Supplementary material

Manuscript title: Towards the elimination of cervical cancer in low- and middle-income countries: Effectiveness and cost-effectiveness of point-of-care HPV self-collected testing and treatment in Papua New Guinea

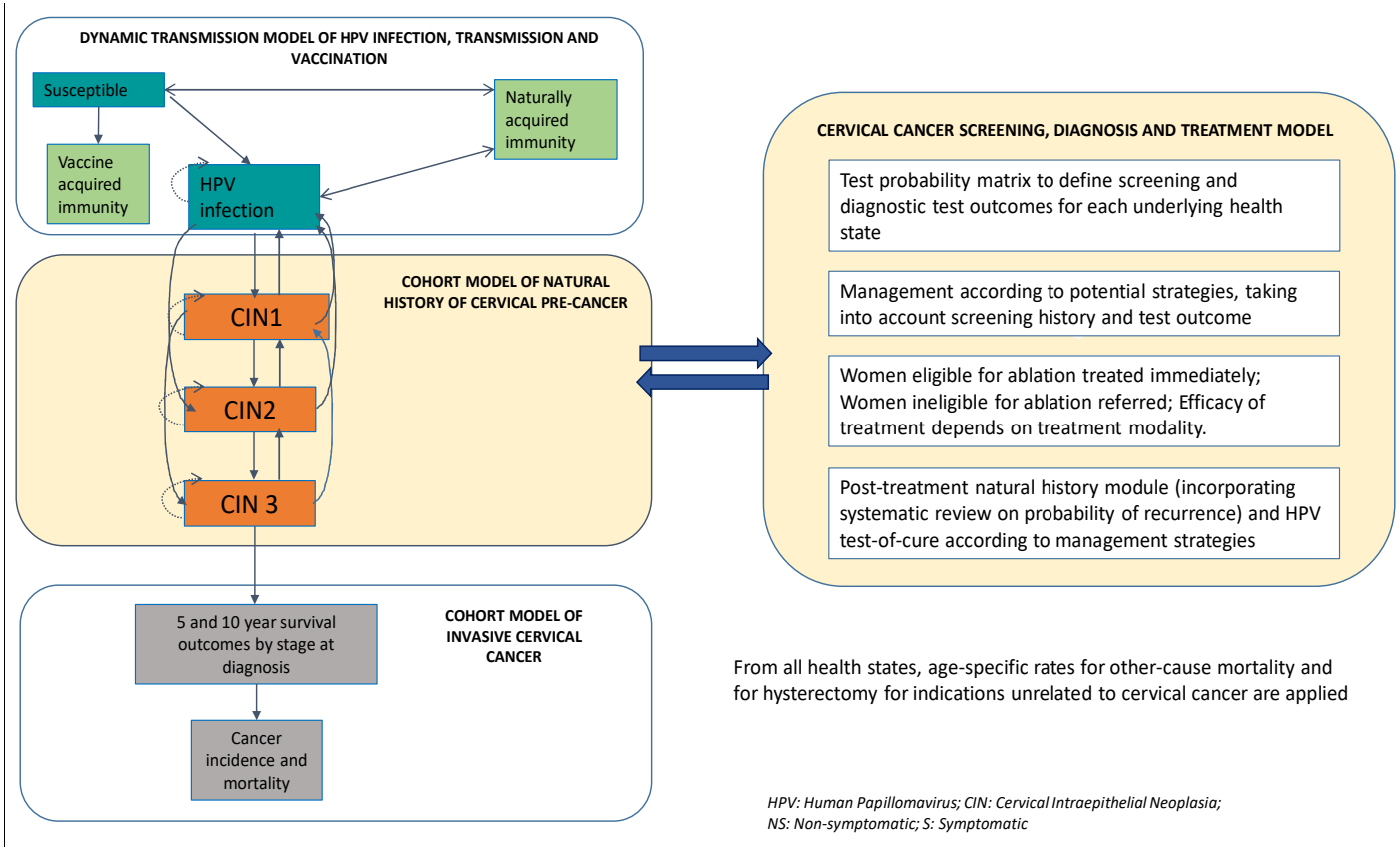
1. Model platform - Policy1-Cervix

A dynamic multicohort model of HPV transmission, HPV vaccination, cervical precancer, cancer survival, screening, diagnosis and treatment *('Policy1-Cervix'*) was used for the evaluation. The model has been used for a wide range of evaluations, including recently being used to predict the timeline to elimination of cervical cancer for 181 countries[1], for 78 low-and lower-middle income countries [Canfell/Brisson], for USA [Burger,JNIC2020] and for Australia[2] It has been used for a range of government-commissioned on behalf of national cervical screening programs in Australia, New Zealand and England; some specific examples of this include: the effectiveness modelling and economic evaluation of cervical screening for both unvaccinated cohorts and cohorts offered vaccination, as part of the Renewal of the cervical screening program in Australia[3], as well as similar screening policy evaluations for New-Zealand[4] and England[5]. It has also been used to inform provide estimates of resource utilization and disease impacts during the transition from cytology to HPV screening in Australia and New Zealand,[6-8] and to inform clinical management guidelines in Australia.[9] It has previously been extensively validated and used to evaluate changes to the cervical cancer screening interval in Australia and the United Kingdom,[10,11] the role of alternative technologies for screening in Australia, New Zealand and England,[12-15] the role of HPV triage testing for women with low-grade cytology in Australia and New Zealand,[13,16] the role of HPV testing for the follow-up management of women treated for cervical abnormalities[17] and the cost-effectiveness of alternative screening strategies and combined screening and vaccination approaches in China.[18,19] The model has also been used to evaluate female vaccination[20] and the incremental impact of vaccinating males in Australia,[21] the impact of the nonavalent HPV vaccine in four developed countries[22] and to assess the cost-effectiveness of the nonavalent HPV vaccine in Australia.[23] Predictions from the dynamic HPV transmission and vaccination model have also been validated against observed declines in HPV prevalence in women aged 18-24 years after the introduction of the quadrivalent vaccine.[24] Model predictions of age-specific cervical cancer incidence and mortality, the rate of histologically confirmed high-grade lesions per 1,000 women screened and overall screening participation rates have been previously validated against national data from Australia, England and New Zealand[3-5] after taking into account local age-specific screening behaviour obtained via analysis of screening registry data. Policy1-Cervix has also been used in conjunction with a model of fertility to estimate the impact of vaccination and screening changes on adverse pregnancy outcomes[25], and with a model of HIV to estimate the impact of HIV control on future cervical cancer.[26] Ethnicity-specific models have been developed for New Zealand.[27]

The model simulates HPV infection which can persist and/or progress to cervical intraepithelial neoplasia grades I, II and III (CIN1, CIN2, CIN3); CIN 3 can then progress to invasive cervical cancer. Progression and regression rates between states are modelled separately for HPV 16, HPV 18 types, other high-risk nonavalent-included types (31/33/45/52/58), and other non-nonavalent-included high risk types (Appendix Figure 1). The model platform captures the increased risk of CIN2+ recurrence in successfully treated women (compared to the baseline risk of CIN2+ in the population), as previously described.[28] (see ***Figure A1***)

For further information, please visit the Policy1-Cervix website
https://www.policy1.org/models/cervix/documentation for detailed description of the Policy1-Cervix model.

