SOUTH AFRICAN LAW COMMISSION

DISCUSSION PAPER 68

Project 85

ASPECTS OF THE LAW RELATING TO AIDS:

National Compulsory Standard for Condoms

Disposable Syringes, Needles and other Hazardous Materials

Universal Work Place Infection Control Measures (Universal Precautions)

Medical Certificates in respect of HIV/AIDS related Deaths

National Policy on HIV Testing and Informed Consent

Regulations relating to Communicable Diseases and the Notification of Notifiable Medical Conditions

CLOSING DATE FOR COMMENT: 15 OCTOBER 1996

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INTRODUCTION

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

The members of the Commission are -

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The Honourable Mr Justice P J J Olivier (Vice-Chairperson)
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PREFACE

This discussion paper (which reflects information gathered up to the end of September 1996), has been prepared by the members of the project committee, who are assisting the Commission with this investigation, and the research staff of the Commission. The idea is to elicit responses which may serve as a basis for the Commission's further deliberations. The discussion paper is published in full so as to provide persons and bodies wishing to comment or to make suggestions for reform with sufficient background information to enable them to place focussed submissions before the Commission. The views, conclusions and recommendations which follow should not at this stage be regarded as the Commission's final views.

Unless representations are marked confidential, the Commission will assume that respondents agree to be referred to. Respondents should be aware that the Commission may be obliged to release information contained in representations under the Constitution of the Republic of South Africa, Act 200 of 1993, pursuant to the constitutional right to freedom of information.

Respondents are requested to submit written comments, representations or requests in any official language of their choice to the Commission by **15 October 1996** at the address appearing on the previous page.

The project leader responsible for this project is The Honourable Mr Justice E Cameron and the researcher, who may be contacted for further information, is Mrs A-M Havenga.

SUMMARY OF PRELIMINARY RECOMMENDATIONS

NATIONAL COMPULSORY STANDARD FOR CONDOMS

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

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

3 Convincing people to use condoms has been one of the most difficult tasks of Health Departments world-wide.

4 Poor manufacturing, packaging, and incorrect storage increase the likelihood of condom failure, and heighten consumer reservations about their use.

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

6 It is recommended that the Minister of Trade and Industry, under the authority granted to him by section 22 of the Standards Act, 29 of 1993 should immediately establish specifications for condoms that coincide with those promulgated by the International Standards Organization and the World Health Organization, and make compliance with these specifications compulsory.

DISPOSABLE SYRINGES, NEEDLES AND OTHER HAZARDOUS MATERIALS

1 Risk of HIV transmission in the work place or health care setting occurs when health care workers recap, re-use, or attempt to sterilise used needles. The use of non-disposable syringes increases the risk of HIV transmission and the transmission of Hepatitis B and other blood-borne pathogens.

2 Re-use of needles and syringes can furthermore lead to **patient-to-patient**

transmission of HIV, Hepatitis B and other blood-borne pathogens.

3 Therefore **patients and health care workers** are put at risk by the use of non-disposable syringes and needles, and the re-use of disposable syringes and needles.

4 Lack of adequate provision of appropriate receptacles for safe disposable of sharps (eg needles, canula, scalpel blades and knives) is associated with increased risk of injuries to health care workers and cleaning staff.

5 It is recommended that statutory provision be made for the destruction of all syringes after single use. The Ministers of Health and Labour should prohibit the use of non-disposable syringes and the re-use of disposable syringes, and also prescribe the safe disposal of syringes and sharps.

UNIVERSAL WORK PLACE INFECTION CONTROL MEASURES (UNIVERSAL PRECAUTIONS)

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 regulations do not explicitly require the use of universal precautions to prevent the transmission of blood-borne pathogens during, or due to, work-place accidents.

2 Through the implementation of universal precautions it is possible to eliminate or substantially reduce the minimal risks of HIV transmission in the workplace. To ensure that these precautions are in fact enforced, as well as to enhance public confidence and understanding of real transmission risks, the relevant statutory regulations need to be amended.

3 Universal precautions are the cheapest and most efficient way to prevent transmission of HIV, Hepatitis B and other blood-borne pathogens in the workplace.

4 It is recommended that the General Safety Regulations, published under section 43 of the Occupational Health and Safety Act, 1993 should be amended to ensure the application of universal precautions, and further reduce the minimal risk of HIV transmission in the workplace.

MEDICAL CERTIFICATES IN RESPECT OF HIV/AIDS-RELATED DEATHS

1 The legal requirements of noting HIV/AIDS as an underlying cause of death on medical certificates on death, and the way that this confidential information is dealt with in practice by the Department of Home Affairs, place doctors in a position of conflict as many consider that their duty of confidentiality is jeopardised because of the public nature of the document.

