

**PREVALENCE OF LATEX ALLERGY IN SPINA BIFIDA PATIENTS IN  
UNIVERSITAS ACADEMIC HOSPITAL**

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8 August 2020

## DECLARATION OF AUTHORSHIP

I, Dr Zwelithini Mpungana, declare that the coursework mini dissertation that I herewith submit in a publishable manuscript format for the Master's degree qualification MMed in Neurosurgery at the University of the Free State is my own, independent work, and that I have not previously submitted it for a qualification at another institution of higher education.

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## **ACKNOWLEDGEMENTS**

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## TABLE OF CONTENTS

DECLARATION OF AUTHORSHIP .....	II
ACKNOWLEDGEMENTS.....	III
TABLE OF CONTENTS .....	IV
LIST OF TABLES.....	VI
ABSTRACT.....	VII
CHAPTER 1: LITERATURE REVIEW .....	8
1.1.    DEFINITIONS AND TYPES OF LATEX ALLERGIES AND REACTIONS.....	8
1.2.    RECOGNITION AND EVALUATION PREVALENCE AND AT-RISK INDIVIDUALS .....	9
1.3.    SIGNS AND SYMPTOMS .....	9
1.4.    OTHER ASSOCIATED ALLERGIES.....	10
1.5.    MANAGEMENT.....	10
1.6.    SCREENING.....	10
1.6.1.    Skin-Patch Test.....	11
1.6.2.    Skin-Prick Test.....	11
1.6.3.    Intradermal Test .....	11
1.6.4.    IgE Antibody Immunoassays .....	11
1.6.5.    Use Test .....	12
1.7.    PREVENTION .....	12
1.7.1.    Use of topical barriers.....	12
1.8.    Aims and objectives .....	13
REFERENCES.....	14
CHAPTER 2: PREVALENCE OF LATEX ALLERGY IN SPINA BIFIDA PATIENTS IN UNIVERSITAS ACADEMIC HOSPITAL .....	17
ABSTRACT.....	18
2.1.    Introduction .....	19
2.2.    Material and methods .....	19
2.3.    Results.....	21
2.4.    Discussion.....	22
2.5.    Conclusion.....	23
REFERENCES.....	24
APPENDIX A: LETTER OF APPROVAL FROM THE RESEARCH ETHICS COMMITTEE .....	25
APPENDIX B : PERMISSION LETTER.....	27

APPENDIX .C: RESEARCH PROTOCOL APPROVED BY ETHICS COMMITTEE. ....	27
APPENDIX D: DATA SHEET .....	34
APPENDIX E: AFRIKAANS AND SESOTHO CONSENT .....	36
APPENDIX F: INSTRUCTIONS TO AUTHORS (SAMJ) .....	37
APPENDIX G. TURNITIN PLAGIARISM SUMMARY .....	38

## LIST OF TABLES

Table 1: Characteristics of study patients: Age and number of operations.....	22
Table 2: Measurement outcomes.....	22

## ABSTRACT

**Background:** Latex allergy in spina bifida patients has attracted a great deal of interest around the world, especially in Europe and the United States, where it is estimated to be as high as 67%. It is one of the primary reasons for anaphylaxis in the operating theatre, which occurs in about 50% of patients with myelomeningocele. Epidemiology from South Africa is scarce, especially for the Free State province.

**Objective:** To estimate the prevalence of latex sensitivity and latex allergy in a population of patients with spina bifida at Universitas Academic Hospital and to describe associated risk factors.

**Methods:** A descriptive, cross-sectional observational study was undertaken. A questionnaire gathered information on family and personal history of allergy, number and types of surgeries undergone, history of symptoms caused by contact with latex, previous hospitalisation, and therapy given. Patients with spina bifida participated in the study after parents gave consent. Patients underwent blood tests for total serum immunoglobulin E and specific immunoglobulin E for latex. Patients with negative immunoglobulin were set to undergo skin-prick tests.

**Results:** In total 39 patients diagnosed with spina bifida were assessed, 25 (64%) of whom were male; their ages ranged from 1 to 156 months. Not all patients completed skin-prick tests, due to staff shortages in the dermatology department. Of the 39 patients, 8 (21%) had latex allergy (positive specific IgE and personal history of allergy reaction in contact with latex); 24(61%) were not allergic, and 7 (17%) showed sensitivity, but not allergy. Of the 21% defined as latex allergic, 50% had been operated on more than five times.

**Conclusion:** According to this study, the prevalence of latex allergy and sensitivity in patients with spina bifida at Universitas Academic Hospital is 21% and 17% respectively.

**Keywords:** myelomeningocele, latex allergy, latex sensitivity, atopy, anaphylaxis

## CHAPTER 1: LITERATURE REVIEW

### 1.1. DEFINITIONS AND TYPES OF LATEX ALLERGIES AND REACTIONS

Latex is a natural sap of the rubber tree (*Hevea brasiliensis*) that coagulates on exposure to air.<sup>1–15</sup> This sap is used to make natural rubber, which is found in more than 40 000 industrial products in the United States.<sup>9,16–20</sup> Approximately 400 such products are used in the medical community.<sup>21</sup> These products are composed of 2 types of substances that may cause medical problems: added chemical antioxidants and natural proteins associated with immunoglobulin E (IgE)-mediated reactions.<sup>16,19,22.</sup>

The chemical antioxidants may cause type IV dermatitis reactions, and the natural proteins may cause type I systemic allergic reactions in some individuals.<sup>5,6,14,20,23,24.</sup> Irritant dermatitis is a nonallergic, localized inflammation of the skin (redness, itching, various skin lesions) caused by chemical irritation that does not involve the immune system.<sup>24</sup> The irritation allows the latex allergens easier access into the body.<sup>15,20,23,25–27.</sup> Type IV dermatitis is limited to the skin and is a chemical contact inflammation (redness, itching, various skin lesions) that is a T-cell (immune system)–dependent reaction caused by chemicals used in latex production.<sup>17,24</sup>

Typically, direct physical contact with a substance containing latex allows increased access for proteins to enter the body. Repeated exposures decrease tolerance and increase the likelihood of a type I reaction.<sup>8–11,14–16,23,25</sup> A type I systemic reaction is a true hypersensitivity reaction moderated by the development of IgE antibodies to specific proteins in latex, causing a serious and potentially lethal reaction.<sup>24</sup>

For some sensitive individuals, it may be associated with cross-reactivity to certain foods.<sup>28</sup>

The reaction is due to the immune response, which causes mast cells and basophils to release histamine, leukotrienes, prostaglandins, and kinins. Signs and symptoms may range from rhinitis to death.<sup>8–10,14–16,20,25</sup>

Type I conditions are categorized by 5 stages:

- **Stage 1**—local urticaria (a vascular reaction of the skin characterized by sudden general eruption of wheals or papules that itch)<sup>1</sup> in the area of contact.<sup>20,23</sup>
- Stage 2—generalised urticaria with angioedema,<sup>20,23</sup> (swelling of skin tissue, mucous membranes, or viscera associated with specific antigen sensitivity).<sup>1</sup>
- Stage 3—urticaria with asthma, eye or nose itching, and gastrointestinal symptoms.<sup>20,23</sup>
- Stage 4—urticaria with anaphylaxis<sup>20,23</sup> (a hypersensitivity reaction to an antigen, which is mediated by interactions between factors released by mast cells and IgE proteins capable of acting as antibodies that attach to mast cells in the respiratory tract and intestinal tract and play a major role in allergic reactions; these interactions produce the antigen-antibody reaction). <sup>1</sup>
- Stage 5—chronic asthma and permanent lung damage.<sup>23</sup>



## **1.2. RECOGNITION AND EVALUATION PREVALENCE AND AT-RISK INDIVIDUALS**

Latex can enter the body through mucous membranes,7,15,17,27–29 contact with the skin,17,25,27,29 open wounds, contact with internal organs (as in surgery),25 intravenous exposure, and inhalation of or contact with latex powder.11,16,17,25,26,29

The incidence of latex allergies has increased for health care workers in the last 10 years because of the institution of mandatory universal precautions for handling bodily fluids.6,10,16–18,21,28,30,31 In the health care profession, latex particles from the powder used inside gloves as a drying agent can spread through the air and be inhaled.4,32

The powder binds with the latex and becomes the carrier of latex molecules when released into the air.8,20–22,28,33,34 Mineral talc was used in gloves until 1940, when it was replaced with cornstarch because the mineral talc binds more firmly to latex molecules. Although mineral talc is heavier and less frequently airborne than cornstarch, it produces a more severe reaction in latex-sensitive individuals. The airborne particles, regardless of the powder used, can enter a person's lungs and mucous membranes, causing an allergic reaction.2,6,31,35,36

The increasing prevalence of latex sensitivity is not only seen in the health care profession but also in children with spina bifida,7,15,17,20,29,37,38 latex-industry workers,7,22–24,27 those who have undergone multiple surgeries (especially on the urinary tract),15,17,19,24,28,29,38 blood donors, individuals with a history of allergies,7,29,30,37 and those who have recurrent contact with latex.2,11,14,18,21,33

The rate of occurrence of latex allergy for children with spina bifida, due to multiple surgeries and congenital denervation of mast cells,37 ranges from 12% to 73%.29,37,38,39

Prevalence is reported to be 3% to 17% in health care workers,10,24,28,32–34,37–39 11% in latex-glove plant workers,7,14,22 and 1% to 6.5% in the general population.2,9,19,40,41

## **1.3. SIGNS AND SYMPTOMS**

An immediate allergic reaction may occur within minutes of coming into contact with latex. Symptoms of a reaction include hives; wheezing; coughing; shortness of breath; sneezing; nasal congestion; runny nose; conjunctivitis (red, itchy, watery eyes)1; nasal, palatal, or ocular itching; urticaria; nasorhinitis (chronic runny nose)1; asthma; and hypotension. 18,22,30,31,33,42–45

