TOGETHER FOR HEALTH PRESENTS:

Strengthening Cervical Cancer Screening and Treatment Programs in LMICs: Addressing Challenges and Leveraging Opportunities

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Tracey Shissler
Jhpiego

December 12, 2024 at 8:00 - 9:15am ET / 2:00 - 3:15pm CET/ 4:00 - 5:15pm EAT

TOGETHER for health

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Cepheid. A better way.

WHO Cervical Cancer Initiative: Cervical screening and treatment to prevent cervical cancer

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Department of Non-Communicable Diseases, Rehabilitation & Disability

World Health Organization

Proposed Elimination Threshold and Targets

Threshold for Elimination as a Public Health Problem:
Age-adjusted incidence rate < 4 / 100,000 women

2030 Targets

90%

of girls fully vaccinated with HPV vaccine by 15 years of age

70%

of women are screened with a high-performance test by 35 and 45 years of age

90%

of women identified with cervical precancer or cancer receive treatment and care

SDG 2030 Target 3.4:
30% reduction in mortality from NCDs

human reproduction programme hrp research for impact
UNDP-UNFPA-UNICEF-WHO-WORLD BANK

World Health Organization

70% women screened with a high-performance test & 90% of women with identified cervical disease treated

- Understand barriers, improve communication/ information to create enabling environment for screening
- Promote simple screening algorithms to increase retention to the screening continuum and improve programmes' efficiency
- Ensure affordable supply of quality assured, high performance screening tests & treatment devices
- Strengthen laboratory and screening services capacity
- Integrate screening and treatment services into primary care, and other health programmes

2021 WHO guideline for screening & treatment of cervical pre-cancer lesions for cervical cancer prevention

Living guidelines to update WHO cervical screening & treatment recommendations

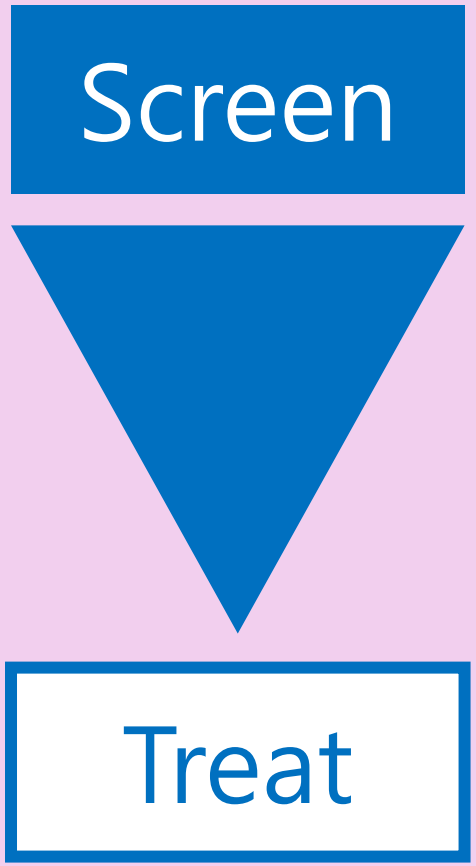
Target Product Profiles for HPV Screening Tests

Dialogues with the HPV Screening Tests Private Sector

World Health Organization

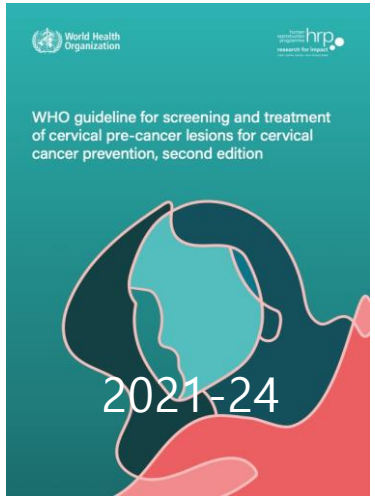
Simplified screening and treatment algorithms

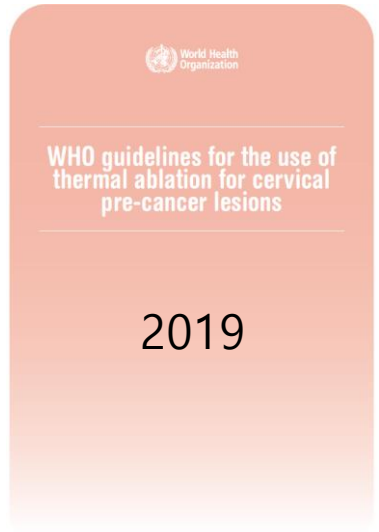
General female population



General female population & women living with HIV

Screening with a high-performance test
Ablative treatment preferably whenever possible





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GENERAL FEMALE POPULATION
Screen-and-Treat or Screen, Triage & Treat

Primary screening test
- High-performance HPV DNA Test
  - On provider- or self-collected samples
  - Starting at age 30
  - Every 5 to 10 years
- High-performance mRNA Test
  - Only on provider-collected samples
  - Every 5 years

Triage with HPV16/18, VIA, Cytology, Colposcopy or Dual-stain cytology

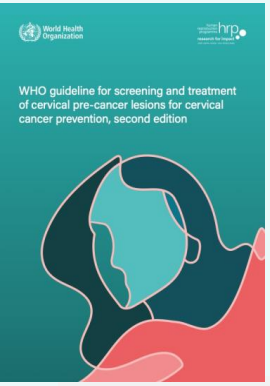
Treatment
- Ablative treatment if eligible
- Referral for excision or other

WOMEN LIVING WITH HIV
Screen, Triage & Treat

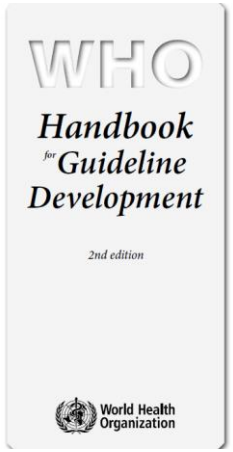
Primary screening test
- High-performance HPV DNA test
  - On provider- or self-collected samples
  - Starting at age 25
  - Every 3 to 5 years

Triage with HPV16/18, VIA, Cytology or Colposcopy

Treatment
- Ablative treatment if eligible
- Referral for excision or other



Technology evolves very fast



- Many emerging or rapidly evolving evidence-based strategies for cervical cancer screening and treatment
- Stakeholders should not have to wait 3 to 5 years for an update of a guideline to know what should be implemented or removed from practice

Living Recommendations and Systematic Reviews Process

- Some recommendations become 'living' within the 3 to 5 year updating process
- More efficient ongoing process of reviewing evidence (all sources) and making recommendations

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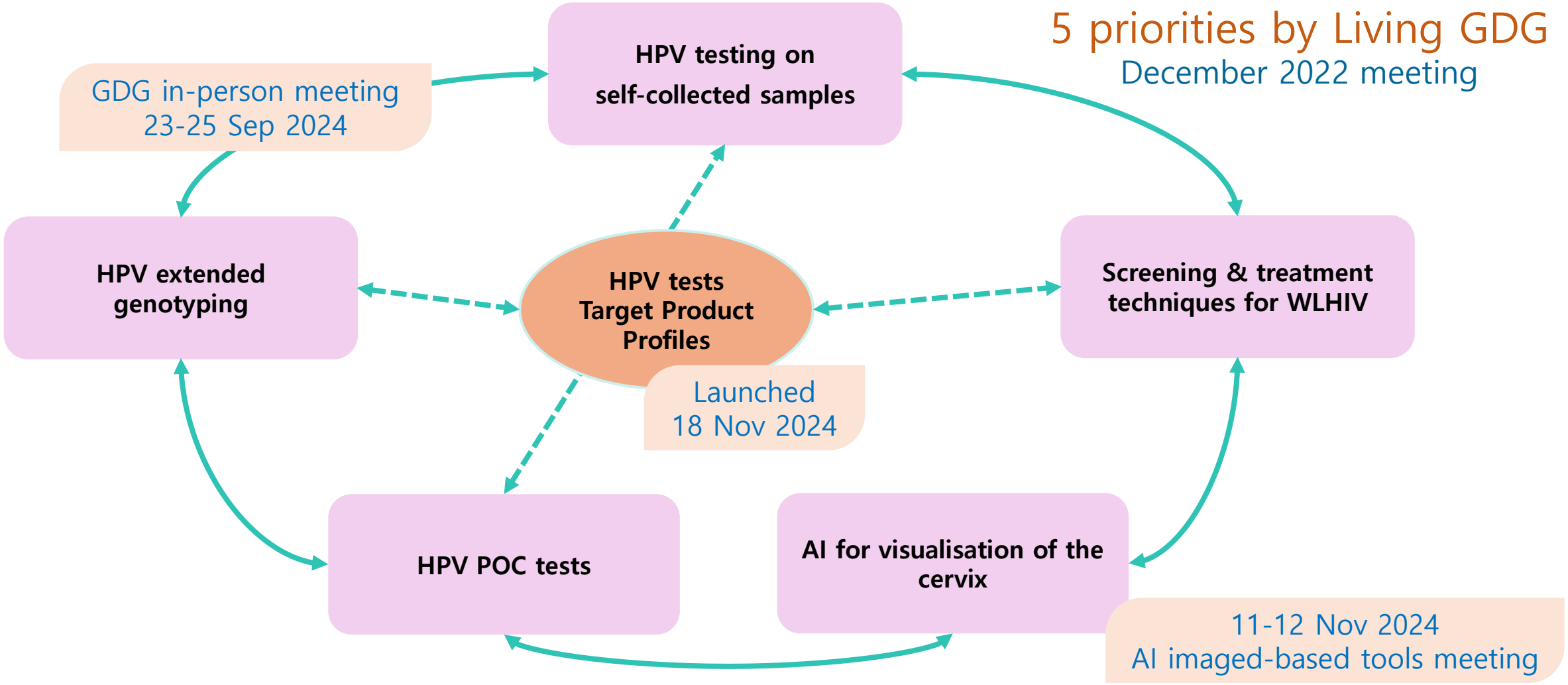
Living Recommendations and Systematic Reviews on Cervical Cancer Screening and Treatment



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Living Recommendations and Systematic Reviews on Cervical Cancer Screening and Treatment

Priorities addressed in 09/2024	Potential new priorities
- HPV extended genotyping	- Follow-up after negative triage, after treatment & rescreening interval
- HPV mRNA testing among WLHIV, screening interval extension	- Novel molecular technologies: methylation, NGS, other
- Thermal ablation & excisional treatment efficacy among women living with HIV	- Prophylactic vaccination to reduce recurrence after cervical precancer treatment
- HPV point-of-care tests	- Screening for vaccinated cohorts
- AI for cervix visualisation, harmonising evidence generation	- Therapeutic HPV vaccines