2 Families of persons who have died of AIDS-related conditions may in addition face ostracism and discrimination.

3 **It is recommended that the Regulations in terms of the Births and Deaths Registration Act, 1992 governing medical certification of death should be altered to protect privacy in relation to HIV/AIDS (and other medical conditions) while at the same time establishing a reliable mechanism for the collation of essential epidemiological information. This could be achieved by requiring medical practitioners to state on one form the full personal particulars of the deceased as well as whether the death was due to natural or unnatural causes and on a separate compulsory form to disclose in an anonymous and unlinked manner the full causes of death.**

NATIONAL POLICY ON HIV TESTING AND INFORMED CONSENT

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.

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

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

4 Uncertainty exists as to what proper informed consent entails. The committee proposes that pre-test counselling forms an integral part of informed consent in the context of HIV testing.

5 The rights of pregnant women and children to privacy, dignity and autonomy should be observed by every health care worker.

6 Testing for HIV/AIDS presents serious medical, legal, ethical, economic and psychological implications. Because HIV is a life-threatening condition reasonable persons or health care workers will, according to established case law, attach significance to the outcome of an HIV test, especially a positive diagnosis. **Adequate information on these issues therefore forms an essential part of informed consent. For these reasons it is recommended that the Minister of Health should issue a national policy on HIV testing and informed consent.**

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

1 Coercive measures that provide for isolation and detention of persons with HIV/AIDS are not successful means of curbing the epidemic. This was accepted in Discussion Paper 58 published by the South African Law Commission in its investigation into Aspects of the Law relating to AIDS (September 1995).

2 Uncertainty exists about the status of the Regulations and whether they may be

used to isolate persons with HIV/AIDS, particularly as the draft Regulations published on the 30 July 1993 removed AIDS from the Annexure listing communicable diseases.

3 The 1987 Regulations could infringe upon (amongst others) the constitutional rights to liberty, privacy, autonomy, freedom of movement, dignity, and administrative justice.

4 The Regulations are inaccurate. HIV is transmitted through clearly defined routes, and does not fit the description of a communicable disease which may be contracted through casual contact.

5 As stated in Working Paper 58 quarantine, isolation and detention create a climate of fear and denial which encourage the spread of the epidemic rather than curbing it.

6 **It is recommended that the Regulations published on 30 July 1993 (and which do not include AIDS as a communicable disease) should be amended, finalised and promulgated**.

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BACKGROUND

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

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.

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 Act (containing a general prohibition against unfair discrimination on the ground of HIV infection) was warranted.

After the appointment of members of the project committee expired, and the appointment of a new representative Law Commission at the beginning of 1996, new appointments were made to the project committee. The 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.

The project committee is pursuing a consultative process in an attempt to resolve the differences. In the mean time, and as an interim measure before submitting any further reports, 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:

* The statutory implementation of a national compulsory standard for condoms according with that of the International Standards Organization.

* A prohibition on the use of non-disposable syringes, needles, and

hazardous material.

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

* The amendment of the Regulations in terms of the Births and Deaths Registration Act, 1992 so as to protect privacy in relation to HIV/AIDS (and other medical conditions) while at the same time establishing a reliable mechanism for the collation of essential epidemiological information.

* The promulgation of a national policy on testing for HIV/AIDS.

* The amendment, finalisation and promulgation of the draft Regulations relating to Communicable Diseases and the Notification of Notifiable Medical Conditions 1993 (and which do not include AIDS as a communicable disease).

Preliminary proposals regarding the above aspects are motivated in this discussion paper. It is to be emphasised that this Paper is published for discussion and that it represents proposals for an interim report. It does not contain the final views of the Commission but represents the preliminary views of the Commission's project committee (drawing on various fields of experience). **The urgent consideration of the Paper and submission of comments upon it, if any, by Tuesday 15 October 1996 are invited.**

PROPOSED STANDARD FOR CONDOMS

7 PRESENT POSITION

The South African Bureau of Standards (SABS) has the authority to examine a commodity and proscribe the manner in which it should be manufactured, handled, stored, and transported. The Minister of Trade and Industry has the authority to issue voluntary and/or compulsory specifications.

7.1 Under the authority of the Standards Act, 29 of 1993 ("the Act"), the SABS has the authority to -

7.1.1 examine, test or analyse articles, materials and substances;

7.1.2 supply information and guidance; and

7.1.3 issue as a national standard a specification ... (Section 3, paragraphs (g) (j) and (l) respectively.)

7.2 Section 16(3)(a)(i) states that the SABS may set and issue as a standard a “specification."

7.2.1 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 ...”.*

7.2.2 A specification also can describe -

"the marking, handling, packing, storage and transport of a commodity".

7.2.3 Section 16(3)(b)(ii) 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*".

7.3 Under SABS 1286-1980 (as amended 1984 and 1991), the SABS has issued a "Standard Specification" for rubber condoms (single use).

7.3.1 Manufacturers of rubber condoms may apply to the SABS for a "Standardization Mark" to illustrate that their product complies with the SABS' requirements. For instance, Durex Condoms carry the SABS mark of approval.

7.4 Compliance with the standard is voluntary and not compulsory.

7.5 The Minister of Trade and Industry has the authority to issue compulsory specifications under Section 22 of the Act, wherever safety, health and consumer protection are concerned.