Figure A1: Model structure – Policy-1 Cervix

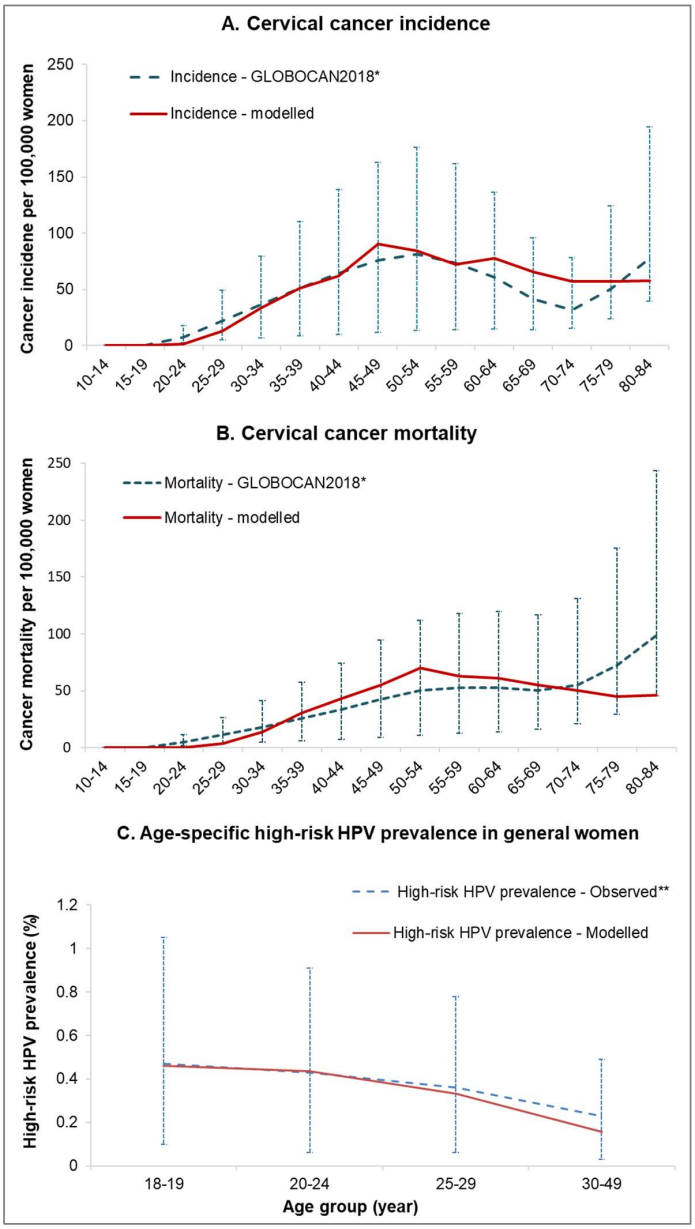


2. Model calibration:

When adapting the existing Policy1-Cervix model platform to PNG setting, natural history of progression and regression from HPV infection to CIN1, CIN2, CIN3 and from CIN3 to invasive cancer remained unchanged, except for the HPV infection rates. The age-specific HPV infection rates for HPV16, HPV18, high-risk HPV types and other high-risk HPV types were adjusted, depending on the age-specific and type-specific HPV prevalence reported for PNG[29] to fit to the age-specific cervical cancer incidence rates that reported for PNG.[30] Additionally, survival rates were also adjusted to fit to age-specific mortality rate.[30]

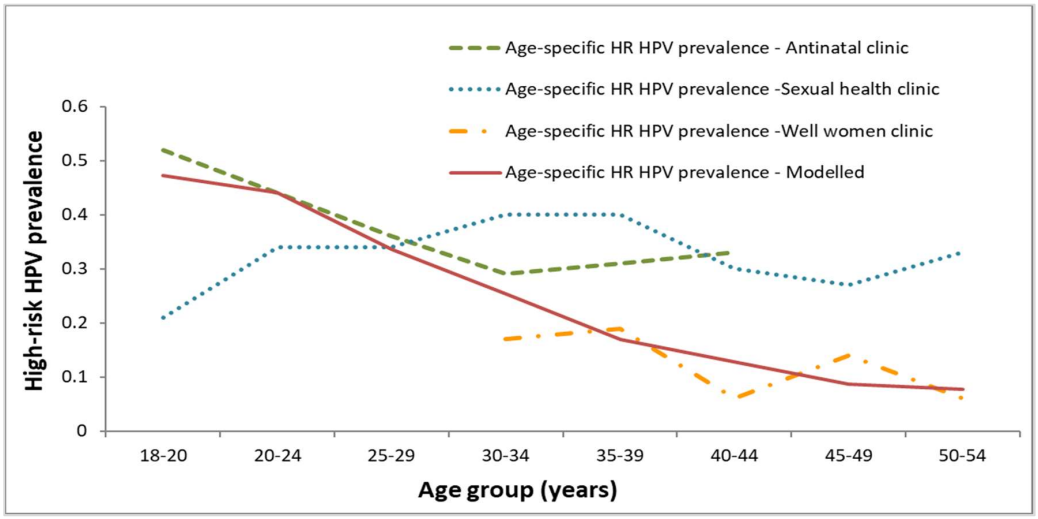
Results of model calibration show in figures below:

Figure A2: Model calibration to cervical cancer incidence (A), mortality (B) and HPV prevalence (C) in PNG



Note: (*) Ferlay J, Ervik M, Lam F, et al. Global Cancer Observatory: Cancer Today. 2018.
ASR: Age-standardized rate to World standard population
(**) Toliman P. Innovative approaches for cervical cancer screening in Papua New Guinea: Evaluation of novel point-of-care test and treat algorithms in a high-burden setting. New South Wales, Australia: UNSW Sydney; 2020.

Figure A3: Modelled HR HPV prevalence compared to observed HR HPV prevalence from clinics in PNG



3. Cancer treatment access rate and survival assumptions:

The model used 5-year and 10-year stage-specific survival rates for PNG, that have previously published[31], but based on advice from local experts on country-specific treatment access rates, we further adjusted to match the cancer mortality estimated by GLOBOCAN 2018.[30] Based on consultation with local experts on cancer treatment access rates, treatment capacity was only available for early-stage cancer and not for advanced cervical cancer. Therefore, in base case analysis we assumed 80% of FIGO I cancer and 20% of FIGO II cancer would be treated with hysterectomy and 0% FIGO III and IV cancer were treated. The modelled distribution of cervical cancer stage in PNG was 14%, 55%, 27% and 3% for FIGO stages I, II, III, and IV, respectively. Assuming 80% of FIGO I and 20% of FIGO II cancers receives treatment resulted in 80*14% + 20*55% + 0*27% + 0*3% = 20% of any diagnosed cancer would be treated in base case analysis. This assumption is higher than the treatment access rate assumed in the global analysis by Canfell et al, 2020, which was the estimated access rate to radiotherapy.[32] Survival rates were informed by stage-specific survival rates for countries with ~20% cancer treatment access to radiotherapy[31] and further adjusted to fit to GLOBOCAN2018 mortality rates. *(Table A1, Appendix)*
In sensitivity analysis, based on comments from local collaborators that the treatment access was even lower in PNG, we assumed 8% overall cancer treat access rate as previously estimated based on radiotherapy in PNG[32] which we assumed a similar survival rates that estimated for PNG as reported by Canfell et al, 2020.[31] We also assumed an upper bound of treatment access rate, using WHO 90% target for precancer and cancer treatment for cervical cancer elimination and we assumed survival rates estimated for countries with high treatment access (90%) to radiotherapy as reported by Cancel et al, 2020[31]. (*Table A1, Appendix*)

Table A1: Assumption on 5-year and 10-year survival rates of symptomatic cervical cancer by FIGO stages

Cancer stage	5-year (10-year) survival rate at (20% treatment access) - base case analysis ~	5-year (10-year) survival rate at 8% treatment access – sensitivity analysis (lower bound)*	5-year (10-year) survival rate at 90% treatment access - sensitivity analysis (upper bound)#
FIGO 1	0.640 (0.300)	0.625 (0.073)	0.870 (0.783)
FIGO 2	0.520 (0.270)	0.480 (0.065)	0.774 (0.693)
FIGO 3	0.120 (0.060)	0.101 (0.049)	0.599 (0.522)
FIGO 4	0.010 (0.008)	0.011 (0.008)	0.117 (0.081)

