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POLICY1-CERVIX: Model Profile

University of Sydney

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Version Table

Version	Date	Notes
1.0.00	2025-09-30	Major update
HI.001.03202020.9999	2020-03-20	Historical release

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Readers Guide

Reader's Guide

Core Profile Documentation

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These topics will provide an overview of the model without the burden of detail. Each can be read in about 5-10 minutes. Each contains links to more detailed information if required.

Model Purpose
This document describes the primary purpose of the model.

Model Overview
This document describes the primary aims and general purposes of this modeling effort.

Assumption Overview
An overview of the basic assumptions inherent in this model.

Parameter Overview
Describes the basic parameter set used to inform the model, more detailed information is available for each specific parameter.

Component Overview
A description of the basic computational building blocks (components) of the model.

Output Overview
Definitions and methodologies for the basic model outputs.

Results Overview
A guide to the results obtained from the model.

Model Purpose

Purpose

The model platform known as '*Policy1-Cervix*' was developed to address several questions related to cervical cancer. *Policy1-Cervix* has been used for a number of evaluations of cervical cancer interventions, such as cost-effectiveness of HPV vaccination, and evaluation of cervical screening technology, intervals, and management. The *Policy1-Cervix* model was one of three models used by the WHO Cervical Cancer Elimination Modeling Consortium (CCEMC) to evaluate the impact of cervical cancer elimination targets in 78 LMIC and was reviewed and endorsed by the WHO Advisory Committee on Immunization and Vaccines-related Implementation Research (IVIR-AC) for the use in CCEMC modelling of elimination for WHO.[1,2] *Policy1-Cervix* was also used to predict the timeline to elimination of cervical cancer for 181 countries,[3] for USA,[4] and Australia.[5] It has been used for a range of government-commissioned studies on behalf of national cervical screening programs in Australia, New Zealand, the United Kingdom and Ireland. 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,[6] as well as similar screening policy evaluations for New-Zealand[7] and England.[8] It has also been used to provide estimates of resource utilization and disease impacts during the transition from cytology to HPV screening in Australia and New Zealand,[9-11]to inform clinical management guidelines in Australia[12] and evaluate the impact of adopting self-collected HPV testing in Australia.[13] It has previously been extensively validated and used to evaluate changes to the screening interval in Australia and the United Kingdom,[8,14]the role of alternative technologies for screening in Australia, New Zealand and England,[8,15,16,17]the role of HPV testing for the follow-up management of women treated for cervical abnormalities,[18] the cost-effectiveness of alternative screening strategies and combined screening and vaccination approaches in China,[19,20]the impact of HPV vaccine hesitancy in Japan[21] and the cost-effectiveness of primary HPV testing and the potential for elimination in Malaysia.[22] The model has also been used to evaluate the impact of HPV vaccination[23] and the incremental impact of vaccinating males in Australia,[24,25]the impact of the nonavalent HPV vaccine on optimal cervical screening in four developed countries[25] and to assess the cost-effectiveness of the nonavalent HPV vaccine in Australia.[26] 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.[27] The *Policy1-Cervix* model was used to predict outcomes for different screening strategies across all 78 LMICs to support the 2021 update of WHO cervical cancer screening guidelines for the general population,[28] as well as for women living with HIV.[29] *Policy1-Cervix* has been used for several analyses in the USA. Some examples include assessing the cost-effectiveness of HPV vaccination for adults aged 30-45 years,[30] estimating cancer risk in females eligible to exit screening,[31] and examining disparities in cervical cancer elimination timing.[32] *Policy1-Cervix* was used to estimate the impact of COVID-19 related disruptions to screening and diagnosis on cervical cancer incidence,[33,34]as well as disruptions to HPV vaccination.[35]

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Model Overview

Summary

This section provides an overview of the *Policy1-Cervix* model. The model consists of four core components:

1. Dynamic HPV transmission and vaccination
2. Cervical carcinogenesis
3. Screening and treatment
4. Cancer treatment and survival

A summary of each component is provided below, and these components will continue to be referred to throughout this document.

