

HIV Care Cascade Modelling Workshop Novotel Paddington, London, UK 22 - 23 September 2014

Summary Meeting Report

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The HIV Modelling Consortium

The HIV Modelling Consortium aims to improve scientific support for decision making through the coordination of a wide-range of research activities in mathematical modelling of the HIV epidemic. This project is currently funded by the Bill & Melinda Gates Foundation through a grant to Imperial College London.

The Consortium's key objectives are to:

- 1. Identify questions that demand mathematical modelling input and identifying new modelling results that may require further validation.
- 2. Facilitate sharing of information; modelling techniques, data and expertise between research groups.
- 3. Provide a forum for rigorous review of new mathematical modelling research and tools.
- 4. Provide funding through sub-contracts to commission research to address those needs.

A Steering Committee of leaders in HIV programme and policy directs the focus of the work of the consortium. Further information on the HIV Modelling Consortium is available in a standard briefing document and information about other work packages undertaken by the HIV Modelling Consortium is available at the website www.hivmodelling.org.

Background: Why model the HIV care cascade?

Over the past decade there has been rapid scale up in provision of anti-retroviral treatment for the management of HIV in sub-Saharan Africa. Despite these efforts there are still high numbers of AIDS related deaths occurring. The pathway of care from testing through to successful virologic suppression is complex and numerous barriers exist that may prevent optimal care being received in real world programmes. Until now little modelling work had been conducted on the continuum of care and this meeting provided an opportunity for those working in the field to discuss progress, limitations and consider future approaches. A meeting was convened with the following aims and anticipated outcomes:

Meeting Aims

- (1) Review current cascade models; what questions are being addressed and what are the gaps?
- (2) Examine results from current cascade models
- (3) Consider how such models could support future decision-making

Outcomes

(1) Shared knowledge and aligned objectives for future research into the cascade of HIV care.

Meeting Summary: Monday 22 – Tuesday 23 September 2014, London, UK Session 1: Aiming for optimal impact with HIV care programmes

Geoff Garnett began the presentations on day one with a summary of the questions posed by the Steering Committee and the Bill and Melinda Gates Foundation, which he found to be closely interlinked. He added that, while expansion of treatment over the last decade has been profound, there are questions about how well programmes are performing on the ground.

He highlighted four key questions currently being considered by the Bill and Melinda Gates Foundation (BMGF) with regard to real world programmes:

- 1. How many people are dying due to HIV?
 - a. Are these estimates or direct measurements? If they are estimates how certain are we?
- 2. Which people or population groups are dying?
 - a. Have those that have died had much engagement with he healthcare system or very little? Are there systematic differences in the profiles of those that are dying?
- 3. What is the impact of ART?
 - a. How has the uptake of ART influenced the two points above? Hoe many people are actually on treatment and virologically suppressed?

He added that to date much focus has been on the clinical aetiology of AIDS deaths rather than the system failure for the death, which should be given greater importance. The BMGF convened a meeting in June 2014 with a number of different programme implementers to review data on real world effectiveness of programmes. It is apparent that the data from the clinic indicate that patients are performing well, but that another population of infected individuals exist in the community who are not engaging with care and who are not doing well that we need to better understand in order to get them into care. The reasons that individuals remain unengaged with care are complex and many (e.g. individuals being diagnosed early are asymptomatic and do not present to care until they feel very sick), and vary in different settings.

Data from studies e.g. DHS show that many individuals remain undiagnosed and do not know their status, whereas other programmes indicate that people are aware of their status, but have not linked to care. In addition, some programmes appear to show that many people are lost from care, whereas new data from Elvin Geng indicates that many people are not lost from care, but instead transfer to other clinics. Therefore big issues remain in keeping track of where individuals are in the care system. There was also discussion about the technical efficiency of pre-ART care; if pre-ART care is currently not providing much value relative to what it costs then an option would be to remove pre-ART care and initiate patients onto treatment, however, an alternate option would be to design pre-ART care so that it can be delivered more efficiently (either through lowering costs, examining how it can provide more health gain or both). Considering the former without the latter perhaps risks being selective about chosen alternatives