(~) *Survival rates at base case (20% treatment access rate) were informed by the survival rates estimated for countries with treatment access rates of ~20% to radiotherapy as reported in Canfell et al., 2020.[31] We further adjusted to fit to GLOBOCAN2018 mortality rates.*
(*) *Survival rates at sensitivity analysis for lower treatment access rate (8%) were similar the survival rates estimated for PNG with 8.4% treatment access rates to radiotherapy as reported in Canfell et al., 2020. [31]*
(#) *Survival rates at sensitivity analysis for upper treatment access rates (90%) were similar survival rates estimated for countries with 90% treatment access rate to radiotherapy as reported in Canfell et al., 2020.[31]*

4. Cost estimates

For costs of point-of-care self-collected HPV testing, VIA testing/visual assessment for ablative treatment, and thermal ablative treatment, we estimated costs based on financial expenditure from field screening trials in PNG. First, total financial expenses associated with point-of-care self-collected HPV testing, VIA testing, and thermal ablative treatment were calculated, based on financial expenditure on personnel, equipment, and consumables in the screening trial in PNG. We estimated expenditure on staff salaries and clinic equipment (including examination table, examination light, speculums,) used for each participating clinic. These costs were shared among either point-of-care HPV self-collected screening or visual inspection with acetic acid (VIA) and thermal ablation treatment which were provided in each clinic. Besides the above shared costs, there were additionally costs required for specific tests or treatment. For HPV testing, we considered expenditure for point-of-care Xpert HPV test cartridges, sample collection kits and barcode specimen labels. For VIA screening or visual assessment for ablative treatment, the cost of acetic acid was added. For thermal ablative treatment, we considered the cost for thermal ablation equipment (WISAP C3 portable thermal coagulator, battery pack). Secondly, based on clinic records we estimated the total number of women that could be screened per year in each clinic. The final estimated unit costs of point-of-care HPV self-collected test, VIA/visual assessment for ablative treatment, and thermal ablative treatment were US$18, US$6, and US$15, respectively.

Regarding costs associated with cervical cancer diagnosis and treatment, unit costs of two available services – biopsy (US$59) and hysterectomy (US$1614) were estimated in consultation with local collaborators. In consultation with local collaborators, we assumed hysterectomy would be used to treat 80% of FIGO I cases and 20% of FIGO II in base case analysis and in sensitivity analysis scenarios, except for the scenario of a 90% cancer treatment access rate. In the sensitivity analysis considering this high treatment access rate, we assumed PNG would provide cancer treatment for 90% cancer cases across all stages. Therefore, we estimated cancer treatment costs for FIGO III and IV from cancer treatment costs of FIGO I by using multiplication factors of 1.4 and 1.0 respectively. These factors were derived from average stage-specific cancer treatment costs estimated for 21 lower-middle-income countries including PNG reported in Campos et al., 2017.[33] Treatment cost for regional-stage cancers was 40% higher than treatment cost for local cancers and treatment cost for distant-stage cancers was about equal to the cost for local-stage cancers.[33] We simply assumed treatment costs for FIGO III and IV would be equal to costs for regional cancer and distant cancer, respectively. We also assumed treatment costs for FIGO I and II would be equal to treatment cost for local cancer. *(Table A2 and Table A3)*

Table A2: Factors of cancer treatment costs among cancer stages

	Local stage	Regional stage	Distant stage
Treatment costs	1765	2494	1689
Factors	1	1.4	1

Source: Campos et al., 2017

Table A3: Estimated cancer treatment costs for PNG that used in sensitivity analysis considering high cancer treatment access rate

	FIGO I	FIGO II	FIGO III	FIGO IV
Estimated costs	US$1614	US$1614	US$2260	US$1614

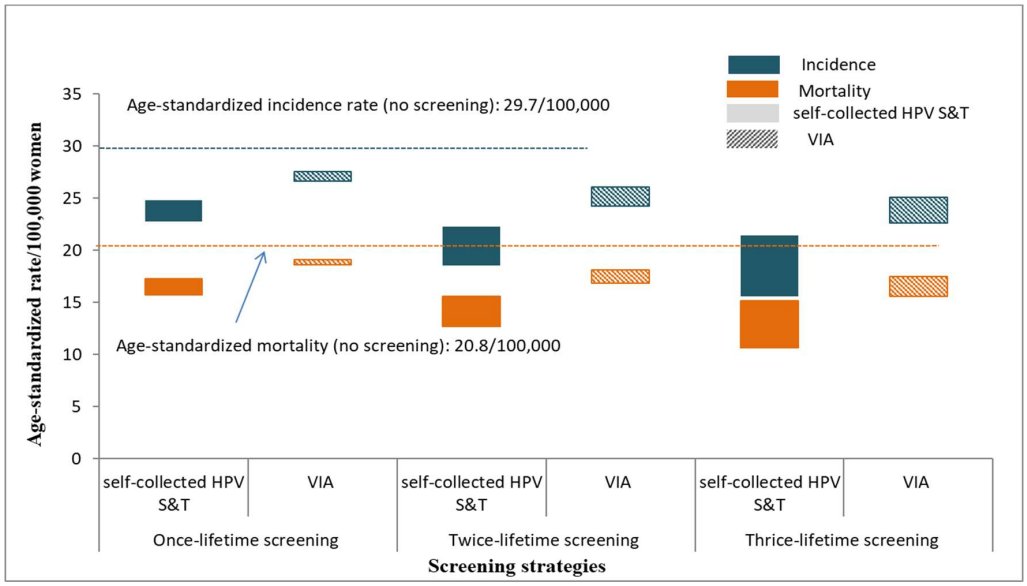
5. HPV self-collected testing

In the point-of care HPV self-collected screen and treat (self-collected HPV S&T) trial in PNG, women who come to participating Well women clinics were assessed for eligibility to participate in the trial of point-of-care HPV test using a self-collected vaginal cytobrush specimen. For women who agreed to participate, clinic staff used a laminated pictorial guide to help them explain the correct way to collect vaginal specimens for testing. During the explanation, staff indicated how samples are to be collected using a specimen collection kit reserved for this purpose, and encourage women to use cytobrushes, and to review the pictorial guide themselves. Women were asked to collect her specimens in a private room or the clinic toilet. Self-collected specimens were returned to clinic staff and immediately placed in 20 ml ThinPrep PreservCyt (Hologic, Marlborough, MA) prior to testing for hrHPV on the GeneXpert platform which were conducted in accordance with manufacturer's instructions and study's specific SOPs.

6. Supplementary results

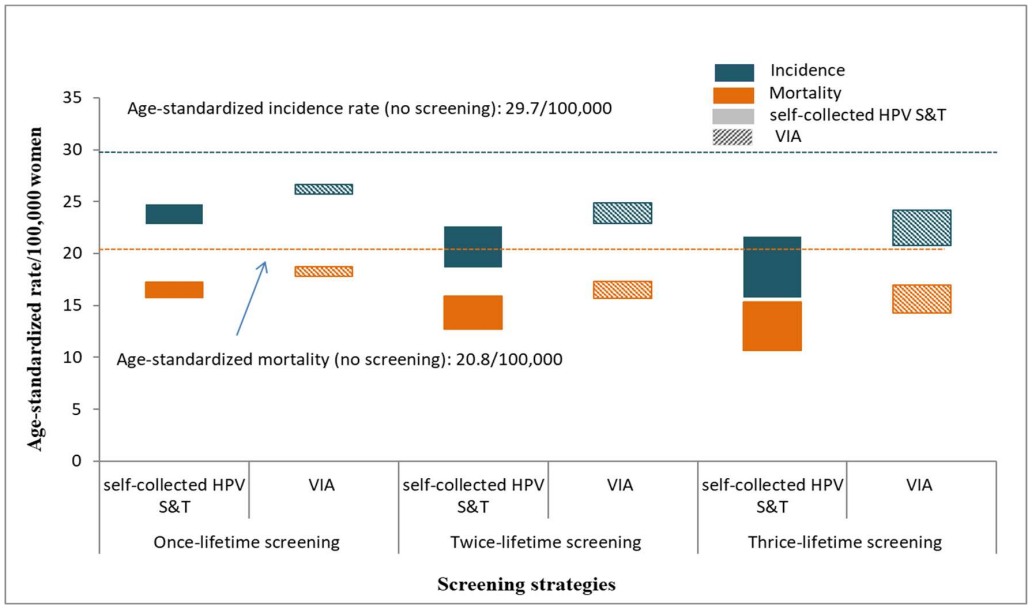
6.1. Health outcomes from a single cohort analysis of 38 scenarios

