are not routinely applied.²⁴

* **Preliminary recommendations contained in Discussion Paper 68**

3.9 The Project Committee recommended that the General Safety Regulations, published under OHSA, should be amended to ensure the application of universal precautions, and further reduce the minimal risk of transmission of HIV, as well as the transmission of hepatitis B and other blood-borne pathogens in the work place.

3.10 To attain this, it was recommended that regulation 3 (First aid, emergency equipment and procedure) of the General Safety Regulations²⁵ be amended to include provisions requiring all employers to promote universal precautions and supplemented in order to clarify the meaning of universal precautions.

842 (A) at 853-854.

²² For the basic elements of practically applicable universal precautions, cf for instance **MASA Guidelines** 13 et seq.

²³ **SAMDC Guidelines** 3.

²⁴ Evidence before the Commission by representatives of MASA on 4 February 1994; cf also McIntyre (Unpublished) 7.

²⁵ The General Safety Regulations, as amended by GN R 2245 of 1992 in **GG** 14192 of 7 August 1992.

* **Comments received**

3.11 In general, there was strong support for the implementation of universal precautions to prevent HIV transmission in the work place. However, some respondents indicated a preference for embodying these principles in professional guidelines rather than legislation.

3.12 The Departments of Labour and Health, as well as COSATU, supported the proposed amendments to the General Safety Regulations.

3.13 The Interim SAMDC re-emphasised that “adherence to universal precautions is the most important and possibly only action that will significantly protect health care workers against infection”.

3.14 The South African Nursing Council was strongly in favour of the proposal, but found it essential that the necessary equipment and training be provided to ensure that universal precautions could be implemented. The Democratic Nursing Organisation of South Africa commended the proposal, but suggested that the health profession be consulted on what constitutes minimum standards of safe and effective precautions.

3.15 The Infection Control Association of Southern Africa suggested additional steps that are reasonable to prevent HIV transmission in the workplace. Several other respondents made specific addendums to the list of universal precautions.²⁶

3.16 Dr E Barker (MASA) and the Department of Health suggested that the proposed legislation should be expanded upon through reference to appropriate professional guidelines.

3.17 The Southern African Society of Occupational Medicine and Dr P W W Coetzer put forward an opinion that the implementation of universal precautions should be provided for

²⁶ These included instruction on hygiene and the use of latex gloves.

in guidelines or protocols rather than legislation.

* **Evaluation of comments**

3.18 In Working Paper 58, the Commission recommended that the application of universal precautions be enforced through legislation. The comments received on the Project Committee's subsequent similar proposal in general strongly supported this principle.

3.19 The Commission amended the proposal in order to make it clear that taking universal precautions would, in certain instances (for example, in a hospital setting), include following the guidelines adopted by organisations like MASA and the Interim SAMDC.

* **Recommendation**

3.20 It is recommended that the General Safety Regulations²⁷ be amended to ensure the application of universal precautions.

3.21 It is recommended that regulation 3 (First aid, emergency equipment and procedure) of the Regulations be amended to include provisions to the following effect:

- 1) An employer shall further take all reasonable steps, including the promotion of universal precautions, to prevent the transmission of HIV, hepatitis B, and other blood-borne pathogens.
- 2) In addition to the training contemplated in subregulation (4), all employers shall take all reasonable steps to ensure that their employees receive adequate training in the use of universal precautions to prevent the transmission of blood-borne pathogens in the work place.

3.22 To clarify the meaning of universal precautions, it is recommended that

²⁷ GN R 1031 of 1986 in **GG** 10252 of 30 May 1986 (as amended by GN R 2245 of 1992 in **GG** 14192 of 7 August 1992) reg 3(2),(3) and (4).

regulation 3 of the Regulations be amended to indicate that universal precautions shall include -

- 1) treating all blood and other body fluids as potentially infectious; and
- 2) taking all reasonable steps that may be appropriate to prevent the transmission of HIV, hepatitis B, and other blood-borne pathogens.

“Reasonable steps” will obviously include such steps as are recommended in accepted standard protocols.

3.23 To ensure that first-aid procedures include the implementation of universal precautions, it is recommended that the list of items first-aid boxes are presently required to contain be amended to include the following:

- 1) Absorbent material for the absorption of spilt blood and other body fluids.
- 2) Disinfectant to sterilise spilt blood and other body fluids.
- 3) Disposable rubber household gloves for handling blood-soaked material in specific instances, eg when broken glass makes the use of latex gloves inappropriate.

3.24 The Commission encourages the Department of Health, in conjunction with relevant role-players, further to develop operational guidelines supporting these legislative directives.

3.25 Draft regulations as recommended are contained in Annexure C.

4 NATIONAL COMPULSORY STANDARD FOR CONDOMS

* Present position

4.1 The SABS has the authority to examine a commodity and prescribe the manner in which it should be manufactured, handled, stored, and transported. According to section 3 of the Standards Act, 29 of 1993 (“the Standards Act”), the objectives of the SABS are, **inter alia** to examine, test or analyse articles, materials and substances; supply information and guidance; and issue as a national standard a specification.²⁸

4.2 Section 16(3)(a)(i) of the Standards Act specifically empowers the SABS to set and issue as a standard a “specification”. A specification is defined by the Act as “a description of a commodity with reference to its characteristics, including its nature, quality, strength, efficacy, purity, ... durability, capacity ... performance, origin or age ...”²⁹ or “the marking, handling, packing, storage and transport of a commodity”.³⁰

4.3 Further, section 16(3)(b)(ii) of the Standards Act states that a standard may be set by referring to any “standard method issued by a foreign or international body having objects similar to any object of the SABS”.

4.4 The Standards Act also grants the Minister of Trade and Industry the authority to issue a **compulsory** specification to promote and maintain standardisation and quality under certain circumstances, if safety, health or consumer protection is concerned.³¹

4.5 Under SABS specification 1286-1980,³² the SABS has issued a “Standard Specification” for “rubber” condoms (single use). This specification was not declared a compulsory standard in terms of the Standards Act.

²⁸ Sec 3, paragraphs (g) (j) and (l) respectively.

²⁹ The Standards Act, 1993 par (a) of the definition of ‘specification’.

³⁰ Ibid, par (b)(i) of the definition of “specification”.

