

Module 7

Prototype issues/response model for decision making in deployment of GM mosquitoes



Module 7, Prototype issues/response model for decision making in deployment of GM mosquitoes, is one of a series of modules produced by the MosqGuide Project to provide best practice guidance relating to the range of requirements for deployment of genetically modified (GM) mosquitoes to control mosquito-vectoring disease, specifically malaria and dengue.

Further information:

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Acknowledgements

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This Module is targeted at an audience of people who plan, finance and operate vector and disease control programmes, who are considering working with genetically modified (GM) vectors.

The objective of this Module is to produce a prototype model to facilitate direct benefit cost comparisons of alternative control measures for malaria, as an example application. This is the specification for such a model, which remains to be developed and validated in the field pending additional funding.

Rationale

The prototype model will offer a formalised and transparent method for comparing relative merits of costs and benefits, across a range of dimensions: units of area, persons protected, DALYs and cost per vector species controlled. No other publication was found to cover all three dimensions in this context. Different dimensions are needed for different planning purposes. A similar framework and dimensions could apply to decisions related to control of dengue or other human diseases vectored by mosquitoes.

Development of Module 7

This proposed structure for Module 7 was developed by Megan Quinlan, John Mumford, Adrian Leach, Jon Knight, Hans Dobson and Graham Matthews. The framework was discussed with the MosqGuide team. Comments were also received from researchers in the USA and UK and the following disease endemic countries: Colombia, Panama.

Send further comments to: mossguide@imperial.ac.uk.

The following specification is for a bio-economic model designed to compare the costs and benefits of various options for malaria control. National decision makers face cost considerations alongside the estimated health benefit of any intervention for disease control. A framework for decision making is particularly useful because of the diverse nature of the interventions and the likelihood that control programmes will use combined measures or an integrated approach to vector control.

This specification is for a bio-economic model to assess the potential economic impact of a genetic strategy employing GM mosquito releases for the control of malaria. This is presented in comparison with current and other novel management practices, over a period of time that shows the phased-in benefits as disease incidence is reduced and some measures become obsolete¹. The model captures the fact that a combination of measures would be necessary for the initial period of releases. The complexity of these interactions requires a scenario-based model, rather than a traditional cost-benefit analysis.

The model will integrate ecological dynamics of wild and released GM mosquitoes with the costs of monitoring, rearing and releasing GM mosquitoes, and would include demographically and epidemiologically derived estimates of benefits from disease prevention. This model is developed specifically for a genetic modification that leads to male-only progeny in *Anopheles gambiae*, thereby reducing the affected population. Many of the components would apply to other approaches to disease reduction through area-wide vector control.

1. The costs of control methods will be gathered from published literature (e.g. RBM, 2009), censuses, spatial data, surveys, expert opinion, or estimated from parallel technologies. The costs of current management activities such as insecticide treated nets (ITNs) and indoor residual spraying (IRS) can be captured from published sources (Binka *et al.*, 1997; Goodman and Mills, 1999; Kroeger *et al.*, 2002; Conteh *et al.*, 2004; Yukich *et al.*, 2007; RBM, 2009; see Appendices 1 and 2). Some estimates of the cost and effectiveness of malaria vaccines are already available (Bojang *et al.*, 2001; Alonso *et al.*, 2004; Smith *et al.*, 2006; Tediosi *et al.*, 2006; Tediosi *et al.*, 2009).
2. Once collated, the cost of malarial controls can be expressed in different ways. The Disability Adjusted Life Year (DALY) is a WHO method for estimating the impact of diseases on human health (Murray and Lopez, 1996). Benefits from novel interventions can be measured by the reduction in DALYs for a specified population (Fox-Rushby and Hanson, 2001; Stein *et al.*, 2005). In the literature cost\benefit metrics have been expressed in a number of different ways².

¹ Current measures become obsolete due to eradication but also may become less effective over time due to mosquito resistance to insecticides and malaria resistance to pharmaceuticals.

