

GETTING RESEARCH INTO POLICY: INCLUDING HSV-2 TREATMENT IN WHO GUD MANAGEMENT GUIDELINES AND THE CASE OF GHANA

Burris H¹, Adu-Sarkodie Y², Parkhurst J¹, Opoku BK², Mayaud P¹

¹ London School of Hygiene & Tropical Medicine, London, UK ² School of Medical Sciences, Kwame Nkrumah University of Sciences & Technology, Kumasi, Ghana

Research Aim, Rationale and Design

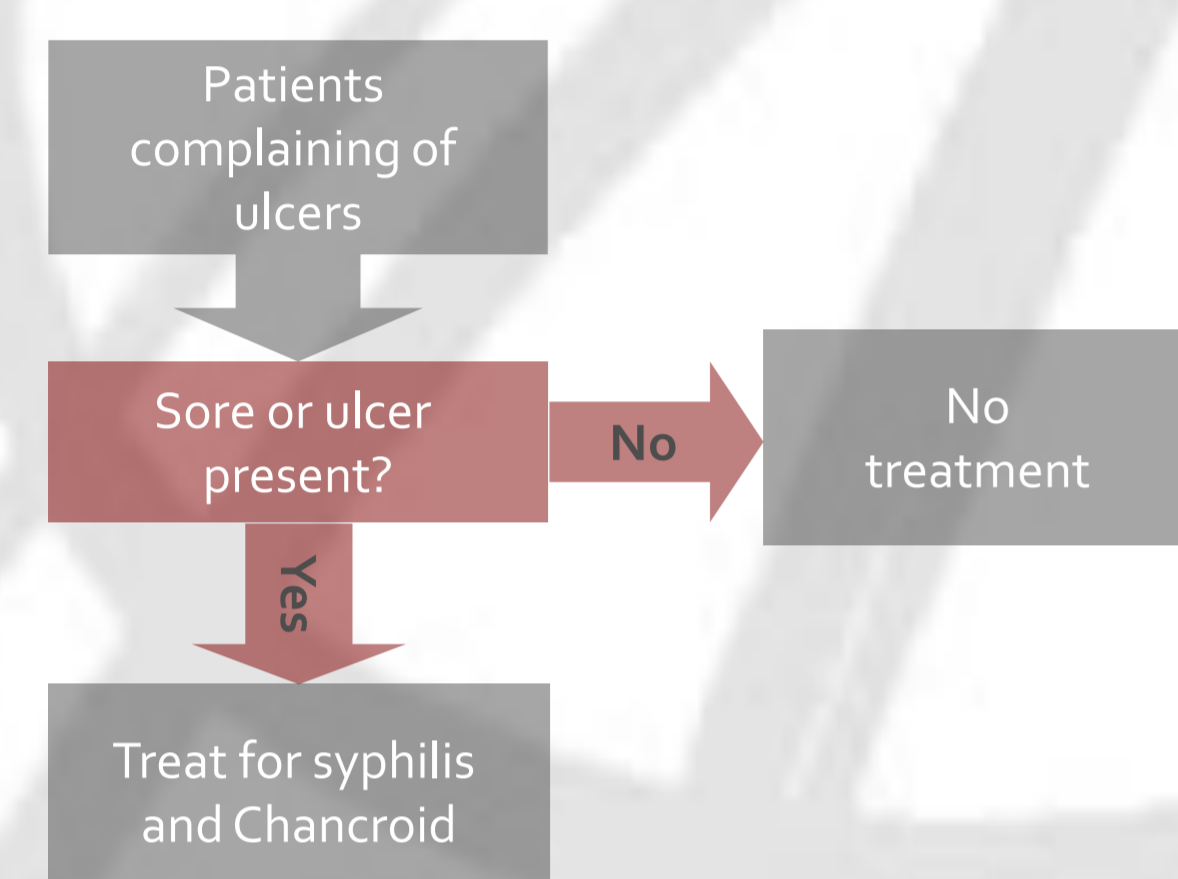
Aim: to evaluate the process of incorporating evidence from international or national research into international and national policies/guidelines.
Rationale: From a DFID-funded Research Programme Consortium (RPC) perspective, it is important to understand how research influences policy and the adoption of best practices at the international and national levels at which.
Design: case study to illustrate and understand how these processes occur.
We chose the development of international and national (Ghana) guidelines for the management of genital ulcer disease (GUD) and the incorporation of Herpes simplex virus (HSV) treatment, for which primary evidence had been generated by the RPC, in particular by conducting a trial in Ghana.

