Evaluation of healthcare resource utilisation and costs associated with anogenital warts in South Africa

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Background. Human papilloma virus (HPV), the most prevalent sexually transmitted infection worldwide, and in particular HPV 6 and 11, contribute to >90% of anogenital warts (AGW) cases, and high-risk HPV serotypes cause >95% of cervical cancers in South Africa (SA). The healthcare resource utilisation (HCRU) and costs related to AGW in SA remain poorly understood, in both the public and private sectors.
Objective. To assess the HCRU patterns and associated treatment costs for AGW across the public and private sectors.
Methods. A descriptive, questionnaire-based study was conducted, involving 50 subject matter experts (SMEs) from SA: 24 from the private sector and 26 from the public sector. The study explored resource use, treatment patterns and cost estimation based on SME responses.
Results. Findings revealed that public-sector SMEs treated a larger volume of AGW patients per month (1 - 300) than private-sector SMEs (0 - 20). Most AGW patients were female, comprising 78% in the public sector and 72% in the private sector. The occurrence of AGW was higher in the public sector, ranging between 21.4% and 34.4%, while in the private sector, the occurrence ranged from 13.1% to 23.2%. The weighted cost per patient per episode was higher for females than males in both sectors. In the private sector, costs were ZAR22 482 for females and ZAR17 812 for males, while in the public sector, costs were ZAR19 220 for females and ZAR14 271 for males. The higher costs for females were driven by invasive diagnostic procedures, including vulvar colposcopy and biopsy, and a higher frequency of medical visits (2.0 - 4.4 visits in the public sector). Recurrence rates of AGW were reported at 37.6% in the private sector and 43.9% in the public sector. The total estimated treatment cost of AGW was notably higher in the public sector for both males (ZAR93.6 - ZAR138.5 billion) and females (ZAR135.2 - ZAR207.7 billion), compared with the private sector (males: ZAR11.0 - ZAR19.4 billion; females: ZAR16.7 - ZAR28.3 billion). Female patients experienced a higher burden of diagnosis, recurrence and complications than males.
Conclusion. AGW imposes a substantial burden on SA's healthcare system, particularly in the public sector, where female patients face significant costs and complications. The use of a quadrivalent or nonavalent HPV vaccine, rather than a bivalent vaccine, could reduce the impact of AGW and its associated healthcare demands.

Keywords: anogenital warts, HPV, anogenital diseases, healthcare costs, healthcare resource utilisation, South Africa

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Human papillomavirus (HPV) is almost exclusively responsible for the development of cervical cancer, and is linked to other conditions, including cutaneous and anogenital warts (AGW) and anogenital and oropharyngeal cancers.[1] Globally, HPV diseases are recognised as the most common sexually transmitted infections, significantly impacting quality of life.[2] Although most HPV infections are asymptomatic and resolve on their own, there is a 50% lifetime risk of contracting HPV for both men and women, which rises to 80% in sexually active individuals.[3] AGW are common manifestations of genital HPV infections, and are often difficult to treat, with high recurrence rates, resulting in a considerable healthcare burden.[4,5]

HPV comprises a family of small, double-stranded DNA viruses that infect epithelial cells, with >200 types identified. Low-risk HPV types 6 and 11 cause >90% of AGW, while high-risk HPV types 16 and 18 are responsible for up to 70% of anogenital cancers.[2,4,6] A synergistic association between anogenital HPV and HIV has been observed worldwide, particularly affecting men who have sex with men and HIV-positive men, who exhibit higher rates of anal cancer due to increased HPV anal infections.[7,8]

South Africa (SA) bears the world's highest HIV prevalence, at ~12.7%,[9] and young women aged 15 - 24 years are particularly vulnerable to HIV.[10] Epidemiological studies in sub-Saharan Africa reveal higher incidence rates of AGW among HIV-positive individuals (3.0 per 100 person-years) compared with HIV-negative individuals, at 1.1 - 2.7 per 100 person-years in women and 1.4 per 100 person-years in men. In Nigeria, AGW incidence is markedly higher in HIV-positive women (1 370 per 100 000 person-years) compared with their HIV-negative counterparts (515 per 100 000 person-years).

Approximately 90% of AGW cases are preventable with quadrivalent and nonavalent HPV vaccines, which cover HPV types 6 and 11. The introduction of these vaccines in developed countries has significantly reduced AGW incidence.[11] In SA, the National Department of Health incorporated HPV vaccination into the National Immunisation Programme in April 2014, using the bivalent vaccine targeting high-risk HPV types 16 and 18 for school-aged girls in the public sector. However, the bivalent vaccine does not protect against low-risk HPV types 6 and 11, which are

covered by the quadrivalent and nonavalent vaccines, which are only available privately.[12]

The choice of vaccine in national programmes is driven by cost-effectiveness. Therefore, data on AGW prevalence, healthcare burden and economic impact are essential for informed decision-making. Most studies on the economic burden of AGW focus on developed countries, with limited data available for SA. A comprehensive understanding of the burden and costs associated with AGW could guide policy-makers and private stakeholders in considering the inclusion of broader-coverage HPV vaccines in the public sector.[13-15]

This survey-based study aims to estimate the healthcare resource utilisation (HCRU) and treatment costs for AGW in SA from both public and private healthcare perspectives, addressing the gap in data on AGW's economic impact within the country.

Objectives

The primary objectives of this study were to describe HCRU patterns among patients with AGW, and to estimate the burden of AGW in SA. The secondary objectives were to estimate direct costs associated with the management of AGW in SA, and to establish sectoral (public and private) and gender differences regarding the burden of disease associated with AGW using the data obtained. Details of the variables used to address the study objectives are provided in section 1.3 of Appendix 1.

Methods

Study design

This was a questionnaire-based study using a cross-sectional survey to evaluate HCRU patterns and treatment costs for AGW in SA. The questionnaire aimed to elicit the opinions of a minimum of 30 subject matter experts (SMEs) from SA on the estimated use of resources in the management of patients with AGW. The participants were stratified based on healthcare sector (public or private), and on sex. This cross-sectional survey was conducted from 14 October 2022, for a duration of 15 weeks. The study was conducted using a web-based online platform, on which the participants responded to a series of questions about resource use in the treatment of AGW, considering demographic data, diagnostic tests, treatment options, clinical guidelines, complications of current treatments and the number of outpatient visits. Appendix 1 provides details on the survey questionnaire.