² per person protected per year; per household treated per year; per case prevented; per death prevented; per year of additional life; subjective assessments of well-being; vector population reduction; per reduction in malaria incidence; sporozoite rates; anaemia; disability adjusted life year (DALY) prevented (morbidity and

3. While it may be appropriate to assess effectiveness in terms of number of cases of malaria or morbidity/death averted, the reality is that the cost to implement the intervention on an area-wide basis varies with the number of people within an area, the population of mosquitoes and the incidence of malaria within that population. In addition, the period over which protection will be required will vary from the whole year to a few months each year depending on rainfall patterns and corresponding epidemiology of the disease. To provide a more complete picture of economic impact of different management measures, costs will be expressed in four different ways:
 - costs per person protected in the project area per year;
 - cost per unit area per year;
 - cost per incidence\morbidity\mortality prevented per year, e.g. DALYs;
 - cost per vector species controlled per year.
4. Cost effectiveness of novel measures (GM mosquitoes and immunization) from spatio-temporal estimates will be compared against those for current malaria control methods in a given project area i.e. the cost effectiveness of *status quo* malaria management activities (combinations of ITNs, anti-malarial drugs, IRS, fogging *etc.*) will be compared against cost effectiveness attributed to releases of genetically modified (GM) mosquitoes and similarly for immunization.
5. While some current vector control methods offer protection from multiple species (ITNs, IRS), eradicating malaria from an area using GM mosquito releases against the primary vector may still require the suppression / eradication of other vector species. When conditions indicate the need for control of additional species, the total cost of all species will be calculated.
6. Inputs such as the price of GM mosquitoes and the cost of building bio-factories can be reasonably extrapolated from projects in which bio-factories have already produced large numbers of insects for use in sterile insect technique (SIT) projects (Quinlan *et al.*, 2008; see Appendix 3).
7. Anticipating the costs of hypothetical GM mosquito release is difficult due to the novelty of the approach and lack of practical experience. In particular, issues relating to spatial aspects of releases, mosquito behaviour, the number of GM mosquitoes required and project duration are more uncertain. Spatially-explicit, stochastic simulation models will be developed to predict the spread, behaviour and interaction of released GM mosquitoes with the wild population.
8. Factors affecting costs will be diverse including biotic, abiotic and anthropogenic issues such as wild mosquito density, heterogeneity of the wild population's distribution, necessary over-

mortality combined); years of life lost (YLL); years lived with disability (YLD); indoor resting density; biting rates; malaria incidence.

flooding ratios and the speed with which benefits are desired. The latter will determine the number and size of concurrent and/or phased release programmes, which are also governed by political considerations that add to uncertainty.

9. The closest analogue to this type of GM vector release is the use of SIT in area-wide suppression and eradication programmes. Experience from SIT suggests that the cost of mosquitoes is likely to be an important component of overall costs (Mumford and Knight, 1996; Knight, 2001; Knight, 2001a).
10. The cost of monitoring the ever increasing mosquito-free area for incursions and outbreaks of wild malarial mosquitoes will also form a significant cost as the releases continue. It will be necessary to maintain emergency capacity in the event that monitoring detects incursions of wild mosquitoes back into mosquito-free areas. Estimates of such costs will be derived from spatio-temporal simulation models for different demographic and land-use scenarios.
11. The model will provide a transparent and logical methodology for dealing with uncertainty. Uncertainty will be presented in three broad categories, following guidance developed in other fields (IPCC, 2005): unpredictability (e.g. human behaviour, political systems, chaotic systems); structural uncertainty (e.g. incomplete or competing conceptual frameworks, ambiguous system boundaries *etc.*); and knowledge uncertainty (e.g. missing, inaccurate or non-representative data, inappropriate spatial or temporal resolution, poorly known or changing model parameters).
12. Knowledge uncertainty in the spatial and economic models will be addressed through a modelling approach where uncertainty in variable estimates and correlations between variables can be included stochastically (Monte Carlo and/or Bayesian Belief Networks). Unpredictability caused by political vacillation will be incorporated through a range of scenarios in which the size of area covered and speed of implementation will represent the degree of political commitment i.e. support from governments and/or donor agencies.
13. Figure 1 shows how the cost benefit framework of inputs and outputs could be applied to any scenario or project area. Appendix 4 shows a checklist for the various data required to perform an economic analysis of a GM mosquito programme.