Figure A4: Predicted impacts of screening strategies on cervical cancer incidence and mortality – Base case – 51% sensitivity



Note: The performance of VIA screening tests was derived from Toliman et al, 2018[34]
Range of bar charts represents the variation of the ASR incidence and mortality by screening ages

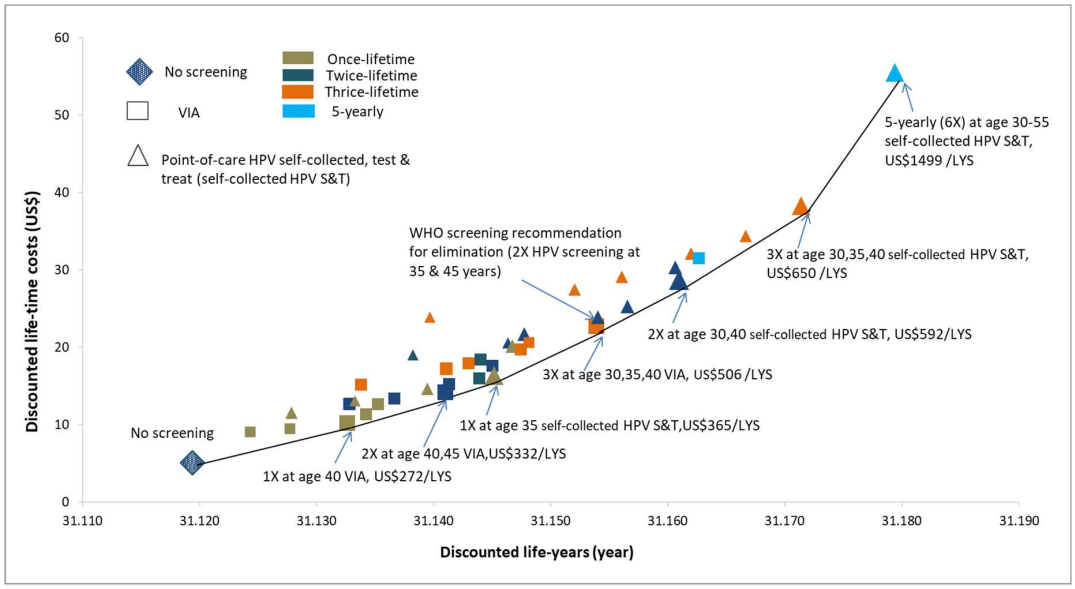
Figure A5: Predicted impacts of screening strategies on cervical cancer incidence and mortality – upper bound – 70% VIA sensitivity



Note: The performance of VIA screening tests was derived from systematic reviews[35,36]
Range of bar charts represents the variation of reduction in ASR incidence and mortality by screening ages

6.2 Cost-effectiveness analysis

Figure A6: Cost-effectiveness analysis for cervical screening, if favourable (70%) sensitivity of VIA testing were achieved - Sensitivity analysis



Note: The performance of VIA screening tests was based on systematic reviews that reported favourable VIA test performance (70%)

The cost-effectiveness analysis included current situation (no screening) and 38 self-collected HPV S&T and VIA screening scenarios. Incremental Cost-effectiveness Ratios (ICERs) were calculated in US$, 2019. The gross domestic product (GDP) per capita for PNG (0.5GDPpc (US$ 1415 or PGK 4723, World Bank 2019) was used as the indicative willingness-to-pay (WTP) threshold for the evaluation. We also secondarily considered a WTP threshold of 1GDPpc (1GDPpc = US$ 2829 or PGK 9446)