Study population

In order to gain a broad understanding of the management of AGW in SA, SMEs from various disciplines in both the public and private sectors were invited to participate in the survey. Of note, the SMEs were not approached based on their affiliation with public or private hospitals, and hospital groups were not approached. Furthermore, the survey did not have restrictions on provinces to be included. The survey link was accessed by 188 SMEs, of whom 87 consented to participate. Among 87 participants, only 50 completed the survey, while 37 either found it too lengthy or did not practise regularly. SMEs representing general practitioners (GPs), dermatologists, gynaecologists and urologists were provided with information regarding the study through professional societies and medical interest groups. Interested individuals were asked to register via the study invitation that was sent by professional societies and were sent their own unique link to provide informed consent (Appendix Fig. S1). SMEs were considered for participation in this cross-sectional survey if they were working in either the public or private sector at study initiation and involved in the management of AGW at study initiation. For public-sector participants, affiliation to one of the following academic institutions was required: University of Pretoria, University of the Witwatersrand, University of KwaZulu-Natal, Stellenbosch University, University of the Free State, Sefako Makgatho University, University of Limpopo, Walter Sisulu University and University of Cape Town. SMEs who were not practising and did not treat patients with AGW were excluded from the study.

Statistical methods

Continuous variables were presented as the number of non-missing observations, means, standard deviations (SDs), medians, first quartile (Q1) and third quartile (Q3). Only descriptive statistics were used to analyse the demographic data. Categorical data were summarised by the frequency and percentage of patients in each category. Categorical variables were displayed using absolute and relative frequencies. Responses of private-sector participants were analysed separately from responses of public-sector participants.

Cost analysis

Cost estimates for AGW treatment and corresponding unit costs were made using survey-based resource utilisation estimates. Country-specific unit costs for the public and private sectors were obtained from published local data sources. Public-sector costs were captured from the latest version of the published Uniform Patient Fee Schedule (2023),[16] and private-sector tariffs were collated from a variety of published medical aid tariffs.[17-19] Drug list prices were used to calculate the cost of pharmaceutical treatments.[20] The cost associated with each resource was calculated by using the formula $Q \times C$ (where Q = quantity of resource and C = unit cost). The cost per episode of care was then calculated by adding the costs associated with the diagnosis, treatment and management of complications and adverse events.

Estimated total cost burden of AGW in SA

The mean percentages of the minimum and maximum occurrence of AGW captured as responses in the descriptive summary were multiplied by the total population of SA to calculate the minimum and maximum number of patients with AGW.[21,22] The derived number of patients was then multiplied by the total average costs per male and female patient, in order to calculate the estimated minimum and maximum total cost burden of AGW in SA.

Ethical considerations

The study protocol was approved by Pharma-Ethics, an independent research ethics committee (ref. no. 220524703). This was a cross-sectional survey involving SMEs; hence the study participants were clinicians and not patients. Informed consent was obtained online prior to accessing the survey, and was in adherence to applicable laws and regulations and sponsor requirements (Appendix Fig. S2).

Results

Study participants and demographics by sector

Overall, 50 SMEs participated in the study, of whom 24 were from the private sector and 26 from the public sector. Most SMEs working in the private (54.2%) and public (73.1%) sectors were male. The participants consisted of 52% private GPs and 25% private gynaecologists, and 26.9% public-sector GPs and 42.3% public-sector gynaecologists. Private-sector SMEs had more experience (~20 years) in treating patients with AGW than public-sector SMEs (~14 years) (Table 1).

HCRU associated with management of AGW

Patient population by sector and gender

Overall, the SMEs had a similar mean (SD) number of total AGW-related consultations per month in the private (319.6 (212.7)) and public (345.4 (260.6)) sectors. Public-sector SMEs had, on average, 1.1 more consultations a day than private-sector SMEs, and treated a four-times higher number of AGW patients per month v. private-sector SMEs (public sector: 24.58 patients/month; private sector: 5.63 patients/month). A higher proportion of female patients (private sector: 71.6%; public sector: 77.8%) v. male patients (private sector: 29.6%; public sector: 32.1%) with AGW were treated by SMEs from both the private and public sectors. The proportion of patients with recurrent disease was higher in the public sector (44%) v. the private sector (38%). In both sectors, most patients with AGW were aged ≥20 years. The proportion of undiagnosed patients was similar in both sectors (Fig. 1). Patients in the public sector, particularly females, were more likely to have vulvar colposcopy and biopsy, and required almost twice the average number of visits (2.0 - 4.4), compared with patients in the private sector.

Table 1. Demographic characteristics of survey participants by sector (*N*=50)

Variable	Sector, *n* (%)*		
	Private (*n*=24)	Public (*n*=26)	Overall, *n* (%)*
Sex			
Male	13 (54.17)	19 (73.08)	32 (64.00)
Female	11 (45.83)	7 (26.92)	18 (36.00)
Specialty			
Urology	-	2 (7.69)	2 (4.00)
Gynaecology	6 (25.00)	11 (42.31)	17 (34.00)
GP	13 (54.17)	7 (26.92)	20 (40.00)
Dermatologist	3 (12.50)	5 (19.23)	8 (16.00)
Other†	2 (8.33)	1 (3.85)	3 (6.00)
Academic affiliation	24 (100)	26 (100.0)	50 (100)
UP	1 (4.17)	1 (3.85)	2 (4.00)
Wits	3 (12.50)	4 (15.38)	7 (14.00)
UKZN	0	5 (19.23)	5 (10.00)
SU	1 (4.17)	3 (11.54)	4 (8.00)
UFS	0	0	0
UCT	0	2 (7.69)	2 (4.00)
SMU	1 (4.17)	6 (23.08)	7 (14.00)
Other‡	2 (8.33)	2 (7.69)	4 (8.00)
Not affiliated	16 (66.67)	3 (11.54)	19 (38.00)
Age, years, mean (SD)	48.88 (12.25)	43.38 (8.18)	46.02 (10.59)
Experience in specialty, years, mean (SD)	19.50 (10.75)	13.62 (7.93)	16.44 (9.75)
Experience treating patients with AGW, years, mean (SD)	19.13 (10.72)	12.65 (7.94)	15.76 (9.84)

GP = general practitioner; UP = University of Pretoria; Wits = University of the Witwatersrand; UKZN = University of KwaZulu-Natal; SU = Stellenbosch University; UFS = University of the Free State; UCT = University of Cape Town; SMU = Sefako Makgatho Health Sciences University; SD = standard deviation; AGW = anogenital warts.