³¹ Ibid, sec 22.

4.6 Manufacturers of condoms may apply to the SABS for a certification mark to indicate that their product complies with the SABS' requirements.³³

* **Motivation for change**

4.7 Condoms are one of the most effective ways to prevent HIV transmission.³⁴ When used correctly, a properly stored and manufactured condom can dramatically reduce the possibility of transmission of HIV and sexually-transmitted diseases.³⁵

4.8 Condom breakage or failure increases the risk of HIV transmission, and consequently discourages the consistent use of condoms. Poor manufacturing and packaging, and incorrect storage increase the likelihood of condom failure, and heighten consumer reservations about their use.³⁶ As it is, convincing people to use condoms is one of the most difficult tasks of Health Departments worldwide.³⁷

4.9 Many brands of condoms sold in South Africa do not carry the mark of SABS approval. This undermines efforts to assure consumers of the high quality of condoms. The SABS can help prevent HIV transmission by promoting the manufacture of high quality condoms.

4.10 The present SABS specification falls short of international standards in certain respects: for instance it does not require an air-burst test, or provide specifications on packaging, even though proper packaging is one of the crucial factors in preventing condom breakage.³⁸ The World Health Organization ("WHO") report on Condom Quality encourages regulatory agencies like the SABS to ensure that "high-quality latex barriers to STD/HIV transmission are

³² As amended in 1984 and 1991.

³³ The Standards Act, 1993 sec 18, 19, and 20.

³⁴ Galavotti et al 1995 **Health Psychology** 570-578.

³⁵ Deschamps et al 1996 **Annotated Internal Medicine** 324-330.

³⁶ Sparrow & Lavill 1994 **Contraception** 117-129.

³⁷ Martin 1992 **Public Health Report** 468-473.

³⁸ Cf WHO **Specifications and Guidelines for Condom Procurement**.

accessible to those who need them”.³⁹

* **Preliminary recommendations contained in Discussion Paper 68**

4.11 It was recommended that the Minister of Trade and Industry, under the authority granted by the Standards Act, should establish specifications for condoms that coincide with international standards. It was also recommended that the Minister use his authority to declare the relevant specification, which has been issued as a standard, to be a “compulsory” specification. The Project Committee further recommended that the Minister, in conjunction with relevant role- players, develop a compulsory specification for female condoms.

* **Comments received**

4.12 Responses to the proposal on quality control for condoms were almost universally favourable.

4.13 Many respondents, including the Departments of Labour, Health, Correctional Services and the South African Police Service, NAPWA, the Interim SAMDC, MASA and the Southern African Catholic AIDS Programme supported the proposal. Additional motivation for implementing a higher standard of quality control on condoms was advanced **inter alia** by the following:

4.13.1 The AIDS Training, Information and Counselling Centre (“ATICC”) in Port Elizabeth reported complaints concerning the quality of SABS condoms and the difficulty it had encouraging condom use as a result.

4.13.2 INBECO, Latex Surgical Products (Pty) Ltd, LRC Industries South Africa and FTO Dental (Pty) Ltd (businesses involved in condom manufacturing, sale, and distribution) agreed with the Project Committee that the SABS specification was deficient in certain respects and that it should be improved to meet international

³⁹ WHO Specifications and Guidelines for Condom Procurement.

standards.⁴⁰

4.13.3 Mr Mitchell Warren, of the Society for Family Health PSI South Africa (one of the largest non-profit condom distributors in Southern Africa), vigorously supported the proposal.

4.13.4 Mr Mark Heywood (AIDS Law Project) drew attention to the fact that the Project Committee's proposal conformed with the "practical and action orientated" guidelines drafted by the United Nations to give effect to Human Rights Commission Resolution 1996/44 on human rights and HIV/AIDS. The United Nations' draft guidelines specifically dictate that "legal quality control on condoms be enforced" and that "compliance with the International Condom Standard should be monitored".

4.14 The comments revealed the following reservations:

4.14.1 The Department of Health supported the proposal, but suggested that the regulation of condoms might be more efficaciously accomplished by regulations made under the authority of the Health Act.

4.14.2 The SABS and Mr Michael D Gillett were concerned that the proposal would inadvertently remove the SABS' authority to place their standardisation mark upon condoms. The SABS, the Minister of Trade and Industry and Mr Gillett consider that all condoms should carry the SABS mark and comply with SABS specifications. To ensure this, these respondents suggested that the Minister of Health rather issue regulations that require all condoms sold or distributed in South Africa to carry the SABS mark.

⁴⁰ Such as ISO 4074 (issued by the International Standards Organisation) and EN 600 (which refers to the European standard for latex condoms). The SABS itself believes that the EN standard is preferable.

4.14.3 Mr Gillett and the SABS suggested that work to establish an international standard for condoms was ongoing, and that no international standard was as yet authoritative. They, for instance, pointed to the present controversy surrounding the value of air-burst testing. In the light of this, the SABS denied that their standard fell short of international specifications. The SABS was not, however, averse to modifying its specification to conform with WHO packaging and shelf-life standards. The SABS' response indicated a willingness to reconvene "the South African technical committee to revise the South African standard, taking the ISO, WHO and EN standards into account"⁴¹ which could include provision for similar standardisation of female condoms.

4.14.4 The only adverse comment received was from Dr P W W Coetzer, who suggested that condoms should not be subject to compulsory SABS specification.

* **Evaluation of comments**

4.15 The Commission accepted from the comments that other countries, such as the United States, have designated condoms "medical instruments" necessary for the prevention of HIV infection.⁴²

4.16 In view of the comments received, the Commission concluded that requiring the SABS to issue a **compulsory** specification, under the authority of the Standards Act, would be impractical and ineffective. As a result of the responses from the Departments of Health, Trade and Industry, and the SABS, the Commission concluded that the Minister of Health should make regulations requiring all condoms to carry the SABS certification mark.

4.17 The Minister of Health has the authority to make regulations relating to condoms to prevent the transmission of HIV. Under the authority of section 33(1) of the Health Act (referred to earlier), the Minister of Health is empowered to make regulations, **inter alia** relating

⁴¹ The SABS is referring to the standards issued by the World Health Organization and the International Standards Organization, and to the European standard for latex condoms.