Benefits of the proposed work:

- A spatial bio-economic model of genetic strategies for control of malaria vectors will provide a virtual testing ground for assessing the feasibility of this novel and untested technology.
- It will provide a transparent framework, easily adjusted with any new data, for making economic comparisons between malarial control strategies currently in use versus the

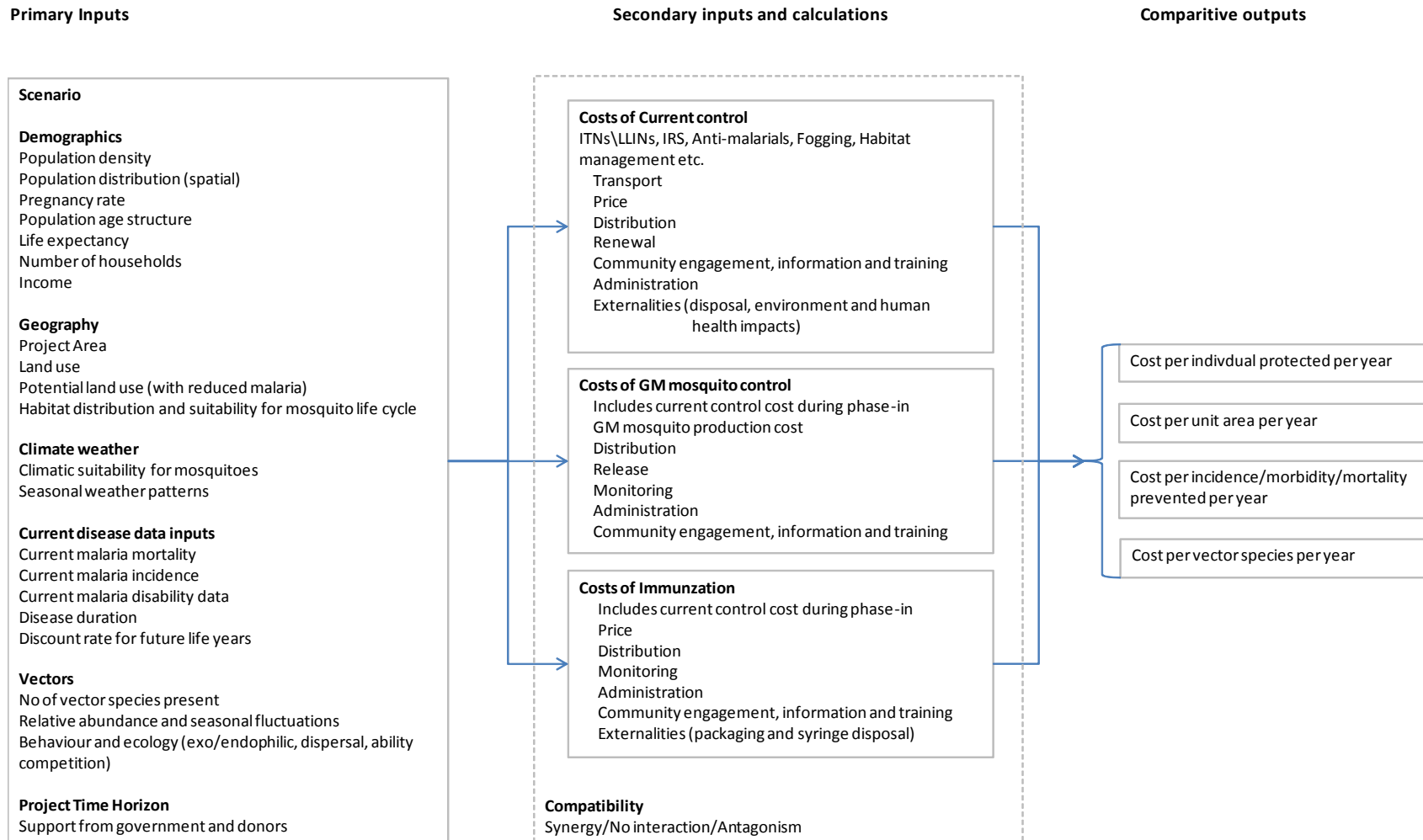
new technologies of GM mosquito releases and immunization. In addition, it will allow sensitivity analysis and “break even” analysis to guide technology development.