*Unless otherwise indicated.

†HIV specialist and sexual health physician.

‡Colleges of Medicine of South Africa and Walter Sisulu University.

Reported prevalence of AGW by sector and gender

The reported prevalence of AGW was higher in the public sector v. the private sector for both males and females (public sector: 21.4 - 31.7% male and 22.4 - 34.4% females private sector: 13.1 - 23.1% male and 13.7 - 23.2% female). The number of female patients seeking medical assistance for their AGW was almost double that of male patients in both sectors (Fig. 2).

Diagnosis by stage of disease and sector presented

In the private sector, the mean proportion of patients with mild (44.0%) and moderate (39.2%) AGW was higher than patients with severe (16.8%) AGW. However, in the public sector, the proportion of patients with moderate (41.3%) and severe (38.5%) AGW was nearly double the proportion of patients with mild (20.2%) AGW. Sections 2.1 to 2.3 of Appendix 1 and Appendix Figs S3 and S4 provide details on various diagnostic tests and procedures conducted among patients with AGW, as well as the screening of sexual partners of patients with AGW.

Treatment patterns

Factors influencing choice of treatment by sex and sector

Most private- and public-sector SMEs ranked the number, size, location and morphology of lesions as the main determinant (ranked first) of treatment choice for both male (private sector: 90.5%; public sector: 77.8%) and female (private sector: 91.7%; public sector: 84.6%) patients (Appendix Table S1).

Proportion of patients receiving first-line treatment by sex and sector

According to the private- and public-sector SMEs, most patients (private sector: males, 68.8% and females, 66.4%; public sector: males, 52.5% and females, 53.6%) received pharmacological patient-applied treatments as first-line treatment. Surgery was the second most common first-line treatment, mainly in the public sector (Fig. 3; Appendix Table S2). Imiquimod and electrocautery were the most common first-line treatments in both the private and public sectors. Patients in the private sector tended to be treated with pharmacological interventions, with imiquimod being the most common treatment option. Electrocautery was the most common surgical treatment used as a first-line treatment in both sectors (Appendix Fig. S5).

Proportion of patients with second-line therapy

According to the private-sector SMEs, only 24% of patients in the private sector and 43.4% of patients in the public sector required second-line therapy. This is attributable to the stage of disease seen in the public sector, which is more severe, complicated disease. Surgery was the most common second-line therapy among male (36.67%) and female (47.19%) patients in the public sector (Appendix Fig. S6).

Proportion of patients receiving treatment for recurrent AGW

Overall, the rate of recurrent AGW was higher in the public sector than the private sector (44% v. 38%). Most patients received pharmacological patient-applied treatment as recurrent therapy in the private sector. However, surgery was the most common therapy for the treatment of recurrent AGW in the public sector (Appendix Fig. S7).

Proportion of patients reporting side-effects and complications

Approximately half the patients who received treatment for AGW experienced side-effects such as burning, itching, or swelling (private sector: males, 47.9% and females, 56.3%; public sector: males, 51.7% and females, 53.5%). Patients in the public sector required a greater