⁴² Comments from Mr Michael D Gillett; see also WHO **Legislative Responses to AIDS** 201-202.

to measures aimed at preventing the occurrence or the spread of communicable diseases or controlling or restricting such diseases. In terms of the definition of “communicable disease” in section 1 of the Act, AIDS is a communicable disease. Measures aimed at preventing the spread of HIV infection would at the same time contribute to the prevention of the occurrence or the spread of AIDS. The Minister is further empowered (under section 40(1)(b) and (c) of the Health Act), in respect of regulations made under section 33, to confer powers on any person and to prohibit the performance of any act. Non-compliance may, in terms of section 57 of the Act, be visited with a criminal sanction.

4.18 The Commission concluded that improved specifications for all condoms were necessary, and that all condoms manufactured, offered for sale, or distributed in South Africa should comply with that specification, subject to penalty in the event of non-compliance.

4.19 The Commission acknowledges the possibility, raised by a latex manufacturer, that similar problems exist in regard to examination gloves.

* **Recommendation**

4.20 It is recommended that the Minister of Health issue regulations, under the authority of section 33(1), read with section 40(1)(b) and (c) of the Health Act, to the effect that all condoms (including female condoms and novelty condoms) manufactured, offered for sale or distributed in South Africa must carry the relevant SABS certification mark, subject to penalty in case of contravention.

4.21 It is further recommended that the SABS revise the existing South African specification for condoms to conform more closely with international standards.

4.22 The SABS should, in consultation with relevant role-players, develop an SABS specification for female condoms conforming with international standards.

4.23 Draft regulations, as recommended, are contained in Annexure A.

5 REGULATIONS RELATING TO COMMUNICABLE DISEASES AND THE NOTIFICATION OF NOTIFIABLE MEDICAL CONDITIONS

* Present position

5.1 The Regulations Relating to Communicable Diseases and the Notification of Notifiable Medical Conditions⁴³ which were issued in 1987 by the Minister of Health in terms of sections 32, 33 and 34 of the Health Act, include provision for coercive measures (for example, isolation and quarantine⁴⁴) in response to scheduled communicable diseases and notifiable medical conditions. The wide definition of “communicable disease” in section 1 of the Act clearly encompasses HIV infection as well as any other disease that can be communicated directly or indirectly. Only certain communicable diseases, however, are expressly listed in the 1987 Regulations as diseases in respect of which specific coercive measures apply **mandatorily**. AIDS (but not HIV infection) is listed in Annexure I to the Regulations as such a disease. (Neither HIV infection nor AIDS are currently declared “notifiable medical conditions” in terms of section 45 of the Health Act. The issue of notifiability is not dealt with in this interim report.)

5.2 Draft regulations, intended to replace the 1987 Regulations, were published for comment under Notice 703 of 1993 in **Government Gazette** No 15011 of 30 July 1993. These make the following changes with regard to HIV/AIDS :

5.2.1 AIDS was removed from Annexure I to the Regulations containing the list of communicable diseases in respect of which coercive measures apply mandatorily.

5.2.2 Regulation 7(4) was added which explicitly prohibits discrimination against pupils with HIV infection.⁴⁵

⁴³ GN R 2438 of 1987 in **GG** 11014 of 30 October 1987.

⁴⁴ Cf reg 17.

⁴⁵ Reg 7(4): “A principal may not refuse attendance of a teaching institution to a pupil who is a carrier of the human immuno-deficiency virus (HIV), or who is suspected of being a carrier of such virus, on this basis only”.

5.2.3 Regulation 15(1) added provisions for measures to be taken when conveying and burying bodies of people known to have died with HIV infection.⁴⁶

5.3 To date the draft Regulations published on 30 July 1993 have not been finalised and promulgated in the **Government Gazette**.

* **Motivation for change**

5.4 Many of the provisions contained in the 1987 Regulations are inappropriate to HIV infection or AIDS.⁴⁷ Although the 1987 Regulations have, apparently, never been applied to people living with AIDS,⁴⁸ the express inclusion of AIDS within Annexure I to the Regulations has been widely criticised.⁴⁹ Furthermore, coercive measures that provide for the isolation and detention of persons with HIV infection or AIDS are not a successful means of curbing the epidemic.⁵⁰ As pointed out in Working Paper 58, quarantine, isolation and detention create a climate of fear and denial which encourages the spread of the epidemic rather than curbing it.

5.5 As pointed out earlier, HIV infection falls within the legal definition of a “communicable disease” in the Health Act (a disease that “can be communicated directly or indirectly ... through any agent to any person or from any person suffering therefrom or who is a carrier thereof to any other person”⁵¹). However, neither HIV infection nor AIDS corresponds with the diseases listed as communicable diseases in respect of which coercive measures apply mandatorily in terms of the 1987 Regulations. The other diseases listed in the Regulations are: chicken pox, cholera, diphtheria, epidemic typhus, German measles, haemorrhagic fever diseases

⁴⁶ Reg 15(1): “The body of a person who ... was a known carrier of HIV at the time of his death may not be conveyed in public in anyway unless - (a) such body is placed in an airtight container and placed in a sturdy non-transparent sealed coffin and the total surface of the body is covered with a 5 cm layer of wood sawdust ...”.

⁴⁷ Cf reg 7 and 17.

⁴⁸ Van Wyk 449; Cameron & Swanson 1992 **SAJHR** 217.

⁴⁹ Cf Van Wyk 259-265; Cameron **Conference Report** 16; Cameron & Swanson 1992 **SAJHR** 211-217; The criticism was accepted in the Commission’s **Working Paper 58** 144 et seq.

⁵⁰ This was accepted in **Working Paper 58** 143 -148.

⁵¹ See the definition of “communicable disease” in sec 1 of the Health Act.

of Africa, haemorrhagic virus conjunctivitis, hepatitis A, leprosy, louse infestation, measles, meningococemia, mumps, plague, poliomyelitis, scabies, tuberculosis of the lungs, typhoid fever and whooping cough.⁵² HIV is transmitted through clearly and narrowly defined routes, and differs from the highly contagious diseases that are subject to mandatory coercive measures under the 1987 Regulations. Because of the particular but limited way by which HIV is transmitted, casual contact between infected and healthy persons presents no threat to public health.⁵³

5.6 Uncertainty exists in the public mind about the status of the 1987 Regulations and whether they may be used in respect of persons with HIV infection or AIDS, particularly as the draft Regulations published on 30 July 1993 removed AIDS from the Annexure listing certain communicable diseases.