Research Methods

In-depth interviews in Montreux, Switzerland (April 08) with international researchers, national and regional STI programme managers, and WHO/Reproductive Health Research Division staff (n=11)
In-depth interviews in Accra, Ghana (July 08) with high-level sexual health government officials, policy-makers, leaders in HIV and reproductive health non-profit community, prominent researchers, and practitioners (n=8)
Analysis using **Research to Practice theoretical frameworks**

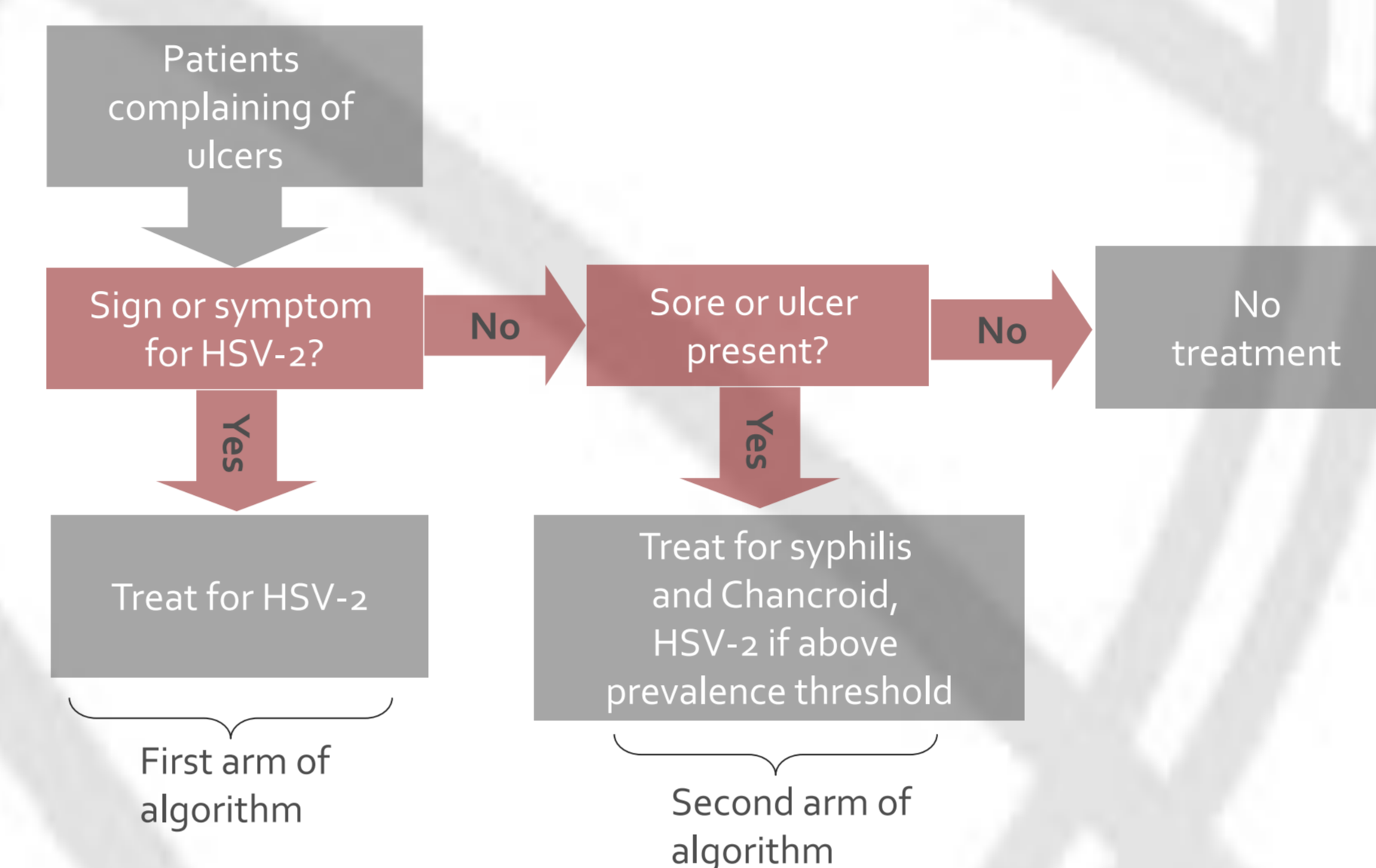
1 A short history of WHO GUD algorithms, HSV-2 treatment policy and the reluctance to treat for HSV-2 in resource-poor settings