7.5.1 Products that do not comply with compulsory specifications may not be sold. (Section 23.)

7.5.2 Section 16(3)(b)(ii) of the Act accepts that certification by an organization recognized by the Minister (such as the United States' Food and Drug Administration [FDA], or the International Standards Organization [ISO]) constitutes compliance with such a compulsory standard.

8 CRITICISM

8.1 The SABS has issued specifications for condoms (SABS 1286), but compliance is voluntary and not compulsory.

8.2 The SABS 1286 specification falls short of the ISO's and the World Health Organization's (WHO) specification on condoms. Certain of the latter specifications should be made applicable in South Africa. For example -

8.2.1 ISO and WHO specifications require an air burst test, which is not part of SABS 1286;

8.2.2 SABS 1286 contains no specification on packaging, even though proper packaging is one of the crucial factors in preventing condom breakage.

9 MOTIVATION FOR CHANGE

Condoms are one of the most effective ways to prevent HIV transmission.[1]

9.1 When used correctly, a properly stored and manufactured condom can dramatically reduce the possibility of transmission of HIV and sexually-transmitted diseases (STDs).[2]

9.2 Convincing people to use condoms is one of the most difficult tasks of

[1]Galavotti C; Cabral RJ; Lansky A; Grimley DM; Riley GE; Prochaska JO, "Validation of measures of condom and other contraceptive use among women at high risk for HIV infection and unintended pregnancy," Women's Health and Fertility Branch, Centers for Disease Control and Prevention, Atlanta, Georgia 30341-3724, USA; Health Psychol 1995 Nov; 14 (6): 570-8.

[2]Deschamps M M; Pape J W; Hafner A; Johnson W D Jr, "Heterosexual transmission of HIV in Haiti," Cornell University Medical College, New York, New York, USA, Ann Intern Med 1996 Aug 15; 125 (4): 324-30

Health Departments world-wide.[3]

3.3 Poor manufacturing, packaging, and incorrect storage increase the likelihood of condom failure, and heighten consumer reservations about their use.

3.4 Condom breakage or failure increases the risk of HIV transmission.[4]

3.5 The SABS can help promote the effective use of condoms by refusing to allow the sale or importation of sub-standard condoms.

3.6 The WHO report on Condom Quality asks regulatory agencies like the SABS to ensure that “high-quality latex barriers to STD/HIV transmission are accessible to those who need them". [5]

3.7 Many brands of condoms sold in South Africa do not even carry the seal of SABS approval. This undermines efforts to provide quality condoms to consumers.

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[3]Martin, David J. "Inappropriate Lubricant Use Condoms by Homosexual Men," 1192 U.S. Department of Health and Human Services, Public Health Reports; Public Health Rep 1992; 107; 468-473.

[4]Sparrow M J; Lavill K, “Breakage and slippage of condoms in family planning clients,”: New Zealand Family Planning Association, Wellington; Contraception 1994 Aug; 50 (2): 117-29.

[5]WHO Specifications and Guidelines for Condom Procurement (1995).

10 PRELIMINARY RECOMMENDATIONS

It is recommended that the Minister of Trade and Industry, under the authority granted to him by section 22 of the Standards Act, 29 of 1993, should immediately establish specifications for condoms that coincide with those promulgated by the ISO and the WHO, and make compliance with these specifications compulsory.[6]

It is recommended that the Minister issue a compulsory specification to the effect that -

1) the SABS specification on condoms (1286-1980) (as amended), shall be further amended to conform more closely with WHO and ISO standards;

2) condoms sold, distributed, or manufactured in South Africa shall comply with this standard, or the ISO standard;

3) compliance shall be compulsory rather than voluntary;

4) until the SABS or ISO promulgates standards on female condoms, all female condoms shall comply with the FDA's standard on female condoms.

10.1 It is further recommended that the Minister of Trade and Industry should, in consultation with the WHO, the ISO and condom manufacturers develop compulsory specifications for female condoms.

[6]Cf ISO Regulation 4074 and the WHO Specification (1995).

DISPOSABLE SYRINGES, NEEDLES AND OTHER HAZARDOUS MATERIALS

11 PRESENT POSITION

11.1 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.

11.2 Under the authority of the Health Act, 63 of 1977, section 42(b), the Minister of Health may make regulations -

11.2.1 *"relating to instruments, equipment or apparatus used or intended to be used in connection with the diagnosis, treatment, prevention or relief of physical defects or disease ...".*

11.3 Under the authority of the Occupational Health and Safety Act, 85 of 1993, section 43(b), the Minister of Labour may make regulations -

11.3.1 *"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 ...".*

12 CRITICISM

12.1 Risk of HIV transmission in the work place or health care setting occurs when health care workers recap, re-use, or attempt to sterilise needles.[7]

[7]Aylward, B. ; Lloyd, J. ; Zaffran, M. ; McNair-Scott, R. ; Evans, P., "Reducing the Risk of Unsafe Injections in Immunization Programmes: Financial and Operational Implications of Various Injection Technologies," Bulletin of the World Health Organization July, 1995, Vol. 73 ; No. 4; Pg. 531; ISSN: 0042-9686.