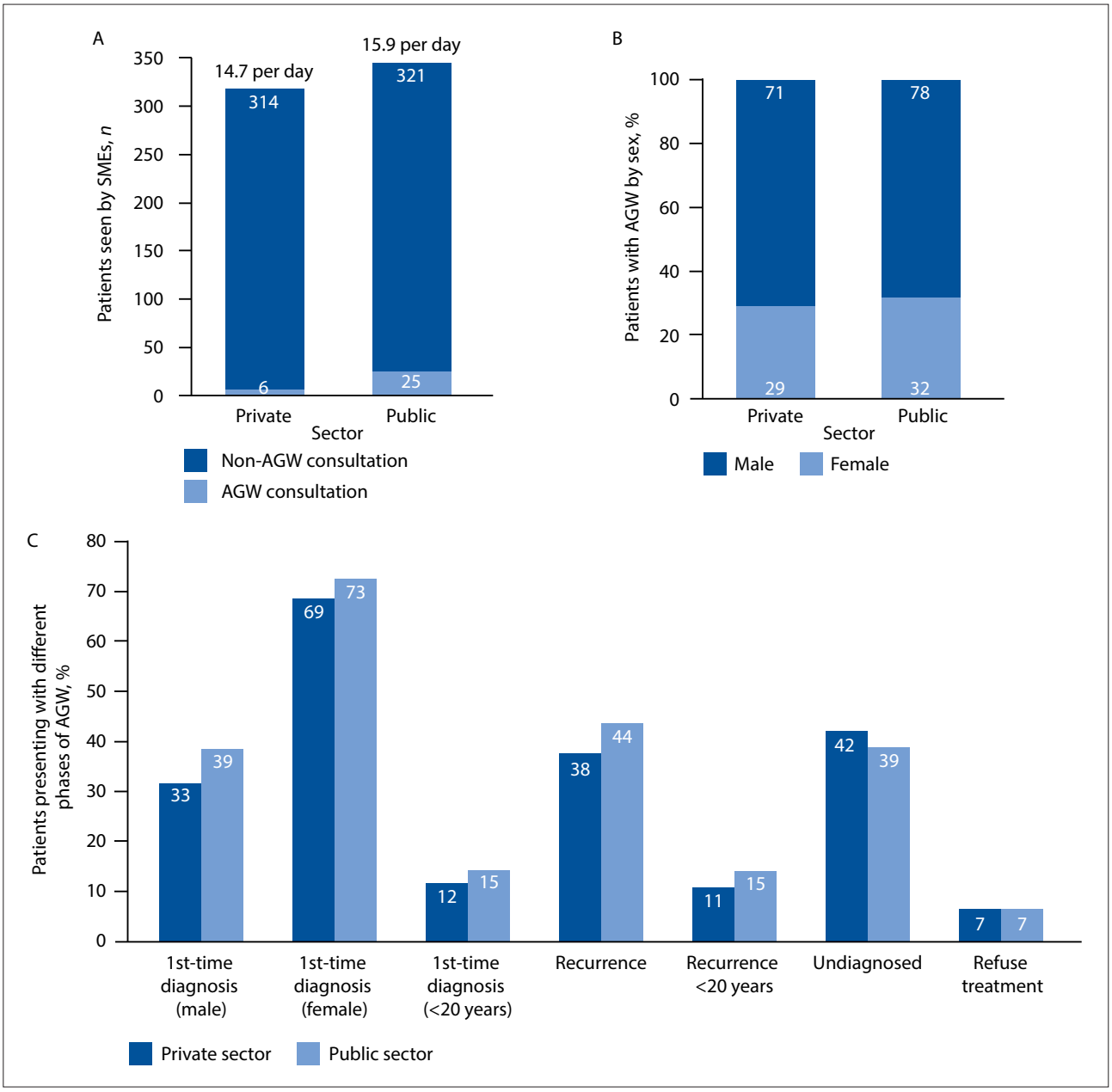

Fig. 1. Summary of subject matter experts' responses regarding patient population by sector. A: Average number of anogenital warts (AGW) and non-AGW consultations per month; B: Private- and public-sector patients with AGW by sex (%); C: Proportion of patients presenting at different phases of AGW by healthcare sector. (SME = subject matter expert.)

number of average visits to treat side-effects compared with patients in the private sector (Appendix Fig. S8). Patients in the private sector had fewer complications during treatment than patients in the public sector (41% v. 42% for itching, 27% v. 40% for discoloration, 21% v. 27% for bleeding).

Female patients in the public sector reported the highest incidence of complications. Burning, itching, or swelling were the most common complications in females treated in the public sector, at 44% (Appendix Fig. S9).

Costs associated with the management of AGW

Cost of diagnosis

Overall, the total cost of diagnosis per patient was higher in female patients than male patients, due to the higher use of hepatitis B virus (HBV) serology, venereal disease laboratory research for syphilis, polymerase chain reaction for HPV and enzyme-linked immunosorbent assay (ELISA) for HIV in both sectors. Similarly, diagnostic procedures per person were also more expensive for female patients than for male patients in the private and public sectors. The largest cost drivers were examinations and biopsies, particularly for female patients in the public sector (Appendix Figs S10 and S11). The differences between genders were driven by vulvar colposcopy conducted in females, and higher proportion of females receiving biopsies (44% v. 31%).

Average costs per line of treatment for patients with suspected AGW

Among all first-line treatment options, the total cost per patient was highest for pharmacological, patient-applied treatment (e.g. podophyllin, imiquimod, sinecatechins ointment) in both sectors. The cost of treating AGW with first-line pharmacological patient-applied

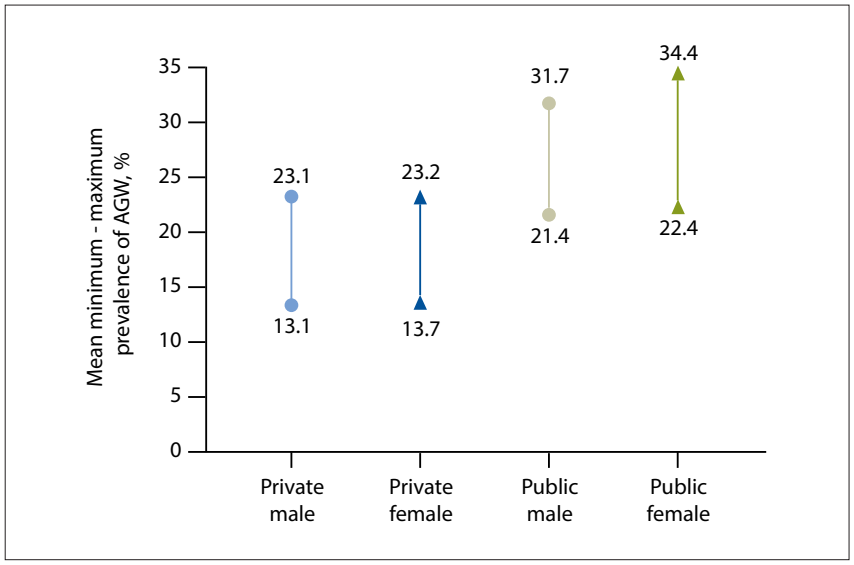

Fig. 2. Prevalence of anogenital warts (AGW) in private and public sectors of South Africa.

treatment was higher in the private sector than the public sector. However, surgery as first-line therapy was more expensive in the public sector than the private sector (Fig. 4).

Surgery was the most expensive second-line treatment among all treatment options in both sectors. Surgery as a second-line treatment was also costlier in the public sector than the private sector, and its cost was highest for male patients visiting the public sector for the treatment of AGW (Appendix Fig. S12).

Weighted total average costs per episode of AGW per patient by sector and sex

Overall, the weighted total average cost of managing AGW without recurrence was higher in the private sector than the public sector among both male and female patients (private sector: males, ZAR17 813 and females, ZAR22 482; public sector: males, ZAR14 271 and females, ZAR19 220). Similar results were reported for managing AGW with recurrent episodes. The total cost per patient for treating AGW was higher in female patients from both sectors, and was mainly driven by invasive diagnostic procedures (Fig. 5).

Estimated total cost burden of AGW in SA

The estimated minimum and maximum total cost burden for managing AGW episodes with or without recurrence was higher in the public sector than the private sector among both sexes. Female patients in the public sector reported the largest total cost burden for managing AGW in SA. Overall, the estimated minimum and maximum total cost burden for managing initial AGW episodes with recurrence was higher in the public sector than the private sector of SA among both sexes (private sector: males, ZAR11.0 - ZAR19.4 billion and females, ZAR16.7 - ZAR28.3 billion; public sector: males, ZAR93.6 - ZAR138.5 billion and females, ZAR135.2 - ZAR207.7 billion) (Fig. 6).