- It can provide a “product profile” with explicit characteristics (e.g. level of efficacy and degree of uncertainty) for laboratory researchers to match in order to provide an effective tool in disease control.
 - It will present a consistent method for incorporating uncertainty (unpredictability, structural and value uncertainties) into the models to ensure the anticipated strategy is comprehensive, transparent and robust.
 - It will assist strategic planning of a campaign in a project area according to its spatial characteristics (topography, land use, population density and distribution, infrastructure, local climate, resources, mosquito and malaria population dynamics).
 - It creates an adaptable business model for a campaign that includes dynamic temporal cost planning to satisfy requirements of programme managers, donors and regulators.
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Figure 1. Flow diagram (low resolution) of inputs and outputs of the cost benefit model.



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Appendix 1. International comparison of the reported annual costs, per person protected, of bednet impregnation and house spraying with deltamethrin (DM), permethrin (PM), or lambda-cyhalothrin (LC) in 2009 prices (after Kroeger *et al.*, 2002).

Insecticide Country	Costs of bednet impregnation (U.S.\$)*		Costs of house spraying (U.S.\$)†		Insecticides used for:		Reference
	Insecticide‡	Total	Insecticide	Total	Bednets	Spraying	
South Africa	1.56	1.95	1.17	3.38	DM tablets or PM (200mg/m ²)	DM (20mg/m ²)	Goodman et al. (2001)
Vietnam	0.35	0.43	0.49	0.64	PM (200mg/m ²)	LC	Verle' et al. (1999)
Colombia							
Nearby comm'ties	2.66	4.69	7.48	9.38	DM (15mg/m ²)	LC	Kroeger et al. 2002
Far-away comm'ties	1.90	10.77	5.07	13.05	DM (15mg/m ²)	LC	Kroeger et al. 2002

*For yearly (South Africa) or twice-yearly (Vietnam and Colombia) impregnations, at the then current value for the U.S. dollar. The cost of the bednets was excluded.

†For yearly (South Africa) or twice-yearly (Vietnam and Colombia) spraying, at the then current value for the U.S. dollar.

‡The costs (in U.S.\$) per impregnated bednet were 0.96–1.8 in South Africa, 0.44 in Vietnam and 1.1 (nearby) or 0.7 (far-away) in Colombia. The corresponding costs reported in Tanzania, for bednets impregnated with LC, were U.S.\$0.42 in 1997 and U.S.\$0.40 in 2000 (Anon., 2001). In Sri Lanka, the total annual costs/individual protected were reported to be U.S.\$2.2 for house spraying with LC and U.S.\$0.57 for bednet impregnation with PM (Korandsen et al., 1999). In the Solomon Islands, the annual cost of spraying was reported to be 2.2 times higher than that of bednet impregnation (Kere and Kere, 1992).

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Appendix 2. Review of IRS costing studies (all costs converted to USD 2009) (after Conteh *et al.*, 2004).