12.2 Re-use of needles and syringes can lead to patient-to-patient transmission of HIV, Hepatitis B and other blood-borne pathogens.[8]

12.2.1 The highest risk of patient-to-patient transmission of blood-borne pathogens occurs during mass immunisation campaigns where unsterilised needles are re-used or a single, disposable syringe is used to immunise a number of subjects.

12.3 Patients and health care workers as well as cleaning staff are put at risk by the use of non-disposable syringes and needles, and the re-use of disposable syringes and needles. [9]

12.4 Lack of adequate provision of appropriate receptacles for safe disposable of sharps (eg needles, canula, scalpel blades and knives) is associated with increased risk of injuries to health care workers and cleaning staff.[10]

12.5 Employers and health care providers (e.g. hospitals) are responsible for HIV exposure that occurs due to their failure to take reasonable precautions, such as providing for the use, and easy destruction, of disposable syringes.

13 MOTIVATION FOR CHANGE

Although the risk of exposure to and transmission of HIV in the health care

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[8]See footnote 5 above. Also see: Wyatt, "HIV: Injections, infections, and sterility," Bloem M, Wolffer X, ed.s The Impact of Injections on Daily Medical Practices, Amsterdam, University Press, 1993.

[9]Fowler, Shantelle, "More Education, Engineering Controls Needed to Prevent Workplace AIDS Exposure, Unions Say, "The Bureau of National Affairs, Inc., Occupational Safety & Health Reporter, Current Report August 28, 1996; Vol. 26, No. 13; Pg. 315.

[10]Mayfield, Eleanor, "Protecting Patients and Professionals From Blood-borne Disease; Includes Related Articles," 1993 U.S. Department of Health and Human Services FDA Consumer, Vol. 27 ; No. 3 ; Pg. 9; ISSN: 0362-1332.

setting is minimal, poor hygiene and the failure to take universal precautions increase those risks.

13.1 HIV, Hepatitis B and other blood-borne pathogens can be transmitted from patient to patient if unsterile needles are used.

13.2 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.

13.2.1 The costs associated with such exposures - counselling, testing, and prophylaxis - are significant, irrespective of whether HIV transmission occurs.[11]

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

7.4 Reports have been made in the media in the recent past of bio-hazardous disposable materials used in patient-care in health care facilities found dumped in municipal and other uncontrolled waste disposal sites. Statutory provision for safe disposal of all such potentially hazardous material will be in the interest of the general public as well.

14 PRELIMINARY RECOMMENDATION

Statutory provision for the compulsory safe disposal of all syringes and needles after their use should be made. The Ministers of Health and Labour should prohibit the use of non-disposable syringes and the re-use of disposable syringes, and also prescribe the safe disposal of syringes and sharps .

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[11]Bleicher, Beatrice K., “Protecting Employees Against Hepatitis B,” American Hospital Association Journal of Health and Hospital Law, February, 1991; Vol. 24, No. 2, HOSPLW Pg. 41.

14.1 It is recommended that the Minister of Health and the Minister of Labour should, under the authority of section 42(b) of the Health Act and section 43(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 - every health care facility, 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 should:*

a) *Ensure the appropriate use of disposable syringes and needles; and*

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

UNIVERSAL WORK PLACE INFECTION CONTROL MEASURES (UNIVERSAL PRECAUTIONS[12])

15 PRESENT POSITION

Employers are required to ensure a reasonably safe working environment and

[12]The concept of "universal precautions" is used worldwide in the context of AIDS to indicate control measures in the health care setting aimed at the prevention of HIV infection. 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 Dyk A C, AIDS: The Health Care Challenge, Alteks, Pretoria 1994: 129-134).

are liable for injuries that result from their failure to do so. Current statutory provisions do not explicitly require the use of universal precautions to prevent the transmission of HIV, Hepatitis B[13] or other blood-borne pathogens during, or as a result of, work-place accidents.

15.1 The Occupational Health and Safety Act, 85 of 1993 presently requires employers to provide and maintain, as far as is reasonably practicable, a safe working environment.

15.1.1 The General Safety Regulations published under the Occupational Health and Safety Act (GN R 1031 in GG 10252 of 30 May 1986), as amended, requires employers to -

1) provide access to prompt first aid;

2) train personnel on its appropriate use; and

3) promote a safe work environment.

15.2 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.

15.2.1 Any failure to provide such equipment constitutes an offense under this Act. (Section 71(2)).

16 UNCERTAINTY OR CRITICISM

[13]In the USA universal precautions include inoculation against Hepatitis B. See Synopsis, "Procedure-specific Approach Recommended to Control Communicable Disease Transmission,"The Bureau of National Affairs, Inc., Occupational Safety & Health Reporter, Current Report, May 8, 1991; Vol. 20, No. 48; Pg. 1676.

