

EUROGIN 2016 Abstracts- HPV FRAME

Session

Scientific Sessions (SS) 15 the FRAME initiative

11:00-12:30, Saturday the 18th of June

Karen Canfell: 1. Introduction

Background/Objective: HPV-FRAME is an initiative to develop a consensus statement and quality framework for modelled evaluations of HPV prevention. This talk will describe the history and rationale of the initiative and will discuss then progress to date and next steps.

Methods: Quality assessment of HPV models will be structured according several which reflect the policy questions of interest in HPV prevention. For each of these domains, a draft framework will be presented by members of the HPV-FRAME coordinating group at EUROGIN 2014. An opportunity for public comment will follow and the framework will eventually be published and disseminated.

Conclusion: The initiative will allow for the development of models in accordance with an explicit reporting and quality framework. This will allow the end-user, often a policy-maker, to appreciate how accurately the model reflects outcomes prior to change, the areas of simplification, whether a model construction and parameterization was appropriate to the decision question and the degree of uncertainty in a decision process.

Marc Brisson: 2. HPV-FRAME and general guidelines for good modelling practice: How do the two relate?

Background/Objectives: HPV-FRAME will be a quality framework which will enable a set of standards that ensure models of HPV prevention contribute to an optimal decision-making process.

Methods: As background to the specific discussion of HPV models to occur in this session, this talk will 'set the scene' via discussion of the general principles of good modelling practice as articulated in the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines for good modelling practice, which include general principles for model calibration, validation and uncertainty and sensitivity analysis.

Conclusion: HPV-FRAME will supplement general principles of good modelling practice as articulated by ISPOR, via the provision of specific guidance on issues of relevance in HPV modelling.

Mark Jit: 3. Presentation of draft framework: General principles for models of universal HPV vaccination in females and/or males

Background/Objectives: Thirteen years have passed since the publication of the first models of HPV vaccination. Since then around a hundred economic models of HPV vaccination have been published, along with many models presenting epidemiological but not economic outcomes. An array of methodological options are available to model HPV vaccination and several best practice guidelines have been published, but are still not well known or adhered to.

Methods: Previous frameworks and guidelines for modelling of HPV vaccination were reviewed. A comprehensive set of reporting requirements were drafted with input from other members of the HPV-FRAME consortium.

Results and conclusion: The draft HPV-FRAME reporting requirements for parameters, calibration targets and validation outputs for both female-only and gender-neutral models of universal HPV vaccination will be presented. There will be the opportunity to give feedback both during the session and afterwards, to be taken into account in future iterations of the draft framework.

Mark Jit: 4. Presentation of draft framework: Additional issues for models of targeted HPV vaccination in MSM

Background/Objective: Men who have sex with men (MSM) have a disproportionately high burden of HPV-related diseases but obtain little indirect benefit from female-only vaccination. Older MSM also do not receive much benefit from male vaccination programmes targeting younger adolescents. Hence targeted HPV vaccination for men who have sex with men is an option that has been implemented in several countries alongside either female-only or gender-neutral programmes. However, the feasibility and cost-effectiveness of such a programme is a key consideration for countries.

Methods: The draft reporting requirements for models of HPV vaccination were extended to targeted MSM programmes with input from other members of the HPV-FRAME consortium.

Results and conclusion: The additional draft HPV-FRAME reporting requirements for parameters, calibration targets and validation outputs for models of targeted vaccination in MSM will be presented. There will be the opportunity to give feedback both during the session and afterwards, to be taken into account in future iterations of the draft framework.

Jane Kim: 5. Presentation of draft framework: Models of alternative vaccine types and reduced-dose schedules.

Background/Objective: As part of the Framework for Modeling HPV Prevention (HPV-FRAME) consortium, general principles for models of universal HPV vaccination in females and/or males will be presented. This talk will present the additional draft HPV-FRAME reporting requirements for parameters for comparative evaluations of different vaccine types and/or reduced dose schedules.

Methods: We identified distinct parameters that are critical to specify in comparative model-based analyses of alternative vaccines including the differential levels of vaccine cross-protection (i.e., level and duration of protection against specific types), cost (per dose) and total cost per vaccinated girl for each vaccine, assumptions regarding type replacement in the model, and any assumptions regarding differential uptake and/or availability of the vaccines. For alternative dosing schedules, important specifications include efficacy and duration of protection against specific types, assumed schedule between more than 1 dose, target age groups for reduced dose schedule, cost (per dose) and total cost per vaccinated girl for 1-dose or 2-dose schedules, assumptions regarding cross-protection for less than three doses, and assumptions regarding differential uptake and scale-up for policies involving different dosage schedules.

Conclusion: Clear and consistent reporting of inputs and assumptions in evaluations comparing different HPV vaccines and alternate vaccine dosing schedules are critical for interpreting results, assessing quality of analyses, and facilitating comparisons across studies.