5.7 The 1987 Regulations raise constitutional questions regarding the infringement of (amongst others) the rights to privacy, freedom of association and of movement, dignity, and administrative justice.⁵⁴

5.8 The draft Regulations published for comment on 30 July 1993, although an improvement on the existing Regulations, still provide unnecessary restrictions on the transportation and burial of the bodies of persons known to have had HIV infection.⁵⁵ This provision can be criticised for -

5.8.1 creating unnecessary regulation regarding the transportation of bodies;

5.8.2 preventing families from having traditional burials or from using traditional burial grounds; and

⁵² The Regulations relating to Communicable Diseases and the Notification of Notifiable Medical Conditions, GN R 2438 of 1987 in **GG** 11014 of 30 October 1987, Annexure I.

⁵³ **Working Paper 58** 145-146; cf also Cameron and Swanson 1992 **SAJHR** 212-213; and the discussion in Van Wyk 449-452.

⁵⁴ Cf the Constitutional Text, as adopted on 8 May 1996 and amended, sec 14, 12, 18, 21, 10 and 33.

⁵⁵ Reg 15 of the draft Regulations relating to Communicable Diseases and the Notification of Notifiable

5.8.3 perpetuating the stigma and discrimination surrounding HIV infection and AIDS and thus bringing great distress to the family of the deceased.

5.9 All cadavers should in fact be handled with full adherence to universal precautions. These regulations therefore do not prevent the transmission of HIV and are misdirected and unnecessary.

* **Preliminary recommendations contained in Discussion Paper 68**

5.10 It was recommended in Discussion Paper 68 that the Regulations published on 30 July 1993 should be finalised and promulgated subject to the amendment of draft regulation 15, which would place unnecessary restrictions on the conveyance of the body of a person who was known to have been a “carrier of HIV” at the time of his or her death.

* **Comments received**

5.11 The above proposal was virtually unanimously accepted. Reticence was expressed by a single respondent, Dr P W W Coetzer.

5.12 The AIDS Legal Network, NAPWA, the Department of Health, MASA and the Interim SAMDC, amongst others, provided additional support and motivation for the proposal.

5.13 The Infection Control Association of Southern Africa stated that the draft regulations regarding cadavers with HIV infection were inappropriate because all corpses should be treated as potentially infectious.

* **Evaluation of comments**

5.14 The Commission found virtually unanimous support for the proposed changes.

* **Recommendation**

5.15 It is recommended that the Draft Regulations relating to Communicable Diseases and the Notification of Notifiable Medical Conditions, published under Notice 703 of 1993 in Government Gazette No 15011 of 30 July 1993 (and which deschedule AIDS as a communicable disease in respect of which certain coercive measures apply mandatorily) should be finalised and promulgated, subject to the amendment of draft regulation 15 (which currently places unnecessary restrictions on the conveyance of the body of a person who was known to have been a “carrier of HIV” at the time of his or her death).

5.16 Draft regulation 15 should be amended to exclude diseases and conditions, such as HIV infection and AIDS, that are not transmissible from a cadaver during conveyance in public.

* Present position: what is informed consent?

6.1 Informed consent in the health care setting refers to an individual's right to self-determination - the right to consent to, or refuse, any medical procedure after the provision of adequate knowledge to make an informed decision.⁵⁶

6.2 Pre-test counselling forms an important part of informed consent in the context of HIV. Testing for HIV infection presents serious medical, legal, ethical, economic and psychological implications. Because HIV infection is a life-threatening condition, reasonable persons or health care workers will attach significance to the outcome of an HIV test.⁵⁷ Adequate information on these issues therefore forms an essential part of informed consent.⁵⁸ In addition, the assurance of the confidentiality of the test result is an important implied feature of consent.⁵⁹

6.3 The principle of informed consent for HIV testing was accepted in the Commission's Working Paper 58 subject to the possibility of limited exceptions. These may include instances of statutory authorisation, and cases where it is deemed necessary for the protection and treatment of a health care worker who has sustained a risk-bearing injury and

⁵⁶ See **Stoffberg v Elliott** 1923 CPD 148; **Lymbery v Jefferies** 1925 AD 236; **Lampert v Hefer** 1955 2 SA 507 (A); **Esterhuizen v Administrator, Transvaal** 1957 3 SA 710 (T); and more recently, **Castell v De Greef** 1994 4 SA 408 (C); **C v Minister of Correctional Services** 1996 4 SA 292 (T); Strauss 8-9. In addition, section 12(2)(c) of the Constitutional Text as adopted on 8 May 1996 and amended states that: "Everyone has the right to bodily and psychological integrity, which includes the right - ... (c) not to be subjected to medical or scientific experiments without their informed consent".

⁵⁷ Cf **Castell v De Greef** 1994 4 SA 408 (C) that contains the most recent elaboration on the principle of informed consent.

⁵⁸ For an overview of the implications of HIV testing for the individual, see Marks & Goldblum in **Face to Face: A Guide to AIDS Counselling** 50-57; Mann et al **A Global Report: AIDS in the World** 748-759; and Burris **AIDS Law Today: A New Guide for the Public** 115-149, which provide a useful legal overview (albeit in the US context) of HIV testing and law.

⁵⁹ In **Jansen van Vuuren v Kruger** 1993 4 SA 842 (A) the Appellate Division held that HIV-related information was personal and private and could not, in the absence of an overriding legal duty, be disclosed without the express consent of the individual.

where PCR⁶⁰ testing is unavailable. In addition, where an individual is unable to consent, proxy consent may be given in certain circumstances.

6.4 The constitutional guarantees of freedom and security of person, and the rights to privacy and dignity, have become the legal cornerstones for patient self-determination, supported by the case law on informed consent. Thus, Kirk-Cohen J in **C v Minister of Correctional Services**⁶¹ sets out the present position as follows:

[I]t is axiomatic that there can only be consent if the person appreciates and understands what the object and purpose of the test is, what an HIV positive result entails and what the probability of AIDS occurring thereafter is. Evidence was led in this case on the need for informed consent before the HIV test is performed ... Because of the devastation which a positive result entails, the norm so developed contains as a requirement counselling both pre- and post-testing, the latter in the event of a positive result.