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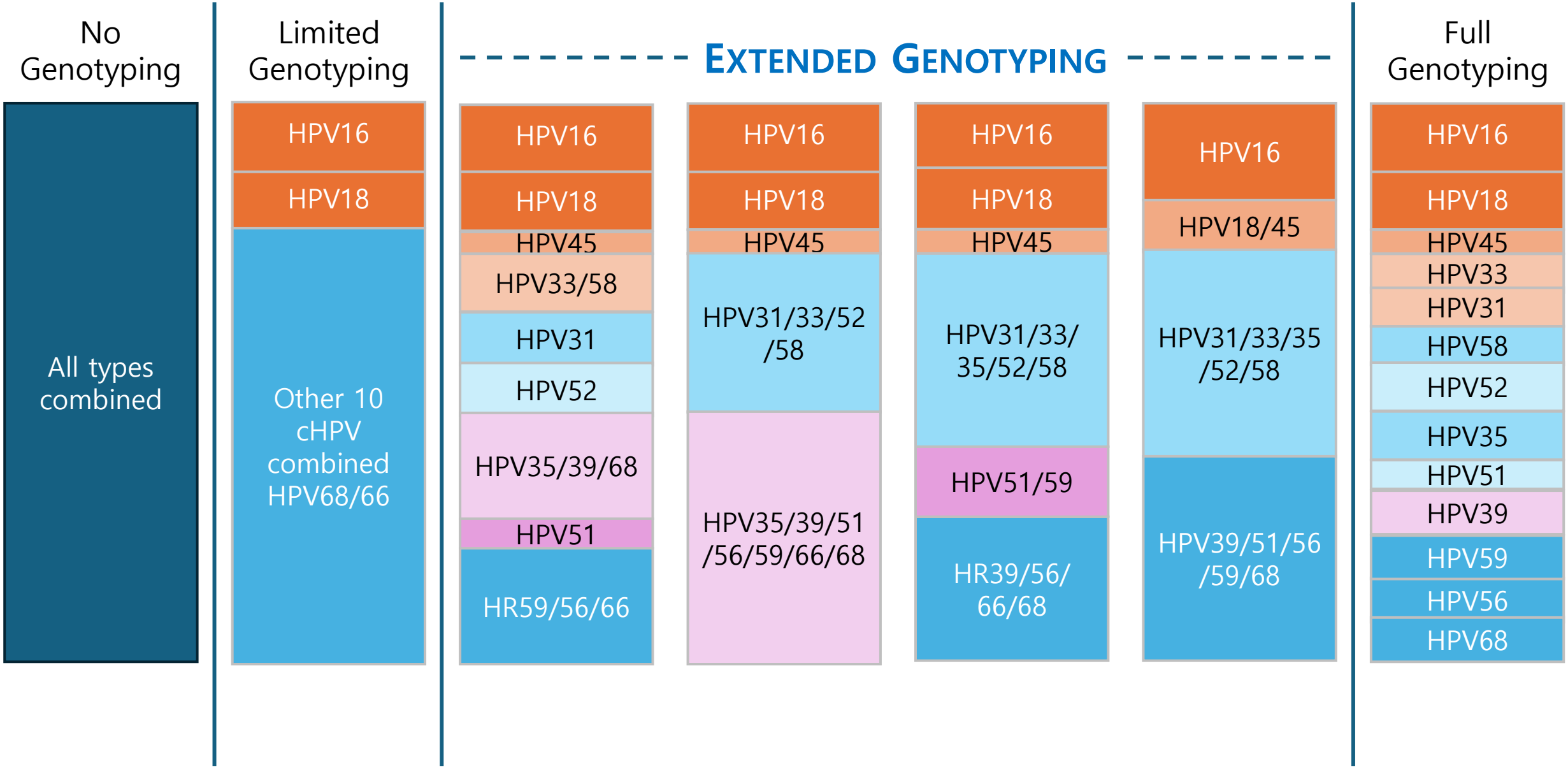
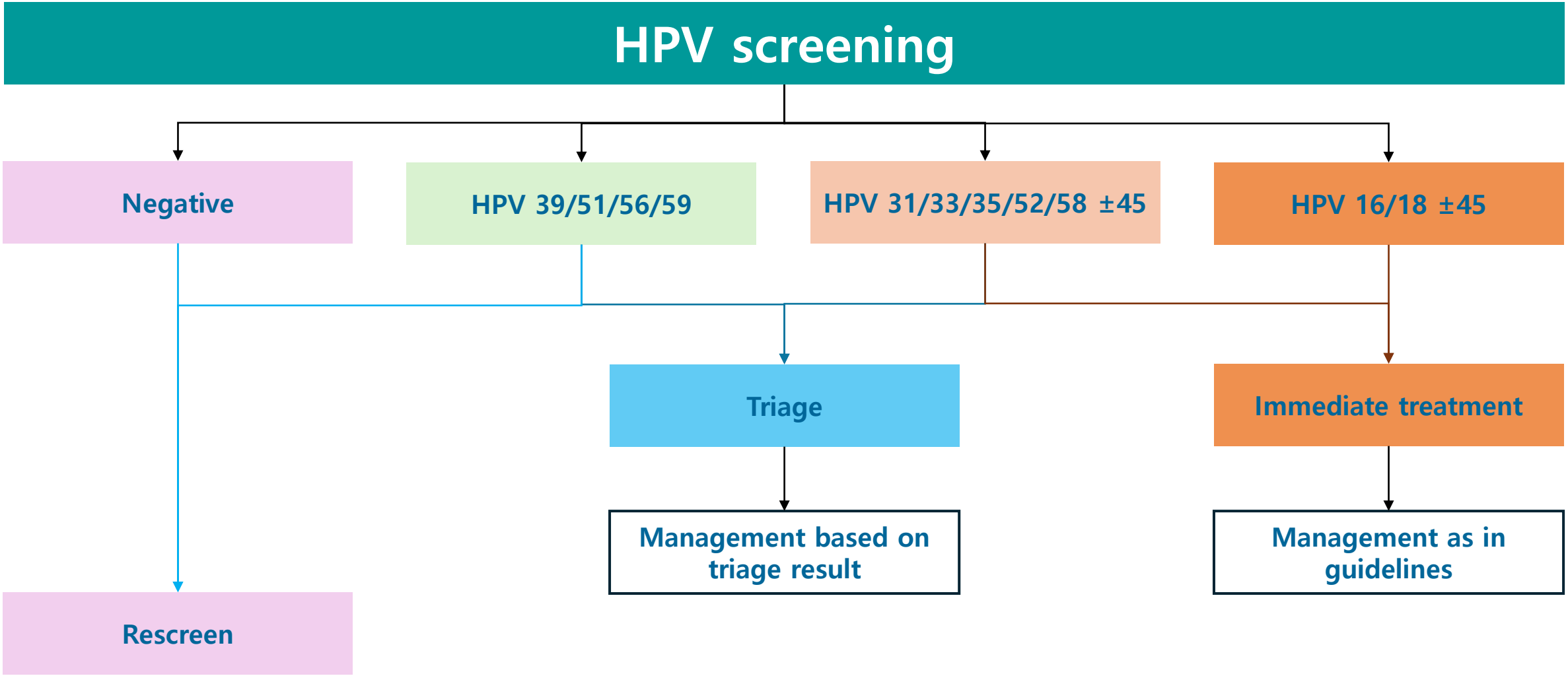
Living Recommendations and Systematic Reviews on Cervical Cancer Screening and Treatment

NO genotyping	Limited genotyping	Extended genotyping	Full genotyping
– No individual HPV types results – Aggregated positive/negative result for 13-14 types, including 12 carcinogenic HPV types: 16, 18, 45, 31, 33, 35, 52, 58, 39, 51, 56, 59 and 1-2 other possibly/probable carcinogenic types: 66, 68	– Individual or combined results for HPV16 and HPV18; may include combined results with HPV45 – All other carcinogenic types combined – Current tests additionally include HPV66 and HPV68	– Results for 12 carcinogenic HPV types in different groups; usually with individual result for HPV16 – Current tests additionally include HPV66 and HPV68	– Individual results for all 12 carcinogenic HPV types and several additional types – Include not carcinogenic HPV types, unnecessarily for screening purposes

Some current HPV genotype configurations



Possible extended genotyping–based management algorithms



264 HPV tests but availability of affordable high-performance HPV tests remains limited!

Number of HPV molecular tests in the market

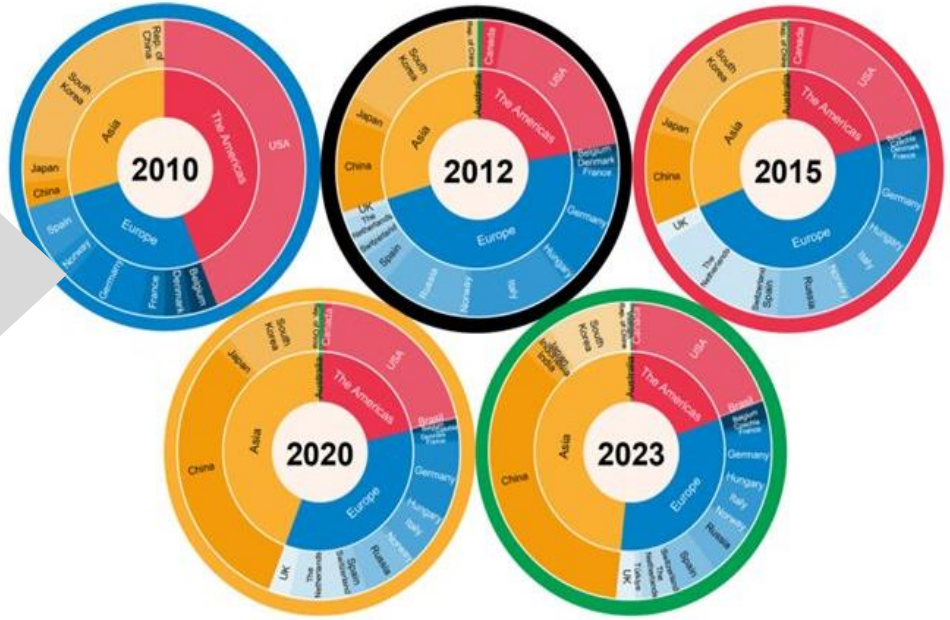
N=70
2010

N=125
2012

N=193
2015

N=254
2020

N=264
2023



79% without clinical validation

Poljak, J Clin Virology 2024

WHO Target Product Profiles for HPV screening tests to detect cervical pre-cancer and cancer

- WHO TPPs guide and coordinate development of new health products with clear product characteristics, considering populations, access and equity from the outset

- WHO TPPs for HPV screening tests aim to direct tests developers & manufacturers to prioritize technologies that can contribute to countries' efforts to reach 70% screening coverage elimination target

- HPV TPPs Technical Development Group (TDG) composed of 39 members
  - ✓ Multiple expertise, stakeholders and women's representatives
  - ✓ Representation balanced by WHO region

- TPPs outline desired profile of a product, with two characteristics per parameter:
  - ✓ minimal (lowest acceptable)
  - ✓ preferred (ideal)

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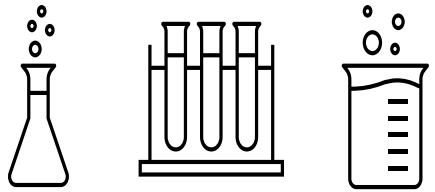
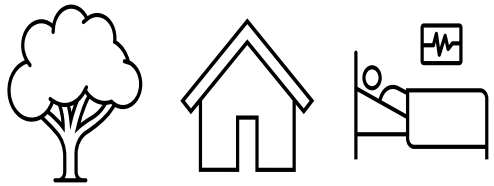
2 Target Product Profiles for HPV screening tests

✓ For laboratory use



✓ For point-of-care use



Minimal and Preferred Characteristics 41 Parameters across Eight Domains

- Scope
- Performance
- Conditions
- Connectivity
- Technical specification
- Design and operation
- Quality and standards
- Cost

How should samples be collected and by who?