Hives can appear anywhere on the body and not necessarily at the point where direct contact with the latex occurred.17 The immediate reactions can “develop into a life-threatening condition when blood pressure drops, airways become blocked, and the throat closes.”17 This condition can eventually progress into anaphylaxis.17,21,26,28,33,42

These symptoms can be exacerbated in certain people when specific foods are ingested.40,46 Latex can cross-react with the heveamine in fruits and may cause an immediate and more serious reaction. A person who comes in contact with latex may sustain a mild allergic reaction. However, when later ingesting a cross-reacting food, new reactions can occur within 5 to 30 minutes, resulting in itching and

irritation of oral tissues, swelling of the lips and tongue, and sometimes papules or blistering of these tissues.<sup>47</sup> The allergens can cross-react after either latex exposure or ingestion of certain foods.<sup>46</sup>

#### **1.4. OTHER ASSOCIATED ALLERGIES**

Allergy to latex rubber involves sensitisation to multiple constituent proteins; therefore, different groups of patients respond to specific latex proteins in various ways.<sup>6,7</sup> These groups of proteins are found in many products, including, but not limited to, certain tree pollens, some plants, and (most commonly) fresh fruits.<sup>6,47,48</sup> Fresh fruits that commonly cause hypersensitivity when associated with latex proteins are avocado, banana, celery, chestnut, and pear.

Less common culprits are apricot, buckwheat, cherry, fig, grape, kiwi, mango, melon, nectarine, orange, papaya, passion fruit, peach, peanut, pineapple, plum, potato, tomato, and walnut.<sup>7,39,40,44.</sup>

The problem manifests itself in two ways:

- The fruit allergy triggers previously undiagnosed recognition of the latex allergy.
- After years of latex exposure and latex sensitivity, the person develops fruit allergies.<sup>6</sup>

Whether this dual latex-fruit sensitivity is determined by common antigens or cross-reacting antigens has yet to be determined.<sup>7</sup>

#### **1.5. MANAGEMENT**

Management of latex allergies consists of treating an emergency, screening for the condition, and preventing reactions and situations from occurring in the first place. Three main levels of allergic reactions, as previously defined, are associated with latex. Therefore, treatment ranges from simple to emergent-care procedures.

For irritant dermatitis, remove the irritating substance, cleanse the area with soap and water, apply topical corticosteroids to reduce the inflammatory response, use hydrating creams after water contact, use hydrating creams overnight covered by cotton gloves, and recommend evaluation by a dermatologist for allergic contact dermatitis.<sup>20,23,24,26,53</sup>

For type IV dermatitis, follow the same procedure as described for irritant dermatitis. The patient should now obtain a serum test for latex IgE.<sup>20,23,24</sup>

For type I systematic reaction, remove the irritating substance, treat life-threatening conditions first (follow the ABCs of cardiopulmonary resuscitation), cleanse the area of contact with soap and water if possible, transfer to a medical facility, monitor vital signs, and continue to administer emergent care as needed.<sup>20,23,24</sup>

#### **1.6. SCREENING**

The first step in prevention is to identify individuals susceptible to latex allergies. It is essential to obtain a thorough medical history and physical examination to initially identify at-risk individuals.<sup>9,14,15,20,23,25–27</sup>

After screening, further assessment and management are determined by whether the history was positive or negative and whether the person is in a high- or low-risk group<sup>9,15</sup>. Several latex-sensitivity tests are used in the United States today.

#### **1.6.1. Skin-Patch Test**

This test is used for irritant and contact dermatitis. A patch with immunogenic rubber chemicals is taped on the person's skin for 48 to 96 hours and then interpreted using standardised techniques.<sup>4,5,8,10,17,20,25,26</sup>

#### **1.6.2. Skin-Prick Test**

This test is used for type I latex-sensitivity diagnosis. To perform the test, a drop of latex extract is placed on the skin, and the skin is scratched with a sharp, bifurcated needle. The person is monitored for signs of an allergic reaction.

#### **1.6.3. Intradermal Test**

This test is used for type I latex-sensitivity diagnosis. A needle containing latex solution is inserted into the skin. Reactions are monitored because this test generates a higher level of allergic reactions than a skin-prick test. It should be performed in a facility with emergency medical equipment available to handle an anaphylactic reaction.<sup>8,22,54,56,57</sup>

Currently, the Food and Drug Administration has not approved a latex extract for the skin-prick or intradermal tests. Typically, a powdered latex glove is cut into an 8-3 8-cm square patch and soaked in 10 mL of extraction fluid overnight. Then it is passed through a sterile Millipore filter (Millipore Corp, Bedford, MA) and diluted to 1:10, 1:100, and 1:1 000 for testing.<sup>58</sup>

Research is being conducted on a standardised, nonammoniated latex extract (Greer Laboratories, Lenoir, NC) for skin-prick tests. The early results show safety (by not causing an anaphylactic reaction) and true-positive results for latex allergy of 95% with the 100 mcg/mL concentration and 99% positive results with the 1 mg/mL concentration. Similarly, the true-negative results were 100% with the 100 mcg/mL and 96% negative results with the 1 mg/mL concentration for those without latex allergy.<sup>59</sup>

#### **1.6.4. IgE Antibody Immunoassays**

These are methods used to identify the IgE antibodies in the serum and to confirm the diagnosis of latex sensitivity.

However, a negative latex-specific IgE test does not rule out a latex allergy.<sup>5,8,56,57</sup> Several methods are described in the literature, including RAST, enzyme-linked immunosorbent assay, AlaSTAT (Diagnostic Products Corp, Los Angeles, CA), ImmunoCAP (Pharmacia Corp, Peapack, NJ), and HY-TEC (Hycor Biomedical Inc, Garden Grove, CA). In one study, the AlaSTAT and CAP assays produced 24% and 27% false-negative results, respectively, whereas the HY-TEC produced a 27% false-positive result when compared with the skin-prick test.<sup>60</sup> In another study, combining assays raised the diagnostic sensitivity

compared with using 1 in vitro test alone.<sup>56</sup> Others have indicated that the assays may lack sensitivity in patients presenting with urticaria only.<sup>61</sup>

#### **1.6.5. Use Test**

This test is performed when the immunoassay tests are negative, but the history of symptoms is compelling. A fingertip is cut from a latex glove, dampened with water, and placed on the person's finger for 15 minutes. A positive test results in urticaria with itching or erythema.

If no reaction occurs, placing an entire dampened glove on the hand for 15 minutes or until a reaction occurs is considered safe.<sup>20,26,62</sup>

### **1.7. PREVENTION**

Currently, as with other allergies, there is no cure for latex sensitivity. The only way of decreasing the allergic reactions is to avoid exposure to latex.<sup>2,14,17,19,21,25</sup> High-risk areas should be identified so they can be avoided.<sup>5,11,22,26,34</sup> Areas subject to high-volume use of latex products include blood banks and medical laboratories. However, many items contain latex; therefore, it is imperative that the allergy-sensitive health care worker or patient be familiar with the diverse sources of latex.<sup>25,27</sup> A number of steps can be taken to avoid exposure, the first being finding safe alternatives.<sup>63</sup> Latex-free alternatives include nitrile, vinyl, neoprene, styrene butadiene, and Tactylon (Tactyl Technologies, Inc, Vista, CA).<sup>21,25</sup> Although these alternatives exist, it is sometimes necessary to use latex products. In this case, the following steps should be taken.

#### **1.7.1. Use of topical barriers**

- Use cotton glove liners
- Wash hands immediately after glove use or contact with other latex products.
- Use nonpetroleum-based moisturising agents, especially over cuts or cracks in skin.
- Avoid touching the mucous membranes during or after contact with a latex product.
- Eliminate unnecessary latex-glove use, and remove the gloves frequently to reduce hyperhydration or excessive occlusion.
- Make sure ventilation is adequate where these products are used and that air filters are changed or cleaned frequently.
- Avoid exposure to people and objects (countertops, drawers, computer keyboards, and telephones) that have come into contact with latex products.
- Avoid using detergents, alcohol, formaldehyde, and antimicrobial agents, usually in the form of hand washes or hand rubs, which may increase latex sensitivity.

Those who exhibit symptoms of severe hypersensitivity, including anaphylaxis, should carry and know how to use an Epi-Pen (Dey, Napa, CA). MedicAlert jewellery (MedicAlert Foundation Intl, Turlock, CA) should also be worn.<sup>2,4,5,11,14,21,26</sup>

## **1.8. AIMS AND OBJECTIVES**

The aim of this study was to investigate the true prevalence of latex sensitisation and latex allergy in patients with spina bifida in Universitas academic hospital.

We also aimed to identify risk factors associated with latex allergy.

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## **CHAPTER 2: PREVALENCE OF LATEX ALLERGY IN SPINA BIFIDA PATIENTS IN UNIVERSITAS ACADEMIC HOSPITAL**

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## ABSTRACT

**Background:** Latex allergy in spina bifida patients has attracted a great deal of interest around the world, especially in Europe and the United States, where it is estimated to be as high as 67%. It is one of the primary reasons for anaphylaxis in the operating theatre, which occurs in about 50% of patients with myelomeningocele. Epidemiology from South Africa is scarce, especially for the Free State province.

**Objective:** To estimate the prevalence of latex sensitivity and latex allergy in a population of patients with spina bifida at Universitas Academic Hospital and to describe associated risk factors.