1994 WHO GUD algorithm



Pictures courtesy of D. Mabey

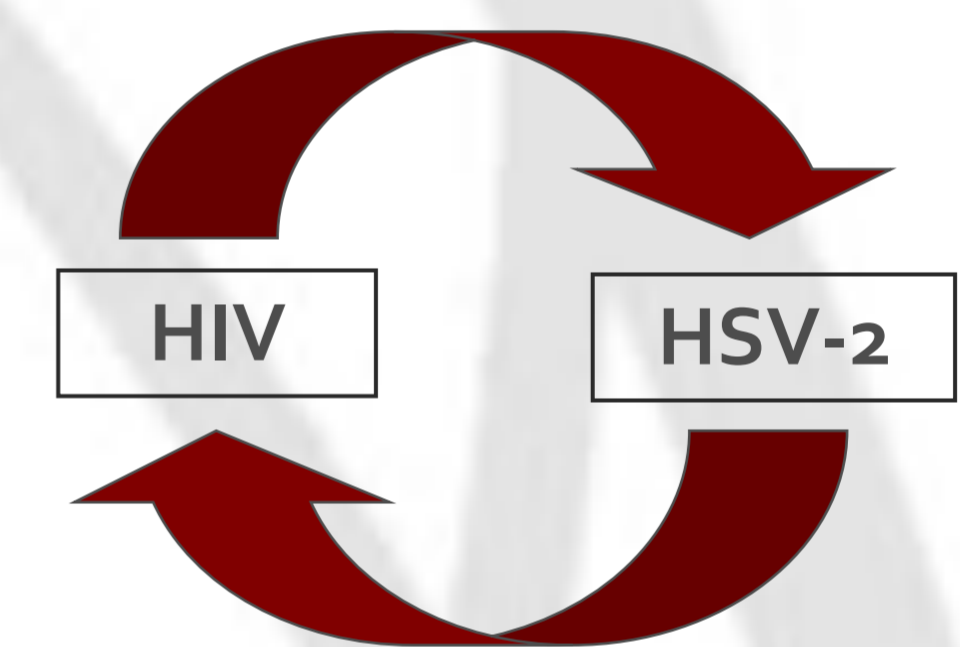
2003 WHO GUD algorithm



- Prevalence threshold in 2003 algorithm: >30% of GUD due to HSV-2
- Threshold criticized as many countries do not have this data and so it provides a loophole not to provide HSV-2 treatment or include it on the national essential drugs list
- HSV-2 not necessarily distinguishable from other types of genital ulcers, particularly in HIV+ individuals
- Reluctance to treat HSV-2 as it is a self-limiting disease (in HIV-), the drugs are suppressive but do not kill the virus, lack of awareness among providers, outbreaks are typically recurrent, lack of access to drugs, drugs were cost-prohibitive (now off-patent)