Session 2: Testing modalities and linkage in the HIV

Roger Ying presented a summary of a systematic Cochrane review that is being conducted to assess different HIV testing strategies with regard to the epidemic setting and population usually targeted by each modality, the number of positive individuals identified, the proportion that are linked to care or prevention and estimated costs. The primary search identified over 1,428 abstracts, which has been refined further refined. Initial results demonstrate that testing modalities vary in effectiveness in different regions or populations (i.e. urban vs. rural, or male vs. female, or first test vs. repeat test), have differing estimates for onward linkage to care, and the proportion of HIV+ve individuals identified. The findings support targeted testing approaches for specific population groups and has identified testing strategies that are in need of improved linkage. Some of the testing methods are conducive to repeat testing and this should be looked for in the literature if it is not already being considered in the study. It was further noted that increasing testing in child malnutrition wards may be another useful entry point in many settings as many children are HIV+ve and it could be a useful way of tracing HIV+ve parents.

The research group are also developing a model of HIV transmission in KwaZulu-Natal that will be used to evaluate cost-effectiveness and impact of different testing modalities (clinic HTC, mobile HTC with higher uptake among males, home HTC with higher uptake among females, mobile and home HTC). Preliminary results suggest that strategies to increase HTC for males (e.g. via mobile HTC) would result in the greatest number of infections averted, but that strategies to increase HTC for females would result in the greatest OALYs.

Session 3: Why are AIDS deaths occurring in the ART era? Review of cascade model results Summary of model presentations

In total six modelling groups presented their work on the cascade of care for HIV. Four modelling groups took a broadly similar approach looking at where losses occur along the cascade, what interventions could be effective to reduce these losses and whether the strategies were likely to be cost-effective. Another two modelling groups took slightly different approaches; one model reviewed possible biases that could occur when not considering the losses occur across treatment programmes and another looking at incidence measurement in America. The details of all six models are listed in the table on the following pages.

	Research question	Model details	Data utilised	Cascade interventions modelled	Outcomes modelled	Key results / conclusions
Eran Bendavid	1.How can epidemiological information about patient flow be represented in an epidemiological model of HIV care in Rwanda? 2.What is the comparative effectiveness of strategies to improve HIV care and reduce patient loss? 3.What is the cost-effectiveness of these strategies?	Rwanda's HIV epidemic. Infection is determined by		In total 10 different scenarios were modelled: 1. Status quo 2: HIV testing to 100% 3: Immediate treatment 4: Linkage to 100% 5: Leakage to 0% 6: LTFU to 0% 7: 2 + 3 8: 2 + 3 + 4 9: 2 + 3 + 4 + 5 10: 2 + 3 + 4 + 5 + 6	on HIV prevalence, HIV incidence and cost	Immediate ART initiation is the most effective strategy for incidence reduction and life years gained.
Valentina Cambiano, Paul Revill, Silvia Bertagnolio, Michael Jordan, Jens Lundgren, Alec Miners, Deenan Pillay, Francois Venter, Andrew Phillip	1. To evaluate the impact and cost-effectiveness of various potential improvements in the cascade of care and changes to the ART eligibility threshold.	Individual based stochastic simulation model.	Data obtained from literature reviews.	In total 20 different scenarios were modelled: (i) provide treatment at CD4 500, rather than CD4 350 (ii) provide treatment immediately (iii) increase testing (iv) increase linkage to care in first year after diagnosis (v) increase % retained in pre-ART care (vi) increase % retained in ART care (vii) reduce median time to switch second line), 12 combinations		Over a 20-year time horizon the single change that would have the greatest health gains and reduction in mortality is increasing retention on ART (from 85% to 92% at 1 year following initiation). Whereas modifying the eligibility criteria to all people diagnosed with HIV had the greatest reduction in HIV incidence over the same time period. Broadly, strengthening the cascade is expected to offer larger health gains relative to