7. Sensitivity analysis

Figure A7: Sensitivity analysis: Impact on cervical cancer incidence

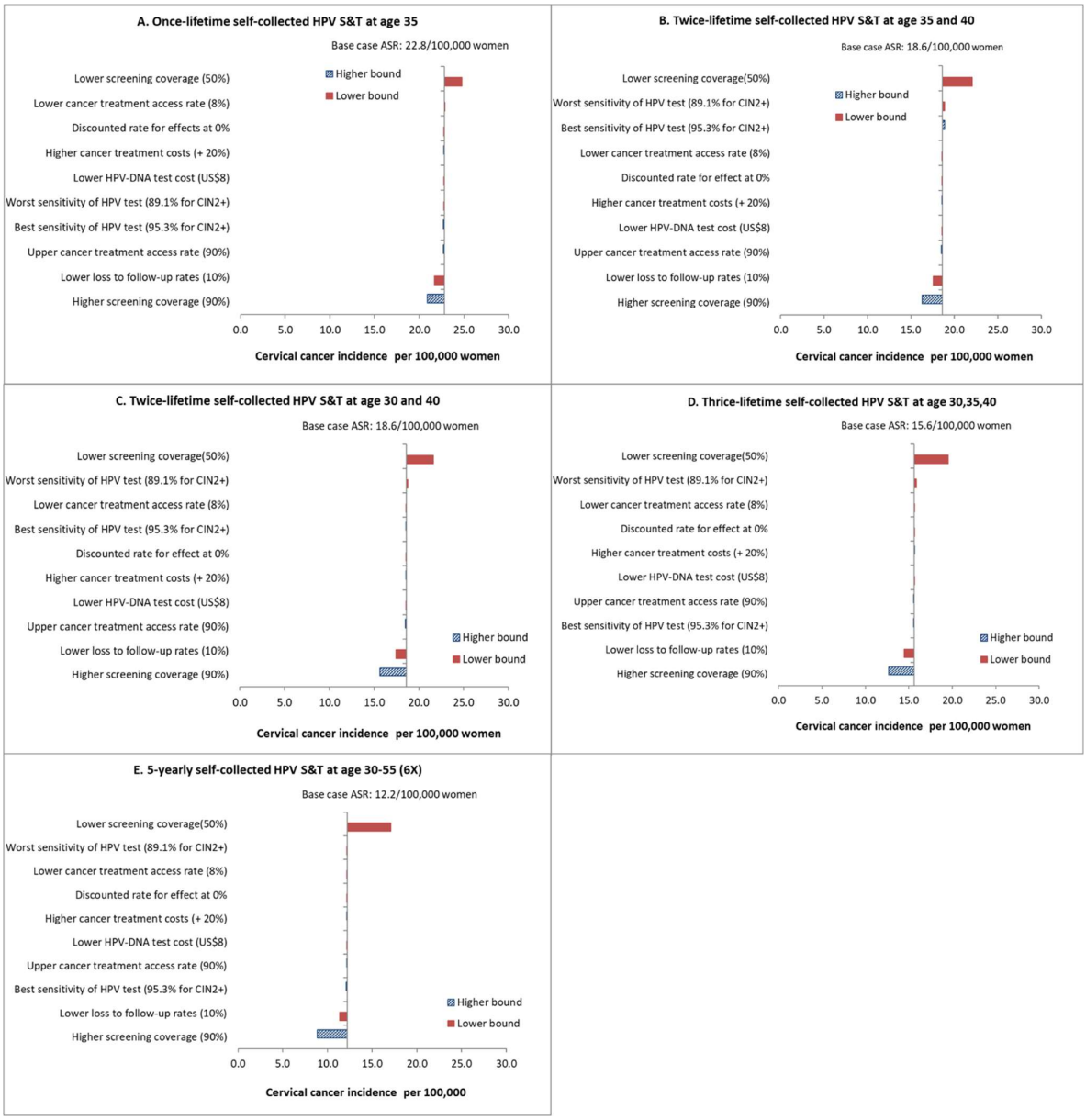
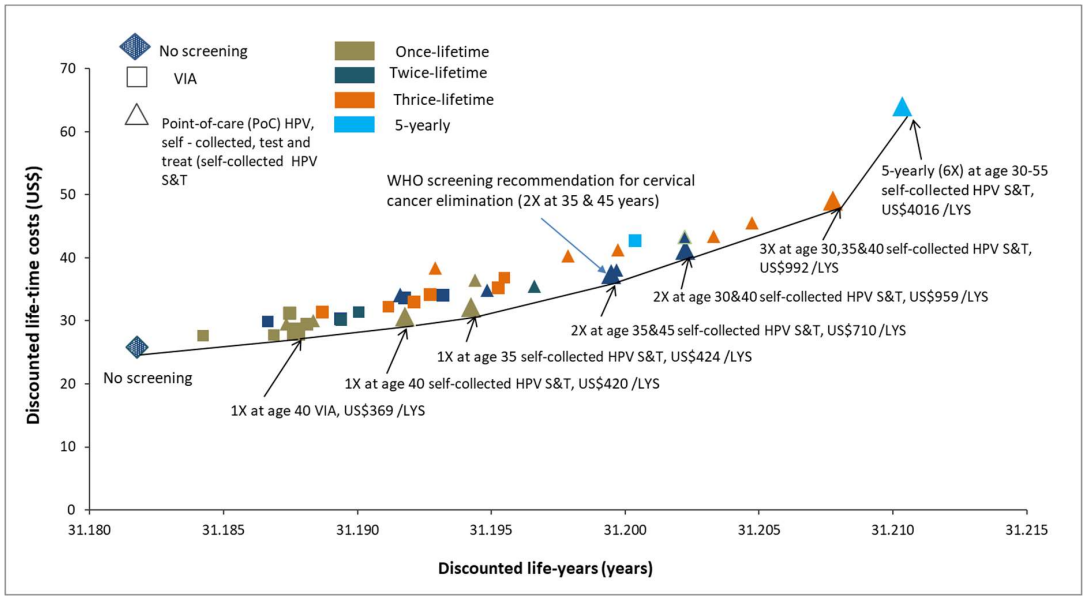
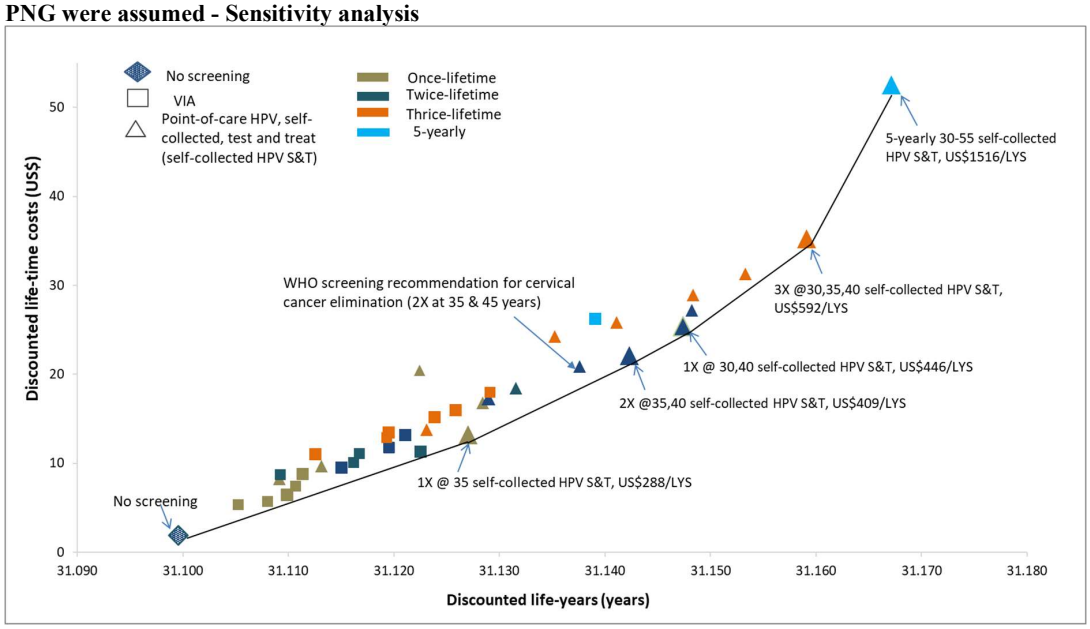


Figure A8: Cost-effectiveness analysis for cervical screening, if a 90% cancer treatment access and survival rate in PNG were achieved - Sensitivity analysis



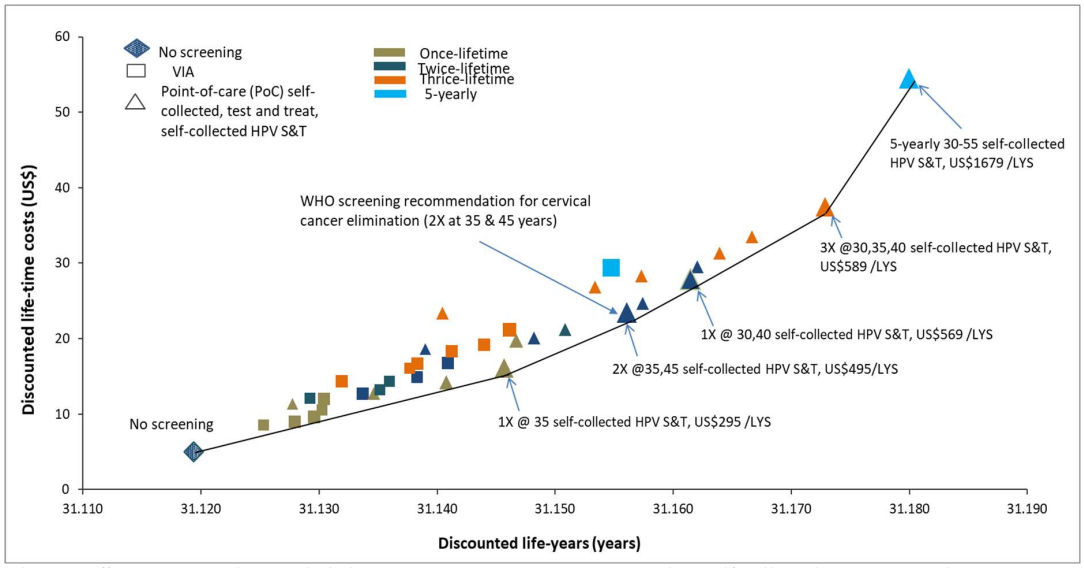
The cost-effectiveness analysis included current situation (no screening) and 38 self-collected HPV S&T and VIA screening scenarios. Incremental Cost-effectiveness Ratios (ICERs) were calculated in US$, 2019. The gross domestic product (GDP) per capita for PNG (0.5GDPpc (US$ 1415 or PGK 4723, World Bank 2019) was used as the indicative willingness-to-pay (WTP) threshold for the evaluation. We also secondarily considered a WTP threshold of 1GDPpc (1GDPpc = US$ 2829 or PGK 9446)

Figure A9: Cost-effectiveness analysis for cervical screening, if an 8% cancer treatment access rate in PNG were assumed - Sensitivity analysis