Discussion

This is the first questionnaire-based descriptive study estimating the burden of AGW in terms of HCRU and healthcare costs in SA on both the public and private sectors, comparing males and females. This study reported a higher burden among patients in the public sector (1 - 300 per month) than in the private sector (0 - 20 per month). A possible reason for this is the two-tiered SA healthcare system, where most of the population receives treatment through the state-funded public sector (85%), while treatment in the private sector is funded through medical insurance schemes. The high cost of private healthcare is unaffordable for most SA patients. In the overburdened public sector, individuals are often unaware of their health status, or wait until their condition becomes intolerable.[24,25]

In this study, SMEs from both the private (71.6%) and public (77.8%) sectors reported a higher proportion of female patients diagnosed with AGW. These results likely reflect the gynaecological and pregnancy-related services used by female patients, which provide an opportunity for the diagnosis of AGW. Male patients were seen to visit reproductive specialists (i.e. urologists) only when they had symptoms.[26] In published literature, the prevalence of AGW was similar among males and females within each healthcare sector. This was not reflected in our study, with a higher proportion of female patients diagnosed with AGW. However, studies conducted in other countries reported a higher prevalence of AGW in female patients.[27,28] The present study also found that a higher estimated proportion of patients had moderate or severe AGW and sought treatment in the public sector (moderate: 41.3%; severe: 38.5%) than the private sector (moderate: 39.2%; severe: 16.8%). There was more second-line treatment in the public sector. These findings suggest that patients in the public sector generally delayed AGW treatment until their condition worsened and became moderate or severe. This resulted in more difficult-to-treat warty lesions, and was associated with higher treatment costs. This delay could be due to a lack of educational awareness, limited access to treatment options, or the social stigma attached to AGW. It is important to note that this study did not specifically assess the prevalence of HIV in the private v. public healthcare sectors. Existing published literature on this topic is limited and characterised by high variability in the available data. In one study, it was estimated that the HIV prevalence in the private sector was 4.3% v. close to 13% in the public sector.[28]

HIV seropositivity and HIV-induced immune suppression are strongly associated with an increased prevalence of AGW, compared with HIV seronegativity.[15] HPV-related malignancies are more frequent among HIV-positive individuals.[29] In sub-Saharan Africa, only 45% of HIV-positive individuals know their HIV status; hence it is important to consider patients' HIV status at the time of AGW treatment initiation.[30] In our study, most patients from the private and public sectors (private sector: 70.3% of males and 77.2% of females; public sector: 72.6% of males and 85.4% of females) were tested for HIV using ELISA. However, the sexual partners of patients presenting with AGW were not systematically evaluated in either healthcare sector, and such testing was almost non-existent in the public sector (<30% in the private and <4% in the public sector). Lack of routine screening of partners, as well as poor education regarding the disease, may contribute to cross-infection and an increase in disease recurrence.

The diagnosis and practice patterns of the panellists in the current study were in line with the guidelines of the International Union Against Sexually Transmitted Infections (IUSTI 2019)-Europe for the management of AGW.[31] Nearly all patients underwent an examination as part of the AGW diagnostic pathway, except for males in the private sector, where a