				of improvements and one reference case.	implementation initiatives to be cost- effective at different CETs	costs than increasing ART eligibility criteria and should first be prioritized.
Dan Klein, Anna Bershteyn	1. What are the drivers of morbidity and mortality in the current system? 2. How important are uncertainties in the care cascade, e.g. dropout and reenrollment? 3. What potential impact could cascadetargeted interventions have?	Individual-based stochastic network model, calibrated to South Africa. Importantly, the model includes a mechanistic care cascade that takes individuals from testing (via VTC, ANC, symptomatic presentation, partner, and child) through staging and linking to ART. Loss to follow-up is modelled throughout the cascade.	Model parameterized using publically available data, see our prior publications. Cascade-drivers of mortality from KZN, RSA calibrated to results presented by T. Barnighausen at CROI '14. CD4 at ART enrollment from various sources, specifically including 2013 Health Indicators Update: Antiretroviral Indicators, a RSA DoH report based on DHIS data.	Map cascade uncertainties and intervention assumptions to potential impact for improving: • Community-based testing • Linkage, e.g. using PoC CD4 • Pre-ART retention • Monitoring and adherence, e.g. using PoC VL • Second line ART retention and return to care	mode of the treatment cascade, age, gender, and year. Specific failure modes were lumped into four main categories: Never in care, Late initiation, Lost from care, and Treatment failure.	is uncertain, rapidly- changing, and spatially heterogeneous. Our current understanding is that a majority of the HIV- related deaths occur amongst individual who do not know their status or have never been staged. The second largest aetiology of mortality is late presentation. The intuitive "best" intervention is outreach, however this would lead to increased losses later in the cascade, and costs would increase. Care tiering, e.g. using DBS technology, and community decentralization should be implemented with outreach.
Jack Olney, Jeff Eaton, Tim Hallett	1. Where are losses occurring in ART-programmes in western Kenya resulting in suboptimal treatment outcomes for patients?	An individual-based microsimulation model, calibrated to Kenya. HIV-negative individuals in western Kenya from 1970 to 2030. Infection through exposure to annual hazard of acquiring HIV. Experience of HIV-positive individuals as	Patient data from the AMPATH Partnership from Port Victoria in Bunyala District in Busia County in Western Province in Kenya. Data from the literature was used to calibrate the Natural	12 individual interventions, where possible these include 'maximum impact' and a 'realistic' impact scenarios: Testing interventions - HBCT and increased VCT	DALYs averted and cost between 2010 and 2030 Care experience among HIV-related deaths between 2010 and 2030	Model results indicate there are areas of improvement in both pre-ART and ART care. Notably large scale universal test and treat interventions would have a large impact on averting disability adjusted life-years;

	2. What interventions or combination of interventions have the biggest impact? 3. Which provides the best value for money?	they move through an ART- programme in western Kenya.	History Model (specifying HIV progression and associated mortality before and after ART initiation). Data to calibrate the events that make up the cascade of care was sourced entirely from AMPATH.	Linkage interventions - HBCT with POC and facilitated linkage pre-ART outreach, improved care, VCT POC, POC, on-ART outreach, adherence programmes, immediate ART, universal test and treat.		however, a combination of multiple smaller-scale interventions may be able to produce a similar impact to UTT, but with a lower ICER.
Joshua Salomon	a high-burden / high- treatment setting including	Two models - a 'cascade' cohort model that tracks people as they progress through stages as well as tracking people as they move in and out of the cascade and a second 'naive' cohort model nested within that is simpler and does not capture the intermediate stages along the cascade, but does capture people becoming eligible.	Linked dataset from Africa Centre Demographic Information System and HIV treatment and care information system.	Focus is on status quo progression through the cascade in empirical program data. Bias estimated in comparative analysis of treatment policies comprising different CD4-based eligibility criteria.	advancing to each stage in cascade in presence of competing risk of death. Primary outcomes examined are overall survival and transmission. Bias expressed as relative measure of incremental	Estimated bias from naive model in the incremental benefits of changing eligibility from CD4 200 to CD4 350 is on the order of a factor of 3-4. Estimated bias for changing eligibility from 350 to 500 is on the order of a factor of 7-8. Much of the knowledge about the HIV care cascade is cross-sectional, and there is high value in adding a longitudinal understanding. Useful to integrate (1) descriptive epidemiology of the care cascade, with (2) implementation research on interventions along the cascade and (3) economic evaluation of overall HIV control strategies
Kimberly Powers, Kate Orroth,	1. Describe the current state of the cascade in North Carolina and	Deterministic model of HIV transmission and HIV cascade in North Carolina	Numerous surveillance, clinical, and programmatic data sources.	Increased uptake of: - ART among those in HIV care; - Care among HIV-	HIV incidence, aggregate viral load measures, and relationships between	TBC - model in development stages.