* **Motivation for change**

6.5 In addition to guidelines in the **NACOSA National AIDS Plan 1994-1995**⁶² (formally adopted by the Department of Health⁶³), MASA and the Interim SAMDC have both produced professional guidelines addressing HIV testing.⁶⁴ For the reasons below, a single national policy that conforms with the above guidelines, international standards⁶⁵ and South African law is indicated:

6.5.1 Voluntary testing for HIV infection with informed consent is recognised as indispensable in the care and support of persons with HIV infection, and to

⁶⁰ The polymerase chain reaction technique (internationally known as the PCR) can detect the virus itself in the blood immediately, without the hazards created by the window period inherent to other testing methods (Crofts **AIDS in Australia** 26-27). These tests enable health care workers, who believe they may have been occupationally exposed to HIV, to immediately determine whether HIV has been transmitted.

⁶¹ 1996 4 SA 292 (T) at 301.

⁶² Cf **NACOSA National AIDS Plan 1994-1995** 47.

⁶³ Cf Hansard 20 October 1994, col 3451.

⁶⁴ **MASA Guidelines** 8 et seq (supplemented by Draft MASA HIV/AIDS Ethical Guidelines June 1995 2-3) and **SAMDC Guidelines** 4-5.

⁶⁵ Bresolin & Rinaldi 1993 **Journal of Health and Hospital Law** 233.

prevention efforts.⁶⁶

6.5.2 In spite of the existing guidelines, health care workers, members of the public and AIDS organisations observe that many patients are subjected to HIV tests without proper informed consent at public and private health care facilities.⁶⁷

6.5.3 The current professional guidelines are binding only on members of the medical profession and people working under their direction.⁶⁸

6.5.4 Through unnecessary testing, women of reproductive age face infringements of their constitutional rights to dignity, autonomy and privacy (as experienced by a member of the Project Committee). As the WHO states:

... [N]ot only is it unethical to pressure or force women to make reproductive or breast-feeding decisions for any reason, including their HIV status, but those women most likely to be HIV infected may try to avoid mandatory testing, precisely in order to avoid pressure in such decision-making. Such avoidance may have the additional unwanted result of discouraging pregnant women from attending antenatal services.⁶⁹

6.5.5 Testing infants for HIV infection without the informed consent of the mother is an invasion of the **infant** and the **mother's** individual constitutional rights.⁷⁰ Where the mother of an infant still has a parental role, her consent should be sought before testing of the infant.

6.5.5.1 A **mother** may not want to know her HIV status because of the additional stress in caring for and supporting her family. She may fear emotional and physical abuse in the home. She may face discrimination in the community, from her employers and other social service providers. As

⁶⁶ Otten et al 1993 **American Journal Public Health** 529-533.

⁶⁷ Cf Cameron 1993 **SAJHR** 24-25; Leech 1993 **SAJHR** 40; **NACOSA National AIDS Plan 1994-1995** 46-47; also confirmed by personal experience of a member of the Project Committee, Ms Merci Makhalemele.

⁶⁸ Cf **Working Paper 58** 33, 99-101.

⁶⁹ WHO/GPA **Statement from the Consultation on Testing and Counselling for HIV Infection** 4.

with the vast majority of women diagnosed with HIV infection, she may not have access to full medical care and treatment because of costs.

6.5.5.2 Where **infants** with HIV infection are denied treatment because of shortened life-expectancy, early diagnosis will not always be in their best interests. Because infants are unable to give their informed consent to an HIV test, it is necessary to procure proxy consent from an appropriate guardian. A mother is generally qualified to determine what is in the best interest of her child.

6.5.5.3 Where the mother is reluctant to give consent for HIV testing of her infant, a nurse, doctor or trained counsellor can explain to her that she can give her consent to test the infant **for treatment purposes** - without necessarily disclosing the test results to her.

6.5.6 Increasingly, it is possible to reduce or eliminate transmission from mother to infant through provision of medication, surgical options or other procedures. To encourage voluntary testing, these **options** should be made clear to women of reproductive age.

6.5.7 A national policy, with guaranteed confidentiality or anonymity, that ensures pre- and post-test counselling, will encourage voluntary testing.

* **Preliminary recommendations contained in Discussion Paper 68**

⁷⁰ The Constitutional Text as adopted on 8 May 1996 and amended, sec 10, 12, 14.

6.6 It was recommended in Discussion Paper 68 that the Minister of Health exercise the statutory power⁷¹ to issue a national policy on HIV testing and informed consent, enunciating the principles discussed above.

* **Comments received**

6.7 The proposed policy on HIV testing and informed consent received broad support, and additional motivation. Comments providing motivation for the proposal include the following:

6.7.1 The ATICC, Western Cape, pointed out the large amount of “thoughtless” and unnecessary testing, and the concomitant violations of rights that occurs.

6.7.2 COSATU fully supported the proposed policy, especially in view of the large number of employees and job applicants that were being tested without informed consent. They further contended that applicants for insurance are not offered pre-test counselling.

6.7.3 NAPWA saw a special urgency in the proposal on HIV testing because of the “horrendous abuses of human rights” that occur because of non-consensual testing.

6.7.4 The Departments of Labour, Correctional Services, Education and the South African Police Service supported implementation of the policy. The Department of Health endorsed the underlying principles of the proposal, and suggested that additional comprehensive guidelines need to be developed to support those basic principles.

6.7.5 The AIDS Consortium suggested that routine (and illegal) testing was being used

⁷¹ A possible statutory vehicle is sec 2 of the National Policy for Health Act, 116 of 1990, or the relevant provision in the proposed new health legislation. Sec 2 of the National Policy for Health Act states that the Minister of Health may determine the “national policy to be applied in respect of any matter which in his opinion will promote the health of the inhabitants of the Republic ...”.

to ration access to health care.

6.7.6 The AIDS Law Project suggested that many of the abuses that people with HIV infection face could be avoided by implementing a national policy on testing for HIV infection.