LABORATORY

Specimen Collection

- ✓ Minimal:
  - vaginal sample self-collected OR
  - vaginal sample collected by health worker OR
  - cervical sample collected by health worker
- ✓ Preferred:
  - vaginal sample self-collected AND
  - vaginal sample collected by health worker AND
  - cervical sample collected by health worker

POINT-OF-CARE

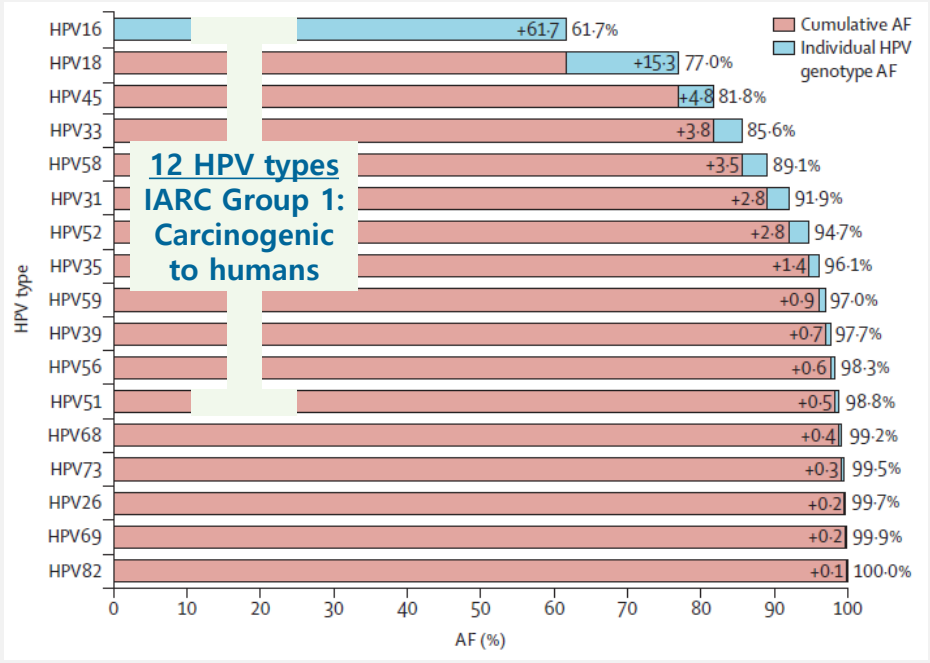
Specimen Collection

- ✓ Minimal:
  - vaginal sample self-collected AND
  - vaginal sample collected by health worker
- ✓ Preferred:
  - vaginal sample self-collected AND
  - vaginal sample collected by health worker AND
  - cervical sample collected by health worker

Which genotype spectrum for a high-performance test?

FACTS

- Several current HPV tests include 13/14 HPV types
- ~99% cervical cancers are caused by 12 HPV types classified as IARC Group 1: Carcinogenic to Humans
- Inclusion of more HPV types such as HPV66 and HPV68 does not add much value



Individual and cumulative HPV genotype-specific Attributable Fraction in invasive cervical cancer at the global level

Source: Wei et al, Lancet 2024

DECISION

The TDG agreed that 12 carcinogenic HPV (cHPV) types that cause ~99% of cervical cancers should be targeted by tests:

16, 18, 45, 33, 58, 31,
52, 35, 59, 39, 56 and 51

Can less-valency HPV tests be considered?

Facts

- 12 cHPV types important for a high-performance test
- Cumulative attributable fraction of Group 1d:
  HPV types 59, 39, 56 and 51 about 3%

Group 1d	Attributable Fraction
HPV59	0.9
HPV39	0.7
HPV56	0.6
HPV51	0.5

- Women positive for either of Group 1d types not at elevated risk

Decision

The TDG agreed that as the risk for cervical cancer granted by HPV types 59, 39, 56 and 51 is low, the 8 carcinogenic types in Groups 1a, 1b and 1c: 16, 18, 45, 33, 58, 31, 52, 35 should be minimally included in tests but it is preferred to include all 12 carcinogenic HPV types

Can a point-of-care test targeting only HPV16/18 be considered?

ARGUMENTS

In Favour

- HPV16/18 POC tests less costly and more scalable than 8/12 cHPV-types tests
- 70% cervical cancers are caused by HPV16/18

Against

- 70% screening coverage twice in life with a HIGH-PERFORMANCE test
- Reassurance to HPV negative women is crucial in a screening programme

DECISION

✓ The TDG agreed that POC tests should include the minimal 8 cHPV types 16, 18, 31, 33, 35, 45, 52, 58

✓ The TDG agreed that the population benefit between scaling up an HPV16/18 POC that can increase screening uptake and retention to treatment vs implementing a HIGH-PERFORMANCE test that can safely allow for rescreening every 5-10 years, needs to be evaluated => Research Gaps

Private Sector Dialogue on HPV Screening Tests

Strengthening concerted action to achieve 2030 elimination targets

WHO preliminary ASKs to private sector

LMICs that have shown a successful pathway to scale-up HPV-based cervical cancer screening face difficulties for sustainability

Current costs of HPV NAT assays remain relatively high, and there is insufficient funding for cervical cancer sceening programmes

264 NATs in the market, 79% without clinical performance &/or analytical performance validation with internationally acceptable criteria

Concerning discrepancy in access prices offered to global donors/procurers and NGOs, compared to prices offered by local distributors for government and other local public sector providers

All required supplies are not procured from same provider, sample collection kits, collection media, self-sampling kits

In summary

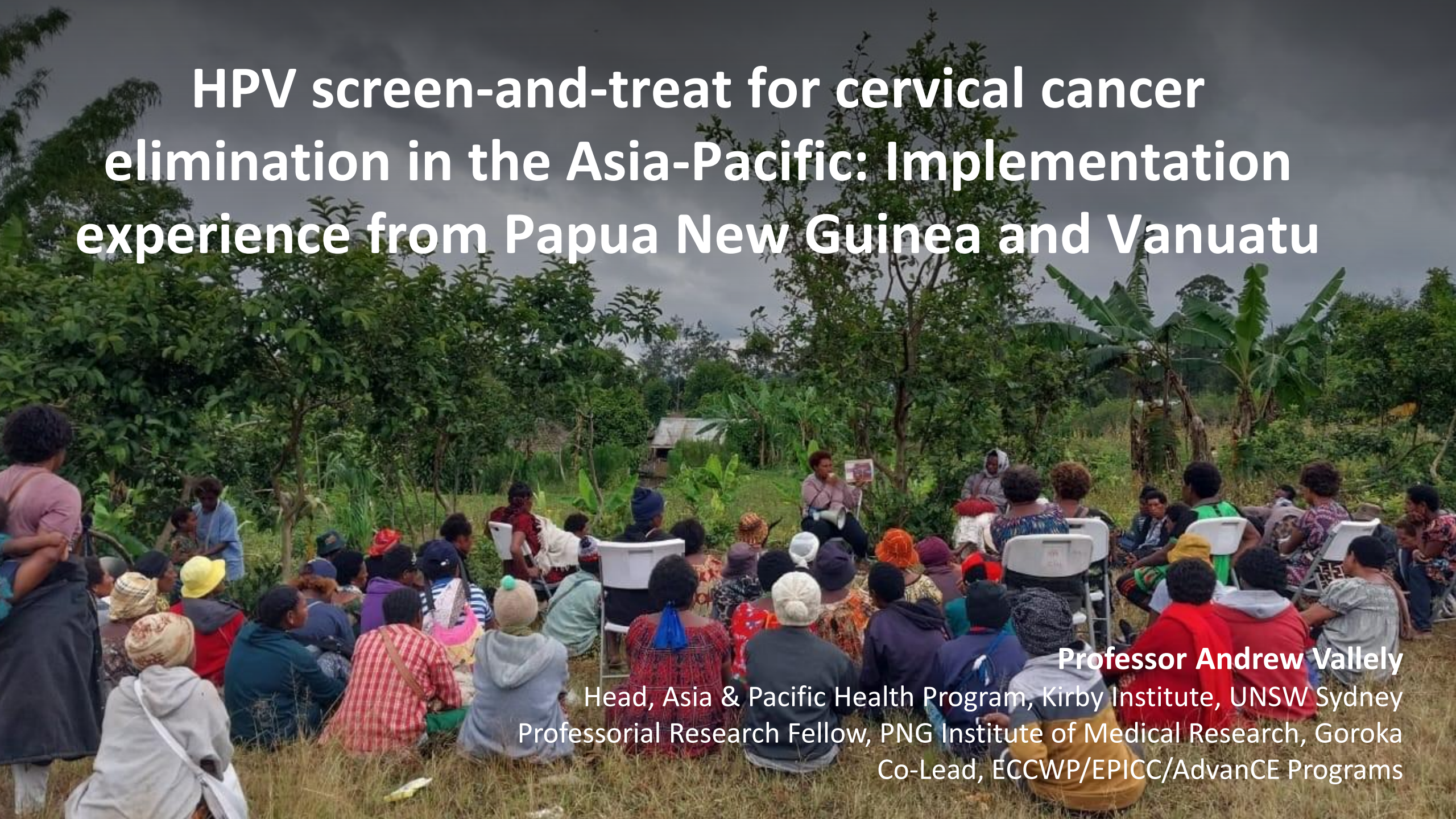
- Technology is evolving fast; innovations offer the opportunity to accelerate cervical cancer
- A process for living recommendations is essential to address evidence accumulated on the performance of new technologies
- Living recommendations should be based on evidence on performance and feasibility to facilitate countries to make informed decision when adoption emerging technologies
- Complementary workstreams will require attention, such as the WHO Target Product Profiles for HPV screening tests, having dialogues with the private sector and WHO Prequalification IVDs to increase impact of guidelines
- A shift on focus towards implementation, strategic investments and coordinated stakeholder action is crucial to reach 2030 cervical cancer elimination goals

Elimination of cervical cancer is commitment we make to all women and girls – to spare millions from the harms of a preventable cancer

NO ONE LEFT BEHIND

Thanks to the Living GDG, HPV TPPs TDG, WHO Secretariat and multiple collaborators

HPV screen-and-treat for cervical cancer elimination in the Asia-Pacific: Implementation experience from Papua New Guinea and Vanuatu



Professor Andrew Vallely
Head, Asia & Pacific Health Program, Kirby Institute, UNSW Sydney
Professorial Research Fellow, PNG Institute of Medical Research, Goroka
Co-Lead, ECCWP/EPICC/AdvanCE Programs

ECCWP / EPICC / AdvanCE

EPICC
ELIMINATION PARTNERSHIP IN THE INDO-PACIFIC FOR CERVICAL CANCER

PAW 1	PAW 2	PAW 3	PAW 4	PAW 5	PAW 6
Strengthening primary prevention of cervical cancer through HPV vaccination	Secondary prevention of cervical cancer through HPV screening and treatment for precancer	Laboratory strengthening for cervical cancer screening and early treatment	canSCREEN™ Digital Health Registry – data for decision making and strengthened models of care	Supporting cervical cancer management (treatment and palliative care)	Policy and modelling support across all pillars of cervical cancer elimination pathway
Lead Organisation: NCIRS	Lead Organisation: Kirby Institute UNSW	Lead Organisation: ACPCC	Lead Organisation: ACPCC	Lead Organisation: Daffodil Centre	Lead Organisation: Daffofil Centre