Shalini Kulasingam: 6. Presentation of draft framework: General principles for models of cervical screening

Background/Objective: HPV-FRAME will provide reporting requirements for HPV modelling studies. This talk will present the general principles for models used for evaluations of cervical screening

Method: We will be summarizing key issues that need to be considered for modeling screening including age, interval, test combinations, options for triage, treatment and incorporating costs and utilities to quantify benefits and harms of screening.

Conclusion: Considerations in regards to alternate age ranges and intervals as well as new technologies in screening will be essential in modelling evaluations of cervical screening in the future.

Johannes Berkof: 7. HPV Frame presentation of draft framework: Models of integrated cervical screening and vaccination approaches

Background / Objectives: Cost-effectiveness modelling is essential to support decision making relating to screening in vaccinated populations. HPV-FRAME will provide reporting requirements for HPV modelling studies.

Methods: Additions to the HPV FRAME reporting requirements for screening in vaccinated populations will be presented. Key issues are data sources presently used for integrated vaccination-screening strategies (randomized screening trials in vaccinated women, screening trials and cohort studies with HPV genotyping, and screening and vaccination registries), calibration targets, screening of cohorts offered first or second generation vaccines, vaccination and screening uptake, and risk based screening.

Conclusion: In the coming years, vaccinated women will become screen-eligible and a timely cost effectiveness assessment is important when preparing an integrated vaccination-and-screening programme. An itemized reporting checklist for modelling studies will provide guidance and support good modelling practice.

Karen Canfell: 8. Presentation of draft framework: HPV-FASTER evaluations

Background/Objective: As part of the Framework for Modeling HPV Prevention (HPV-FRAME) consortium, general principles for models of HPV vaccination and for integrated models of vaccination and cervical screening will be presented. This talk will present the additional draft HPV-FRAME reporting requirements for parameters for evaluations of 'HPV-FASTER' strategies which are broadly defined as including HPV vaccination in older women and/or men (>20-26 years) and/or combined vaccination/screening strategies where vaccination is performed in older women.

Methods: We identified distinct parameters and assumptions that are critical to specify in model-based analyses of vaccination with or without screening in women and men aged over 20-26 years. In addition to the general requirements for reporting on models of screening or integrated screening and vaccination strategies, modelling of 'HPV-FASTER' options should report assumptions on HPV exposure at older ages as well as the age-and type- specific assumptions about the probability of disease progression in individuals infected with HPV at older ages. The calibration and reporting on outputs for natural history models of disease at these relatively older ages will be a key focus. The role of threshold analysis on vaccine price will be discussed.

Conclusion: There is emerging interest in delivering HPV vaccination to older individuals, but this poses challenges for models since the population-level effectiveness and cost-effectiveness of such strategies depends not only on vaccine delivery methods and costs but also, critically on the modelling of HPV exposure (incidence) and persistence in older people. Given the probability of HPV exposure and/or progression is lower in older people than in unvaccinated adolescents, vaccination at older ages (at a given vaccine price) is less likely to be cost-effective than it is for pre-adolescents. Adequate reporting on modelling of the natural history of HPV infection in older individuals will enable assessment of quality of the analysis, and to facilitate comparison across studies.

Jane Kim: 9. Presentation of draft framework: Additional issues for models of HPV prevention in low and middle income countries

Background/Objective: As part of the Framework for Modeling HPV Prevention (HPV-FRAME) consortium, general principles for models of HPV vaccination and for models of cervical screening will be presented. This talk will present the additional draft HPV-FRAME reporting requirements for parameters for evaluations of HPV prevention in low- and middle-income countries (LMIC).

Methods: We identified distinct parameters and assumptions that are critical to specify in model-based analyses of vaccination and/or screening in LMIC. In addition to the general requirements for reporting on country- or setting-specific information on burden of infection and disease, analyses in LMIC should report assumptions of the feasibility of implementation and sustainability of screening or HPV Frame_ EUROGIN 2016 Abstracts 15th April 2016

vaccination programs, as well as the data that inform these assumptions. This includes scenarios of current "status quo" practice (e.g., existing immunization programs and existing screening programs), as well as specification of additional constraints that may inhibit implementation and scale-up of intervention(s). Analyses of vaccination should report on the assumed vaccine target population(s) and corresponding delivery mechanism. Budget or cost- effectiveness evaluations should specify currency (and year) for costs, as well as the method of cost inflation and/or conversion, for example, using purchasing power parity index for comparisons across settings and assumptions of tradeable versus non-tradeable goods. The willingness to pay threshold for a particular country should be clearly specified and justified.

Conclusion: Analyses in the context of LMIC should be held to the same reporting standard as those for high- income countries (specified in the general principles for models of HPV vaccination and cervical screening). In addition, there are inputs that are unique to analyses in LMIC that are also important to disclose to ensure proper interpretation of results, to enable assessment of quality of the analysis, and to facilitate comparison across other studies.