Background

Dynamic HPV transmission and vaccination

Heterosexual behavior is modeled by stratifying the population by sex, age, and level of sexual activity (i.e., four sexual activity groups) using data from national behavioral surveys of sexual behavior. The model has been extended to include semi-assortative and age-and sex-specific mixing parameters; a revised sexual mixing matrix; the capacity to vary the annual per-partner transmission probability according to HPV type, sex, and sexual activity group; and the ability to capture the effects of more rapid change in behavior (by single year of age) during adolescence and early adulthood. There is capacity to simulate alternative assumptions for the duration of naturally-conferred type-specific immunity against HPV infection and its waning. A multi-type structure is used, and women can become infected with eight possible HPV type groups: HPV16, HPV18, HPV31, HPV33, HPV45, HPV52, HPV58 and other Hr-HPV types grouped.

The dynamic model simulates vaccination uptake by single year of age, sex, and chronological time. Vaccination of older females (and males) in catch-up programs, if applicable, is modeled by single year of age, taking into account the potential for prior HPV type-specific exposure and its impact on type-specific vaccination efficacy at different ages. Male vaccination uptake is also modeled to account for incremental herd immunity effects in females. The model allows varying vaccine properties (e.g., efficacy, waning).

Cervical carcinogenesis

This component takes cohort- and type-specific HPV incidence from the dynamic model as input and involves a complex multi-cohort microsimulation implementation of the natural history of cervical pre-cancer. Progression and regression between states representing HPV infection, CIN1, 2 and 3 (due to particular HPV types or groups) are modeled, as is progression from CIN3 to invasive cervical cancer. The model accounts for age-specific hysterectomy rates (for any reason) in the population.

Screening and treatment

The sensitivity and specificity of cytology are setting-specific and fitted to local data (e.g., on the distribution of cytology test results, cytology-histology correlations) in a particular setting. Fitted test characteristics are constrained to be consistent with findings from international meta-analyses which report the absolute and relative sensitivity and specificity of cytology and HPV testing. Detailed analysis of registry data on the age at which young women first initiate screening is performed, and for all ages rates of return to screening or follow-up management over a multi-year period is simulated, according to last screening test result, the follow-up recommendation and age. Post-treatment natural history and recurrent disease following treatment for CIN are based on a review of the literature on outcomes after pre-cancer treatment. A separate model has been developed for estimating adverse reproductive outcomes in the population given alternative screening strategies and associated CIN excisional treatment rates by age.

Cancer treatment and survival

Cancer staging and progression is modeled, accounting for symptomatic detection and the possibility of downstaging at diagnosis due to screening. Predictions for age-specific cervical cancer incidence and mortality have been calibrated to observed rates in unscreened populations. The model is then additionally validated against country-specific registry data for incidence and mortality, when run with an overlay of screening according to country-specific guidelines. The stage and interval-specific cancer survival parameters are based on analysis of data from cancer registries and validated against observed data.

Assumption Overview

Summary

This section outlines the key assumptions made in the *Policy1-Cervix* model and will provide justification for assumptions as appropriate.

Background

The model assumptions are informed from the literature, and updated regularly. When data is not available from the literature, expert opinion is sought.

Assumption Listing

Dynamic HPV Transmission

We assume men and women fall within 4 possible sexual behaviour groups, and if one partner is infected with HPV, each heterosexual partnership has a chance to transmit the virus. Viral clearance and progression are also modeled.

Vaccine duration is an input parameter and can be lifelong or waning. 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.

Cervical carcinogenesis

We consider lesions and cervical cancers are caused by HPV and do not model precancer lesions that arise in the absence of the virus (as these lesions do not progress to cancer). Woman can be uninfected, infected with HPV (with two states for productive infection, labelled HPV and CIN1), or CIN2, CIN3 or invasive cancer. Women can have multiple infections and multiple lesions associated with different infections. We consider eight HPV type-groups, including HPV 16, 18, 31, 33, 45, 52, 58 and other high-risk HPV types (as a pooled group), and progression and regression rates are modelled as a function of HPV type/ group and age. The HPV types/groups modelled are assumed to be independent and simultaneous (i.e. a female can have one infection per type/group but an infection of one type/group does not impact the incidence or transition rates of another type/group). We also assume that health states can transition from any CIN/infected state to a state that is within a distance of two states away with the exception of cervical cancer which can only be accessed from the CIN3 state.

Screening and treatment

We assume that screening test results are based on a woman's true underlying health state, including any underlying HPV type. Women who undergo precancer treatment have a small chance of treatment failure; for developed settings, we simulate near-term follow-up with successful re-treatment. We assume that the subgroup of women who have a CIN2/3 lesion identified are at somewhat higher risk of cervical precancer and cancer (even after treatment) for the remainder of their lives.