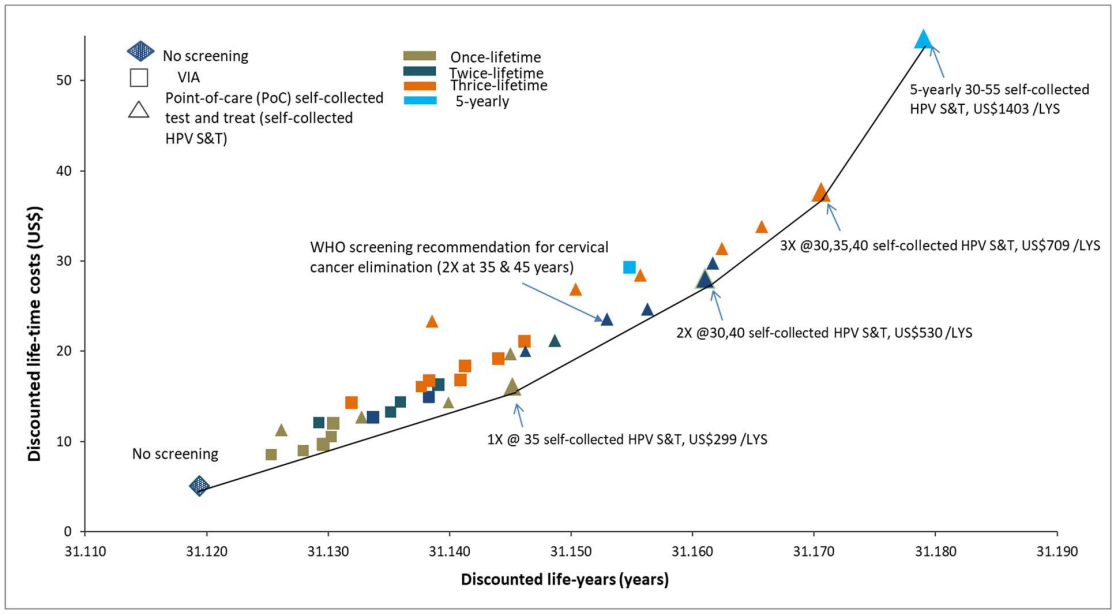
The cost-effectiveness analysis included current situation (no screening) and 38 self-collected HPV S&T and VIA screening scenarios. Incremental Cost-effectiveness Ratios (ICERs) were calculated in US$, 2019. The gross domestic product (GDP) per capita for PNG (0.5GDPpc (US$ 1415 or PGK 4723, World Bank 2019) was used as the indicative willingness-to-pay (WTP) threshold for the evaluation. We also secondarily considered a WTP threshold of 1GDPpc (1GDPpc = US$ 2829 or PGK 9446)

Figure A10: Cost-effectiveness analysis of cervical screening, if best HPV-DNA test sensitivity were achieved - Sensitivity analysis



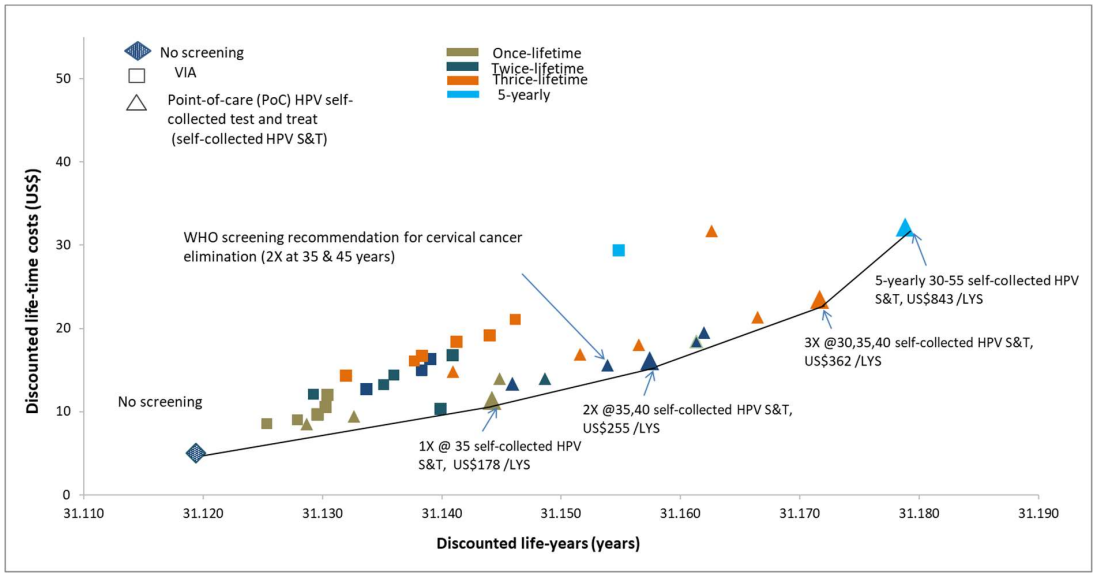
The cost-effectiveness analysis included current situation (no screening) and 38 self-collected HPV S&T and VIA screening scenarios. Incremental Cost-effectiveness Ratios (ICERs) were calculated in US$, 2019. The gross domestic product (GDP) per capita for PNG (0.5GDPpc (US$ 1415 or PGK 4723, World Bank 2019) was used as the indicative willingness-to-pay (WTP) threshold for the evaluation. We also secondarily considered a WTP threshold of 1GDPpc (1GDPpc = US$ 2829 or PGK 9446)

Figure A11: Cost-effectiveness analysis of cervical screening, if a worst HPV-DNA test sensitivity were achieved - Sensitivity analysis



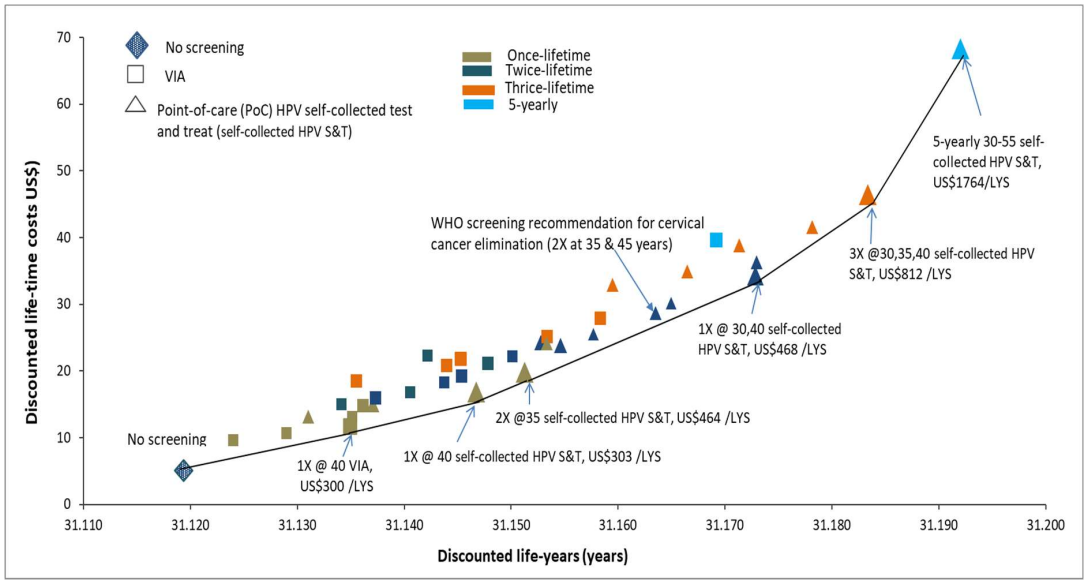
The cost-effectiveness analysis included current situation (no screening) and 38 self-collected HPV S&T and VIA screening scenarios. Incremental Cost-effectiveness Ratios (ICERs) were calculated in US$, 2019. The gross domestic product (GDP) per capita for PNG (0.5GDPpc (US$ 1415 or PGK 4723, World Bank 2019) was used as the indicative willingness-to-pay (WTP) threshold for the evaluation. We also secondarily considered a WTP threshold of 1GDPpc (1GDPpc = US$ 2829 or PGK 9446)