**Methods:** A descriptive, cross-sectional observational study was undertaken. A questionnaire gathered information on family and personal history of allergy, number and types of surgeries undergone, history of symptoms caused by contact with latex, previous hospitalisation, and therapy given. Patients with spina bifida participated in the study after parents gave consent. Patients underwent blood tests for total serum immunoglobulin E and specific immunoglobulin E for latex. Patients with negative immunoglobulin were set to undergo skin-prick tests.

**Results:** In total 39 patients diagnosed with spina bifida were assessed, 25 (64%) of whom were male; their ages ranged from 1 to 156 months. Not all patients completed skin-prick tests, due to staff shortages in the dermatology department. Of the 39 patients, 8 (21%) had latex allergy (positive specific IgE and personal history of allergy reaction in contact with latex); 24(61%) were not allergic, and 7 (17%) showed sensitivity, but not allergy. Of the 21% defined as latex allergic, 50% had been operated on more than five times.

**Conclusion:** According to this study, the prevalence of latex allergy and sensitivity in patients with spina bifida at Universitas Academic Hospital is 21% and 17% respectively.

## **2.1. INTRODUCTION**

Latex allergy is an immunoglobulin E-mediated hypersensitivity reaction that can cause a variety of symptoms, from mild local manifestations, to life-threatening anaphylactic shock.(1) It is estimated that the risk of anaphylaxis in the operating theatre for patients with spina bifida is as high as 50%.(1,2) Preventing patients belonging to the risk group from coming into contact with latex has shown to reduce the morbidity and mortality in these patients significantly.(3)

Latex allergy in myelomeningocele patients has attracted a great deal of interest in the United States of America and countries in Europe. Latex allergy occurs in the general population at a rate of 1% to 2%,(1) while, for spina bifida patients in the United States and Europe, the incidence ranges between 10% and 67%.(4) In healthcare workers based in hospital settings, the prevalence of latex allergy is 7–9%.(5)

A study done in Cape Town in 2005 on myelomeningocele patients found a low overall prevalence of latex sensitisation, of 16%. Strict avoidance of latex exposure and low frequency of surgical procedures are postulated as possible reason for this finding.(3) Higher incidence of latex allergy patients with spina bifida is suspected to be related to early and repeated exposure to latex-containing products. Other factors found to have a positive correlation with development of this allergy include personal atopy and family history.(6)

Myelomeningocele is a failure of the neural tube to close, and involves ectoderm and mesodermal structures. It has been postulated that the cause of this failure is related to multiple factors, some possibly genetic, and others environmental.(5) Folic acid deficiency has been found to be a common cause; this is why all pregnant women are started on this supplement as early in their pregnancies as possible – it is recommended that folic acid supplementation should actually be started when women reach the age of conception. Late bookings and teenage pregnancy in South Africa are among the reasons why patients do not take early folic acid supplements. Patients with myelomeningocele are exposed to latex during the first hours after birth, as a result of the many medical and surgical procedures these patients require. Strict avoidance of latex by certain facilities can contribute to limiting anaphylaxis during operations.(5)

In spite of the high prevalence of latex allergy in the world, limited data is available for South Africa, especially in the Free State and, as a result, little is being done to promote, prevent and recognise latex allergy in patients with spina bifida. Most rural hospitals are unaware of the danger involved in handling these patients during birth and transportation, which could be the reason for high the high rate of sensitivity.

This lack of information is the gap that needed to be researched. This study is the result of the need to collect epidemiology data on the prevalence of latex allergy and associated risk factors in spina bifida patients at Universitas Academic Hospital, Free State province.

## **2.2. MATERIAL AND METHODS**

*Design:* A descriptive, cross sectional and observational study was conducted.

*Population:* All patients, regardless of age, who had been diagnosed with spina bifida and who attended the neurosurgery clinic and/or were admitted in Universitas Academic Hospital in Bloemfontein from 2017 to 2019 were included in this study.

*Exclusion criteria:* Patients who refused to participate or to sign the informed consent form were excluded.

*Outcome measures:* The following outcome measures were assessed.

**Demographic information:** Age (months), sex and ethnicity.

**Personal history of allergy:** Patients were considered to have positive personal history if they had asthma, rhinitis, eczema or food allergy. This outcome was separated into positive (yes) and negative (no) responses to a questionnaire.

**Family history of allergic conditions:** Patients were considered to have positive family history if they had first-degree family members with asthma, eczema, or drug or food allergies. The outcomes were separated into positive (yes) and negative (no).

**Previous history of allergic reaction to latex:** A questionnaire was used to establish if patients had had previous reactions to latex, as evidenced by nasal congestion, difficulty breathing, asthma attack, or pruritic rash when in contact with objects containing latex. Patients answered yes or no.

**Number of surgeries:** Previous surgery (yes) or (no), number of surgeries performed since birth to time of the study, and types of surgeries were investigated. Patients were categorised into fewer than 5 and more than 5 surgeries.

**Previous hospitalisation/evaluation and therapy for allergic reaction:** Yes or no.

**Total serum immunoglobulin E:** This parameter was measured using Ku/l, and serum levels of IgE greater than mean plus 1 standard deviation for age suggested the presence of allergic disease, though not specifically a latex allergy. Positive or negative responses were gathered.

**Specific immunoglobulin E for latex:** This parameter was measured using latex immunoCAP K82 IgE. Patients were either positive or negative.

**Skin-prick test:** The plan was to test patients who were negative for specific latex IgE, however, due to staff shortages, not all patients could be tested.

*Pilot study:* The first five patients were used for a pilot study. There were no complaints from the patients or their parents regarding the questionnaire or procedure or taking of blood, thus, the study continued. All five patients were included in the study's data.

*Analysis of data:* Analysis was done by biostatistics. Quantitative outcomes were described by means of frequency distribution, cumulative frequencies and percentages. Quantitative outcomes measures were summarised using means, standard deviations and/or medians, according to data distribution. A univariate analysis was done using patients allergic to latex as a dependent outcome measure.

*Ethical aspects:* The study was approved by Health Science Research Ethics Committee of the University of Free State. All patients and their parents or legal guardians were informed of the nature of the study and were asked to give their informed consent by signing the form.

### **2.3. RESULTS**

In total, 39 patients with spina bifida participated in the study: 14 were female (36%) and 25 male (64%), with average age of 4 months: the youngest was 1 month and oldest 156 months. The majority of patients were black 38 (97%).

Patients with history of allergic reaction to contact with latex numbered 8 (21%). All patients had undergone some sort of surgery (n=39, 100%). About 94% had myelomeningocele repair – only 5% were without repair – and all of them had had ventriculo-peritoneal shunts inserted (100%). The majority of patients (n=35, 9%) had been operated fewer than five times, while four patients (10%) had undergone more than five operations.

There were two (5%) patients with family history of allergic condition, while rest (n=37, 94%) had no family history of allergic conditions. All patients did not report personal history of any allergic reaction.

Of the 39 patients, 8 (21%) had positive specific immunoglobulin E (IGE) for latex, and a personal history of reaction to contact with latex (defined as allergic). No previous hospitalisation, evaluation and treatment for allergic reaction were reported by patients or guardians.

None of patients underwent skin-prick tests, which is a gold standard for diagnosing latex allergy. These tests could not be done, and could have increased the number of patients diagnosed with allergy in this population group.

For the univariate analysis, patients allergic to latex were used as the dependent outcome measure. No significant association was observed between latex allergy and family history of allergic condition, as only 2 (5%) had family history of allergic reaction as shown on table 2.

Table 1 provides data regarding patient age and number of operations undergone.

**Table 1: Characteristics of study patients: Age and number of operations**

Gender	Number of patients	Percentage
Female	14	36%
Male	25	64%
<b>Number of operations</b>		
<5 operations	35	89%
>5 operations	4	10%

Table 1 indicates that patients were mostly male (64%). Most patients had undergone fewer than five operations (90%), while 10% had undergone more than five operations.

Table 2 provides information on measurement outcomes.

**Table 2: Measurement outcomes**

Outcome	Number of patients	Percentage
Previous allergic reaction to latex	8	21%
Family history of allergy	2	5%
Personal history of allergy	0	0%
Specific latex IgE	8	21%
Skin-prick test	Not performed	
Previous hospitalisation for allergic reaction	0	0%

From Table 2 it is clear that both positive specific IgE for latex, and previous latex allergic reaction, were reported for 21% of the group of 39 patients. All patients didn't report any personal history of allergy. None of the above patients underwent the skin-prick test.

## **2.4. DISCUSSION**

A latex allergy in patients with spina bifida has serious health-related and socioeconomic implications. Thus, an exploration of effective measures to prevent latex sensitisation is of great interest. Certain protocols, such as hospital-wide latex-free policies and procedures, have been established and have resulted in reducing primary sensitisation of patients with spina bifida.

In 2005, researchers at the the Red Cross Children's Hospital investigated the prevalence of latex allergy in a group of 24 children with spina bifida, and found the latex sensitivity in these patients to be 16%. This study, found a similar prevalence to that of other studies published in international literature.(3,5)

In this study, latex-specific IgE was positive in approximately 8 (21%) patients. Only 7 (17%) (slightly more than the 16% found by the Cape Town study)(3), showed sensitivity to latex. These patients are at high risk of developing symptoms unless preventive measures are taken. International studies have estimated that the risk of anaphylaxis due to latex is 50% higher in patients with myelomeningocele.(1,2)

Multiple risk factors have been described for developing latex allergy in spine bifida patients, including history of atopy, number of surgeries and family history. In this study, out of eight patients who had latex allergy, four (50%) had been operated more than five times, which indicates that more operations on these patients increase the risk of latex allergy, as quoted by other researchers.(5)

Latex allergy in patients with myelomeningocele seems to have a multifactorial origin, related to sensitisation tendencies, exposure and number of surgeries. Considering the results of this study, it is important to do risk assessment for these patients, and to provide a "latex safe" environment, which might prevent severe allergic reactions. Primary preventive measures in children with myelomeningocele may reduce likelihood of latex sensitisation; therefore, it is important to prevent latex exposure in these patients from birth. These measures mean that education of staff at peripheral hospitals about latex and handling of these patients is needed.