Study	Intervention	Population covered	Cost per person covered per year (\$)	Reference	IRS Cost per person covered per year (2009 adjusted)
Southern Mozambique					
LSDI (Zone 1)	Two rounds p.a. 1 FICAM, 1 Propoxur	71047	3.48	Conteh et al., 2004	\$4.41
Mozal (Zone 1A)	Two rounds p.a. FICAM	180871	2.16	Conteh et al., 2004	\$2.74
Kenya	One round p.a. lambdacyhalothrin	1752	0.88	Guyatt et al., 2002	\$1.12
KwaZulu-Natal, South Africa	One round p.a. deltamethrin	26703	2.47	Goodman et al., 2001	\$3.13
Tanzania	One round p.a. lambdacyhalothrin	1000	2.45	Curtis et al., 1998	\$3.11
Solomon islands	Two rounds p.a. DDT	7712	5.87	Kere & Kere, 1992	\$7.44
Sri Lanka	Two or three rounds p.a. fenitrothion, malathion or lambdacyhalothrin	2575	2.36–3.22	Konradsen et al., 1999	\$ 2.99–\$ 4.08
Pakistan	One round p.a. malathion	1658942	0.69	Guinness, 1997	\$0.87
Vietnam	One round p.a. lambdacyhalothrin	26748	0.51	Verlé et al., 1999	\$0.65
Sub-Saharan Africa (modelling study)	One round p.a. lambdacyhalothrin	Not applicable	Income level: very low, 6.32–11.17; middle, 6.57–11.58; higher, 10.01–19.29	Goodman et al., 2000	\$ 8.01–\$ 14.16 \$ 8.33–\$ 14.68 \$ 12.69–\$ 24.45
					4.44*

* Average does not include the Pakistan and Vietnam costs nor middle and higher range for Sub-Saharan Africa modelling study

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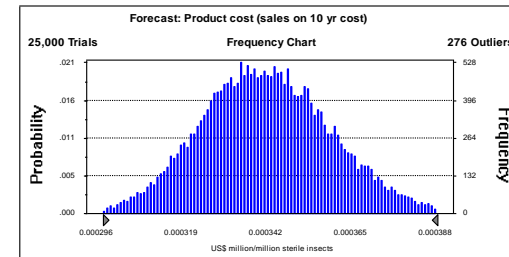
Appendix 3. Output of financial planning model for a bio-factory (Quinlan et al., 2008) to be adapted from current SIT programmes to GM mosquitoes.

Biofactory Financial Planning Model - ten year period

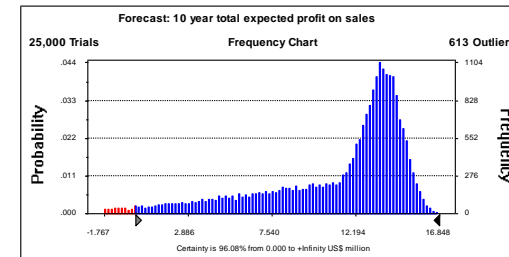
07/01/2002*

This financial model is based on construction of a fixed capacity factory for Medfly, with loan capital. Inflation/deflation not included in either costs or prices, except for labour/wage rates (enter as a variable) to allow for these exceeding general inflation in some cases.