Through the implementation of universal precautions, it is possible to eliminate or substantially reduce, the minimal risks of transmission of HIV, Hepatitis B and other blood-borne pathogens in the workplace. To ensure that these precautions are in fact enforced, as well as to enhance public confidence and management understanding of real transmission risks, the relevant statutory provisions need to be amended.

16.1 The Regulations issued under the Occupational Health and Safety Act are incomplete in that they omit to prescribe the use of universal precautions in response to all work place accidents.

17 MOTIVATION FOR CHANGE

Universal precautions are the cheapest, most efficient way to prevent transmission of HIV, Hepatitis B and other blood-borne pathogens in the workplace. [14]

17.1 Universal precautions means treating all blood and body fluids as potentially infectious. The scale of the epidemic suggests that all workplaces will have employees with HIV, and that universal precautions would help reduce the possibility of transmission.

17.2 Within the work environment, where a range of accidents may occur, it is impossible to determine which blood or body fluids are infectious.[15] In

[14]Synopsis, "Draft Copy of OSHA's Proposed Standard for Blood-borne Pathogens," The Bureau of National Affairs, Inc., Occupational Safety & Health Reporter, Current Report January 18, 1989; Vol. 18, No. 33; Pg. 1492

[15]Fowler, Shantelle, "More Education, Engineering Controls Needed to Prevent Workplace AIDS Exposure, Unions Say" The Bureau of National Affairs, Inc., Occupational Safety & Health Reporter,

any event, treating all blood as potentially infectious is cheaper than testing all blood for pathogens.

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17.3 A few simple steps can prevent transmission of blood-borne pathogens in the workplace:

17.3.1 Cloth or other material should be used to absorb spilt blood;

17.3.2 gloves should be used to handle blood or potentially bloody objects;

17.3.3 syringes should be disposed of after use; and

17.3.4 a 10% freshly diluted bleach solution should be used as a disinfectant.

18 PRELIMINARY RECOMMENDATIONS

It is recommended that the General Safety Regulations, published under the Occupational Health and Safety Act, 1993 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 workplace.

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

1) An employer shall further take all reasonable steps, including the promotion of universal infection control,

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Current Report, August 28, 1996; Vol. 26, No. 13; Pg. 315.

to prevent the transmission of HIV, Hepatitis B, and other blood-borne pathogens.

2) In addition to the training contemplated in sub-regulation (4), all employers with more than ten employees shall provide training on the use of universal precautions to prevent the transmission of blood-borne pathogens in the workplace.

18.2 To clarify the meaning of universal precautions, it is recommended that the Annexure to the General Safety Regulations be amended to add:

Universal Precautions shall include:

1) Treating all blood and body fluids as potentially infectious; and

2) taking such reasonable steps as may be appropriate to prevent the transmission of HIV, Hepatitis-B, and other blood-borne pathogens.

18.3 Regulation 3(4) of the General Safety Regulations already requires that employers with more than 10 employees maintain a first aid box for use in case of workplace accidents. The Annexure to these Regulations lists 18 items that must be included within the first aid box. It is recommended that, to comply with national and international standards on universal precautions, the Annexure to the Regulations be amended to provide for the addition of the following three items within first-aid boxes:

1) *Absorbent material such as cloth, for the absorption of spilt blood and other body fluids.*

2) *Disinfectant, such as sodium hypo chlorite to clean up remaining spillage.*

3) *Rubber house-hold gloves for handling blood soaked material.*

MEDICAL CERTIFICATES IN RESPECT OF HIV/AIDS RELATED DEATHS

19 PRESENT POSITION

Medical certificates on death at present require medical practitioners to disclose “the cause” of a person’s death when registering the death with the Ministry of Home Affairs.

19.1 The Births and Deaths Registration Act, 51 of 1992 ("the Act") prescribes the manner in which deaths are registered.

19.1.1 Section 15(1) requires a medical practitioner who is satisfied that the death of a person who was attended before his death by that practitioner was due to natural causes, to issue a "prescribed certificate stating the cause of death."

19.1.2 Section 15(2) provides that a medical practitioner who did not attend a person before his death but after the death examined the corpse and is satisfied that the death was due to natural causes, may issue a prescribed certificate to that effect.

19.2 The Minister of Home Affairs has issued regulations under the Act to prescribe the form of medical certificate on death that medical

practitioners must complete. (See the Annexures contained in GN R 2139, GG 14182 of 9 September 1992.)

19.2.1 Annexure 5, section prescribes the medical certificate in respect of death that requires a medical practitioner to state -

19.2.1.1. what the final disease or condition resulting in death was;

19.2.1.2. what the contributory cause, if any, resulting in death was;

19.2.1.3. what the underlying cause (disease/injury) that initiated events resulting in death was;

19.2.1.4. and to certify that the death was due solely and exclusively to natural causes.

19.2.2 Annexure 4 prescribes the form and the information to be supplied in a death register which elicits the cause of death from a specified informant.