6.8 Other respondents supported the basic principles of the proposal, making recommendations for clarifying and strengthening the testing policy. Questions were raised concerning the clarity of the proposed policy, in regard to the rights of health care workers exposed to HIV by needle-stick injury, the best interests of infants, and the necessary procedures for obtaining consent from persons who are legally incapable. These include the following:

6.8.1 Dr E Barker (MASA) stated that health care workers should be explicitly prohibited from testing patients, even with informed consent, for the perceived purpose of protecting themselves from exposure. He also noted that a patient could under current guidelines be tested without his or her informed consent - after following specific procedures - when a medical practitioner had been exposed to potentially infectious material by a risk-bearing event.

6.8.2 The Interim SAMDC supported Dr Barker's submission by emphasising that an individual's right to self-determination should not overrule a practitioner's right to self-protection in given circumstances.

6.8.3 Kwazulu-Natal AIDS Legal Network suggested broader consultation on a national testing policy. It asked whether the policy did not privilege the right of mothers over the rights of the new-born.

6.8.4 AIDSCAP/South Africa raised questions concerning how the testing policy would protect the rights of the mentally and emotionally challenged, and the rights of children under the age of 14.

6.8.5 Dr P W W Coetzer suggested that informed consent and confidentiality are no

different in respect of HIV infection than of any other comparable disease, such as syphilis, and that policy guidelines rather than law should enforce ethical conduct.

6.8.6 Several respondents, including some of the ATICCS, mentioned the need to include references to **post**-test counselling within the policy.

6.8.7 The Life Offices' Association ("the LOA") agreed that "informed consent is both necessary and desirable" but "reserve(d) (its) opinion on the desirability of making pre-test counselling mandatory for all people wishing to take an HIV antibody test". The practicability of pre-test counselling was also a concern of the South African Society of Occupational Medicine.

6.8.8 The LOA expressed concern that the policy might be used to "effectively eliminate the possibility of pre-insurance testing for HIV". The LOA and the Old Mutual specifically stated that they were in the process of developing an "informed consent" form in conjunction with other lobbies. The LOA stated that the insurance industry was not in favour of a general requirement of pre-test counselling, although they recognized that pre- and post-test counselling were included in the legal norm.

6.8.9 The South African National Council for Child and Family Welfare raised questions on the process of obtaining consent to test abandoned children.

* **Evaluation of comments**

6.9 The broad-based support for the policy confirmed the Commission's observation that implementation of a national policy on testing was generally not controversial and was urgently necessary.

6.10 The proposed policy has now been adapted to accommodate and respond to questions raised by respondents. Amendments include: provision in regard to health care

workers exposed to potentially infectious blood; provision for proxy consent; and provision for post-test counselling.

6.11 In the light of the exposition and recommendations in Working Paper 58 (Chapter 3E), as well of submissions received from child welfare and mental health professionals, the Commission has decided to hold over for separate consideration the position of abandoned children and persons in mental institutions.

6.12 In certain instances, the Commission retained the original proposal:

6.12.1 In the light of the judgment by Kirk-Cohen J in **C v Minister of Correctional Services**⁷² the Commission concluded that it was no longer tenable to suggest that the legal norm for informed consent did not include pre-test counselling.

6.12.2 In response to concerns about the feasibility of providing adequate pre-test counselling in **all** instances of HIV testing, the Commission acknowledges that posters, pamphlets and other media (including videos) may be used in making information on HIV/AIDS available, but re-stated its original position that this cannot be regarded as a general substitute for pre-test counselling. In view of comments that supported its conclusions, the Commission reiterated that an unnecessary number of HIV tests was being performed.

6.12.3 In response to the suggestion that broader consultation be initiated to develop guidelines, the Commission endorses the Department of Health's offer to initiate the further drafting of comprehensive guidelines to support the principles enunciated in a legislated policy.

6.12.4 In response to the suggestion that guidelines, on their own, would be preferable to a legally binding policy, the Commission re-emphasises the observation in Working Paper 58 that the health care setting in South Africa does not lack clear

⁷² 1996 4 SA 292 (T) at 301.

professional standards and principles concerning HIV infection and AIDS, but that the problem lies in the implementation and enforcement of those standards,⁷³ and also to the observation above that professional guidelines would not necessarily be binding on all service providers.⁷⁴

6.12.5 In response to the concern that legislation cannot cover the complexity of HIV testing in all circumstances, the Commission underscores that the suggested national policy sets out the basic legal principles that must be adhered to but does not prescribe in detail the necessary course of action for every instance. The Department of Health, in conjunction with other role-players, has offered to develop comprehensive guidelines that will assist service providers to apply these principles.

* **Recommendation**

6.13 It is recommended that the Minister of Health should, under the authority of section 2 of the National Policy for Health Act, 116 of 1990,⁷⁵ adopt a national policy on HIV testing and informed consent.

6.14 It is recommended that the Life Offices' Association continue to develop, with the relevant role-players, professional guidelines for the insurance industry that encompass and advance the legal principles contained in the national policy.

6.15 A draft national HIV testing policy, as recommended, is contained in Annexure D.

⁷³ Working Paper 58 34; cf Barker (Unpublished) 1-4.

⁷⁴ See par 6.5.3 and fn 68 above.

⁷⁵ Sec 2 of the National Policy for Health Act, 116 of 1990, states that the Minister of Health may determine the "national policy to be applied in respect of any matter which in his opinion will promote the health of the inhabitants of the Republic ...".

ANNEXURE A

NOTICE ... OF 1997

DRAFT REGULATIONS

HEALTH ACT, 1977
(ACT NO. 63 OF 1977)

REGULATIONS RELATING TO THE PREVENTION OR CONTROL OF CERTAIN COMMUNICABLE DISEASES

The Minister of Health has made the regulations contained in the Schedule hereto in terms of sections 33 and 40 of the Health Act, 1977 (Act No. 63 of 1977).

SCHEDULE

1. Any person who is responsible for providing medical equipment for use in any hospital, clinic, health care centre, ambulance or any other institution or facility where syringes and needles are used in any medical procedure must take all reasonable steps to ensure -
 - (a) that sufficient disposable syringes and needles are at all times available for use in such institutions or facilities; and
 - (b) that provision is made for their safe disposal.