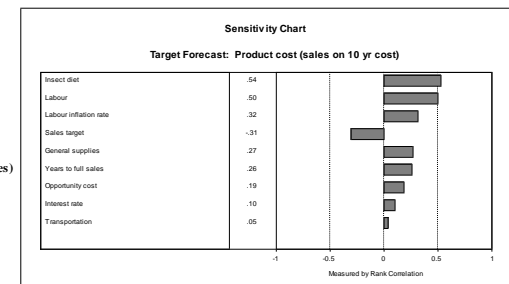
Item	Year	1	2	3	4	5	6	7	8	9	10	10-yr total
Production												
Sales (millions/week average per year)		0	250	500	750	1000	1000	1000	1000	1000	1000	7500
Capital												
All values below are in US\$ million												
Capital outlay		13.520										13.520
Credit line interest cost			0.054	0.288	0.181	0.002	0.000	0.000	0.000	0.000	0.000	0.525
Principal repayment			3.380	3.380	3.380	3.380	0.000	0.000	0.000	0.000	0.000	13.520
Interest cost on capital outlay			1.082	0.811	0.541	0.270	0.000	0.000	0.000	0.000	0.000	2.704
Opportunity cost			0.357	0.692	1.006	1.298	1.298	1.298	1.298	1.298	1.298	9.843
Depreciation												0.000
Fixed												
Administration		0.116	0.146	0.182	0.228	0.284	0.356	0.445	0.556	0.695	0.869	3.876
Utilities and communications		0.060	0.119	0.187	0.250	0.313	0.313	0.313	0.313	0.313	0.313	2.495
Insurance/security (loss & liability)		0.172	0.172	0.172	0.172	0.172	0.172	0.172	0.172	0.172	0.172	1.721
Research and development		0.250	0.250	0.250	0.250	0.250	0.250	0.250	0.250	0.250	0.250	2.500
Quality management		0.000	0.021	0.032	0.035	0.037	0.037	0.037	0.037	0.037	0.037	0.311
Effluent management		0.000	0.017	0.035	0.052	0.069	0.069	0.069	0.069	0.069	0.069	0.517
Sales/promotion		0.030	0.030	0.030	0.030	0.030	0.030	0.030	0.030	0.030	0.030	0.300
Variable												
Insect diet		0.000	1.125	2.250	3.375	4.500	4.500	4.500	4.500	4.500	4.500	33.750
General supplies		0.020	0.088	0.171	0.254	0.337	0.337	0.337	0.337	0.337	0.337	2.555
Labour		0.000	0.644	1.556	1.945	2.432	3.041	3.802	4.754	5.944	7.432	31.552
Transportation		0.029	0.029	0.042	0.060	0.072	0.072	0.072	0.072	0.072	0.072	0.591
Total cost		-0.677	-7.513	-10.078	-11.758	-13.448	-10.475	-11.325	-12.388	-13.717	-15.379	-106.760
Income												
Sales at annual cost		0.000	7.513	10.078	11.758	13.448	10.475	11.325	12.388	13.717	15.379	106.083
Sales at 10-year average cost		0.000	3.554	7.109	10.663	14.216	14.216	14.216	14.216	14.216	14.216	106.625
Sales at 10-year average cost+profit		0.000	3.910	7.820	11.729	15.638	15.638	15.638	15.638	15.638	15.638	117.287
Cumulative income (inc profit) minus costs		-0.677	-4.280	-6.539	-6.568	-4.378	0.785	5.098	8.347	10.268	10.527	10.527
Profit												
Annual net on sales		-0.677	-3.603	-2.259	-0.029	2.190	5.163	4.313	3.250	1.921	0.259	10.527
Cumulative proportion on expenditure		-1.000	-0.523	-0.358	-0.219	-0.101	0.015	0.078	0.107	0.112	0.099	0.099
Net present value (10 years) on profits \$m		4.567*										
Variables values to set												
Capacity	(millions/week)	1132										
Sales target proportion of capacity		0.88										
Years to full sales		4										
Interest rate		0.08										
Opportunity cost rate		0.08										
Repayment period on loan years		5										
Depreciation period in years		0										
Labour inflation rate		0.2502872										
Planned profit on sales rate		0.10										
Maximum competitive price/million		0.000375										
Fixed costs (annual per capacity)												
Administration		0.116										
Utilities and communications		0.313										
Insurance/security (loss & liability)		0.172										
Research and development		0.250										
Quality management		0.037										
Effluent management		0.069										
Sales/promotion		0.030										
Subtotal		0.988										
Variable costs (per 1 million sales)												
Insect diet		0.000100										
General supplies		0.000050										
Labour		0.000057										
Transportation		0.000010										
Subtotal		0.000217										
Product cost and price												
On average 10 year sales/total cost		0.000273										
Proposed price/million		0.000301										