William	identify key pressure		diagnosed;	incidence and viral load	
Miller,	points for		- Testing among HIV-	measures under	
Jeffrey	intervention.		infected.	different intervention	
Eaton,	2. Predict the impact		These cascade-based	and risk behaviour	
Christophe	of increased testing,		interventions will be	scenarios	
Fraser	care, and treatment		modelled against		
	uptake on HIV		different backgrounds		
	incidence.		related to:		
	3. Assess the		TasP effects on		
	performance of		behaviour:		
	aggregate viral load		- None,↑risk (risk		
	metrics as:		compensation), ↓ risk		
	a. predictors of HIV		(counselling); and		
	incidence; and		Coinciding effects on		
	b. markers of		behaviour from other		
	"treatment as		forces:		
	prevention" (TasP)		- None,↑risk		
	impact.		behaviour,↓risk		
			behaviour		

The group discussed the results from the four models that are investigating mortality along the cascade in sub-Saharan African settings and thought that there was a level of qualitative agreement amongst the work presented with regard to general patterns of care and where patients tend to be lost. The results were also viewed alongside data from programmes that also seemed to depict a similar story. However, it was very clear that results from each region and programme did differ and the reasons behind these variations may not be similar as a consequence of numerous contextual factors that should be taken into consideration. For example, there could be broad qualitative differences in the reasons that patients disengage from care in one clinic setting may be very different to why patients disengage in another. It was agreed that there is a need to better understand who is truly disengaged from care, for how long (and how long is true disengagement considered in each setting) or whether individuals are actually transferring to another clinic. There are clear policy implications if it is perceived that a large number of patients are dropping out and disengaging from care, but in reality many are simply moving clinics, but are not being traced. Further to this better longitudinal data about the amount of time that patients are spending in different parts of the cascade is very important. The models generally agreed that the uncertainty in and incomplete understanding of patient flow through the care continuum have large policy implications, and that the value of reducing these uncertainties is potentially large.

The group discussed the use of cost-effectiveness analysis in modelling studies and agreed that more needed to be done to ensure figures reported were more representative of what is occurring in real programmes. In order to do this more data from programmes on cost and retention would be valuable and that the move by PEPFAR to make such costs available in the future was welcomed. The group discussed whether the current costs estimated by the models are likely to be underestimates. There was general agreement that the figures reported might be an underestimate of the overall cost, as the models may not reflect the full resources required when delivering programmes or alternative strategies. In particular it was noted that the models tended to focus on the marginal costs at a patient level and generally did not incorporate 'programme/system level' costs. The key issue here is whether and how these system/programme level costs are likely to differ across evaluated alternatives – to the extent that they are fixed across alternatives they would simply 'net out' and so would not necessarily need to be incorporated. It was suggested that it might be reasonable to assume that introducing something new would likely lead to greater programme/system costs than 'continuing as usual' and that there should be particular caution when new interventions or approaches are suggested.

Session 4: Health economic considerations for cascade modelling

(1) HTC modalities: Systematic review of costs

Monisha Sharma provided an update on progress of a systematic review of costs of different testing modalities in sub-Saharan Africa. Preliminary results indicate that there are a number of factors that influence the cost of testing: number of persons tested, HIV prevalence, location (urban/rural), or costing strategy. One crucial point was that the costs varied greatly dependent on the point in the programme that was being investigated (i.e. year 1 or year 2), but that further to this there was also great variation within a 12 month period particularly during the scale up period where first quarter costs tended to be much higher than later periods. Preliminary investigations in an additional line of work evaluating the costs of home and mobile HTC in South Africa and Uganda was also presented. This is ongoing and is due to be completed later in 2014.