A limitation of this study is that none of patients underwent a skin-prick test or latex challenge test, which is the gold standard for latex allergy diagnosis. Another limitation is that there is limited data on the specificity and sensitivity of the ImmunoCAP K82 IgE for latex; an additional test, such as ELISA and western blotting could have made a contribution to this study.

## **2.5. CONCLUSION**

This study demonstrated that the prevalence of latex sensitivity and allergy in patients with spina bifida at Universitas Academic Hospital is 21%, which is similar to that found in the rest of the world. It is important to take appropriate measures to ensure primary and secondary prevention of the of allergy developing, and to limit sensitisation that may lead to allergy. The prevalence of severe anaphylaxis in operating theatres warrants cautious handling of susceptible patients with non-latex products, to prevent death.

Further research on the topic of this study could involve gathering information on the knowledge of healthcare staff with regard to latex allergy in patients with spina bifida, so that education workshops can be conducted and protocols established for staff at primary healthcare facilities.


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## APPENDIX A: LETTER OF APPROVAL FROM THE RESEARCH ETHICS COMMITTEE

UNIVERSITY OF THE  
FREE STATE  
UNIVERSITEIT VAN DIE  
VRYSTAAT  
YUNIBESITHI YA  
FREISTATA

 UFS·UV  
HEALTH SCIENCES  
GESONDHEIDSWETENSAPPE

IRB nr 00006240  
REC Reference nr 230408-011  
IORG0005187  
FWA00012784  
13 November 2017

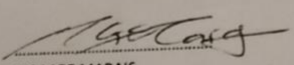
MPUNGANA, ZWELITHINI  
DEPT OF NEUROSURGERY  
FACULTY OF HEALTH SCIENCES  
UFS

Dear Mpungana, Zwelithini

HSREC 59/2017 (UFS-HSD2017/0551)  
PRINCIPAL INVESTIGATOR: MPUNGANA, ZWELITHINI  
SUPERVISOR: BASSON, JUSTIN  
PROJECT TITLE: PREVALENCE OF LATEX ALLERGY IN SPINA BIFIDA PATIENTS IN UNIVERSITAS ACADEMIC HOSPITAL



**APPROVED**

1. You are hereby kindly informed that the Health Sciences Research Ethics Committee (HSREC) approved this protocol after all conditions were met. This decision will be ratified at the next meeting to be held on 05 December 2017.
2. The Committee must be informed of any serious adverse event and/or termination of the study.
3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.
4. A progress report should be submitted within one year of approval and annually for long term studies.
5. A final report should be submitted at the completion of the study.
6. Kindly use the **HSREC NR** as reference in correspondence to the HSREC Secretariat.
7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services-research (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

  
MS MGE MARAIS  
HEAD: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE ADMINISTRATION

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Health Sciences Research Ethics Committee  
Office of the Dean: Health Sciences  
T: +27 (0)51 401 7795/7794 | E: ethicsfhs@ufs.ac.za  
Block D, Dean's Division, Room D104 | P.O. Box/Posbus 339 (Internal Post Box G40) | Bloemfontein 9300 | South Africa



07 November 2017

Dr Z Mpungana  
Dept. of Neurosurgery  
Faculty of Health Science  
UFS

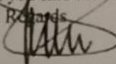
Dear Dr Z Mpungana

**Subject: Prevalence of latex allergy in spina bifida patients in Universitas academic hospital.**

- Please ensure that you read the whole document, Permission is hereby granted for the above – mentioned research on the following conditions:
- Participation in the study must be voluntary.
- A written consent form for each participant must be provided.
- Serious Adverse events to be reported to the Free State department of health and/ or termination of the study
- Ascertain that your data collection exercise neither interferes with the day to day running of Universitas Hospital nor the performance of duties by the respondents or health care workers.
- Confidentiality of information will be ensured and please do not obtain information regarding the identity of the participants.
- **Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).**
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of Free State and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of the University of Free State and to Free State Department of Health.
- **Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to [sebeelats@fshealth.gov.za](mailto:sebeelats@fshealth.gov.za) before you commence with the study**
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with the institution manager/CEOs on commencement for logistical arrangements
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- Researchers will be required to enter in to a formal agreement with the Free State department of health regulating and formalizing the research relationship (document will follow)
- You are encouraged to present your study findings/results at the Free State Provincial health research day
- Future research will only be granted permission if correct procedures are followed see <http://mhrd.hst.org.za>

Trust you find the above in order.

Kind Regards

  
Dr D Motau  
HEAD: HEALTH

Date: 8/11/2017

**APPENDIX B : PERMISSION LETTER**



20 April 2017

**For attention: Ethics Committee  
Faculty of Health Sciences**

**Title of project: Prevalence of latex allergy in spina bifida patients in  
Universitas Academic Hospital**

**Researcher:**

Dr Z Mpungana

I hereby confirm that I approve of the study design and statistical analysis of the above-mentioned protocol. I have also gave input regarding the measurement and measuring instrument.

Yours faithfully

FC van Rooyen  
Therapm

Departement Biostatistiek  
Department of Biostatistics  
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225 Nelson Mandela Drive/Rylands, P.O. Box: Paarlwaa, Bloemfontein 3301, South Africa/Suid-Afrika  
P.O. Box: Postbus 334 (630), Bloemfontein 3300, South Africa/Suid-Afrika. [www.ufs.ac.za](http://www.ufs.ac.za)



**APPENDIX .C: RESEARCH PROTOCOL APPROVED BY ETHICS COMMITTEE.**

Title: Prevalence of latex allergy in spina bifida patients in Universitas Academic Hospital.

Investigator:

Dr Z Mpungana

Registrar Department of Neurosurgery, Universitas Academic Hospital

HPCSA: MP0717983

Student number:

Address: 60 Kommandant Erwee Street, Wilgehof, Bloemfontein 9301.

Cell number: 0713506562

Email: [mzwelithini@yahoo.com](mailto:mzwelithini@yahoo.com)

Supervisor:

Dr J. Basson, Head Of Department Of Neurosurgery Universitas Academic Hospital

Co-Supervisor: Profesor W. Sinclair

Biostatistics: Dr F.C. van Rooyen, Department of Biostatistics, University of the Free State

## **Introduction**

Latex allergy in spina bifida patients has gained lot of interests in many countries especially in Europe and America.

Latex allergy in general population is 1% to 2 % ( 1), while spina bifida patient the incident is as high as 67 % ( 2) as quoted in other studies in America and Europe. Healthcare worker based in hospital settings prevalence is 7-9, 2 % ( 4) compare to general population.

The risk of anaphylaxis in the operating room in patients with spina bifida is as high as 50 % ( 1& 9) in comparison to control groups.

The possibility for this occurrence is due early and repeated exposures to latex containing products in patients with spina bifida. Other factors found to have a positive correlation with development of such allergy includes personal atopy.

In as much as high prevalence of this across the globe, limited data is available in South Africa especially in Free State and as a result little is being done to promote, prevent and recognize latex allergy in patients with spina bifida.

The study done in Cape Town 2005 on these patients showed a low overall prevalence of latex sensitization of 16 % ( 5). Strict avoidance of latex exposure and low frequency of surgical procedures have been postulated as possibility behind these findings.

## **Aims and objectives**

The aim of this study is to investigate the true prevalence of latex sensitization and latex allergy in patients with spina bifida in Universitas academic hospital.

We also aim to identify risk factors associated with latex allergy.

## **Methodology**

### **Study design**

Descriptive, cross sectional and observational study.

All Patients regardless of age and diagnosed with spina bifida attending neurosurgery clinic and/or admitted at univeristas academic hospital in Bloemfontein from July 2017 onwards would be included in the study. Additional patient information will be collected from mediTech data base for re-scheduling of their appointments.

Exclusion criteria patients who refuses to participate or to sign informed consent.

### **Measurements**

Questionnaires: be available in English and shall be filled by the investigator during the structured interview. Translation shall be provided to the patients for understanding of the questions.

- Demographics. Age, sex, ethnicity.
- Number of surgeries, type's surgeries especially neurosurgery procedures e.g. ventricular - peritoneal shunt, ECT.
- Family history of allergy/atopy
- Questionnaire.
  - I. Previous allergic reaction to latex and food products.
  - II. Personal history of allergic Symptoms (rhinitis, asthma, dermatitis, conjunctivitis).
- Total serum IgE determination.
- Specific IgE determination
- Skin- prick test

**All patients or parents/legal guardians for children under age will sign consent form.**

**Older children will give and sign assent for the study.**

Blood will be collected by the investigator and sent laboratory in all patients and the k82 Latex immunoCAP system will be used to determine total serum and specific IgE to latex antigen.

All subjects who tested negative to blood test will undergo **skin- prick test** to identify those that could have be missed by blood test.

The skin prick tests will be conducted by department of dermatology, in all patients to increase sensitivity and specificity for this test and will be conducted in safe environment where resuscitation and drugs are available in case of anaphylaxis.

### **Analysis of data**

Descriptive statistics namely means and standard deviations or medians and percentiles will be calculated for continuous data. Frequencies and percentages will be calculated for categorical data. The analysis will be done by the department of biostatistics

### **Pilot Study**

The first 5 cases will be considered a pilot study. The pilot study data will be included in the main study.

### **Implementation of findings**

The result of the study shall be used to raise awareness about prevalence of latex allergy and sensitization on patient with spina bifida.

Results shall be used to develop guidelines to promote and prevent latex sensitization and/or allergic reaction on these patients.