19.2.3 Annexure 9 prescribes a death certificate that, when completed, lists the cause of death.

20 CRITICISM

To conform with international standards, epidemiological research should be performed with anonymous and unlinked reporting of deaths and their causes. At present the Regulations governing medical certification in respect of death do not adequately protect the privacy and dignity of families of persons who have

died of HIV/AIDS and other diseases.

20.1 The current forms are inadequate.

20.1.1 The legal requirements of noting HIV/AIDS as an underlying cause of death on medical certificates on death and the way that this confidential information is dealt with by the Department of Home Affairs, place doctors in a position of conflict as many consider that their duty of confidentiality is jeopardised because of the public nature of the document.

20.1.2 Families of persons who have died of AIDS related conditions may in addition face ostracism and discrimination.

14.1.3 Insurance companies and their clients may make adequate provision for obtaining information without recourse to a public document.

14.1.4 The medical certificate on death is not the appropriate mechanism to inform sexual partners that they may have been put at risk of exposure to HIV by the deceased.

15 MOTIVATION FOR CHANGE

There are alternate, less invasive, and more efficient ways to compile information on causes of death, that do not require recording private information on a public document.

15.1 The purpose of the Births and Deaths Registration Act is to establish procedures for notifying the Director-General of Home Affairs that a death has occurred, and to investigate unnatural deaths by requiring medical practitioners to notify the police authorities when a death is due to unnatural causes.

15.2 The Minister of Home Affairs in conjunction with the Minister of Health

should establish separate procedures for recording necessary epidemiological information.

15.3 Unlinked and anonymous records can and should efficiently record causes of death for epidemiological purposes.

15.4 These procedures can follow the French, Dutch, Canadian and Australian jurisdictions which have two forms - one which records that Citizen X has died of natural (or unnatural) causes, and another form which is anonymous and unlinked and contains a full record of the cause of death and sufficient demographic (but not personal) data.[16]

15.5 The benefits accruing from the recommended system will extend to persons who die from all illnesses and conditions because intensely private and personal information previously recorded on a public document will remain private.

16 PRELIMINARY RECOMMENDATIONS

It is recommended that the Regulations in terms of the Births and Deaths Registration Act, 1992 governing medical certification of death be changed to protect privacy rights in relation to HIV/AIDS (and other medical conditions) while at the same time establishing a reliable mechanism for the collation of essential epidemiological information.

16.1 To attain this it is suggested that section B of Annexure 5 of the Regulations be modified to the following effect to protect the confidentiality and privacy of each person:

1) The medical practitioner should still be expected to certify in accordance with paragraph 13.2.1.4 (above) that the death was

[16]Documentation available through the AIDS Consortium.

due to natural causes.

2) The questions referred to in subparagraphs 13.2.1.1-3 above, should, however, be deleted from this form, and transferred to a separate form, required by the Department of Health in conjunction with the Department of Home Affairs for epidemiological purposes. This form should be required to be subject to compulsory completion by the medical practitioner in question, to ensure anonymous and unlinked reporting of all deaths, including AIDS-related deaths.

16.2 It is further recommended that both Annexure 4 and Annexure 9 of the Regulations be modified so that the question "cause of death?" is replaced by the requirement that the appropriate medical practitioner certify that the cause of death was either natural or unnatural.

A NATIONAL POLICY ON HIV TESTING AND INFORMED CONSENT

17 PRESENT POSITION: WHAT IS INFORMED CONSENT?

Informed consent in the health care setting refers to the patient's right of self-determination - the right to consent to or refuse any medical procedure after the provision of adequate knowledge to make an informed decision. [17]

17.1 The principle of informed consent was accepted in the Commission's Working Paper 58 subject to the possibility of limited exceptions.

17.2 Pre-test counselling is an important part of informed consent in the context of HIV: Testing for HIV/AIDS presents serious medical, legal, ethical, economic and psychological implications. Because HIV is a

[17] See *Stoffberg v Elliott* 1923 CPD 148; *Lymbery v Jefferies* 1925 AD 236; *Lampert v Hefer NO* 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). In addition, section 12(2)(c) of the constitutional text as adopted on 8 May 1996 states that: "**Everyone has the right to bodily and psychological integrity, which includes the right not to be subjected to medical or scientific experiments without their informed consent**."

life-threatening condition reasonable persons or health care workers will, according to established case law,[18] attach significance to the outcome of an HIV test, especially a positive diagnosis. Adequate information on these issues therefore forms an essential part of informed consent.[19]

17.3 In Jansen van Vuuren NNO v Kruger[20] the Appellate Division held that HIV-related information was personal and private and could not be disclosed even by health care workers without the express consent of the patient.

17.4 The constitutional guarantees of freedom and security of person, and the rights of privacy and dignity, have become the legal cornerstones for patient self-determination supported by the case law on informed consent.