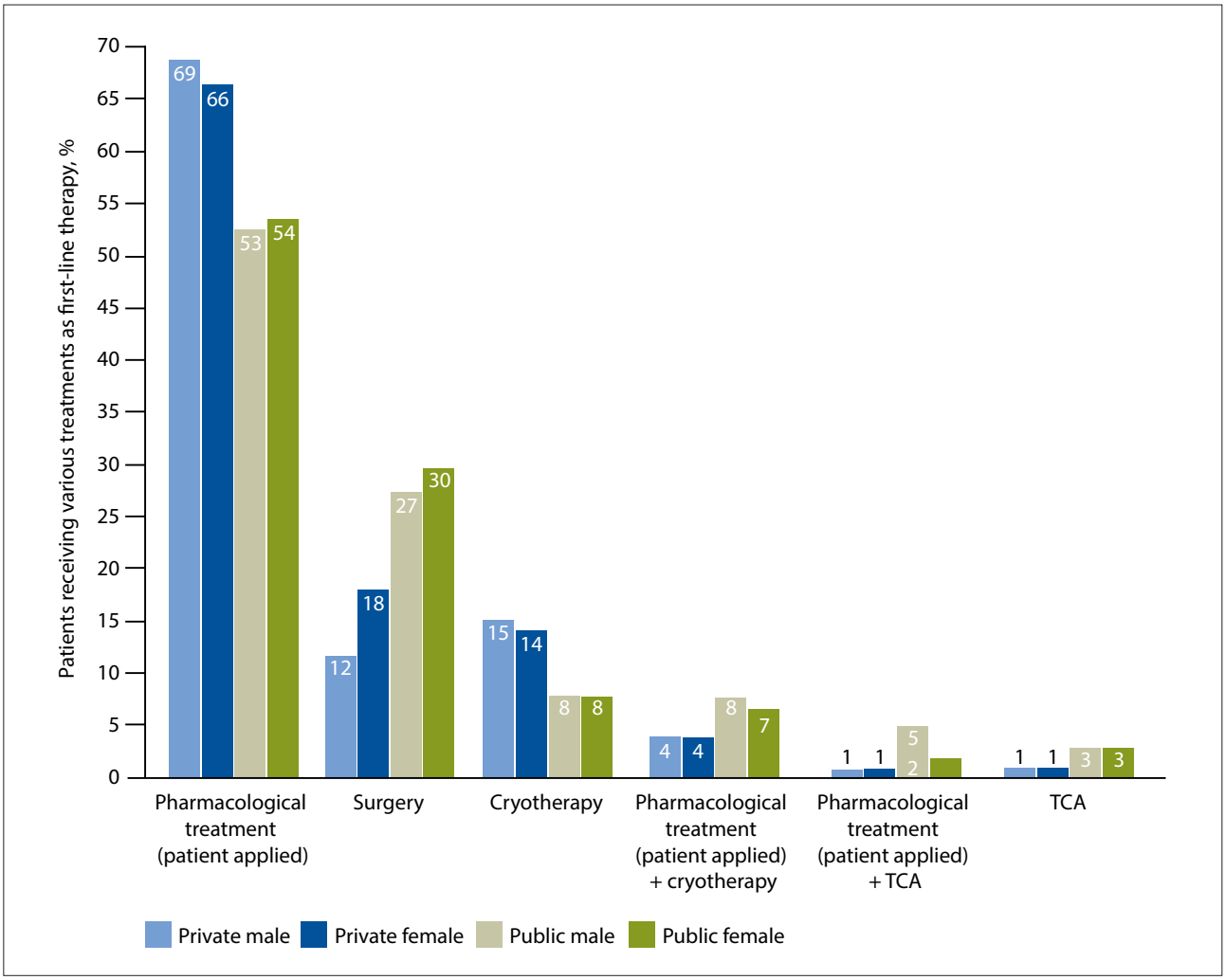

Fig. 3. Patients with anogenital warts who received various treatments as first-line therapy by sex and sector. (TCA = trichloroacetic acid.)

physical examination was performed in 88% of cases. International guidelines also recommend a visual inspection as the best method for diagnosing AGW.[32,33] Patients in the public sector, particularly females, were more likely to have vulvar colposcopy and biopsy, and required almost twice the average number of visits (2.0 - 4.4) as patients in the private sector. Invasive procedures such as anoscopy and penoscopy were used almost exclusively in the public sector. This could be due to patients with more severe disease reporting to the public sector, requiring advanced diagnostic procedures and a greater number of visits for the management of AGW. In the present study, most patients received pharmacological patient-applied treatments (imiquimod followed by podophyllin) as first-line treatment for AGW. Surgery was the second most common first-line treatment, particularly in the public sector, which could be due to more advanced disease in the patients presenting to this sector. These results are in line with the IUSTI-Europe guidelines recommending topical agents and surgical removal as the most convenient and effective options for AGW treatment.[32,33]

National data on the economic burden of AGW are scarce, making our study the most comprehensive estimate for SA. The study finds a significant economic burden of AGW in both public and private sectors, with higher reported costs for female patients (private sector: ZAR22 482; public sector: ZAR19 220) than male patients. Invasive diagnostic procedures were the primary cost driver, especially for females in the public sector, likely due to more advanced AGW cases and increased visits. Pharmacological treatments and surgeries were the most expensive first- and second-line treatments across both sectors. Factoring in the reported prevalence of AGW (16.5% - 29.5%) within the total population, the estimated total cost burden was higher in the public sector, reflecting its role in serving a larger population.[20,21] Female patients in the public sector carried the greatest economic burden (ZAR135.2 - ZAR207.7 billion), due to more invasive interventions, adverse events and specialist visits.

Previous studies have reported HCRU and costs associated with AGW in the USA, Canada, Europe and Australia.[20,32-34] A systematic review by Raymakers *et al.*[35] analysed the economic burden of AGW from studies in developed countries (the USA, Europe and Australia) and reported costs per episode of AGW in different countries of USD240 - USD1 711 (in 2023, using an online currency converter).[13,34-37] Studies conducted in Spain, Canada and Morocco have also reported an average cost of AGW of USD220 - USD1 281 per person.[14,26,38] This SA study is not comparable with various published studies across the globe due to differences in study designs, populations, socioeconomics and healthcare systems across various countries. However, a few of our results, such as the higher reported costs associated with AGW among female v. male patients, more visits for female patients than male patients, and diagnostic test costs being higher for female patients, are in line with observations reported in previous studies.[26,36,37]