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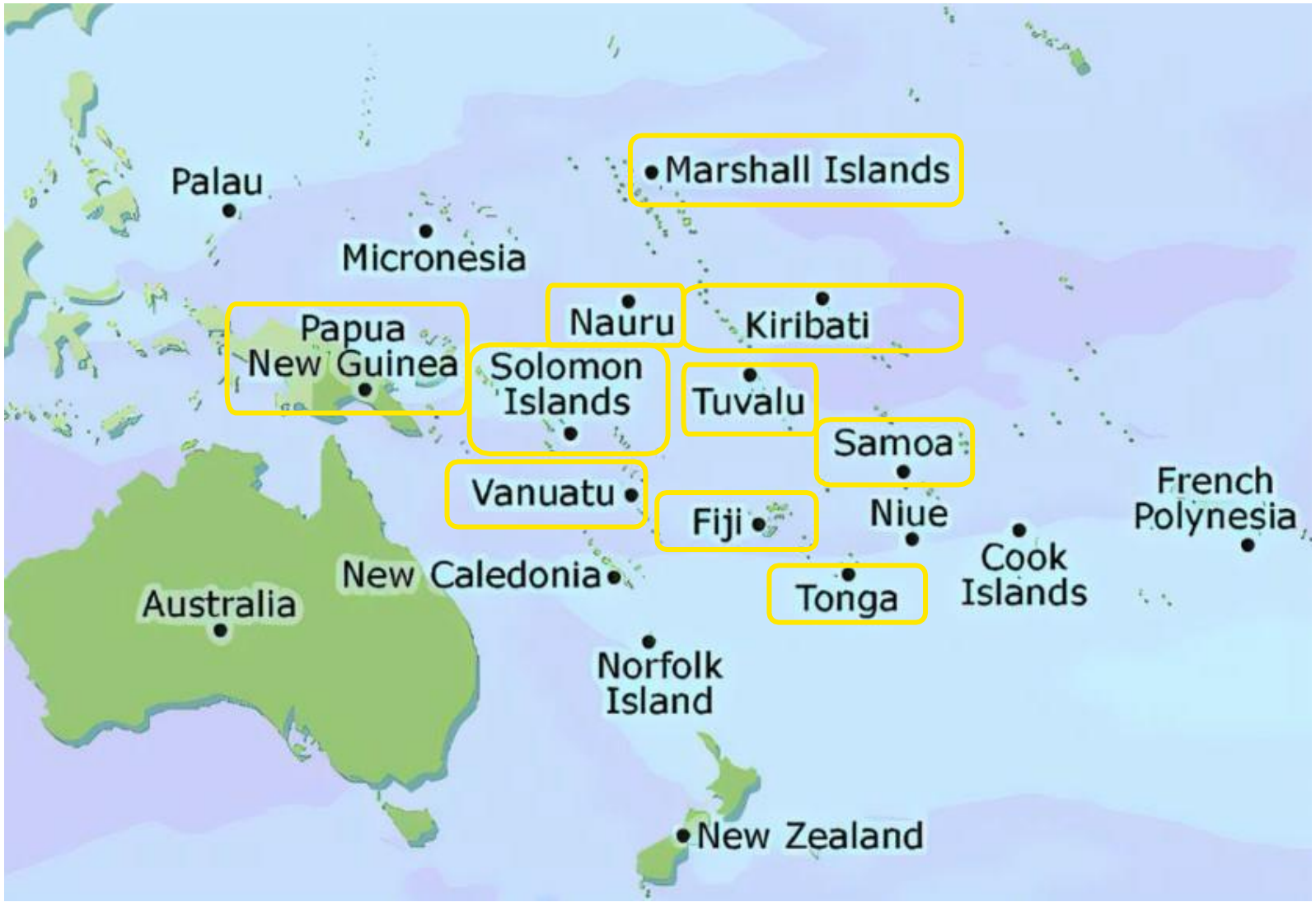
Australian Government
Department of Foreign Affairs and Trade
SWIRE

EPICC
ELIMINATION PARTNERSHIP IN THE INDO-PACIFIC FOR CERVICAL CANCER

ECCWP (2021-)
PNG, Vanuatu
60,000 HPV SAT

EPICC (2023-)
PNG, Vanuatu, Solomon Islands, Tuvalu, Nauru, Fiji, Timor-Leste, Malaysia
60,000 HPV SAT

AdvanCE (2024-)
Kiribati, Samoa, Tonga, Marshall Islands, Fiji, Solomon Islands, Vanuatu
130,000 HPV SAT



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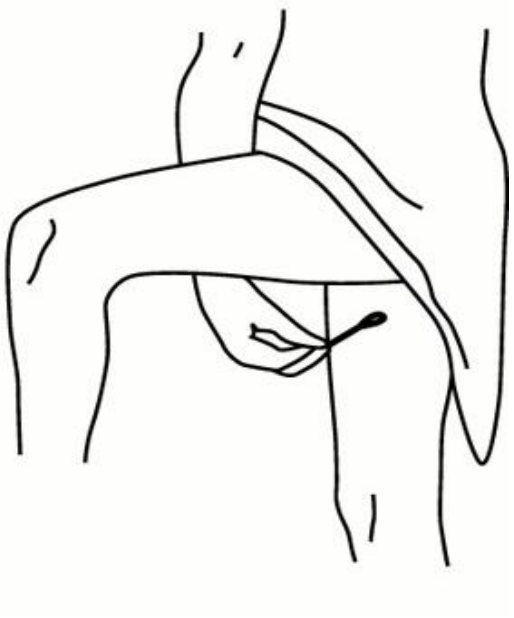
Papua New Guinea

- **Leading cause of cancer** (28.0/100,000) and **cancer death** among women (19.9/100,000)
- **706,894** age-eligible girls for HPV vaccination and **1,413,787** age-eligible women for HPV screen-and-treat
- Excellent **in-country leadership** and **vision** to establish robust elimination program built on locally-generated and international evidence

Point-of-care HPV screen-and-treat



Self-collect

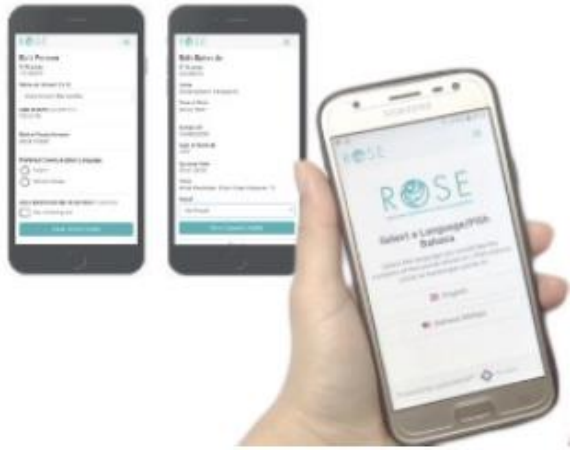
1

Test

2

Treat

3



Register

4

Point-of-care HPV DNA testing of self-collected specimens and same-day thermal ablation for the early detection and treatment of cervical pre-cancer in women in Papua New Guinea: a prospective, single-arm intervention trial (HPV-STAT)

Andrew J B Vallely, Marion Saville, Steven G Badman, Josephine Gabuzzi, John Bolnga, Glen D L Mola, Joseph Kuk, Malts Wai, Gloria Munnull, Suzanne M Garland, Julia M L Brotherton, Angela Kelly-Hanku, Christopher Morgan, Pamela J Toliman, Zure Kombati, Grace Kariwiga, Delly Babona, Grace Tan, Kate T Simms, Alyssa M Cornall, Sepehr N Tabrizi, Handan Wand, Rebecca Guy, Karen Canfell, John M Kaldor

Lancet Glob Health 2022

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S2214-109X(22)00271-6

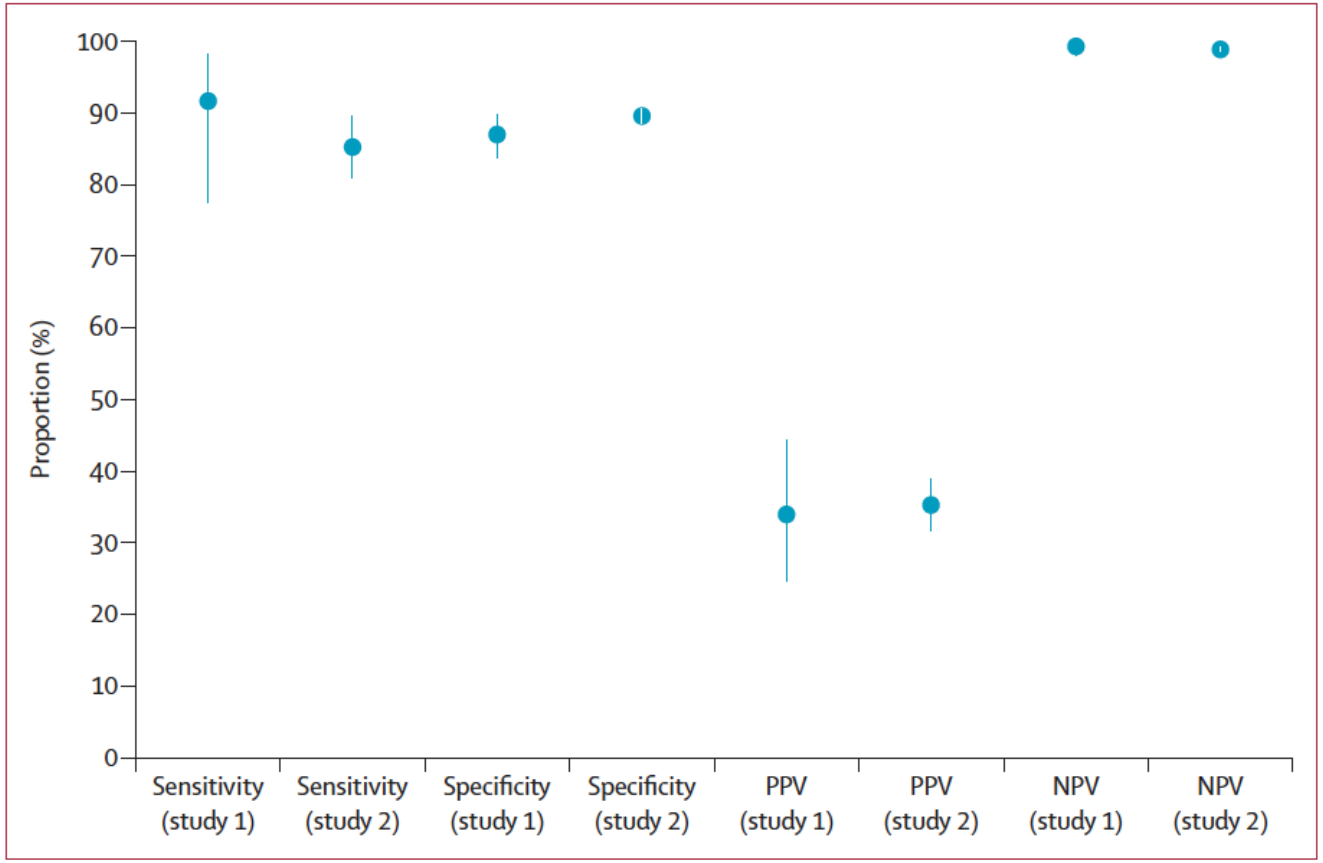


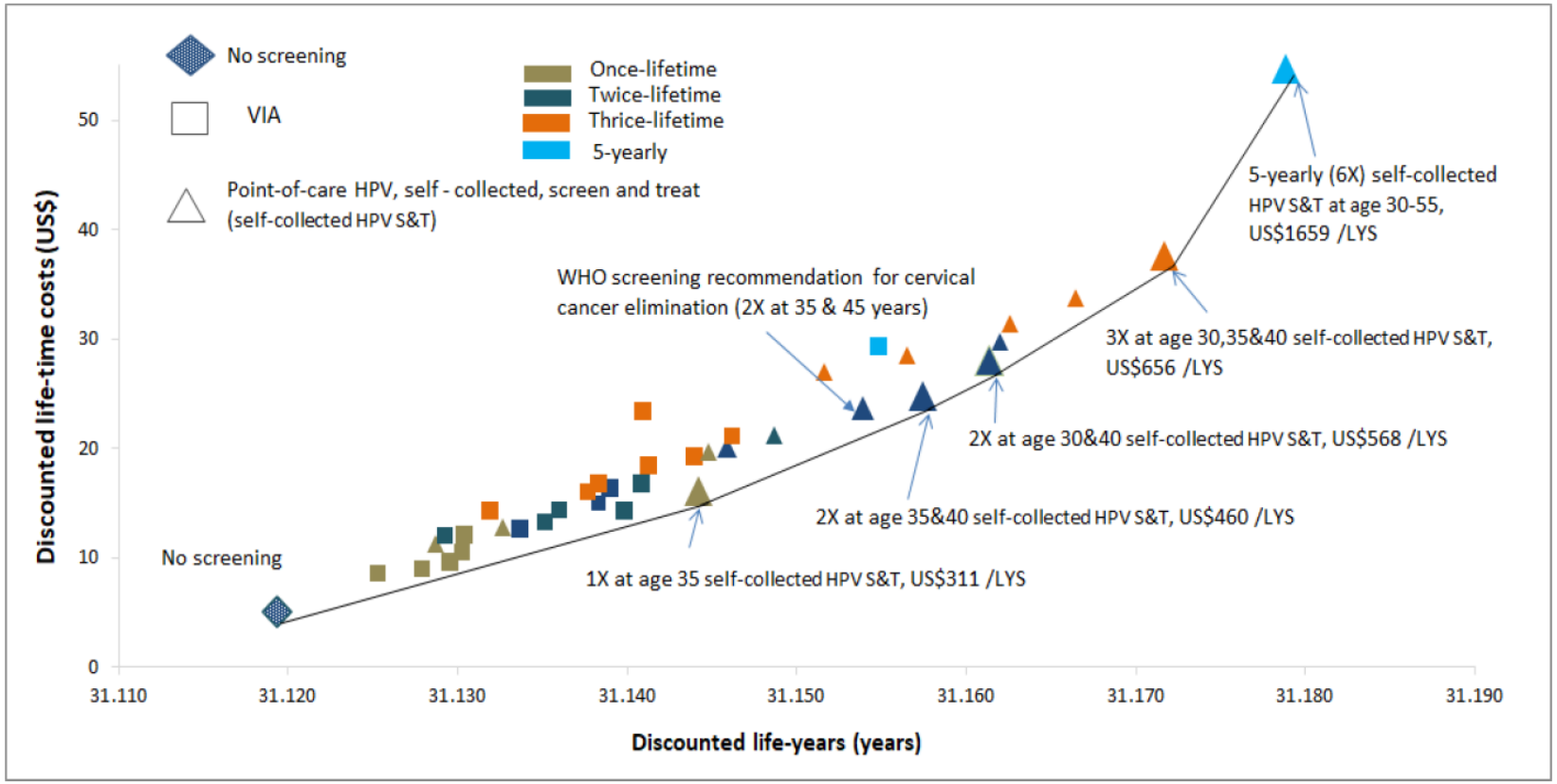
Figure 2: **Clinical performance of point-of-care HPV testing for detection of HSIL or worse in two trials in Papua New Guinea**