18 MOTIVATION FOR CHANGE

In addition to the Guidelines on Testing in the National AIDS Convention of South Africa's National AIDS Plan (adopted by the Department of Health), at least two other sets of ethical guidelines on testing for HIV exists. The Medical Association of South Africa (MASA) and the South African Medical and Dental Council (SAMDC) have both produced guidelines.[21] A single national policy that conforms with the above guidelines, international standards[22] and South African law will be indispensable to patients and health care workers. Some of the

[18]Castell v De Greef 1994 (4) SA 408 © contains the most recent elaboration on the principle of informed consent.

[19]For an overview of the implications of HIV testing on the individual see Marks and Goldblum "The Decision to Test: A Personal Choice" in Dilley et al Face to Face: A Guide to AIDS Counselling The AIDS Health Project, San Francisco(1989); a global overview on HIV testing may be found in Mann et al 1992 A Global Report: AIDS in the World Harvard, Cambridge pp748-759; also Burris, S. (1993) "Testing, Disclosure and the Right to Privacy" provides a useful legal overview (albeit in the U.S. context) of HIV testing an law in AIDS Law Today: A New Guide for the Public Yale University Press, 1993: 115-149.

[20]Jansen van Vuuren NNO v Kruger 1993 4 SA 842 (A).

[21]See the MASA's HIV/AIDS Ethical Guidelines 26 January 1996 and the SAMDC's The Management of Patients with HIV infection or AIDS (July 1994).

[22]Bresolin, Linda B., Ph.D, Rinaldi, Robert C. Ph.D., "HIV Blood Test Counselling Guidelines" American Hospitals Association, Journal of Health and Hospital Law, August, 1993; Vol. 26, No. 8, HOSPLW Pg. 233.

reasons for this are set out below.

18.1 Voluntary testing for HIV with informed consent is recognised as indispensable in the care and support of persons with HIV, and to prevention efforts.[23]

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

18.3 Women of reproductive age face constant infringements of their constitutional rights to dignity, autonomy and privacy. Increasingly, however, it is possible to reduce or eliminate transmission from mother to infant. As the WHO states:

> *"... not 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."*[24]

18.4 Testing infants for HIV without the informed consent of the *mother* is an

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[23]Otten MW Jr; Zaidi AA; Wroten JE; Witte JJ; Peterman TA, "Changes in sexually transmitted disease rates after HIV testing and post-test counselling, Miami, 1988 to 1989," Division of STD/HIV Prevention, Centers for Disease Control and Prevention, Atlanta, Ga. 30333; Am J Public Health 1993 Apr; 83 (4): 529-33.

[24]WHO/GPA Statement from the Consultation on Testing and Counselling for HIV Infection November

invasion of the child *and* the mother's individual constitutional rights. A mother may not want to know her HIV status because of the additional stress in caring and supporting her family; she may fear emotional and physical abuse in the home; as with the vast majority of women diagnosed with HIV, she will not have access to full medical care and treatment because of costs; and, she may face discrimination in the community, from her employers and other social services.

18.5 Early diagnosis will not always be in the best interests of the child where children with HIV are denied treatment because of shortened life-expectancy.

18.6 Where the mother of the child still has a parental role, her consent should first be sought before the testing of the child.

18.7 It is suggested that a national policy will encourage voluntary testing accompanied by pre- and post-test counselling with guaranteed confidentiality or anonymity at health facilities.

19 PRELIMINARY RECOMMENDATIONS

The Minister of Health should exercise her statutory powers to issue a national policy on testing for HIV/AIDS.[25]

19.1 Section 44(a)(ii) of the Health Act, 63 of 1977 states that the Minister may make regulations in respect of private health care facilities by "*prescribing minimum standards with which such hospitals, homes or institutions shall comply".*

1992 p4.

[25]The appropriate statutory power is section 44(a)(ii) of the Health Act, 63 of 1977, which is presently under review. An alternative power would be found under section 2 of the National Policy for Health Act, 116 of 1990.

19.2 Section 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 ...*".

19.3 It is recommended that the Minister of Health should, under the authority vested in her, adopt the appended policy on HIV-testing and informed consent. (See Annexure A).

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

20 PRESENT POSITION

The former Department of Health in 1987 promulgated communicable disease regulations entitled *Regulations Relating to Communicable Disease and the Notification of Notifiable Medical Conditions* in terms of sections 32, 33 and 34 of the Health Act, 63 of 1977.

20.1 These Regulations (contained in GN R 2438) were promulgated on 30 October 1987 in Government Gazette 11014. They include provisions for numerous coercive measures, including isolation and quarantine, which are inapplicable and inappropriate[26] to HIV/AIDS.

20.2 Draft communicable disease regulations were published for comment under Notice 703 of 1993 on the 30 July 1993 in GG No 15011. These make the following changes with regard to HIV/AIDS :

20.2.1 AIDS was removed from the Annexure to the Regulations containing the list of communicable diseases.

[26]Cf Reg 2, 6, 14 and 17.