(2) Determining value from healthcare delivery systems

Paul Revill and Simon Walker provided the group with a number of factors that should always be considered when trying to evaluate the cost-effectiveness of interventions along the HIV care cascade. Crucially it is important to realise that the cost or cost effectiveness of each intervention will vary greatly between settings and that it is crucial to consider the cost of any health foregone that might occur as a consequence of reallocating resources in order to adopt new strategies. The cost-effectiveness of cascade strengthening interventions depends upon the costs and effects of downstream interventions. They provided real world examples to illustrate these effects.

Session 5: Roundtable discussion on the role of cascade models in decision-making

(1) What are the gaps and limitations of current HIV care cascade models?

The groups were in agreement that there have been some complexities and issues around parameterisation, conducting uncertainty analyses, and validation. While different approaches have been taken, with Andrew Phillips (and Dan Klein, to some extent) utilising data from literature reviews and Jack Olney and Eran Bendavid using specific data sets, neither approach has been simple. Further to this, it has not been simple for the models to conduct a formal uncertainty analysis, as it would be time consuming due to the complexity of each of the models used. Validating the model results has been difficult (in particular inability to validate models to data on diagnosis/ART status at death was noted) and there is a need to go further to validate these models. All model results presented were individual based models and no results are yet available from a simple deterministic compartment model, which may be able to include uncertainty bounds. Consensus was not reached on whether a deterministic model or individual based model approach was more advantageous for responding to this question, but that they both have differing merits.

(2) Is model development limited by data availability and what additional data would be of use to improve modelling efforts?

There was much discussion amongst the group regarding limitations in current data, specifically in the sub-Saharan African countext. Specific mention was made of the lack of clear hospital and clinic mortality records. Another limitation that was noted was that much of the data available is from the clinic, which is likely to have very different health outcomes to the community where there may be a pool of individuals who are not engaging with care. It was added that many DSS sites and are often not linked to the sites within them which could perhaps be done relatively easily and help provide a solution in some areas. Value of information analyses could be used to identify which data would be most advantageous and should be prioritised.

Further to this the utility of unique identifiers was discussed in order to link patient data through the health system (i.e. from testing to the clinic and their experience from all the clinics they might attend) and follow their trajectories, whether this includes disengagement from care or clinic transfer. Additionally the need for a clear population census frame for where the data are arising would be very valuable for modelling. From an economic perspective there is much needed information on budget costing for real programmes, that expenditure data aligned with detailed costing studies would be really important to understand the cost of scaling and executing a programme.

(3) What are the considerations for inclusion of costs and health economics?

There was agreement that aiming for providing guidance in terms of cost-effectiveness thresholds (based upon the health gains offered through alternative investments – i.e. opportunity costs), but that two key caveats would need to be put forward: (i) limited cost data (ii) context-specific interventions and the need to model strategies rather than technologies.

Conclusions:

- 1. Avoid the use of high willingness to pay thresholds (i.e. 1x 2x GDP) and that a lower value of ~ 0.5 x GDP per capita would be more appropriate. Results can also be presented for a range of different thresholds (e.g. \$300, \$500, \$1000 etc.)
- 2. To aim for statements of the form: "it would be cost-effective to pay up to \$x for a certain outcome at a cost-effectiveness threshold of \$x"

(4) Do we want to formulate a new package of work that would support future decision-making?

The group agreed that a formal model comparison would not be appropriate for such a question, but that having multiple minds on the same question for a sustained period of time, using data from multiple sites may have great value. It was agreed that further to the modelling that was conducted for the 2013 WHO consolidated guidelines, more could be done regarding their implementation for programmes.

The group proposed the following approach to the WHO:

a) Collectively continue discussions with WHO regarding the guidelines.

- b) Jointly develop an integrative report, which sets into context the independent modelling work that has been completed and adds the caveats around that we think are important that come from the modelling directly or indirectly.
- c) Report will include, where necessary new modelling analyses that is responsive to the questions posed by the WHO, which is based on one model, but with the aim of using multiple data sets from different programmes so as to provide different case study examples.