2. Every person who performs any medical procedure or other health care service which involves the use of syringes and needles must -

- (a) unless the procedure in question on medical grounds requires otherwise, make use only of disposable syringes and needles;
- (b) take all reasonable steps to ensure that used disposable syringes and needles -
 - (i) are not re-used; and
 - (ii) are disposed of in a safe manner.

3. No condom, including a condom designed for use by a female, may be manufactured, offered for sale or distributed for use in South Africa unless it bears a certification mark of the SABS.

4. Any member of the South African Police Service as defined in the South African Police Service Act, 1995 (Act No. 68 of 1995), may seize any condom manufactured, offered for sale or distributed in South Africa, which does not bear a certification mark of the SABS.

5. Any person who manufactures, offers for sale or in any manner whatsoever distributes any condom in South Africa which does not bear a certification mark of the SABS is guilty of an offence and on conviction liable to a fine or to imprisonment for a period not exceeding six months.

ANNEXURE B

NOTICE ... OF 1997

DRAFT REGULATIONS

OCCUPATIONAL HEALTH AND SAFETY ACT, 1993

(ACT NO. 85 OF 1993)

REGULATIONS RELATING TO THE USE OF DISPOSABLE SYRINGES AND NEEDLES

The Minister of Labour, after consultation with the Advisory Council for Occupational Health and Safety and with the Minister of Health, has made the regulations contained in the Schedule hereto in terms of section 43(1)(b) of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).

SCHEDULE

1. Every employer who is responsible for the provision of medical equipment for use in any work place where syringes and needles are used in any medical procedure must take all reasonable steps to ensure -

- (a) that sufficient disposable syringes and needles are at all times available for use in such work place; and
- (b) that provision is made for their safe disposal.

2. Every person who in any work place performs any medical procedure or other health care service which involves the use of syringes and needles must -

- (a) unless the procedure in question on medical grounds requires otherwise, make use only of disposable syringes and needles; and
- (b) take all reasonable steps to ensure that used syringes and needles -
 - (i) are not re-used; and
 - (ii) are disposed of in a safe manner.

ANNEXURE C

NOTICE ... OF 1997

DRAFT REGULATIONS

OCCUPATIONAL HEALTH AND SAFETY ACT, 1993

(ACT NO. 85 OF 1993)

The Minister of Labour has, after consultation with the Advisory Council for Occupational Health and Safety and with the Minister of Health, made the regulations contained in the Schedule hereto in terms of section 43 of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993).

SCHEDULE

Definition

1. In these regulations “the Regulations” means the General Safety Regulations, published under Government Notice No. R. 1031 of 30 May 1986, as amended by Government Notice No. R. 1791 of 9 September 1988 and Government Notice No. R. 2245 of 7 August 1992.

Insertion of subregulations (1A) and (1B) in regulation 3 of the Regulations

2. The following subregulations are hereby inserted after subregulation (1) of regulation 3 of the Regulations:

“(1A) An employer shall take all reasonable steps -

- (a) to promote the use of universal precautions for the prevention of the transmission of the human immuno-deficiency virus, hepatitis B and any other blood-borne pathogens in the work place; and
 - (b) to ensure that all his or her employees receive adequate training in the use of universal precautions for the prevention of the transmission of the human immuno-deficiency virus, hepatitis B and any other blood-borne pathogens in the work place.
- (1B) For the purposes of subregulation (1A) “universal precautions” shall include -
- (a) treating all blood and other body fluids as potentially infectious; and
 - (b) taking all reasonable steps for the prevention of the transmission of the human immuno-deficiency virus, hepatitis B and other blood-borne pathogens.”

Amendment of the Annexure to the Regulations

3. The Annexure to the Regulations is hereby amended by the addition of the following items:

- “Item 19. An adequate supply of absorbent material for the absorption of spilt blood and other body fluids.
- Item 20. Disinfectant to sterilise spilt blood and other body fluids.
- Item 21. 2 Pairs large and 2 pairs medium disposable rubber household gloves.”.

ANNEXURE D

NOTICE NO ... OF 1997

DEPARTMENT OF HEALTH

NATIONAL POLICY FOR HEALTH ACT, 1990 (ACT NO. 116 OF 1990)

I, Nkosazana Clarice Dlamini Zuma, Minister of Health, hereby give notice in terms of section 2 of the National Policy for Health Act, 1990 (Act No. 116 of 1990), that I have determined the national policy to be applied in respect of testing for HIV as set out in the Schedule hereto.

SCHEDULE

NATIONAL POLICY ON TESTING FOR HIV

Testing for HIV infection presents serious medical, legal, ethical, economic and psychological implications in the health care setting. Because HIV infection is a life-threatening condition, reasonable persons or health care workers will attach significance to the outcome of an HIV test, especially a positive diagnosis. For these reasons, and in accordance with the constitutional guarantees of freedom and security of the person, and the right to privacy and dignity, the following HIV testing policy shall constitute national policy. This policy applies to persons able to give consent on their own behalf, as well as to those legally entitled to give consent on behalf of others (proxy consent).

When can HIV testing be done

1. (1) Testing for the human immuno-deficiency virus may be done only -
 - (a) upon individual request, for diagnostic or treatment purposes, with the informed consent of that individual;
 - (b) on the recommendation of a medical doctor that such testing is clinically

indicated, with the informed consent of the individual;

- (c) as part of anonymous and unlinked testing for epidemiological purposes undertaken by the national, provincial or local health authority or an agency authorised by any of these bodies;
- (d) where statutory provision or other legal authorisation exists for testing without informed consent; or
- (e) where an existing blood sample is available, and an emergency situation necessitates testing the source patient's blood (eg when a health care worker has sustained a risk-bearing accident such as a needle-stick injury and polymerase chain reaction (PCR) testing is not feasible), but only after informing the source patient that the test will be performed, and providing for the protection of privacy. The information regarding the result may be disclosed to the health care worker concerned but must otherwise remain confidential and may only be disclosed to the source patient with his or her informed consent.

(2) No partially or wholly publicly funded health care facility may engage in any form of testing for HIV infection which is a pre-requisite for obtaining some benefit .

(3) Routine testing of a person for HIV infection for the perceived purpose of protecting a health care worker from infection is impermissible regardless of consent.

(4) Proxy consent, that is consent by a person legally entitled to grant it on behalf of an individual, may be given where that individual is unable to give consent.