Figure A12: Cost-effectiveness analysis of cervical screening, if a lower HPV-DNA test cost (US$8) were achieved - Sensitivity analysis



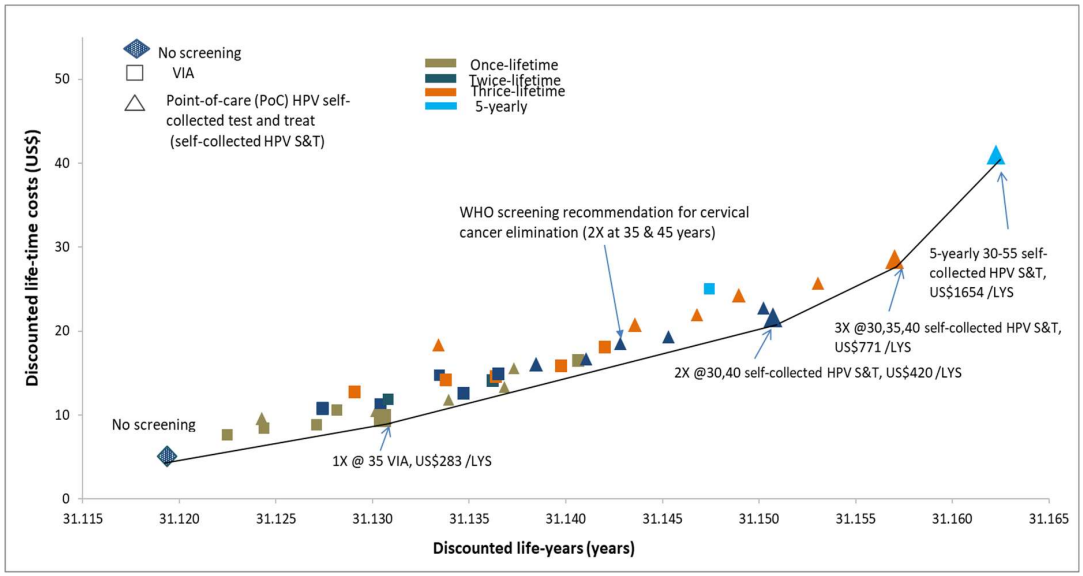
The cost-effectiveness analysis included current situation (no screening) and 38 self-collected HPV S&T and VIA screening scenarios. Incremental Cost-effectiveness Ratios (ICERs) were calculated in US$, 2019. The gross domestic product (GDP) per capita for PNG (0.5GDPpc (US$ 1415 or PGK 4723, World Bank 2019) was used as the indicative willingness-to-pay (WTP) threshold for the evaluation. We also secondarily considered a WTP threshold of 1GDPpc (1GDPpc = US$ 2829 or PGK 9446)

Figure A13: Cost-effectiveness analysis of cervical screening, if a 90% screening coverage were achieved – Sensitivity analysis



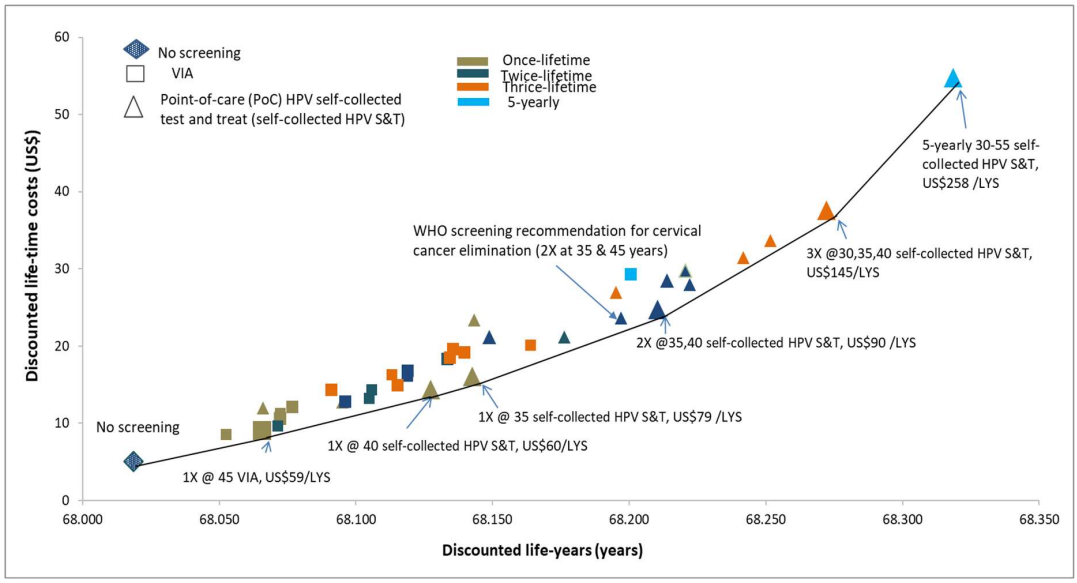
The cost-effectiveness analysis included current situation (no screening) and 38 self-collected HPV S&T and VIA screening scenarios. Incremental Cost-effectiveness Ratios (ICERs) were calculated in US$, 2019. The gross domestic product (GDP) per capita for PNG (0.5GDPpc (US$ 1415 or PGK 4723, World Bank 2019) was used as the indicative willingness-to-pay (WTP) threshold for the evaluation. We also secondarily considered a WTP threshold of 1GDPpc (1GDPpc = US$ 2829 or PGK 9446)

Figure A14: Cost-effectiveness analysis of cervical screening, if a 50% screening coverage were achieved – sensitivity analysis



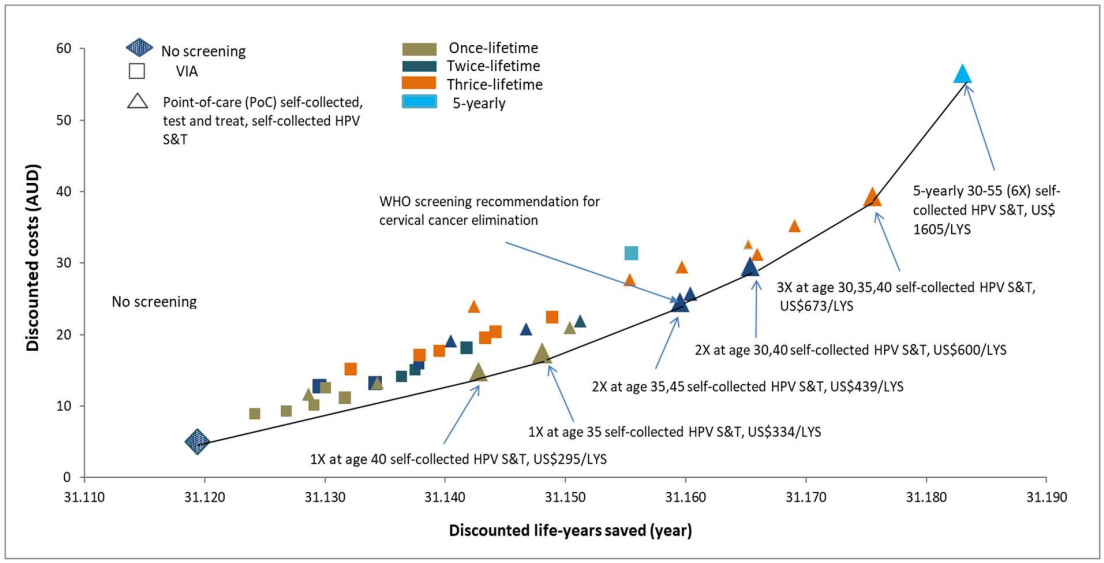
The cost-effectiveness analysis included current situation (no screening) and 38 self-collected HPV S&T and VIA screening scenarios. Incremental Cost-effectiveness Ratios (ICERs) were calculated in US$, 2019. The gross domestic product (GDP) per capita for PNG (0.5GDPpc (US$ 1415 or PGK 4723, World Bank 2019) was used as the indicative willingness-to-pay (WTP) threshold for the evaluation. We also secondarily considered a WTP threshold of 1GDPpc (1GDPpc = US$ 2829 or PGK 9446)