Study 1 refers to a field evaluation of 1005 women by Toliman and colleagues[10] and study 2 refers to this current interventional trial of 3638 women. Error bars represent 95% CI. p>0·5 for study 1 versus study 2 across all performance characteristics. HPV=human papillomavirus. HSIL=high-grade squamous intraepithelial lesion. PPV=positive predictive value. NPV=negative predictive value.

Original research

Towards the elimination of cervical cancer in low-income and lower-middle-income countries: modelled evaluation of the effectiveness and cost-effectiveness of point-of-care HPV self-collected screening and treatment in Papua New Guinea

Diep Thi Ngoc Nguyen ,[1] Kate T Simms,[1] Adam Keane,[1] Glen Mola,[2,3] John Walpe Bolnga ,[4] Joseph Kuk,[5] Pamela J Toliman,[6,7] Steven G Badman,[6] Marion Saville,[8] John Kaldor,[6] Andrew Vallely,[6,7] Karen Canfell[1]



BMJ Global Health, 2022 Mar;7(3):e007380.

Camara *et al. BMC Public Health* (2021) 21:1503
https://doi.org/10.1186/s12889-021-11554-6

BMC Public Health

RESEARCH ARTICLE Open Access

Self-collection for HPV-based cervical screening: a qualitative evidence meta-synthesis

Hawa Camara[1*], Ye Zhang[1], Lise Lafferty[1,2], Andrew J. Vallely[1,3], Rebecca Guy[1] and Angela Kelly-Hanku[1,3]

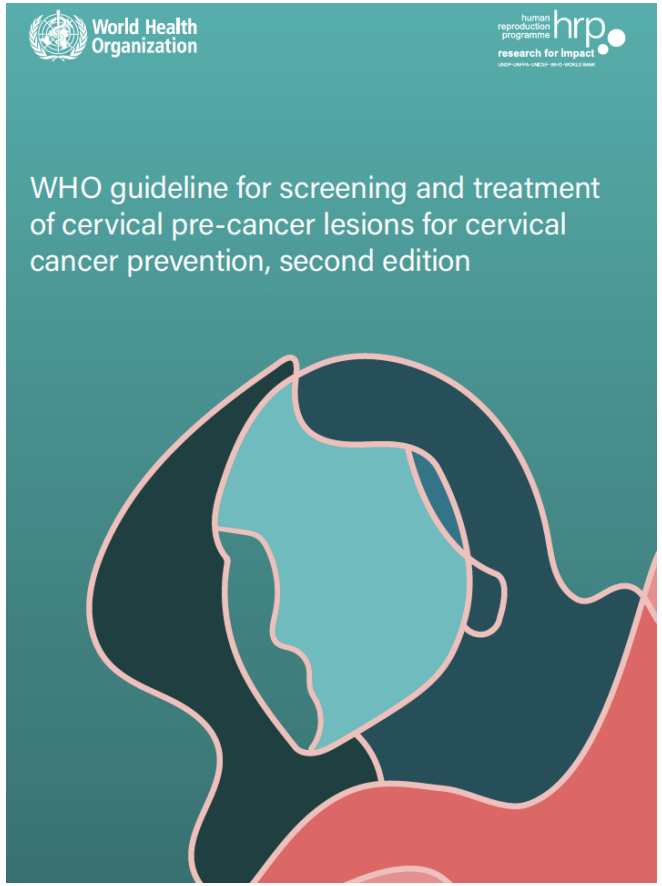
Camara *et al. BMC Health Services Research* (2022) 22:1514
https://doi.org/10.1186/s12913-022-08842-1

BMC Health Services Research

RESEARCH Open Access

Women's acceptability of a self-collect HPV same-day screen-and-treat program in a high burden setting in the Pacific

Hawa Camara[1*], Somu Nosi[2], Gloria Munnull[2,3], Steven G. Badman[1], John Bolgna[3], Joseph Kuk[4], Glen Mola[5], Rebecca Guy[1], Andrew J. Vallely[1,2] and Angela Kelly-Hanku[1,2]



HPV screen-and-treat algorithm, PNG (Dec2021)

HPV-DNA testing
(self-sampled or clinician-collected) [a]

Negative

Re-screen in 5-10 years with HPV DNA test

Positive

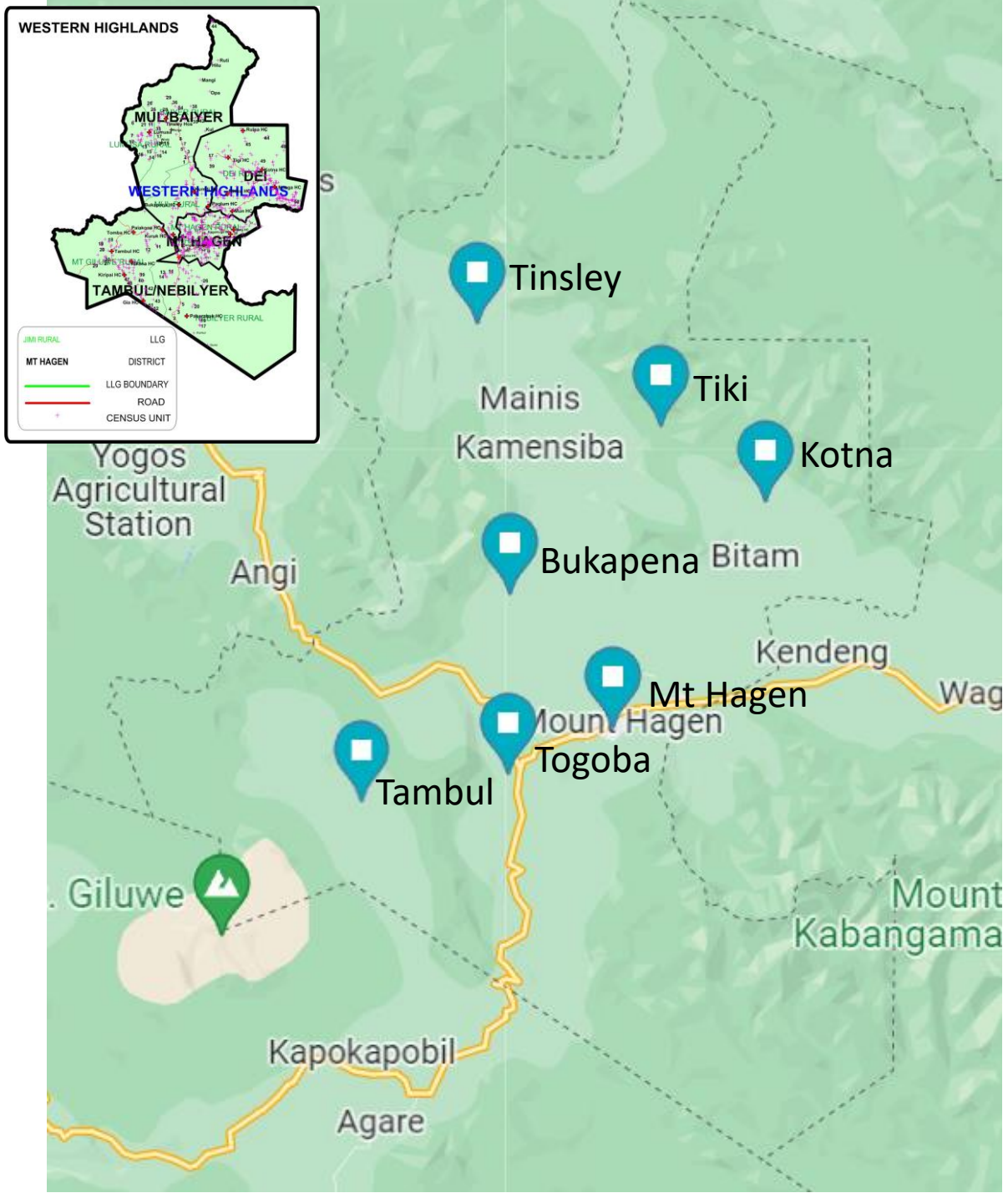
Determine eligibility for ablative treatment
(after application of 3–5% acetic acid with or without magnification) [b]

- **Eligible for ablation**
  - **Same-day thermal ablation** [d]
    - **Post-treatment follow-up and repeat HPV testing in 6-12 months** [f]
- **Not eligible for ablation** [c]
- **Suspected cancer**

→ **Referral for evaluation, biopsy, further management** [e]

[a] Point-of-care HPV-DNA testing of self-collected vaginal specimen is preferred choice.
[b] Visualisation to assess eligibility for same-day ablation not for clinical triage.
[c] If transformation zone (TZ) cannot be seen in its entirety and/or a lesion is seen that makes same-day ablation difficult e.g. cervical polyp, refer for gynaecology review.
[d] Thermal ablation should be applied to the entire TZ in multiple applications if required; use cryotherapy if thermal ablation not available.
[e] Gynaecologist to manage according to clinical findings: if able to fully visualise TZ, consider thermal ablation; if a cervical lesion seen, consider biopsy, cold knife conization (CKC) or LLETZ (large-loop excision of the transformation zone).
[f] Follow-up at 6-12 months irrespective of HPV type at first visit – see Algorithm 2.