Meeting Agenda

<u>Day 1 - Monday 22 September</u>

Time	Session	Speaker
09:00	Welcome coffee	-
09:30	Welcome and introduction	
	Overview of meeting schedule and aims	Tim Hallett
09:40	Session 1: Aiming for optimal impact with HIV care	
	programmes	
	Review and analysis of current programme knowledge	Geoff Garnett
	and direction taken so far.	
	The question posed by the Steering Committee and	
	direction of the Bill and Melinda Gates Foundation	
10:00	Session 2: Testing modalities and linkage in the HIV	
	care cascade	
	Findings from systematic review	Roger Ying
10:30	Coffee break	-
11:00	Session 3: Why are AIDS deaths occurring in the ART	
	era? Review of cascade model results* Discussion	
	chaired by Tim Hallett	
	Building Blocks: Barriers to Achieving Viral	Eran Bendavid
	Suppression in Rwanda (30 mins)	** 1
	How can the South African ART programme be	Valentina
	enhanced to cost-effectively deliver health gains? (30	Cambiano &
40.00	mins)	Andrew Phillips
12:00	Lunch	-
13:30	Session 3: Why are AIDS deaths occurring in the ART	
	era? Review of cascade model results* (continued)	
	Discussion chaired by Jeff Eaton	Dan Klein
	Cascade Drivers of Mortality: Findings from the IDM HIV Model (30 mins)	Dan Kieni
	 Evaluating Strategies to Improve HIV Care Outcomes in 	Jack Olney
	Western Kenya (30 mins)	Jack Onicy
	The HIV Cascade of Care and Evaluation of Treatment	Joshua Salomon
	Policies (30 mins)	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
	The HIV Cascade and Aggregate Viral Load Metrics in	Kim Powers
	North Carolina (15 mins)	
15:15	Coffee break	_
15:45	Collee Dieak	
	Session 4: Health economic considerations for cascade	
-	Session 4: Health economic considerations for cascade	
-	Session 4: Health economic considerations for cascade modeling. Discussion chaired by Joshua Salomon	Monisha Sharma
-	Session 4: Health economic considerations for cascade modeling. Discussion chaired by Joshua Salomon • HTC modalities: Systematic review of costs (15 mins)	Monisha Sharma Paul Revill & Simon
-	Session 4: Health economic considerations for cascade modeling. Discussion chaired by Joshua Salomon • HTC modalities: Systematic review of costs (15 mins)	
16:30	 Session 4: Health economic considerations for cascade modeling. Discussion chaired by Joshua Salomon HTC modalities: Systematic review of costs (15 mins) Determining value from healthcare delivery systems (30 mins) 	Paul Revill & Simon
	 Session 4: Health economic considerations for cascade modeling. Discussion chaired by Joshua Salomon HTC modalities: Systematic review of costs (15 mins) Determining value from healthcare delivery systems 	Paul Revill & Simon Walker

Day 2 - Tuesday 23 September

Time	Session	Speaker
09:00	Welcome coffee	-
09:30	Session 5: Roundtable discussion on the role of cascade	
	models in decision-making	
	 What are the gaps and what the limitations of the models? 	All
	 Are the models being responsive to the questions that are being asked about the cascade? 	
	What gaps are not being addressed?	
	 Are there limitations caused by data availability? 	
	 What data are available and are there more that 	
	need to be sought?	
11:00	Coffee break	-
11:30	Session 5: Roundtable discussion on the role of cascade	
	models in decision-making (continued)	
	 Do we want to formulate a new package of work that 	All
	would support future decision making?	
12:30	Closing remarks	Tim Hallett
12:30	Meeting close	-

*Guidance for presentations:

You will be aware that there are myriad questions being asked about HIV care cascade, which are of high priority to funders and implementers of HIV programmes. These include:

- Why are AIDS deaths occurring in the ART era?
- Do current HIV care programmes optimally deliver care?
- To the extent that they do not, what changes could be made to make programmes more impactful? We aim to share the work that modelling groups have been doing around these questions, recognising that

We aim to share the work that modelling groups have been doing around these questions, recognising that each group will have focused on different aspects of this topic. We are providing ample time for descriptions of the modelling work. Presentations should identify the research questions, data used, technical specification of the model, results, interpretation and planned next steps.

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