Figure A15: Cost-effectiveness analysis of cervical screening, if a 0% discount rate for effect were considered – sensitivity analysis



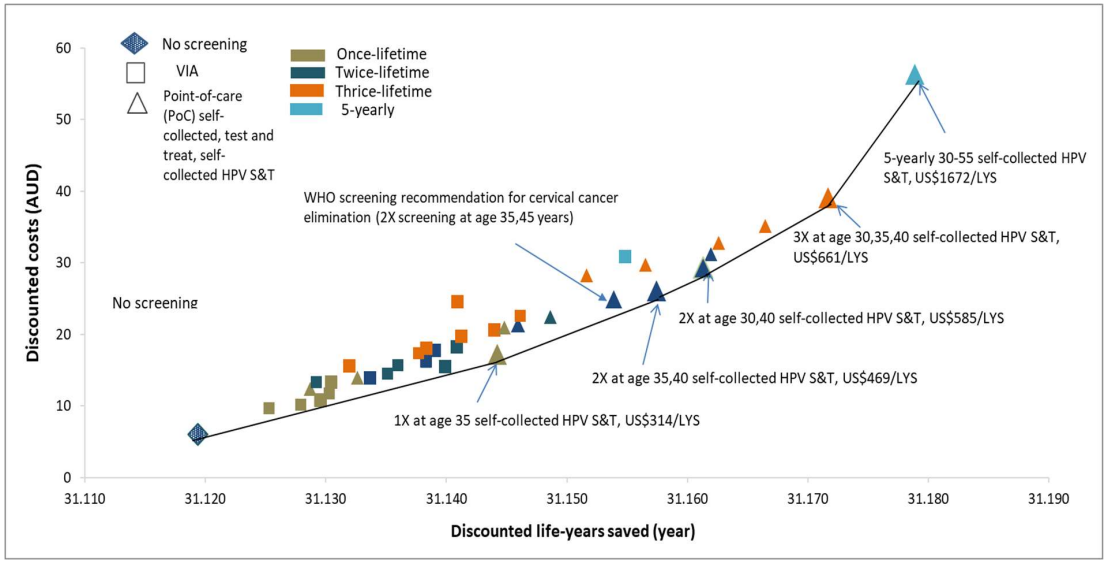
The cost-effectiveness analysis included current situation (no screening) and 38 self-collected HPV S&T and VIA screening scenarios. Incremental Cost-effectiveness Ratios (ICERs) were calculated in US$, 2019. The gross domestic product (GDP) per capita for PNG (0.5GDPpc (US$ 1415 or PGK 4723, World Bank 2019) was used as the indicative willingness-to-pay (WTP) threshold for the evaluation. We also secondarily considered a WTP threshold of 1GDPpc (1GDPpc = US$ 2829 or PGK 9446)

Figure A16: Cost-effectiveness analysis of cervical screening, if a low loss-to-follow-up (10%) at post-ablative treatment of eligible precancers at 12 months were considered – sensitivity analysis



The cost-effectiveness analysis included current situation (no screening) and 38 self-collected HPV S&T and VIA screening scenarios. Incremental Cost-effectiveness Ratios (ICERs) were calculated in US$, 2019. The gross domestic product (GDP) per capita for PNG (0.5GDPpc (US$ 1415 or PGK 4723, World Bank 2019) was used as the indicative willingness-to-pay (WTP) threshold for the evaluation. We also secondarily considered a WTP threshold of 1GDPpc (1GDPpc = US$ 2829 or PGK 9446)

Figure A17: Cost-effectiveness analysis of cervical screening, if higher cancer treat costs (+20% of that costs at base case) were considered – sensitivity analysis



The cost-effectiveness analysis included current situation (no screening) and 38 self-collected HPV S&T and VIA screening scenarios. Incremental Cost-effectiveness Ratios (ICERs) were calculated in US$, 2019. The gross domestic product (GDP) per capita for PNG (0.5GDPpc (US$ 1415 or PGK 4723, World Bank 2019) was used as the indicative willingness-to-pay (WTP) threshold for the evaluation. We also secondarily considered a WTP threshold of 1GDPpc (1GDPpc = US$ 2829 or PGK 9446)

Table A4: Summary of impact on ICERs in sensitivity analyses - for strategies that appeared on the cost-effectiveness frontier in the base case (arrows compare to base case ICER)**

Screening strategies	1X age 40 self-collected HPV S&T	1X age 35 self-collected HPV S&T	2X age 35, 40 self-collected HPV S&T	2X age 30,40 self-collected HPV S&T	3X age 30, 35,40 self-collected HPV S&T	5-yearly 30-55 self-collected HPV S&T	2X age 35,45 self-collected HPV S&T #	1X VIA age 40 *
Base case	**Dominated**	**$311**	**$460**	**$568**	**$656**	**$1659**	**Dominated**	**Dominated**
Best sensitivity of HPV test (95.3% for CIN2+)	Dominated	$295	$495	$569	$589	$1679	Dominated	Dominated
Worst sensitivity of HPV test (89.1% for CIN2+)	Dominated	$299	Dominated	$530	$709	$1403	Dominated	Dominated
Higher screening coverage (90%)	$303	$464 ↑	Dominated	$468 ↓	$812 ↑	$1764 ↑	Dominated	$300
Lower screening coverage (50%)	Dominated	$283 ↓	Dominated	$420 ↓	$771 ↑	$1654 ↓	Dominated	Dominated
Lower loss to follow-up rates (10%) at post-treatment follow-up at 12 months	$295	$334 ↑	Dominated	$600 ↑	$673 ↑	$1605 ↓	$439	Dominated
Lower HPV-DNA test cost (US$8)	Dominated	$178 ↓	$255 ↓	$401 ↓	$362 ↓	$843 ↓	Dominated	Dominated
Higher cancer treatment costs (+ 20%)	Dominated	$314 ↑	$469 ↑	$585 ↑	$661 ↑	$1672 ↑	Dominated	Dominated
Discounted rate for effect at 0%	$60	$79 ↓	$90 ↓	$145 ↓	$258 ↓	$59 ↓	Dominated	Dominated
Lower treatment access (8%)	Dominated	$288 ↓	$409 ↓	$446 ↓	$592 ↓	$1516 ↓	Dominated	Dominated
High end assumption cancer treatment access and survival (90%)	$420	$424 ↑	Dominated	$959 ↑	$992 ↑	$4016 ↑	$710	$369

Incremental Cost-effectiveness Ratios (ICERs) were calculated in US$, 2019
The gross domestic product (GDP) per capita for PNG (0.5GDPpc (US$ 1415 or PGK 4723, World Bank 2019) was used as the indicative willingness-to-pay (WTP) threshold for the evaluation. We also secondarily considered a WTP threshold of 1GDPpc (1GDPpc = US$ 2829 or PGK 9446)
(#) WHO cervical screening recommendation for cervical cancer elimination was added for comparison
(*) VIA screening strategy appeared in some sensitivity analysis scenarios
(**) Please see cost-effectiveness plan figures in the main manuscript and in appendix for detail of cost-effective scenarios and ICERs presented in this table.

Appendix References

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