WHO Jul 2021: https://www.who.int/publications/i/item/9789240030824



‘Hub & Spoke' model WHP, PNG (2022-)

A. Provincial ‘Hub’

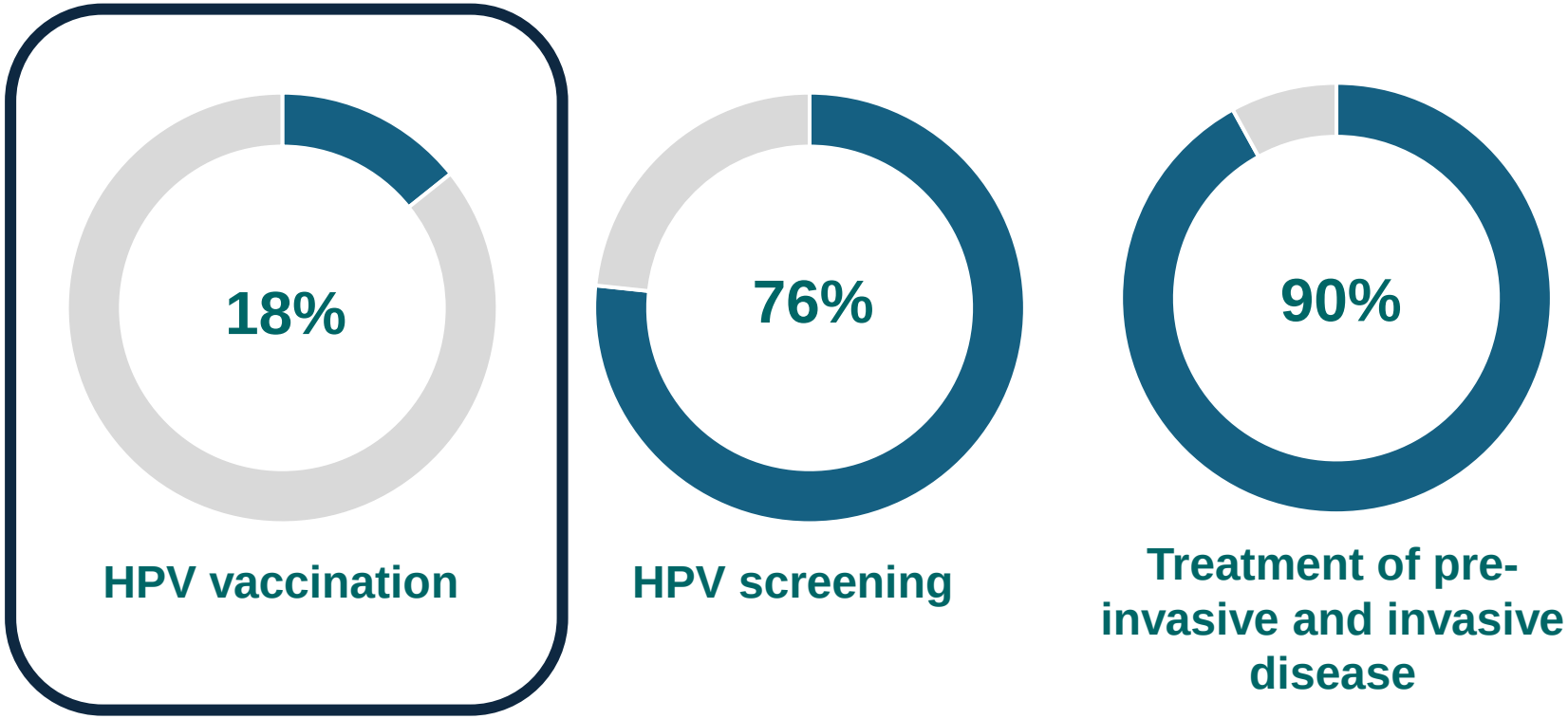
- Well Woman Centre
- Centre of Clinical Excellence in Cancer Care
- Provincial Coordinating Centre

B. Rural ‘Spoke’

- Rural health facility
- Community outreach

Rural Outreach: an unprecedented response

Elimination of Cervical Cancer in the Western Pacific (ECCWP) - WHP



Nov 2024

GACD
GLOBAL ALLIANCE FOR CHRONIC DISEASES
AN ALLIANCE OF HEALTH RESEARCH FUNDERS

Australian Government
National Health and Medical Research Council

WESTERN HIGHLANDS PROVINCIAL HEALTH AUTHORITY

Cepheid

MINDEROO FOUNDATION

New Ireland Province

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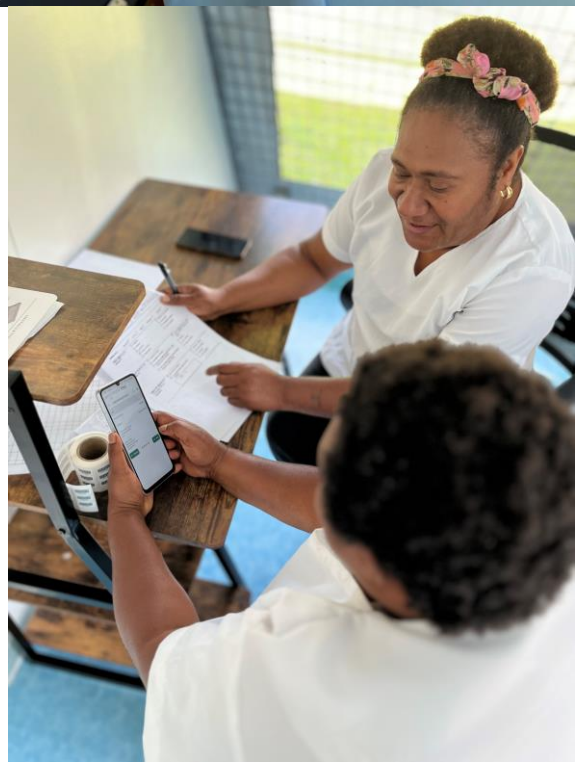
AN ALLIANCE OF HEALTH RESEARCH FUNDERS

Australian Government
National Health and Medical Research Council

NEW IRELAND PROVINCIAL HEALTH AUTHORITY

Australian Government
Department of Foreign Affairs and Trade

Southern Highlands Province



canSCREEN™PNG

Andrew Valley | Mt Hagen Hospital clinic | ? Help | Sign out

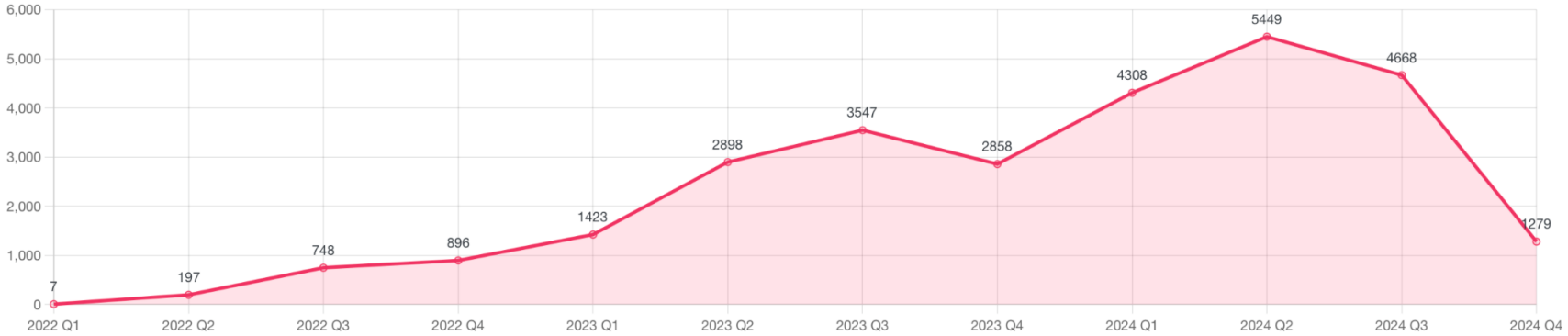
Search | Follow Up | Data | Document Management | Follow Up Admin | System Admin

Person/Patient Search | Reporting

- Dashboard
- Map
- Custom Query (Beta)
- Person/Patient Demographics Reports
- Episode Reports
- Person/Patient and Episode Combined Reports
- Person/Patient Follow Up Reports
- Diary Entry Reports
- WHO Reports
- Vaccination Report
- School Vaccination Extract

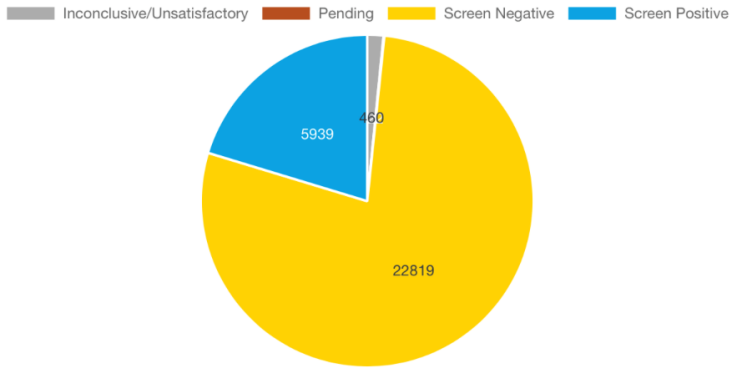
Displaying Data From: Today (01 / 01 / 2022) **To:** Today (29 / 10 / 2024) **Province:** **Place/Clinic:** Search Refresh

No. Women Screened (Total: 28278)



Data based on Episode Date of patient's first Cervical Screening Episode

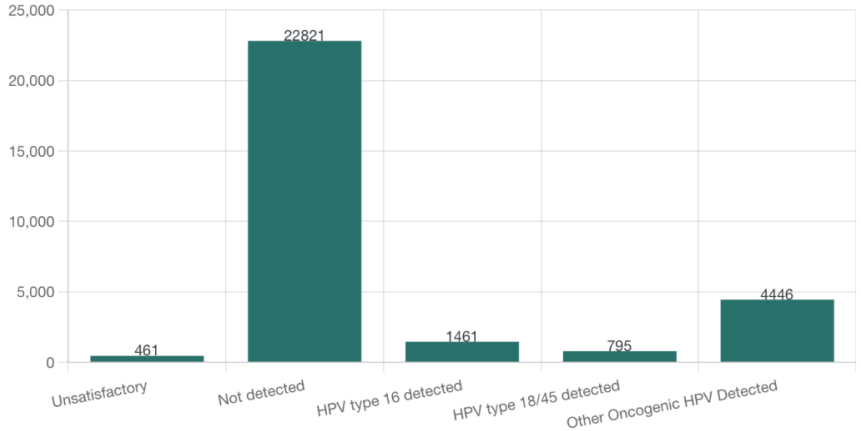
Total Cervical Screening Episode Results



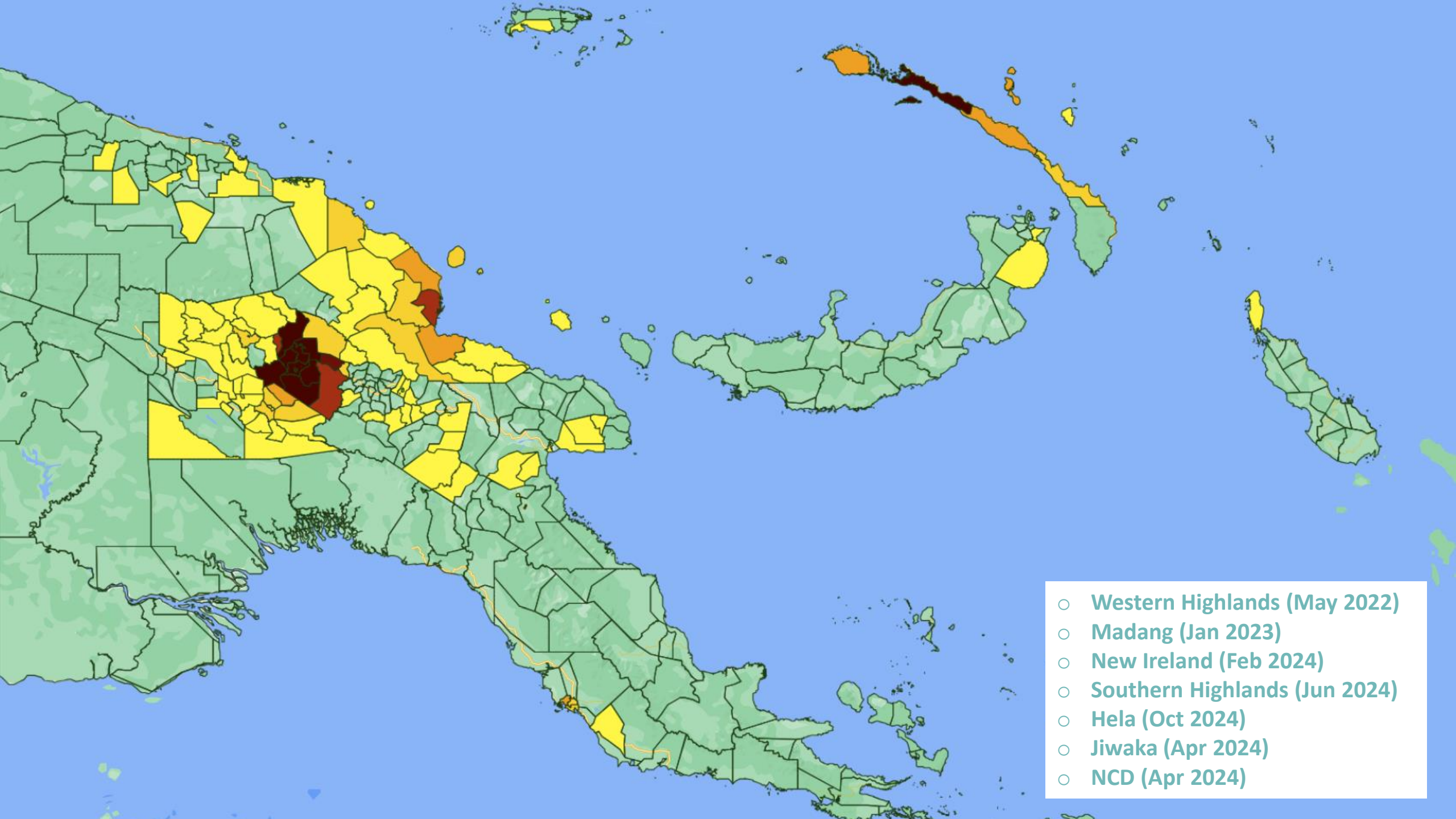
Data based on results of all Cervical Screening Episodes