2 Synergy between HIV and HSV-2

- Bi-directional epidemiological, clinical and biological synergy between HIV and HSV-2: HSV-2 appears to increase both the susceptibility to HIV (*acquisition*) and in HIV and HSV-2 co-infected individuals, their infectivity (and therefore *transmission*) (Diagram).
- In 2001, WHO, UNAIDS and international researchers defined an international research agenda and recommended that trials be conducted to explore the impact of HSV-2 treatment as both episodic therapy (short term, when patients present with ulcers) and suppressive therapy (daily) in terms of HIV acquisition, HIV infectivity (viral shedding), HIV transmission (in sero-discordant couples) and HIV disease progression.
- Results of completed trials, biological, modelling and economic analyses were presented at a WHO/RHR/STI Meeting in Montreux, April 2008.
- The research demonstrated the lack of impact of HSV suppressive therapy in preventing HIV acquisition, that HSV suppressive therapy could reduce infectivity (viral shedding and plasma viral load) in dually infected people, although the impact on HIV transmission in sero-discordant couples was still awaited. HSV episodic therapy incorporated in GUD algorithms had modest impact on healing rates but some impact on HIV viral shedding in lesions and the sperm of infected men, but not in cervical secretions of HIV in women.
- Despite somewhat disappointing results, the recommendation was made to modify the WHO GUD management guidelines to include anti-herpetic therapy based on HSV prevalence data collected during the trials, some clinical benefits, and a potentially favourable cost-benefit profile.



Effect of HIV on HSV-2

- High HIV/HSV co-infection rate (up to 90%)
- ↑ duration and severity of lesions particularly in IS
- ↑ frequency of HSV-2 shedding

Effect of HSV-2 on HIV

- HSV-2 ↑ HIV acquisition 2-4 fold
- HSV-2 ↑ HIV levels in plasma & genital tract
- GUD ↑ HIV transmission 3-4 fold

3 Research Findings

Influencing international policy: the WHO and GUD treatment guidelines

A **policy window** is necessary for attracting attention to an otherwise marginalized cause. The observance of a synergy between HIV and HSV-2 and the international attention and donor focus on HIV served to push HSV-2 on to the international stage.

“**Two-worlds**” between researchers and policy makers/ program managers. Each group wanted something different out of the research findings: program managers were looking to the scientists for evidence to be used as an advocacy tool, policy-makers were hoping to find a sound reason to change policy. Researchers were interested in the significance of the trials and the implications for further studies – a favourable policy climate would positively influence the research agenda. Policy change was made possible, however, through involvement of all groups throughout the process and a common desire to change the then current policy (in this case based on quality-of-life and right-to-treatment arguments).

Intellectual clubs were instrumental in bringing policy-makers and researchers together to set the research agenda, the same researchers then carried out much of the research, and then program managers, who were connected to the research through affiliation with the WHO/RHR joined the other two parties in formulating policy after the outcome of the trial.

Mechanisms of getting research into policy in Ghana:

Donor pressure in the form of requirements for funding eligibility is the single strongest impetus for policy change. Donors have a lot of power in Ghana in terms of shaping research agendas, programming decisions, and policy, as they provide the vast majority of resources for these functions.

A **champion of the cause**, either placed directly within the Ministry of Health or the National HIV/STI Control Program, makes a strong case for the change. This mechanism is particularly effective for getting operational research into policy. To instigate change through this mechanism, there are conditions. The policy change must (a) save money in the long run, (b) be highly visible and good for public relations, (c) be beneficial to the population at no extra cost, (d) extra costs are covered by donor agencies, and/or (e) have the potential to attract additional donor funding.

Intellectual clubs of researchers, practitioners and government officials include key individuals able to influence policy. These individuals will then act to reform policy based on clear pressure from within the group and in order to maintain the respect of the group. Within these communities often a single champion of a cause carries the issue and generates the pressure, however, this is not necessarily always the case.

4 Recommendations for getting Research into Policy

International Level - WHO

- Researchers should continue work with policy-makers throughout the research process (from defining agenda to dissemination) to bridge the “two-worlds”
- Identify “intellectual clubs” and work with their natural leaders
- Respond to identified needs and emerging agendas to best utilize windows of opportunity

National Level – Ghana

- Engage donors in research findings
- Identify key individuals within the Ghanaian government and involve them throughout
- Identify “intellectual clubs” and work with their natural leaders
- Clearly outline and communicate the policy-reform implications of any new research