Results shall be used for publication for academic purposes.

### **Time schedule**

May 2017–July 2018

Ethics approval: May 2017

Free State Department of Health review: June 2017

### **Rotation for intermediates exams for 6 months.**

Data collection and rechecking data collected: February 2018-April 2018

Analysis and Interpretation of data: May 2018

Writing Study: June 2018-July 2018

### **Budget**

ImmunoCAP for latex cost R200 per patient and maximum of patients for study will 50-80.

Total R16 000.

Skin prick test is offered free of charge at the hospital done by dermatology department.

Application for fund shall be made if not approved researcher shall subsidize himself to pay for costs.

### **Ethical aspects**

Patient names will not be recorded on the Microsoft Excel sheet to aid with confidentiality. Patient information such as hospital number, age, sex, clinical assessment, outcome e.t.c. will be recorded on the Microsoft Excel data form and will only be seen by the investigator, supervisor and statistician.

All hard copy paper / documents used for data collection and rough drafting will be transferred to electronic format which will be a password protected, read-only file and subsequently the raw data and hard copy paper / documentation will be destroyed by means of shredding.

Blood collected shall be disposed after testing has been completed

Patients and their parents or legal guardians will sign consent form to have them tested for latex sensitivity.

No conflict of interests.

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**CONSENT TO PARTICIPATE IN RESEARCH PROJECT.**

PROJECT TITLE

.....

You have been asked to participate in a research project.

You have been informed about the study by .....

You may contact..... at ..... any time if you have any questions about the research.

You may contact the secretariat of the Ethics Committee of the faculty of health Sciences, UFS at telephone number 0514052812 if you have any questions about your rights as a research patient.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to terminate participation.

If you agree to participate, you will be given a signed copy of this document as well as the participant information sheet, which is written is a summary of the research.

The research study, including the above information has been verbally described to me. I understand what my involvement in the study means and I voluntarily agree to participate.

Signature of participant ..... Date .....

Parent/guardian ..... Date.....

Signature of witness ..... Date .....

Signature of translator ..... Date .....

**APPENDIX E: AFRIKAANS AND SESOTHO CONSENT**

**TOESTEMMING OM DEEL TE NEEM AAN NAVORSINGS PROJEK**

**PROJEK TITEL**

.....

**U is gevra om deel te neem aan n navorsings projek**

**U is ingelig oor die studie deur.....**

**U kontak.....by.....enige tyd indien u enige vra het oor die navorsing**

**U kan die sekretariaat van die Etiese Komitee van die fakulteit van gesondheid en wetenskap, UFS kontak by 0514052812 indien u enige vrae het oor u regte as n navorsings pasient.**

**U deelneem aan die navorsing is vrywillig, en u sal nie gepenaliseer word of enige voordele verloor as u weier om deel te neem of besluit om u deelname te beendig.**

**As u besluit om deel te neem, sal u 'n getekende dokument ontvang so wel as die nodige inligting wat insluit n opsoming van waaroor die navorsing gaan.**

**Die navorsing studie, ingesluitende die bogenoemde informasie is mondelings beskryf aan my. ek verstaan wat my deelname aan die studie beteken en ek neem vrywilliglik deel.**

**Handtekening van deelneemer..... Datum.....**

**Ouer/ Voog ..... Datum.....**

**Handtekening van getuie..... Datum.....**

**Handtekening van vertaller..... Datum.....**

Tumellano ya ho nka karolo tshebetsong ya dipatlisiso.

Sehlooho sa tshebetso.

.....

O kopilwe ho nka karolo tshebetsong ya dipatlisiso.

O bolelletse ka dipatlisiso ke .....

O ka ikopanya le ..... Sebaka ..... ka nako efe kapa efe ha ona le dipotso ka dipatlisiso.

Ha ona le dipotso ka ditokelo tsa hao jwalo ka ya nkeng karolo ,O ka kopana ke le ofisi ya komiti ya maitshwaro lefapheng la saense ya tsa bophelo ka UFS . Mohala 0514052812.

Karolo ya hao tshebetsong ena ke boithaopo, ebile o ka se ahlolelwe kapa wa lahlehelwa ke letho ha.

O sa battle kapa o tlohela ho nka karolo .

Ha o dumela o tla fumana khopi ya tokomane e saennweng le leqhephe le okaretsang dintlha ka patlisiso ho ya nkang karolo.

Dipatlisiso ,ho kenyeletsa le lesedi ka tsona di hlahositswe ka puisano le mna. Kea utlwisisa hore ho nka karolo ho bolelang, ebile kea dumela ka bo-mna ho nka karolo.

Ya nkang karolo ..... letsatsi .....

Motswadi/mohlokomedi .....letsatsi .....

Paki ..... letsatsi .....

Toloko .....letsatsi .....

## **APPENDIX F: INSTRUCTIONS TO AUTHORS (SAMJ)**

<http://www.samj.org.za/index.php/samj/information/authors>

#### Author Guidelines

The SAMJ has launched a new submission and tracking system. Authors will be required to register a profile on the Editorial Manager platform in order to submit a manuscript.

To submit a manuscript, please proceed to the SAMJ Editorial Manager website:

[www.editorialmanager.com/samj](http://www.editorialmanager.com/samj)

To access and submit an article already in production, please see the guidelines [here](#).

#### Author Guidelines

Please view the [Author Tutorial](#) for guidance on how to submit on Editorial Manager.

Please take the time to familiarise yourself with the policies and processes below. If you still have any questions, please do not hesitate to ask our editorial staff (tel.: +27 (0)21 532 1281, email: [submissions@hmpg.co.za](mailto:submissions@hmpg.co.za)).

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[Copyright notice](#)

[Privacy statement](#)

[Ethnic classification](#)

[CPD](#)

[Manuscript preparation](#)

[Preparing an article for anonymous review](#)

[General article format/layout](#)

[Preparation notes by article type](#)

[Illustrations](#)

[Tables](#)

[References](#)

[From submission to acceptance](#)

[Submission and peer-review](#)

[Production process](#)

[Changing contact details or authorship](#)

[Publication](#)

[Online versus print](#)

[Errata and retractions](#)

[Indexing](#)

SAMJ Policies

Type of articles considered by the SAMJ

The SAMJ will no longer limit the articles accepted to those that have ‘general medical content’, but is intending to capture the spectrum of medical and health sciences, grouped by relevance to the country’s burdens of disease. This content will include research in the social sciences and economics that is relevant to the medical issues around our burden of disease. Please see [‘A new vision for the SAMJ – and a call for papers’](#) for a full discussion of the new directions for the SAMJ.

We accept the following types of articles:

[Research](#)

[Reviews](#)

[Clinical trials](#)

[Editorials](#)

[In Practice](#) (Previously Forum incl. Case Reports)

[Correspondence](#)

[Obituaries](#)

## [Book reviews](#)

[Ad hoc supplements](#) e.g. guidelines, conference/congress abstracts, Festschrifts\*

The following articles are by invitation only:

Guest editorial

Continuing Medical Education (CME)

\*Contact [claudian@hmpg.co.za](mailto:claudian@hmpg.co.za) for information on submitting ad hoc/commissioned supplements, including guidelines, conference/congress abstracts, Festschrifts, etc.

## Publication Fees

All articles published in the South African Medical Journal are open access and freely available online upon publication. This is made possible by applying a business model to offset the costs of peer review management, copyediting, design and production, by charging a publication fee of R5 250 (ex vat) for each research article published. The charge applies only to Research articles submitted after 1 March 2017. The publication fee is standard and does not vary based on length, colour, figures, or other elements.

When submitting a Research article to the SAMJ, the submitting author must agree to pay the publication fee should the article be accepted for publication. The publication fee is payable when your manuscript is editorially accepted and before production commences for publication. The submitting author will be notified that payment is due and given details on the available methods of payment. Prompt payment is advised; the article will not enter into production until payment is received. Queries can be directed to [claudian@hmpg.co.za](mailto:claudian@hmpg.co.za).

Please refer to the section on 'Sponsored Supplements' regarding the publication of supplements, where a charge is applicable. Queries can be directed to [dianes@hmpg.co.za](mailto:dianes@hmpg.co.za) or [claudian@hmpg.co.za](mailto:claudian@hmpg.co.za)

## Authorship

Named authors must consent to publication. Authorship should be based on: (i) substantial contribution to conceptualisation, design, analysis and interpretation of data; (ii) drafting or critical revision of important scientific content; or (iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to [www.icmje.org](http://www.icmje.org))

If authors' names are added or deleted after submission of an article, or the order of the names is changed, all authors must agree to this in writing.



Please note that co-authors will be requested to verify their contribution upon submission. Non-verification may lead to delays in the processing of submissions.

Author contributions should be listed/described in the manuscript.

#### Conflicts of interest

Conflicts of interest can derive from any kind of relationship or association that may influence authors' or reviewers' opinions about the subject matter of a paper. The existence of a conflict – whether actual, perceived or potential – does not preclude publication of an article. However, we aim to ensure that, in such cases, readers have all the information they need to enable them to make an informed assessment about a publication's message and conclusions. We require that both authors and reviewers declare all sources of support for their research, any personal or financial relationships (including honoraria, speaking fees, gifts received, etc) with relevant individuals or organisations connected to the topic of the paper, and any association with a product or subject that may constitute a real, perceived or potential conflict of interest. If you are unsure whether a specific relationship constitutes a conflict, please contact the editorial team for advice. If a conflict remains undisclosed and is later brought to the attention of the editorial team, it will be considered a serious issue prompting an investigation with the possibility of retraction.

#### Research ethics committee approval

Authors must provide evidence of Research Ethics Committee approval of the research where relevant. Ensure the correct, full ethics committee name and reference number is included in the manuscript.