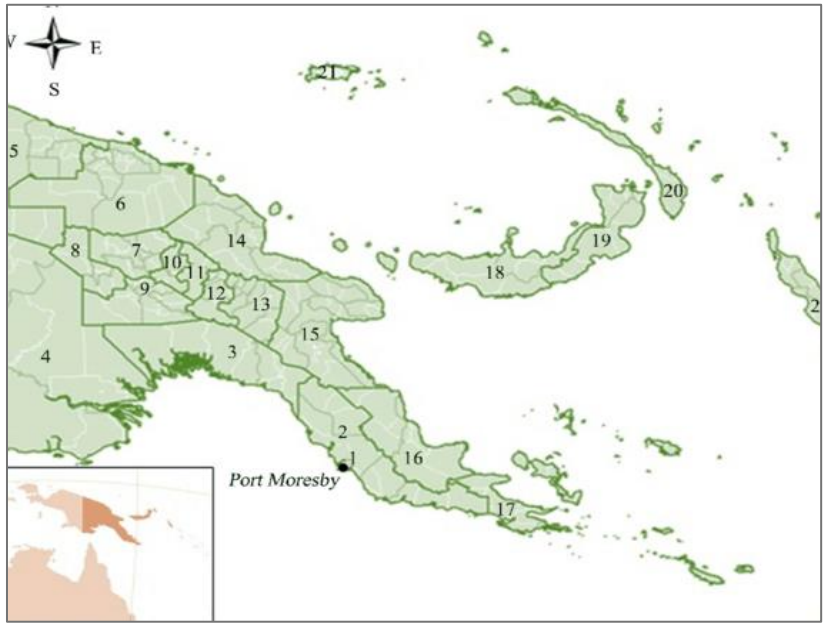
| %

HPV Test Results

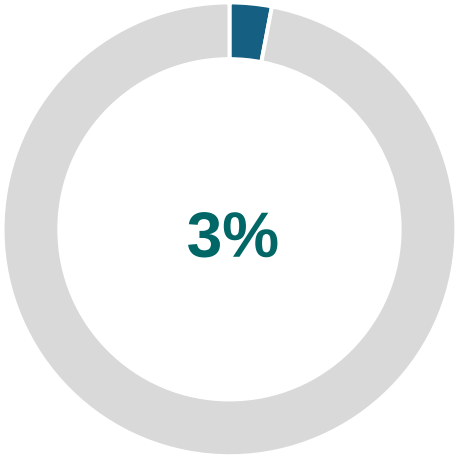


Data based on results of all Cervical Screening Episodes

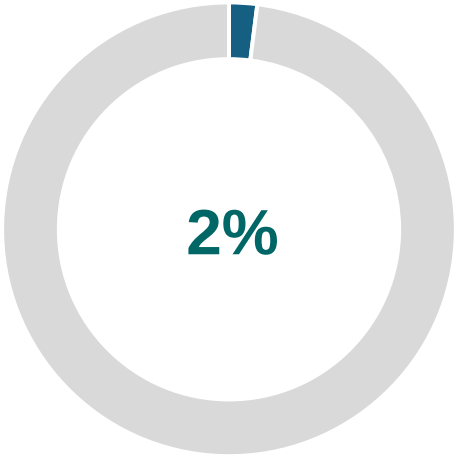

Western Highlands (May 2022)
Madang (Jan 2023)
New Ireland (Feb 2024)
Southern Highlands (Jun 2024)
Hela (Oct 2024)
Jiwaka (Apr 2024)
NCD (Apr 2024)



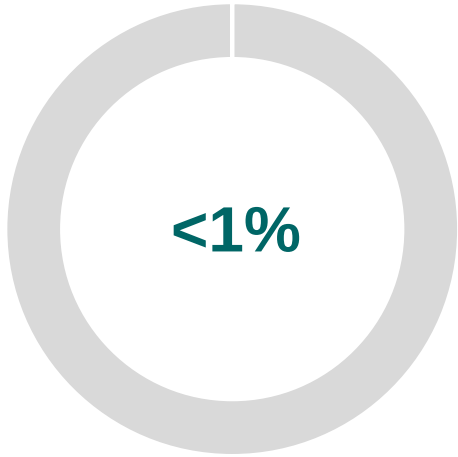
WHO 2030 Coverage Targets



HPV vaccination



HPV screening

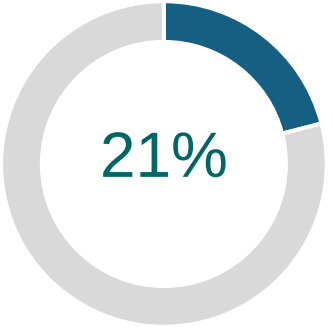


Treatment of pre-invasive and invasive disease

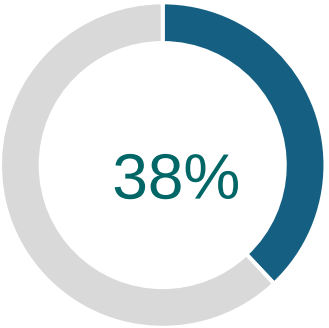
*Achieving the WHO coverage targets by 2030 would save around **41,000 lives** by 2070 and **150,000 lives** over the next century in PNG*

Vanuatu

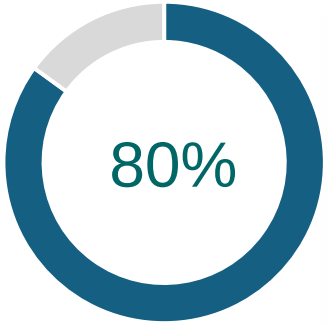
- **2nd leading cancer** (14.5 cases/100,000 women) and **leading cause of cancer death** among women
- 20,000 age-eligible girls for HPV vaccination and 34,000 age-eligible women for HPV screening



HPV vaccination



Cervical screening with HPV test.



Treatment of cancer and precancer

MINISTRY OF HEALTH
GOVERNMENT OF VANUATU

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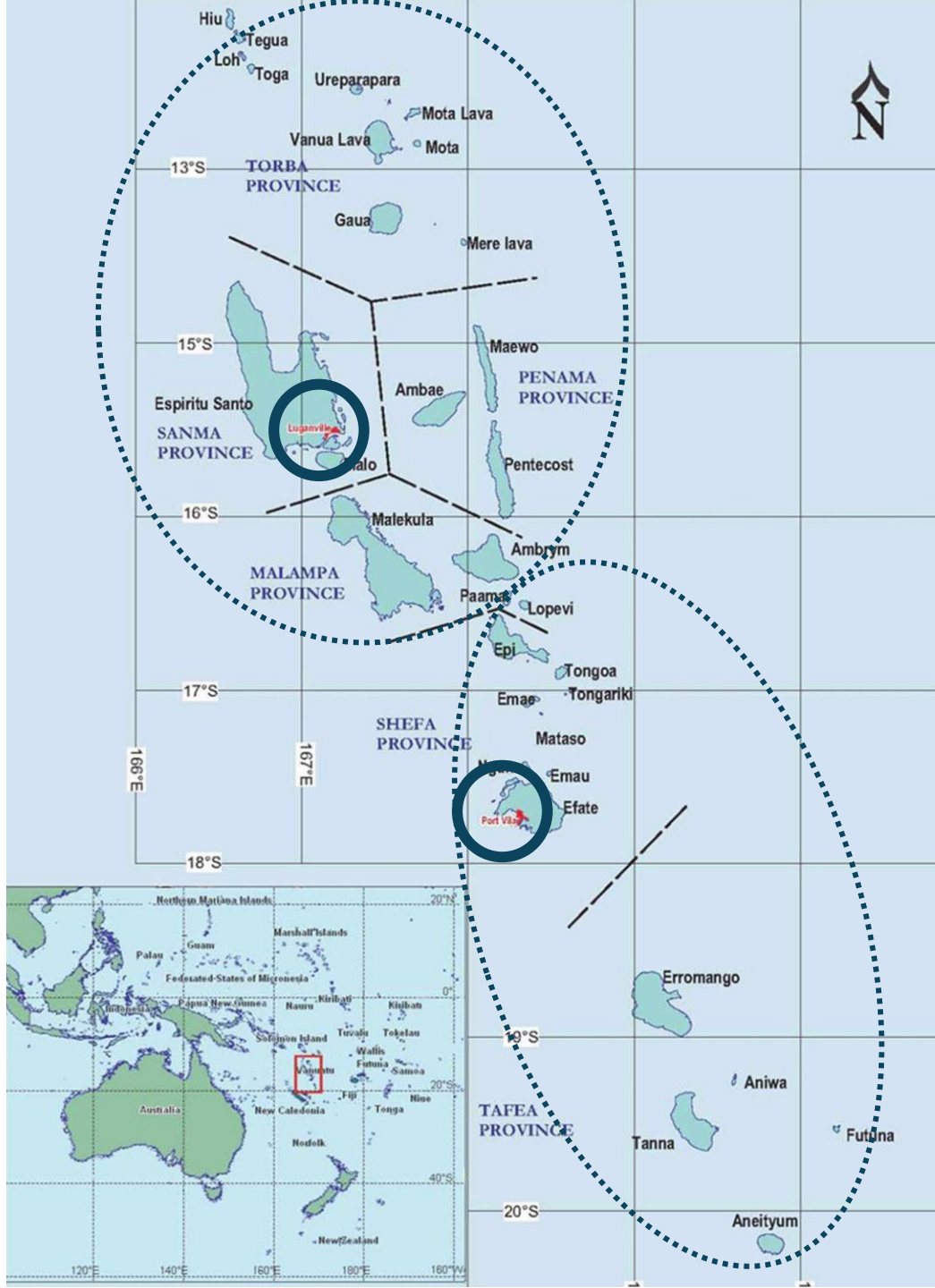
‘Hub & Spoke' model - Vanuatu

A. Provincial ‘Hubs’

- Well Woman Clinics (VCH, NPH)
- Centre of Clinical Excellence in Cancer Care (VCH)