20.2.2 Reg 7(4) was added which explicitly prohibits discrimination against pupils with HIV.[27]

20.2.3 Reg 15(1) added provisions for measures to be taken when transporting and burying bodies of people known to have died with HIV.[28]

20.3 To date the draft regulations published on the 30 July 1993 have not been finalised and promulgated in the Government Gazette.

21 CRITICISM

21.1 Coercive measures that provide for isolation and detention of persons with HIV/AIDS are not successful means of curbing the epidemic. This was accepted in Working Paper 58 published by the South African Law Commission in its investigation into Aspects of the Law relating to AIDS (September 1995).

21.2 Uncertainty exists about the status of the Regulations and whether they may be used to isolate persons with HIV/AIDS, particularly as the draft Regulations published on the 30 July 1993 removed AIDS from the Annexure listing communicable diseases.

21.3 The 1987 Regulations could infringe upon (amongst others) the constitutional rights to liberty, privacy, autonomy, freedom of movement,

[27]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 carrier of such virus, on this basis only."

[28]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 ..."

dignity, and administrative justice.

21.4 The Regulations are inaccurate. HIV is transmitted through clearly defined routes, and does not fit the description of a communicable disease which may be contracted through casual contact.

21.5 As pointed out in Working Paper 58 quarantine, isolation and detention create a climate of fear and denial which encourage the spread of the epidemic rather than curbing it.

21.6 The draft Regulations published for comment on the 30 July 1993, although an improvement on the existing regulations, still provide unnecessary restrictions on the transportation and burial of bodies of persons known to have HIV. These provisions have been criticised for -

21.6.1 creating unnecessary regulation over the transportation of bodies. Such steps do not prevent the further transmission of the virus - all cadavers should be handled with full adherence to universal precautions;

21.6.2 preventing families from having traditional burials or from using traditional burial grounds;

21.6.3 bringing great distress to the family of the deceased; and

21.6.4 perpetuating the stigma and discrimination surrounding HIV.

22 MOTIVATION FOR CHANGE

22.1 Coercive measures to curb the epidemic are not effective. This has been recognised both internationally and in South Africa.

22.2 The 1987 Regulations indicate an outdated approach to HIV/AIDS prevention.

22.3 Clarity is needed on this issue to prevent uncertainty, confusion and discrimination.

23 PRELIMINARY RECOMMENDATIONS

23.1 It is recommended that the Regulations published on 30 July 1993 in Government Gazette No. 15011 should be amended, finalised and promulgated.

23.2 Draft Regulation 15 should be amended to exclude all diseases or conditions that are not transmissible from a cadaver including HIV/AIDS.

ANNEXURE A

PROPOSED NATIONAL POLICY ON HIV TESTING AND INFORMED CONSENT

Testing for HIV/AIDS presents serious medical, legal, ethical, economic and psychological implications in the health care setting. Because HIV is a life-threatening condition reasonable persons or health care workers , according to established case law, 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 be implemented nationally.

1 INFORMED CONSENT AND PRE-TEST COUNSELLING POLICY

1.1 HIV testing at all health care facilities will be carried out with informed consent, which includes pre-test counselling and with guaranteed confidentiality.

1.2 In the context of HIV/AIDS, testing with informed consent means that the patient has been made aware of the implications of the test. This includes benefits, risks, alternatives and the possible social implications of the HIV test.

1.3 This information has to be imparted in a language and in terms that the patient understands.

1.4 Pre-test counselling, a confidential dialogue between a trained HIV counsellor and patient, constitutes the most effective means of passing on

information and gaining consent.

1.5 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 by a trained HIV counsellor should be arranged before an HIV test is performed.

1.6 Where a patient presents with recognisable HIV/AIDS specific symptoms and where no facilities exist for adequate pre-test counselling, treatment for the specific symptom or illness may be undertaken without an HIV test. Referral to a specialist counsellor for pre-test counselling should be undertaken at the earliest opportunity.

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

1.8 The use of posters, pamphlets and other media are encouraged to assist in making information on HIV/AIDS available but cannot be regarded as a general substitute for pre-test counselling.

1.9 A trained HIV counsellor should accept, after personal consultation, a client's decision to refuse pre-test counselling. Psychological competence in 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 be recorded in writing by the counsellor.

2 WHEN CAN HIV TESTING BE DONE?

2.1 Testing will be done only with informed consent under the following circumstances:

2.1.1 On individual request for diagnostic and treatment purposes; and

2.1.2 when clinically indicated on recommendation from a medical doctor.

2.2 Anonymous and unlinked testing for epidemiological purposes may only be undertaken by the national, provincial or local health authority or an agency authorised by any of these bodies.

2.4 Test results will be confidential.[29]

2.5 No partially or wholly publicly funded health care facility may engage in any form of testing for HIV which is mandatory, or compulsory, or a pre-requisite for obtaining some benefit .

2.6 The rights of pregnant women and children to privacy, dignity and autonomy, should be observed by every health-care worker.

[29]For guidelines on confidentiality, see MASA HIV/AIDS Ethical Guidelines (1996).