Cancer treatment and survival

Women who progress to cancer will initially progress to localized cancer and, until cancer is detected, stage progression may occur and is a function of age. Cancer survival is a function of stage at diagnosis and time since diagnosis and is assumed to be better for women who had cancer detected through screening rather than symptomatic presentation. We have also previously validated our model against observations of the proportion of cancers that are localized, regional and distant at the time of diagnosis, by age, in a well-screened setting.

Parameter Overview

Summary

This document describes the parameters used to inform the *Policy1-Cervix* model.

Background

The model assumptions are informed from the literature and are updated regularly. When data is not available from the literature, expert opinion is sought, and differing parameter values are explored to identify the impact of the unknown parameter values on key outcomes. When an evaluation is performed, extensive sensitivity analysis is performed to capture uncertainties in parameter values.

In this section, the parameters for *Policy1-Cervix* are outlined for each of the four core components. The parameters in the *Policy1-Cervix* model also fall under three general classifications: 1) Input Parameters, 2) Calibrated Parameters, and 3) Calibration Targets. Input parameters use available data from literature or external analysis that can be incorporated into the model, e.g. life tables. Calibrated parameters are obtained through the calibration process and provide the best fit to the calibration targets, e.g. health state transition rates. Calibration targets are used in the calibration process but are not directly required to operate the model, e.g. HPV prevalence.

Parameter Listing Overview

Dynamic HPV transmission and vaccination component

- We assume a median age of sexual debut of 16-17 for females and males, and a median lifetime number of sexual partners of 4 in females and 7 in males, with these numbers informed from sexual behavior data from Australia (ASHR). Age of sexual debut and lifetime number of sexual partners were reviewed for the USA and found to be similar to Australia.
- Vaccine efficacy rates are based on published trial data and coverage by age and year is based on local reported coverage rates specific to a setting.

Cervical carcinogenesis component

- Life tables, by age (Input parameter – Berkeley Life Table)
- Hysterectomy rates, by age (Input parameter – NHDS/Doll/SASD)
- HPV incidence rates, by age (Output of HPV Transmission component)
- Disease state transition rates, by age (Calibrated parameters)
- Cancer stage progression rates, by age (Calibrated parameters)
- Symptomatic cancer detection rates, by age and stage (Calibrated parameters)
- HPV prevalence, by age and type (Calibration target – New Mexico HPV Pap Registry)
- HPV type distribution in CIN1, 2 and 3 (Calibration target – New Mexico HPV Pap Registry)
- HPV type distribution in cancer (Calibration target – Saiyara published data)

Screening and treatment component

- Test Positive Matrices (TPMs) are from published test performance data for USA for HPV and cytology testing.
- Screening initiation, routine attendance, and follow-up attendance rates (Input parameter – NMHPVPR/KPNC)
- Treatment failure rates (Input parameter – English NHS)

Cancer treatment and survival component

- The model is calibrated to cancer incidence in an unscreened population, by age (Calibration target – cancer incidence across 22 unscreened settings from IARC)
- Cancer survival by stage and time since diagnosis (based on SEER data on survival)

Component Overview

Summary

This document describes how the separate components of *Policy1-Cervix* link together to create a cohesive model.

Overview

The *Policy1 Cervix* model has four core components: dynamic HPV transmission and vaccination, cervical carcinogenesis, screening and treatment, and cancer treatment and survival. All four components work in conjunction to produce evaluations of cervical cancer prevention strategies.

Component Listing

Dynamic HPV transmission and vaccination

This component can be operated independently of the other core components. Its primary purpose is to provide the HPV incidence parameters used by the cervical carcinogenesis component. The dynamic HPV transmission component incorporates vaccination parameters, such as efficacy and duration, and outputs the resulting relative reduction of HPV incidence by age and HPV type. These relative reduction outputs are applied to the setting-calibrated HPV incidence parameters and fed into the cervical carcinogenesis model.

Cervical carcinogenesis

The predicted rate of new infections output from the dynamic HPV transmission and vaccination component feed into the cervical carcinogenesis component. This component operates in conjunction with the screening and treatment component, which is essentially an overlay onto the cervical carcinogenesis component. These two components operate simultaneously and directly feed back into each other. Screening outcomes depend on progression along the cervical carcinogenesis pathway, and treatment will alter the course of the cervical carcinogenesis pathway.