Informed consent and pre-test counselling

2. (1) Testing for HIV infection at all health care facilities will be carried out with informed consent, which includes pre-test counselling. The information regarding the result of the test must remain fully confidential, and may be disclosed in the absence of an overriding

legal or ethical duty only with the individual's fully informed consent.

(2) In the context of HIV/AIDS, testing with informed consent means that the individual has been made aware of, and understands, the implications of the test. This includes the benefits, risks, alternatives and possible social implications of the outcome. This means that the information has to be imparted in a language and in terms that the patient understands.

(3) Pre-test counselling, a confidential dialogue between an individual and a suitably qualified person, such as a doctor, nurse or trained HIV counsellor, constitutes the most effective means of passing on information and gaining consent.

(4) Consent in this context means the giving of express agreement to HIV testing in a situation devoid of coercion, in which the individual should feel equally free to grant or withhold consent. Written consent should be obtained where possible.

(5) Posters, pamphlets and other media (including videos) may be used in making information on HIV/AIDS available, but cannot be regarded as a general substitute for pre-test counselling.

(6) A doctor, nurse, or trained HIV counsellor should accept, after personal consultation, an individual's decision to refuse pre-test counselling. Psychological competence in understanding and dealing with the diagnosis of a life-threatening condition, rather than educational or social status, should be the yard-stick for this decision. Such a decision should only be made on a case-by-case basis and should be recorded in writing.

(7) Where a health care facility lacks the capacity to provide a pre-test counselling service, a referral to a counselling agency or another facility with the capacity to provide pre-test counselling should be arranged before an HIV test is performed.

(8) Where a patient presents with recognisable HIV/AIDS-specific symptoms but no facilities exist for pre-test counselling, then treatment for the specific symptom or illness should proceed without an HIV test. Referral for pre-test counselling with a view to a possible HIV test

should occur at the earliest opportunity.

Interpretation of policy

3. In all instances, this policy shall be interpreted to ensure respect for rights to privacy, dignity and autonomy.

ANNEXURE E

**LIST OF PERSONS AND ORGANISATIONS RESPONDING
TO DISCUSSION PAPER 68**

- * Abdool Karim, Ms Q (former Director, National AIDS Programme, Department of Health)
- * Abdool Karim, Dr S (Director, Centre for Epidemiological Research in Southern Africa at the Medical Research Council)
- * AIDS Consortium
- * AIDSCAP/SOUTH AFRICA
- * AIDS Law Project
- * AIDS Legal Network - national response endorsed by AIDS Law Project; National AIDS Convention of South Africa Lobbying Office; AIDS Consortium; ATICCS of Cape Town, Johannesburg, Pietermaritzburg, Pietersburg, Port Elizabeth and Nelspruit; Lawyers for Human Rights; National Coalition for Gay and Lesbian Equality; and National Association of People Living with HIV/AIDS
- * AIDS Legal Network, Kwazulu-Natal - response endorsed by Pietermaritzburg AIDS Action Group; Diakona Council of Churches; Hillcrest AIDS Centre; Molweni AIDS Centre; LRC Durban; Lawyers for Human Rights Durban Region; Black Sash Advice Office; ATICC Pietermaritzburg; and Province of Kwazulu-Natal Health Services
- * AIDS Training, Information and Counselling Centre (ATICC), Port Elizabeth Municipality
- * AIDS Training, Information and Counselling Centre (ATICC), Western Cape
- * Barker, Dr E M (Chairman: Science and Education Committee, Medical Association of South Africa)
- * Centre for Epidemiological Research in Southern Africa at the Medical Research Council (CERSA)
- * Coetzer, Dr P W W (Department of Community Health, MEDUNSA - responding in his personal capacity)
- * COSATU
- * Davidoff, Dr Avri (Medical School, WITS University)
- * Democratic Nursing Association of SA (DENOSA)
- * Department of Community Health, University of Cape Town

- * Director-General, Department of Trade and Industry
- * Director-General, Department of Health (including responses from the Department's legal unit, and its division for regulation, services and programmes)
- * Director-General, Department of Education
- * Director-General, Department of Correctional Services
- * Director-General, Department of Labour
- * Friends for Life
- * FTO Dental (Pty)Ltd
- * Gillett, Michael D
- * Heywood, Mark (Acting Project Head, AIDS Law Project)
- * Infection Control Association of Southern Africa (ICASA)
- * INBECO
- * Interim National South African Medical and Dental Council (Interim SAMDC)
- * Joemat, Ms T M (MEC Education, Northern Cape Province)
- * Latex Surgical Products (Pty)Ltd
- * Lekoeneha, Ms Kuni (PAO Legal Advisers)
- * Lawyers for Human Rights (LHR), National Directorate
- * The Life Offices' Association of South Africa (LOA)
- * LRC Industries South Africa
- * MacMillan Publishers
- * Mariba, Dr J (MEC Health and Welfare, Northern Province)
- * Medical Association of South Africa (MASA) (Mr Gavin Damster, Manager: Medical Ethics)
- * Metcalfe, Ms M (MEC Education, Gauteng Province)
- * Mini, Dr Clarence (Chairperson, NACOSA)
- * National AIDS Convention of South Africa (NACOSA), Lobbying Office
- * Naidoo, Rajen (Co-ordinator, Occupational Health Programme, Department of Community Health, University of Natal)
- * National Association of People Living with HIV/AIDS (NAPWA), South Africa
- * National Occupational Safety Association (NOSA)
- * Old Mutual
- * Olckers, Ms M (MEC Education and Culture, Western Cape Province)

- * Planned Parenthood Association of SA (PPASA)
- * South African Police Service
- * South African Bureau of Standards (SABS)
- * South African Society of Occupational Medicine (SASOM)
- * Sebokeng Hospital Committee
- * Society for Family Health
- * South African National Council for Child and Family Welfare
- * South African Federation for Mental Health
- * South African Nursing Council
- * South African Association of Social Workers in Private Practice
- * South African Council for Social Work
- * Southern African Catholic AIDS Programme
- * Superintendent, Weskoppies Hospital
- * United Nations Development Programme - Regional Project on HIV and Development for sub-Saharan Africa (UNDP)
- * United Nations Population Fund, Africa Division (UNFPA)