If the study was carried out using data from provincial healthcare facilities, or required active data collection through facility visits or staff interviews, approval should be sought from the relevant provincial authorities. For South African authors, please refer to the guidelines for submission to the [National Health Research Database](#). Research involving human subjects must be conducted according to the principles outlined in the Declaration of Helsinki. Please refer to the National Department of Health's guideline on [Ethics in Health research: principles, processes and structures](#) to ensure that the appropriate requirements for conducting research have been met, and that the HPCSA's [General Ethical Guidelines for Health Researchers](#) have been adhered to.

#### Clinical trials

As per the recommendations published by the International Committee of Medical Journal Editors (ICMJE), clinical trial research is any research that assigns individuals to an intervention, with or without a concurrent comparison/control group to study the cause-and-effect relationship between the intervention and health outcomes. All clinical trials should be registered with the appropriate national clinical trial registry (or any international primary register, if relevant), and the trial registration number should be cited at the end of the abstract. All clinical trial reports must also contain a data sharing statement as per the recommendations of the ICMJE. Statements are to indicate:

whether individual deidentified participant data will be shared;

what data in particular will be shared; whether additional, related documents will be available; when the data will become available and for how long; by what access criteria data will be shared.

Please see the ICJME announcement for further details and illustrative examples of data sharing statements: [ICMJE Data Sharing Statements for Clinical Trials](#)

Since 1st December 2005, all clinical trials conducted in South Africa have been required to be registered in the South African National Clinical Trials Register. The SAMJ therefore requires that clinical trials be registered in the relevant public trials registry at or before the time of first patient enrollment as a condition for publication. The trial registry name and registration number must be included in the manuscript.

Please refer to the general guidelines for all papers at the top of this article for additional requirements with respect to ethics approval, funding, author contributions, etc. The format of original research articles should be followed for reporting of clinical trial results.

#### Patient Consent

Information that would enable identification of individual patients should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) has given informed written consent for publication and distribution. We further recommend that the published article is disseminated not only to the involved researchers but also to the patients/participants from whom the data was drawn. Refer to [Protection of Research Participants](#). The signed consent form should be submitted with the manuscript to enable verification by the editorial team.

#### Other individuals

Any individual who is identifiable in an image must provide [written agreement](#) that the image may be used in that context in the SAMJ.

#### Copyright notice

Copyright remains in the Author's name. The work is licensed under a [Creative Commons Attribution - Noncommercial Works License](#). Authors are required to complete and sign an [Author Agreement form](#) that outlines Author and Publisher rights and terms of publication. The [Author Agreement form](#) should be uploaded along with other submissions files and any submission will be considered incomplete without it.

Material submitted for publication in the SAMJ is accepted provided it has not been published or submitted for publication elsewhere. Please inform the editorial team if the main findings of your paper have been presented at a conference and published in abstract form, to avoid copyright infringement. All research already published as 'Conference proceedings' needs to be substantially re-written, with a new title, a new abstract and new and important results to back up any study before it will be considered for a new publication. The SAMJ does not hold itself responsible for statements made by the authors.

#### Previously published images

If an image/figure has been previously published, permission to reproduce or alter it must be obtained by the authors from the original publisher and the figure legend must give full credit to the original source. This credit should be accompanied by a letter indicating that permission to reproduce the image has been granted to the author/s. This letter should be uploaded as a supplementary file during submission.

#### Privacy statement

The SAMJ is committed to protecting the privacy of its website and submission system users. The names, personal particulars and email addresses entered in the website or submission system will not be made available to third parties without the user's permission or due process. By registering to use the website or submission system, users consent to receive communication from the SAMJ or its publisher HMPG on matters relating to the journal or associated publications. Queries with regard to privacy may be directed to [publishing@hmpg.co.za](mailto:publishing@hmpg.co.za).

#### Ethnic/race classification

Use of racial or ethnicity classifications in research is fraught with problems. If you choose to use a research design that involves classification of participants based on race or ethnicity, or discuss issues with reference to such classifications, please ensure that you include a detailed rationale for doing so, ensure that the categories you describe are carefully defined, and that socioeconomic, cultural and lifestyle variables that may underlie perceived racial disparities are appropriately controlled for. Please also clearly specify whether race or ethnicity is classified as reported by the patient (self-identifying) or as perceived by the investigators. Please note that it is not appropriate to use self-reported or investigator-assigned racial or ethnic categories for genetic studies.

#### Continuing Professional Development (CPD)

SAMJ is an HPCSA-accredited service provider of CPD materials. Principal authors can earn up to 15 CPD continuing education units (CEUs) for publishing an article; co-authors are eligible to earn up to 5 CEUs; and reviewers of articles can earn 3 CEUs. Each month, SAMJ also publishes a CPD-accredited questionnaire relating to the academic content of the journal. Successful completion of the

questionnaire with a pass rate of 70% will earn the reader 3 CEUs. Administration of our CPD programme is managed by Medical Practice Consulting. To complete questionnaires and obtain certificates, please visit [MRP Consulting](#)

## Manuscript preparation

### Preparing an article for anonymous review

To ensure a fair and unbiased review process, all submissions are to include an anonymised version of the manuscript. The exceptions to this are Correspondence, Book reviews and Obituary submissions.

Submitting a manuscript that needs additional blinding can slow down your review process, so please be sure to follow these simple guidelines as much as possible:

An anonymous version should not contain any author, affiliation or particular institutional details that will enable identification.

Please remove title page, acknowledgements, contact details, funding grants to a named person, and any running headers of author names.

Mask self-citations by referring to your own work in third person.

### General article format/layout

Accepted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction, which will delay publication.

#### General:

Manuscripts must be written in UK English.

The manuscript must be in Microsoft Word format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes).

Please make your article concise, even if it is below the word limit.

Qualifications, full affiliation (department, school/faculty, institution, city, country) and contact details of ALL authors must be provided in the manuscript and in the online submission process.

Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.

Include sections on Acknowledgements, Conflict of Interest, Author Contributions and Funding sources. If none is applicable, please state 'none'.

Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dL).

Litres is denoted with an uppercase L e.g. 'mL' for millilitres).

Units should be preceded by a space (except for % and °C), e.g. '40 kg' and '20 cm' but '50%' and '19°C'.

Please be sure to insert proper symbols e.g.  $\mu$  not u for micro,  $\alpha$  not a for alpha,  $\beta$  not B for beta, etc.

Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160.

Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'

Round brackets (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.

If you wish material to be in a box, simply indicate this in the text. You may use the table format –this is the only exception. Please DO NOT use fill, format lines and so on.

SAMJ is a generalist medical journal, therefore for articles covering genetics, it is the responsibility of authors to apply the following:

- Please ensure that all genes are in italics, and proteins/enzymes/hormones are not.

- Ensure that all genes are presented in the correct case e.g. TP53 not Tp53.

\*\*NB: Copyeditors cannot be expected to pick up and correct errors wrt the above, although they will raise queries where concerned.

- Define all genes, proteins and related shorthand terms at first mention, e.g. '188del11' can be glossed as 'an 11 bp deletion at nucleotide 188.'

- Use the latest approved gene or protein symbol as appropriate:

Human Gene Mapping Workshop (HGMW): genetic notations and symbols

HUGO Gene Nomenclature Committee: approved gene symbols and nomenclature

OMIM: Online Mendelian Inheritance in Man (MIM) nomenclature and instructions

Bennet et al. Standardized human pedigree nomenclature: Update and assessment of the recommendations of the National Society of Genetic Counselors. J Genet Counsel 2008;17:424-433: standard human pedigree nomenclature.

Preparation notes by article type

[Research](#)

[Editorials](#)

[CME](#)

[In Practice and Case reports](#)

[Reviews](#)

[Clinical trials](#)

[Correspondence](#)

[Obituaries](#)

[Book reviews](#)

[Guidelines](#)

Research

Guideline word limit: 4 000 words

Research articles describe the background, methods, results and conclusions of an original research study. The article should contain the following sections: introduction, methods, results, discussion and conclusion, and should include a structured abstract (see below). The introduction should be concise – no more than three paragraphs – on the background to the research question, and must include references to other relevant published studies that clearly lay out the rationale for conducting the study. Some common reasons for conducting a study are: to fill a gap in the literature, a logical extension of previous work, or to answer an important clinical question. If other papers related to the same study have been published previously, please make sure to refer to them specifically. Describe the study methods in as much detail as possible so that others would be able to replicate the study should they need to. Results should describe the study sample as well as the findings from the study itself, but all interpretation of findings must be kept in the discussion section, which should consider primary outcomes first before any secondary or tertiary findings or post-hoc analyses. The conclusion should briefly summarise the main message of the paper and provide recommendations for further study.

Select figures and tables for your paper carefully and sparingly. Use only those figures that provided added value to the paper, over and above what is written in the text.

Do not replicate data in tables and in text .

Structured abstract

This should be 250-400 words, with the following recommended headings:

Background: why the study is being done and how it relates to other published work.

Objectives: what the study intends to find out

Methods: must include study design, number of participants, description of the intervention, primary and secondary outcomes, any specific analyses that were done on the data.

Results: first sentence must be brief population and sample description; outline the results according to the methods described. Primary outcomes must be described first, even if they are not the most significant findings of the study.

Conclusion: must be supported by the data, include recommendations for further study/actions.

Please ensure that the structured abstract is complete, accurate and clear and has been approved by all authors.

Do not include any references in the abstracts.

[Here](#) is an example of a good abstract.

## Main article

All articles are to include the following main sections: Introduction/Background, Methods, Results, Discussion, Conclusions.

The following are additional heading or section options that may appear within these:

Objectives (within Introduction/Background): a clear statement of the main aim of the study and the major hypothesis tested or research question posed

Design (within Methods): including factors such as prospective, randomisation, blinding, placebo control, case control, crossover, criterion standards for diagnostic tests, etc.