Screening and treatment

This component captures detailed screening pathways management and overlays the cervical carcinogenesis component, as described above.

Cancer treatment and survival

This component is directly linked to the cervical carcinogenesis component. Upon transition from preclinical cancer to clinical cancer, the cervical carcinogenesis component ceases to operate and the cancer treatment and survival component commences.

Output Overview

Summary

This document describes the outputs produced by *Policy1-Cervix*.

Overview

Policy1-Cervix produces outputs that can be generally categorised into one of three groups: calibration outputs, validation outputs, and predictive outcomes. Calibration outputs are used by a calibration algorithm to achieve a 'best fit' with target data, by varying calibrated input parameters based on this fitting algorithm. Validation outputs are compared to observed data but aren't considered in the calibration algorithm. Input parameters aren't changed to match these targets; these validation targets are instead used as a flag to highlight issues with the model. Predictive outcomes are the outputs that are used for evaluation of cervix cancer interventions. These outcomes are also used in comparing different models and seeing the effects of different assumptions on how the underlying model operates.

Output Listing

Calibration Outputs

- HPV prevalence by HPV type (16/18/31/33/35/52/58/OHR): age based, recorded in yearly intervals, includes CIN lesions as well as HPV
- Cancer incidence: recorded upon detection of underlying cancer either through symptoms or screen detection
- HPV type distribution in cancer: age based, recorded in yearly intervals, the proportion of total cancer incidence made up by each type of HPV infection
- HPV type distribution in CIN: age based, recorded in yearly intervals, the proportion of total cancer incidence made up by each type of HPV infection

Validation Outputs

- Cancer mortality
- Hysterectomy incidence and prevalence
- Screening tests: cytology tests, HPV tests, colposcopies
- Screening outcomes: histologically-confirmed high grade/low grade abnormalities
- 5-year risk of CIN3+ by cytology test result

Predictive Outcomes

- Health state dwell times of cancer-causing HPV infections
- Health outcomes: life years, cancer cases, cancer deaths
- Resource outcomes: screening tests, colposcopies, pre-cancer treatments
- Health economic outcomes: costs, quality adjusted life years (QALYs), cost-effectiveness of cervical cancer interventions.

Results Overview

Summary

This document describes the results produced by *Policy1-Cervix*.

Overview

Policy1-Cervix has produced results used for several evaluations of cervical cancer interventions, such as the impact of HPV vaccination, evaluation of cervical screening technology, intervals, and management, and modelling around cervical cancer elimination timing and planning.

Results List

Cervical cancer elimination modelling

- Impact of elimination targets in 78 LMIC. [1,2]
- Timeline to elimination for 181 countries, Australia and the USA. [3-5]
- Disparities in elimination timing in the USA. [6]
- Potential for elimination in Malaysia. [7]

Evaluations of cervical screening

- Effectiveness of HPV screening in Australia, New Zealand, England and China, [8-12]including in follow-up management after treatment for cervical abnormalities in Australia. [13]
- Resource utilization and health impacts during transition from cytology to HPV screening in Australia and New Zealand. [14-16]
- Informing clinical management guidelines in Australia. [17]
- Impact of changes to the screening interval in Australia and the United Kingdom. [10,18]
- Impact of adoption of self-collected HPV testing in Australia. [19]
- The role of alternative technologies for screening in Australia, New Zealand and England. [10,20,21,22]
- Estimating cancer risk when exiting screening in the USA. [23]
- Impact of disruptions to screening due to COVID-19 in Australia and the USA. [24,25]
- Cost-effectiveness of screening strategies in 78 LMICs. [26,27]

Evaluations of HPV vaccination

- Impact of HPV vaccination in Australia. [28]
- Incremental impact of male HPV vaccination in Australia. [29,30]
- Impact of vaccine hesitancy in Japan. [31]
- Cost-effectiveness of vaccination in Australia [32], and for adults aged 30-45 years in the USA. [33]
- Optimal screening in the context of HPV vaccination in Australia, New Zealand, England and the USA. [30]
- Impact of disruptions to HPV vaccination due to COVID-19 in Australia. [34]

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