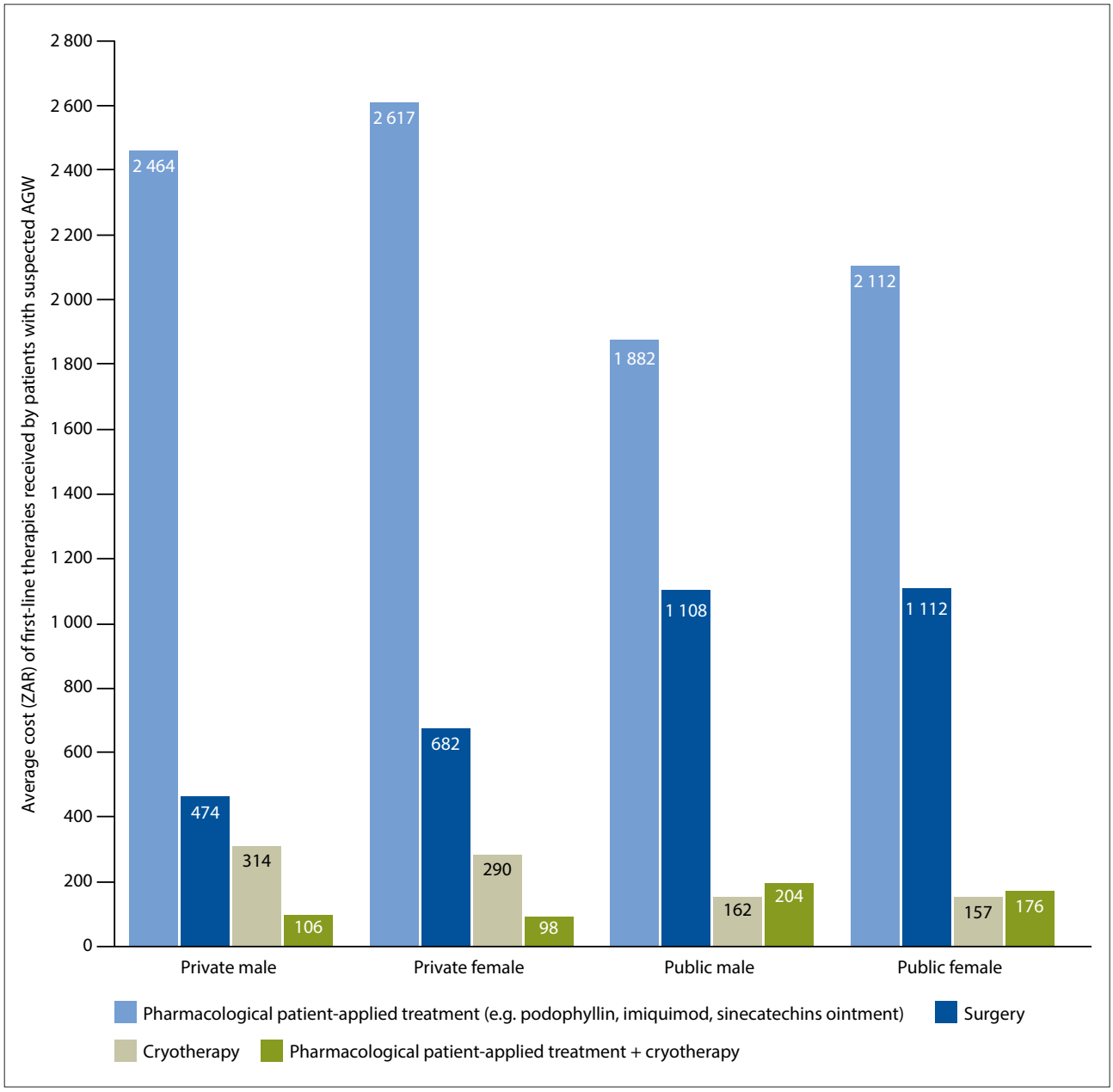

Fig. 4. Average cost of first-line therapies received by patients with suspected anogenital warts (AGW).

A study conducted in the USA in 2008 estimated a direct medical cost of USD5 billion per year for managing HPV-related conditions, which further increased to USD8 billion in 2010.[39,40] In resource-constrained countries such as SA, the HPV vaccination programme is an effective alternative strategy to prevent pre-cancer and cancer caused by HPV. Using a vaccine protecting against HPV types 6 and 11 may further reduce the economic burden caused by AGW. The vaccination programme may be associated with lower direct medical costs annually than screening and management at private- or public-sector hospitals. Previous studies have already shown that the incidence of AGW has decreased among both the vaccinated female population and the unvaccinated male population in countries implementing organised HPV vaccination with the quadrivalent vaccine.[5,41] In 2014, the SA National Department of Health introduced HPV vaccination as part of the national immunisation programme. The Expanded Programme on Immunisation offers HPV vaccination against cervical cancer using the bivalent HPV vaccine in the public sector, which does not offer protection against AGW. A quadrivalent or nonavalent vaccine offering protection against HPV types 6 and 11, that will provide additional benefits in the prevention of AGW, is currently available only in the private sector in SA.

Of note is that in the private sector, the cost of a bivalent vaccine is comparable with that of a quadrivalent vaccine. However, in the public sector, only the lowest-priced bivalent vaccine was awarded for tender.

It is important to note that there are limitations to this study. The primary limitation is that the data are based on expert opinion rather than objective and quantitative medical records or administrative databases. As a result, the study offers insight into the burden of AGW from the perspective of SMEs, and does not provide an estimate of the healthcare burden and associated costs of AGW in SA. Calculation using the total population instead of the population that sought care in the selected provider types could