Setting (within Methods): level of care, e.g. primary, secondary, number of participating centres.

Participants (instead of patients or subjects; within Methods): numbers entering and completing the study, sex, age and any other biological, behavioural, social or cultural factors (e.g. smoking status, socioeconomic group, educational attainment, co-existing disease indicators, etc) that may have an impact on the study results. Clearly define how participants were enrolled, and describe selection and exclusion criteria.

Interventions (within Methods): what, how, when and for how long. Typically for randomised controlled trials, crossover trials, and before and after studies.

Main outcome measures (within Methods): those as planned in the protocol, and those ultimately measured. Explain differences, if any.

## Results

Start with description of the population and sample. Include key characteristics of comparison groups.

Main results with (for quantitative studies) 95% confidence intervals and, where appropriate, the exact level of statistical significance and the number need to treat/harm. Whenever possible, state absolute rather than relative risks.

Do not replicate data in tables and in text.

If presenting mean and standard deviations, specify this clearly. Our house style is to present this as follows:

E.g.: The mean (SD) birth weight was 2 500 (1 210) g. Do not use the  $\pm$  symbol for mean (SD).

Leave interpretation to the Discussion section. The Results section should just report the findings as per the Methods section.

## Discussion

Please ensure that the discussion is concise and follows this overall structure – sub-headings are not needed:

Statement of principal findings

Strengths and weaknesses of the study

Contribution to the body of knowledge

Strengths and weaknesses in relation to other studies

The meaning of the study – e.g. what this study means to clinicians and policymakers

Unanswered questions and recommendations for future research

## Conclusions

This may be the only section readers look at, therefore write it carefully. Include primary conclusions and their implications, suggesting areas for further research if appropriate. Do not go beyond the data in the article.

## Editorials

Guideline word limit: 1 000 words

These opinion or comment articles are usually commissioned but we are happy to consider and peer review unsolicited editorials. Editorials should be accessible and interesting to readers without specialist knowledge of the subject under discussion and should have an element of topicality (why is a comment on this issue relevant now?) There should be a clear message to the piece, supported by evidence.

Please make clear the type of evidence that supports each key statement, e.g.:

expert opinion

personal clinical experience

observational studies

trials

systematic reviews.



## CME (by invite only)

CME is intended to provide readers with practical, up-to-date information on medical and related matters. It is aimed at those who are not specialists in the field.

From January 2016, all CME articles will be printed in full in the SAMJ. Please try to adhere strictly to the guidelines on word count as we have a page limit for the print issue of the SAMJ. We reserve the right to place some tables and reference lists online if this is necessary for space.

In practice, this means that each CME topic usually covers two issues of the print issue of the SAMJ.

The guest editor, in consultation with the editor, is responsible for convening a team of authors, deciding on the subjects to be covered and for reviewing the manuscripts submitted. The suggestion is for 4 - 5 articles, although there is some room for flexibility contingent on discussions with the editor.

For queries about these guidelines please feel free to contact the CME editor, Dr Bridget Farham, by email ([ugqirha@iafrica.com](mailto:ugqirha@iafrica.com)) or telephone (+27 (0)21 789 2331).

## Review process

The guest editor reviews the articles and returns them to the CME editor for review and final approval.

## Guest editorials

Guideline word limit: 1 000 words

Include the guest editor's personal details (qualifications, positions, affiliation, e-mail address, and a short personal profile (50words)).

If possible, include a photograph of the author(s) at high enough resolution for print. It is preferable to provide two guest editorials, one for each issue, so that the content of the articles in each issue is covered.

## Articles

Guideline word limit: 2 000 - 3 000 words

Each article requires an abstract of  $\pm 200$  words.

The editor reserves the right to shorten articles but will send a substantially shortened article back for author approval.

## Personal details

Please supply: Your qualifications, position and affiliations and MP number (used for CPD points); Address, telephone number and fax number, and your e-mail address; and a short personal profile (50 words) and a few words about your current fields of interest.

## In Practice

Guideline word limit: 2 000 - 3 000 words

This section includes articles that would previously have been accepted into the Forum section, and case reports.

In practice articles are those that draw attention to specific issues of clinical, economic or political interest regarding medicine and healthcare in southern Africa. They are assigned to a topic:

Case report

Clinical practice

Clinical alert

Issues in medicine

Issues in public health

Healthcare delivery

Consensus/Position statement

Medicine and the environment

Medicine and the law

Cochrane corner

An In Practice article should follow the following format – sub-headings are not necessary, but may be used for clarity:

**Author affiliations and qualifications:** to be the same as for Research. Provide all authors' names and initials, qualifications and full affiliations, and corresponding author.

**Short abstract:** does not need to be structured, but should capture the essential features of the article

**Introduction:** the reason for the article and the issue being addressed

**Recent research, discussion, local policy around the issue – include your own research where appropriate**

All statements should be referenced and, if opinion only, this should be stated

Discussion: how this article adds to the discussion around a particular topic

If a clinical practice or policy point is at issue, this needs to be emphasised, using a box with highlights if appropriate.

Essentially In practice is an opportunity for a more discursive approach to topics of clinical, economic or political importance in southern African health systems. It is not an opportunity to put forward unsubstantiated opinions!

### Case reports

The SAMJ has recently started to accept case reports. The cases must come from Africa, preferably southern Africa unless the condition is common to all African countries, and must be either a completely new description of a clinical condition or result (use Google!) or a case that highlights important practice or management issues.

Please use the following format for case reports:

Title of case: do not include the words 'a case report' in the title

Summary/abstract: up to 150 words summarising the case presentation and outcome

Background: why is this case important and why did you write it up?

Case presentation: presenting features, medical, social, family history as appropriate

Case management: should be according to best practice, and if not, please explain why

Investigations, if relevant: save space by simply saying 'normal' if, for example, renal function was completely normal, rather than listing normal results, highlight the abnormal – or indeed the normal if this is clinically significant

Differential diagnosis, if relevant

Treatment, if relevant

Outcome and follow-up

Discussion – a VERY BRIEF review of similar published cases

Teaching points: 3 - 5 bullet points

References: as per the SAMJ house style

Tables and figures: keep to a minimum. Use clinical images where relevant – we need hi-res versions for print, and identifiable persons must have a consent form

Patient consent: please include a statement about patient consent to a written case report. This should be uploaded as a supplementary file.

## Clinical trials

Guideline word limit: 4000 words

As per the recommendations published by the International Committee of Medical Journal Editors (ICMJE), clinical trial research is any research that assigns individuals to an intervention, with or without a concurrent comparison/control group to study the cause-and-effect relationship between the intervention and health outcomes. All clinical trials should be registered with the appropriate national clinical trial registry (or any international primary register, if relevant), and the trial registration number should be cited at the end of the abstract. Since 1st December 2005, all clinical trials conducted in South Africa have been required to be registered in the [South African National Clinical Trials Register](#). The SAMJ therefore requires that clinical trials be registered in the relevant public trials registry at or before the time of first patient enrollment as a condition for publication. The trial registry name and registration number must be included in the manuscript.

Please refer to the general guidelines for all papers at the top of this article for additional requirements with respect to ethics approval, funding, author contributions, etc. The format of original research articles should be followed for reporting of clinical trial results.

## Review articles

Guideline word limit: 4 000 words

These are welcome, but should be either commissioned or discussed with the Editor before submission. A review article should provide a clear, up-to-date account of the topic and be aimed at non-specialist hospital doctors and general practitioners.

Please ensure that your article includes:

**Abstract:** unstructured, of about 100-150 words, explaining the review and why it is important

**Methods:** Outline the sources and selection methods, including search strategy and keywords used for identifying references from online bibliographic databases. Discuss the quality of evidence.

**When writing:** clarify the evidence you used for key statements and the strength of the evidence. Do not present statements or opinions without such evidence, or if you have to, say that there is little or no evidence and that this is opinion. Avoid specialist jargon and abbreviations, and provide advice specific to southern Africa.

Personal details: Please supply your qualifications, position and affiliations and MP number (used for CPD points); address, telephone number and fax number, and your e-mail address; and a short personal profile (50 words) and a few words about your current fields of interest.

Correspondence (Letters to the Editor)

Guideline word limit: 500 words

Letters to the editor should relate either to a paper or article published by the SAMJ or to a topical issue of particular relevance to the journal's readership

May include only one illustration or table

Must include a correspondence address.

Book reviews

Guideline word limit: 400 words

Should be about 400 words and must be accompanied by the publication details of the book. Provide a hi-res image of the cover if possible (with permission from the copyright holder).

Obituaries

Guideline word limit: 400 words

Should be offered within the first year of the practitioner's death, and may be accompanied by a photograph.

Guidelines

Guidelines should always be discussed with the Editor prior to submission.

Because of the intensive review process required to ensure Guidelines are independent, evidence-based and free from commercial bias, they are usually published as a supplement to the SAMJ, the costs of which must be covered by sponsorship, advertising or payment by the guideline authors/association. We will provide a quote based on the expected length of the guideline and whether it is to appear online only, or in print, which must be accepted by the body putting the guidelines together before submitting the work to the SAMJ.

The Editor reserves the right to determine the scheduling of supplements. Understandably, a delay in publication must be anticipated dependent upon editorial workflow.

All guidelines should include a clear, transparent statement about all sources of funding and an explicit, clear statement of conflicts of interest of any of the participants in the guidelines about industry funding for lectures, research, conference participation etc.

All guidelines should be structured according to [Agree II](#).

Please access this website before putting the guidelines together, download the Agree 11 instrument and use this to put the guidelines together.