Production cost per million on 10 yr average costs



10 year profit total



Proportional sources of uncertainty

Appendix 4. Checklist of necessary data

1. General Project Data

1.1. Demographics

Population density
Population distribution (spatial)
Pregnancy rate
Population age structure
Life expectancy
Number of households
Income

1.2 Malarial mosquitoes

Diversity
Relative abundance
Transmission ability of each species
Behaviour (exo or endophilic, dispersal ability)
Population fluctuations (also leading to fluctuations in human immunity or tolerance to malaria)
Anophelene community dynamics (competition and dominance)

1.3 Land use

Project Area
Land use
Potential land use (with reduced malaria)
Habitat distribution and suitability for mosquito life cycle

1.4 Climate weather

Climatic suitability for mosquitoes
Seasonal weather patterns

1.5. DALY inputs

Current malaria mortality for DALY estimation
Current malaria incidence for DALY estimation
Current malaria disability data for DALY estimation
Disease duration
Discount rate for future life years

1.6 Current management

1.6.1 Anti-malarial Drug Use

Coverage
Types
Cost per type

1.6.2. Bed nets

Cost of net (retreatable or LLIN)
Cost of treating an untreated net or retreatment (Insecticide + ancillary items)
Cost of ensuring net is used (Supply of nails, string to hang the net)
Retreatment frequency
Bed net replacement frequency
Transportation to villages
Training users
Delayed acquisition of immunity
Bed net usage (% people)
Bed net disposal costs
Externalities (poisonings, disposal of containers, environmental impacts etc.)

1.6.3. Indoor Residual Sprays

Coverage (% households)
Cost of sprayers at country of use
Cost of Insecticide at country of use
Cost of persons doing the spraying (salaries and per diem costs)
Ancillary equipment (PPE etc)
Maintenance of equipment (spare parts and workshop staff costs)
Transport costs to villages (getting equipment and personnel to individual villages)
Training staff
Medical check on spray operators
Externalities (poisonings, disposal of containers, environmental impacts etc.)
Residual Spray frequency

1.6.4. For both IRS and ITN

Research
Education - Sensitise users about the control treatments.
Management/coordination
Storage of equipment, nets, insecticides
Monitoring and evaluation of impact.
Quality assurance
Recycling and disposal of items.
Importation costs, taxes

1.6.5. Other control methods

Fogging
Area fogged
Cost of fogging/ha
Frequency
Externalities (poisonings, disposal of containers, environmental impacts etc.)

1.6.6. Standing water

Drainage cost
Insecticide treatment
Oil cover

2. *Competing novel technologies*

2.1. Vaccines

Coverage
Cost per inoculation
Frequency of inoculation
Externalities (disposal of syringes)
Training/publicity

2.2. SIT of vector control

Factory costs
Factory running cost
Cost of sterile insects
Persistence in field
Sterile male competitive ability
Release rates
Release costs (Labour, vehicles, fuels, packaging, plane/helicopter hire)
Monitoring
Administration
Training and publicity

3. *GM Mosquito release*

3.1. GM mosquito factory

3.1.1. Capital

Capital outlay
Credit line interest cost
Principal repayment
Interest cost on capital outlay
Opportunity cost
Depreciation

3.1.2. Fixed

Administration
Utilities and communications
Insurance/security (loss & liability)
Research and development
Quality management
Effluent management
Sales/promotion

3.1.3. Variable

Insect diet
General supplies
Labour
Transportation

3.1.4. Income?

Sales at annual cost
Sales at 10-year average cost
Sales at 10-year average cost + profit

3.2. Release

Release rate (number GM mosquitoes per hectare per week)
GM mosquito cost per million
Labour
Vehicles
Plane\helicopter lease

3.3 Monitoring

Monitoring method
Trap density
Trap servicing
Transport
Labour
Lure
Insecticide
Servicing\checking frequency

3.4. Administration

3.5. Information and training