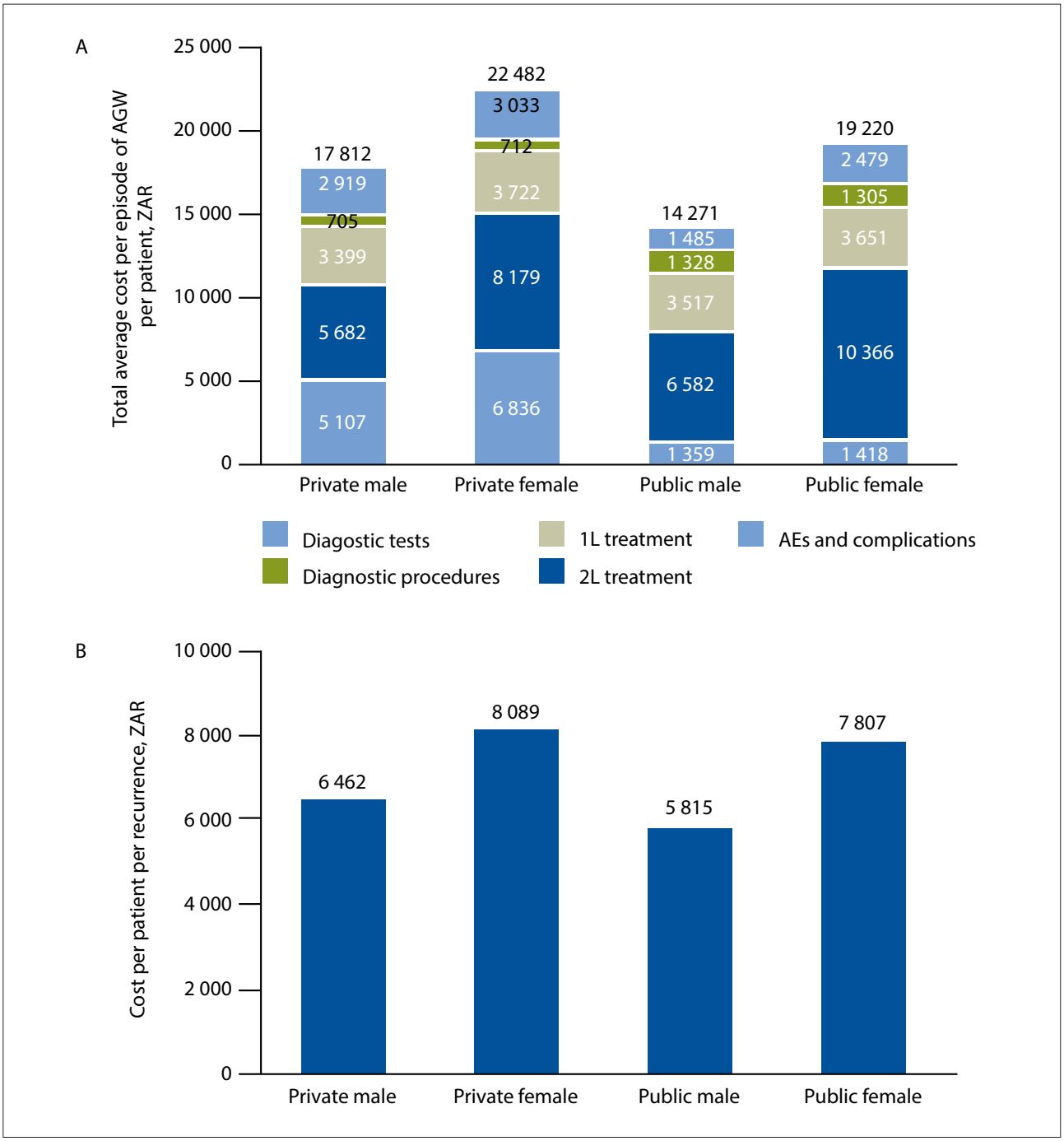

Fig. 5. Total average costs per episode of anogenital warts (AGW) per patient. A: Weighted cost per patient for diagnosis, treatment, adverse effects (AEs) and complications; B: Weighted cost per patient for recurrence. (1L = first-line; 2L = second-line.)

overestimate the burden of AGW and the economic burden. When the inclusion/exclusion criteria were defined for this study, great care was taken to emphasise objectivity, but there was no consensus on the definitions of expertise. The experts were based solely in SA, making these data relevant only to SA. Cross-country comparisons of study data are of limited relevance.

Conclusion

The results of this study offer insights into the burden of AGW from the perspective of SMEs in SA, and highlight the prevalence and considerable treatment costs of the disease to health institutions in the public and private sectors. Female patients in the public sector present the largest economic burden of AGW, and more often endure more aggressive treatment than males in either sector or females in the private sector. Lack of awareness, knowledge and regular partner screening could lead to cross-infection and higher prevalence and recurrence rates of AGW. There is an urgent need for healthcare policies to prioritise timely incorporation of educational programmes, especially those related to AGW- and HPV-associated cancers, to increase HPV knowledge and vaccination rates in the SA population. These results may assist policy-makers in making more informed decisions regarding the need for a quadrivalent or nonavalent HPV vaccine in the public sector.

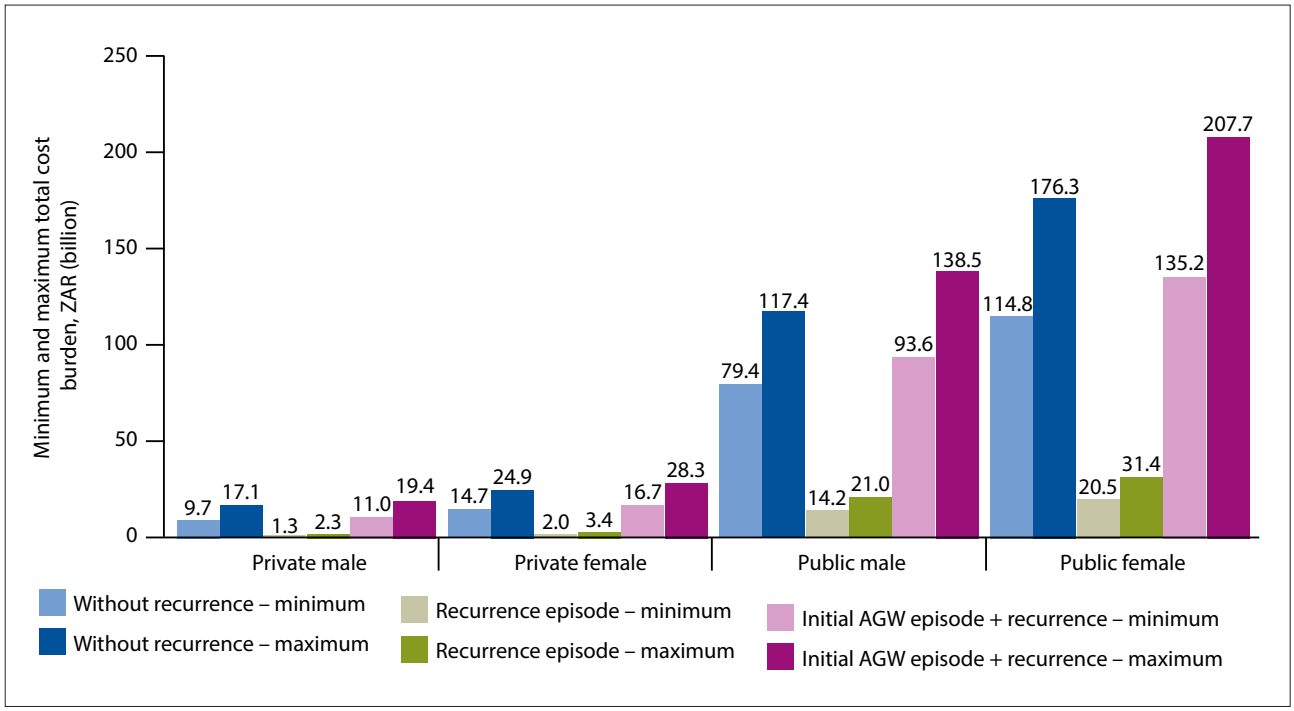

Fig. 6. Estimated total cost burden for patients with anogenital warts (AGW) in South Africa.[21-23]
Mean percentages for minimum and maximum prevalence from responses captured in descriptive summary (survey question no. 7) were used along with population information to arrive at minimum and maximum number of patients. They were calculated separately for males and females. Formula: patients with AGW (n) *= % prevalence from descriptive summary × population.*
The derived number of patients was multiplied by total costs per patient of males and females for both sectors to arrive at estimated minimum and maximum total cost burden. These were calculated with and without recurrence options. Formula: cost burden without recurrence = patients with AGW (n) *× total cost per patient without recurrence. Cost burden of recurrence = patients with AGW* (n) *facing recurrence episode × total cost per patient of recurrence episode. (AGW = anogenital warts.)*

Declaration. None.

Data availability. The data used for this study are available upon request from the IQVIA medical writing team, and Merck Sharp & Dohme (MSD).

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