B. Rural ‘Spoke’

- Rural health facilities
- Community outreach
- Mobile outreach e.g. HELPR-1

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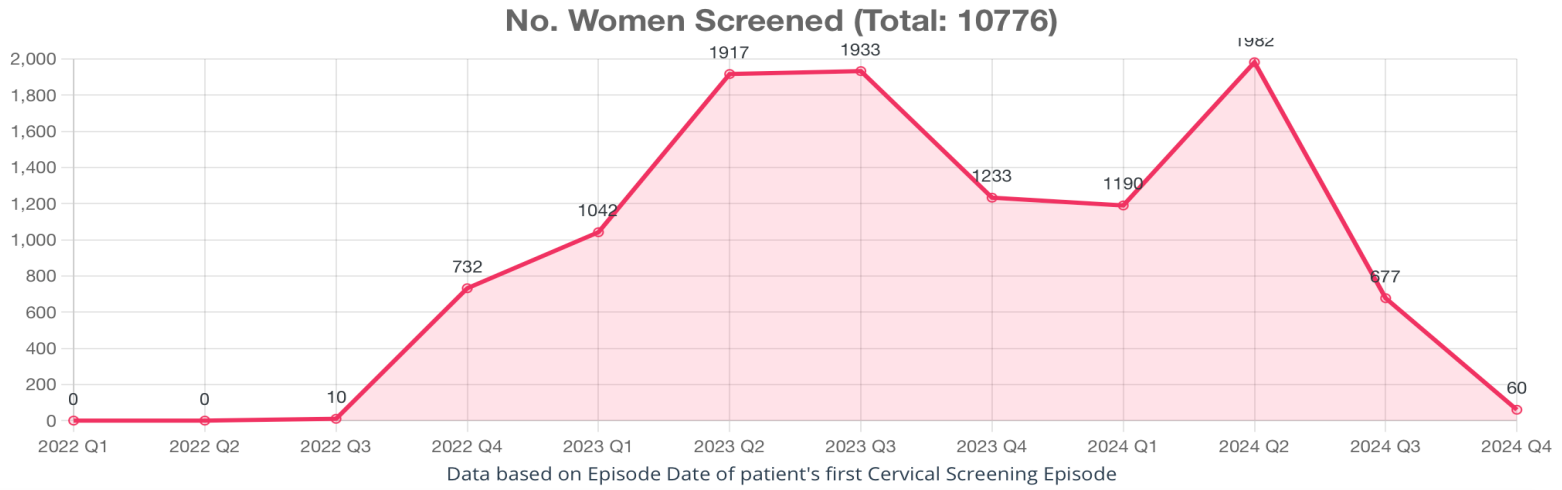
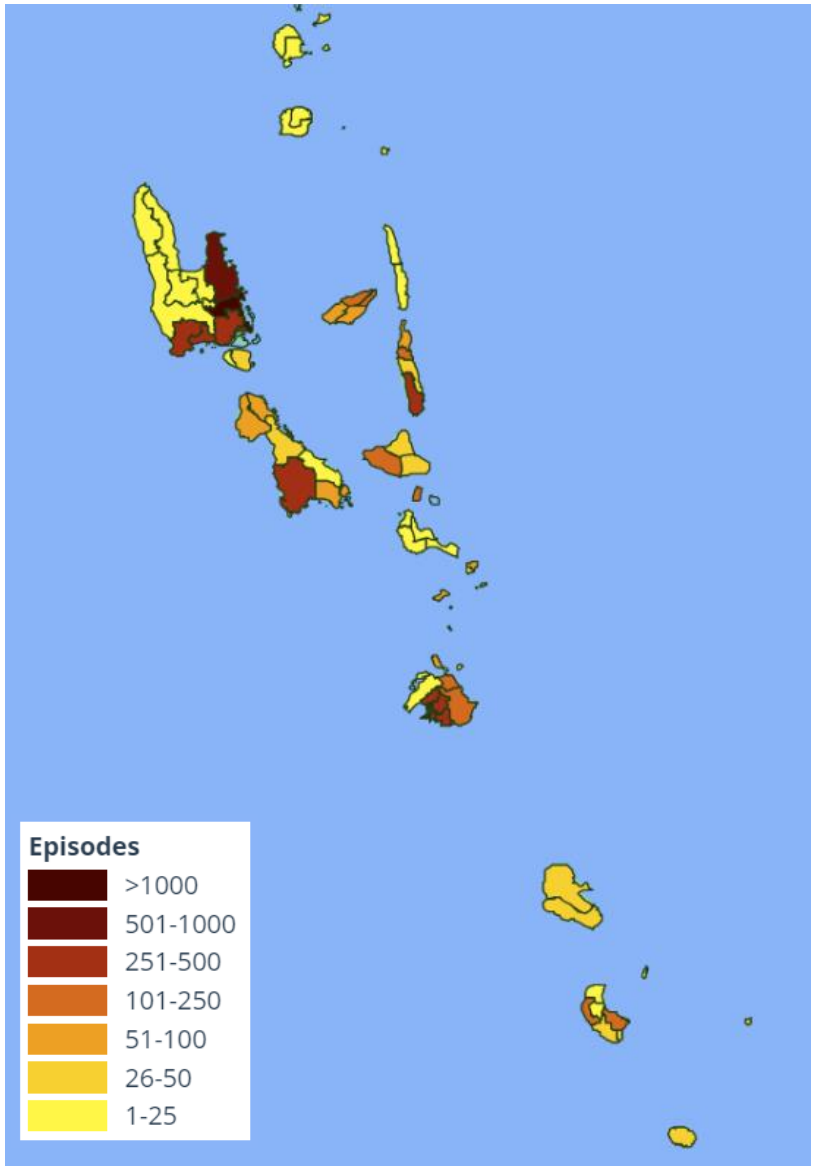
HELPR

Elimination of Cervical Cancer in the Western Pacific - Vanuatu

No. Women Screened, Vanuatu Oct 2022 - Oct 2024



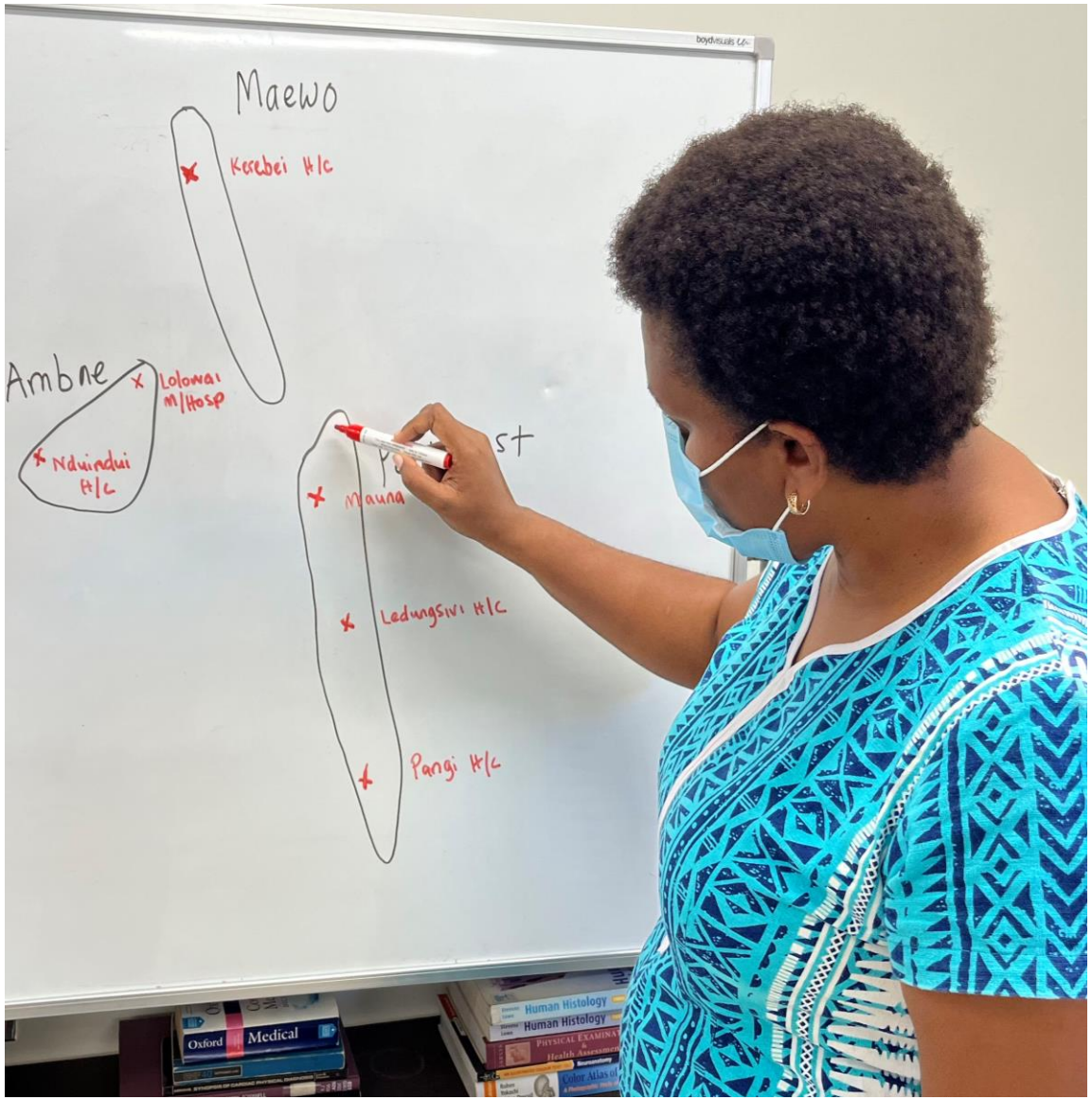


Key challenges

- Ensuring and **maintaining quality** clinical and diagnostic components of HPV SAT as scale-up proceeds.
- Reaching women in **rural and remote communities**; and achieving high rates of **clinical follow-up** at 12 months across all settings.
- The hardest part of 90: achieving effective, efficient, appropriate **referral for women with invasive disease**, including access to essential **histopathology** and **diagnostic radiology** services, and **palliative care** services.
- **Sustainability**, funding, integration.

Lessons learned

- Critical importance of **local leadership** and champions; of **clear vision, strategy and governance**; and a willingness to take evidence-informed **risks** in implementation, even if means ‘failing forward’.
- Importance of **real-time implementation evidence**, monitoring, evaluation and program support through canSCREEN electronic screening registry, supplemented by robust qualitative research.
- Importance of **strengthening the broader health systems** within which HPV SAT is delivered, including primary care, OBGYN, sexual and reproductive health, and community outreach services.



Lessons learned

- Trade offs btw **same-day HPV SAT** vs. multi-visit outreach model of community-based collection, offsite testing, community-based results and treatment (**modified HPV SAT**).
- HPV SAT as a **foundation for HPV vaccination** - and opportunities this provides for integrated screening and vaccination programs.
- Planning for success: HPV SAT as a potential foundation for **integrated NCDs and cancer screening** and management following completion of first screening round.

Acknowledgements

- Ministry of Health, national and provincial health authorities in PNG and Vanuatu
- PNG Institute of Medical Research
- PNG Obstetrics & Gynaecology Society
- PNG TWG on Comprehensive Cervical Cancer Control
- Vanuatu Family Health Association
- PNG Cancer Foundation
- Kirby Institute, UNSW Sydney
- University of Sydney
- Australian Centre for Prevention of Cervical Cancer
- Family Planning Australia
- Donor partners and agencies
- Women, their families, and their communities

EP&CC ELIMINATION PARTNERSHIP IN THE INDO-PACIFIC FOR CERVICAL CANCER

MINDEROO FOUNDATION

SWIRE

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Department of Foreign Affairs and Trade

Cepheid

Santos Foundation


‘Eliminate Cervical Cancer in Vanuatu’
TES LONG NEK BLONG BASKET BLONG BEBE HEMI SAVE SAFEM LAEF.
1 Sapos yu kat 30-54 yia, kam visitim Cervical Cancer Screening Clinic.
2 Tes hemi FRI mo yu karem resal mo tritmen long sem dei nomo.
3 Sapos tes hemi positiv, majoriti blong woman i save kasem tritmen long sem dei o bae oli referem yu i ko long wan spesalist blong tritim yu.
Cervical Cancer Screening Clinic
Konsaltesen
Tes & Resal
Tritmen

Panelist Q&A

TOGETHER for health

Thank you!

TOGETHER for health

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