All submitted guidelines will be sent to the local Agree II appraisal committee for review and must be endorsed by an appropriate body prior to consideration and all conflicts of interest expressed.

A structured abstract not exceeding 400 words (recommended sub-headings: Background, Recommendations, Conclusion) is required. Sections and sub-sections must be numbered consecutively (e.g. 1. Introduction; 1.1 Definitions; 2.etc.) and summarised in a Table of Contents.

#### Illustrations/photos/scans

If illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.

Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Fig. 1)'.

Each figure must have a caption/legend: Fig. 1. Description (any abbreviations in full).

All images must be of high enough resolution/quality for print.

All illustrations (graphs, diagrams, charts, etc.) must be in PDF or jpeg form.

Ensure all graph axes are labelled appropriately, with a heading/description and units (as necessary) indicated. Do not include decimal places if not necessary e.g. 0; 1.0; 2.0; 3.0; 4.0 etc.

Scans/photos showing a specific feature e.g. Intermediate magnification micrograph of a low malignant potential (LMP) mucinous ovarian tumour. (H&E stain). –include an arrow to show the tumour.

Each image must be attached individually as a 'supplementary file' upon submission (not solely embedded in the accompanying manuscript) and named Fig. 1, Fig. 2, etc.

#### Tables

Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged.

Large tables will generally not be accepted for publication in their entirety. Please consider shortening and using the text to highlight specific important sections, or offer a large table as an addendum to the publication, but available in full on request from the author

Embed/include each table in the manuscript Word file - do not provide separately as supplementary files.

Number each table in Arabic numerals (Table 1, Table 2, etc.) and refer to consecutively in the text.

Tables must be cell-based (i.e. not constructed with text boxes or tabs) and editable.

Ensure each table has a concise title and column headings, and include units where necessary.

Footnotes must be indicated with consecutive use of the following symbols: \* † ‡ § ¶ || then \*\* †† ‡‡ etc.

Do not: Use [Enter] within a row to make 'new rows':

Rather:

Each row of data must have its own proper row:

Do not: use separate columns for n and %:

Rather:

Combine into one column, n (%):

Do not: have overlapping categories, e.g.:

Rather:

Use <> symbols or numbers that don't overlap:

## References

NB: Only complete, correctly formatted reference lists in Vancouver style will be accepted. Reference lists must be generated manually and not with the use of reference manager software. Endnotes must not be used.

Authors must verify references from original sources.

Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization,<sup>[2]</sup> and others.<sup>[3,4-6]</sup>

All references should be listed at the end of the article in numerical order of appearance in the Vancouver style (not alphabetical order).

Approved abbreviations of journal titles must be used; see the [List of Journals in Index Medicus](#).

Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al.

Volume and issue numbers should be given.

First and last page, in full, should be given e.g.: 1215-1217 not 1215-17.

Wherever possible, references must be accompanied by a digital object identifier (DOI) link). Authors are encouraged to use the DOI lookup service offered by [CrossRef](#):

On the Crossref homepage, paste the article title into the 'Metadata search' box.

Look for the correct, matching article in the list of results.

Click Actions > Cite

Alongside 'url =' copy the URL between { }.

Provide as follows, e.g.: <https://doi.org/10.7196/07294.937.98x>

Some examples:

Journal references: Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. *Stat Med* 1998;289(1):350-355. <http://dx.doi.org/10.1000/hgjr.182>

Book references: Jeffcoate N. *Principles of Gynaecology*. 4th ed. London: Butterworth, 1975:96-101.

Chapter/section in a book: Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA, Sodeman WA, eds. *Pathologic Physiology: Mechanisms of Disease*. Philadelphia: WB Saunders, 1974:457-472.

Internet references: World Health Organization. *The World Health Report 2002 - Reducing Risks, Promoting Healthy Life*. Geneva: WHO, 2002. <http://www.who.int/whr/2002> (accessed 16 January 2010).

Legal references

- Government Gazettes:

National Department of Health, South Africa. National Policy for Health Act, 1990 (Act No. 116 of 1990). Free primary health care services. *Government Gazette No. 17507:1514*. 1996.

In this example, 17507 is the Gazette Number. This is followed by :1514 - this is the notice number in this Gazette.

- Provincial Gazettes:



Gauteng Province, South Africa; Department of Agriculture, Conservation, Environment and Land Affairs. Publication of the Gauteng health care waste management draft regulations. Gauteng Provincial Gazette No. 373:3003, 2003.

- Acts:

South Africa. National Health Act No. 61 of 2003.

- Regulations to an Act:

South Africa. National Health Act of 2003. Regulations: Rendering of clinical forensic medicine services. Government Gazette No. 35099, 2012. (Published under Government Notice R176).

- Bills:

South Africa. Traditional Health Practitioners Bill, No. B66B-2003, 2006.

- Green/white papers:

South Africa. Department of Health Green Paper: National Health Insurance in South Africa. 2011.

- Case law:

Rex vJopp and Another 1949 (4) SA 11 (N)

Rex vJopp and Another: Name of the parties concerned

1949: Date of decision (or when the case was heard)

(4): Volume number

SA: SA Law Reports

11: Page or section number

(N): In this case Natal - where the case was heard. Similarly, (C) would indicate Cape, (G) Gauteng, and so on.

NOTE: no .after the v

Other references (e.g. reports) should follow the same format: Author(s). Title. Publisher place: Publisher name, year; pages.

Cited manuscripts that have been accepted but not yet published can be included as references followed by '(in press)'.

Unpublished observations and personal communications in the text must not appear in the reference list. The full name of the source person must be provided for personal communications e.g. '(Prof. Michael Jones, personal communication)'.

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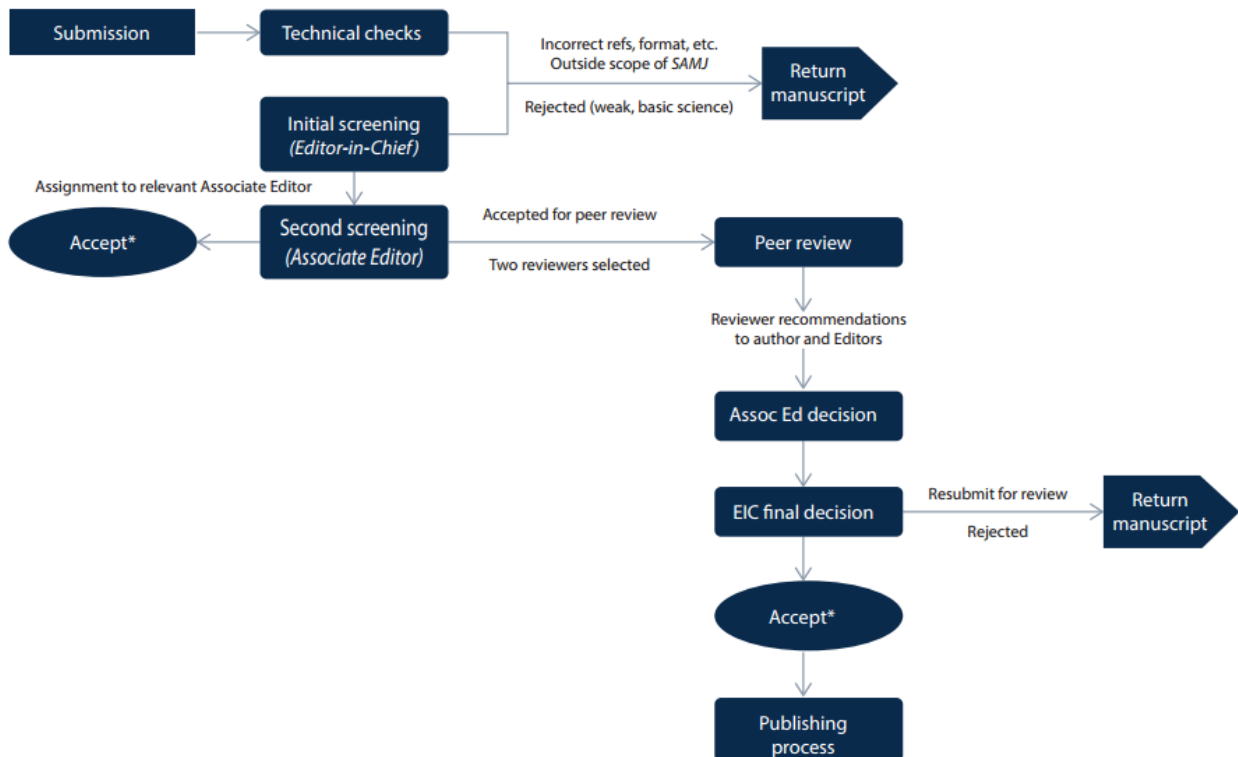
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## APPENDIX G. TURNITIN PLAGIARISM SUMMARY

### PREVALENCE OF LATEX ALLERGY IN SPINA BIFIDA PATIENTS IN UNIVERSITAS ACADEMIC HOSPITAL

#### ORIGINALITY REPORT

<b>23%</b>	<b>23%</b>	<b>7%</b>	<b>1%</b>
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

#### PRIMARY SOURCES

<b>1</b>	<b>www.sap.org.ar</b> Internet Source	<b>15%</b>
<b>2</b>	<b>apallergy.org</b> Internet Source	<b>3%</b>
<b>3</b>	<b>thejns.org</b> Internet Source	<b>2%</b>
<b>4</b>	<b>Submitted to University of the Free State</b> Student Paper	<b>1%</b>
<b>5</b>	<b>Asmah Johar. "Low prevalence of latex sensitivity in South African spina bifida children in Cape Town", Pediatric Allergy and Immunology, 3/2005</b> Publication	<b>1%</b>
<b>6</b>	<b>curis.ku.dk</b> Internet Source	<b>1%</b>
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