

# Guide for cost-benefit analysis for investments in laboratory biosafety and biosecurity in animal health systems

## Summary

Cost-benefit analysis (CBA) has historically been the economic tool of choice for appraising public investments in animal health (Rushton, 2009). Costs and benefits are compared, typically over a long period of time, and an analysis is created using discounting to reflect their value over time, taking opportunity costs into account. CBAs are limited by their heavy reliance on data and assumptions, yet the results from such an analysis can provide a strong motivator to effect change.

Animal health laboratories are a crucial part of an animal health system, with broad ranging benefits from farm-level control of diseases to wider ranging impacts on trade at both local and international levels. Documenting both macro and micro-level costs and benefits using a standard set of economic assumptions within a single analysis can be challenging. The containment of pathogens and substances with potential harm to animals and people is also a critical core function of laboratories. Yet, under-investment in laboratories threatens their overall viability and economic sustainability, while at the same time compromising their biosafety and biosecurity efforts. It can be challenging to identify and quantify all costs and benefits associated with the broad functions of animal health laboratories.

This document outlines an approach for appraising investments in animal health laboratories by considering both the direct and indirect benefits that may come from improved biosafety and biosecurity. Considerations are also given to how existing OIE tools can be integrated into the approach and key performance indicators can be used to both inform and monitor the impact of internal and external investments.

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## Abbreviations and acronyms

BSL	Biosafety level
CBA	Cost benefit analysis
DALY	Disability-adjusted life year
FMD	Foot-and-mouth disease
KPI	Key performance indicator
LIMS	Laboratory information management system
LMIC	Low- and middle-income countries
OIE	World Organisation for Animal Health
PVS	Performance of Veterinary Services
SCA	State-contingent analysis
UK	United Kingdom
USDA	United States Department of Agriculture

## Economics and animal health laboratories

“Economics is the study of making rational choices/decisions in the allocation of scarce resources for the achievement of competing goals” (Rushton, 2009). This allocation of resources produces goods and services that benefit people (Howe, 2017). Within an animal health system, there are many competing elements putting varying demands on limited public resources. Decision makers need to decide the optimal time and place to allocate resources so that the maximum benefit is realised. One important component of the animal health system is the presence of a laboratory network which contributes to effective disease management, increases production and profitability, facilitates compliance with requirements for national and international trade, and contributes to public health through surveillance activities for zoonotic pathogens, antimicrobial resistance, and food safety.

By nature of the activities of an animal health laboratory, the presence of pathogens or toxic materials present a hazard if release were to occur (OIE, 2018). Laboratory “escapes”, whether accidental or deliberate, have the potential to cause widespread disruption and potentially far-reaching economic consequences for national and international trade. A high-profile example is the escape of foot-and-mouth disease (FMD) virus from the laboratories in Pirbright, United Kingdom in 2007, which was estimated to cost £47m (approximately US\$94m) to the UK government and £100m (approximately US\$200m) to industry despite only affecting eight (8) farms (Anderson, 2008). There are numerous other examples of laboratory escapes of FMD virus in Africa, Europe, Russia, and the U.S. (USDA-APHIS, 1994; United States Government Accountability Office, 2008; Valarcher et al., 2008; Sangula et al., 2011).

There are also several reports of laboratory-acquired infections among staff with a 2018 review reporting incidents involving dengue virus, *Arthroderma* spp., *Brucella* spp., *Mycobacterium* spp., *Rickettsia* spp., and *Shigella* spp in the Asia-Pacific region (Siengsanant-Lamont and Blacksell, 2018). Adequate biosafety and biosecurity measures can mitigate these risks, but investments in these areas need to be economically justified and proportionate considering the required timescale. Investments improving biosafety and biosecurity may have other tangential benefits in the laboratory network that should be taken under consideration. Moreover, the anticipated benefits may take place over a long period which may make investment less appealing to governments seeking to gain maximum return on investments. This document provides guidance to animal health laboratories on the use of cost-benefit analysis to assist in advocating for appropriate sustainable investment in biosafety and biosecurity from national authorities.

## Background on cost-benefit analysis

A cost-benefit analysis (CBA) is the most commonly-used economic tool when assessing investments with public funds and is used by many governments and international and regional development banks (The World Bank, 2010). The CBA framework considers all monetary costs and benefits related to an investment. Different cost and benefit streams are projected over time and adjusted (“discounted”) to reflect the time value of money; i.e. costs and benefits occurring in the future are valued at a lower level than those in the present, capturing elements of uncertainty over the future and the opportunity cost of capital. These varying opportunity costs and benefits are estimated using a “discount rate” which is typically constant over time and is the same for both costs and benefits. The discount rate represents the opportunity cost and is applied to estimate the “present value” of future costs and benefits which in turn are used to generate metrics to guide decision making on investments (Table 1). Note that a cost-effectiveness analysis is an alternative approach whereby the benefits are described in non-monetary terms (see Annex C of the final report).

The discount rate used can have a large impact on the estimated return of a project and can be challenging to define. Two approaches have been described to define such rates (Harrison, 2010). A “descriptive” approach is based on the opportunity cost if the investment is made elsewhere in the private sector. A “prescriptive” or “normative” approach is more subjective and influenced by ethics and longer-term benefits like those seen with environmental improvements. The World Bank uses an 8% discount rate, which is similar to that used by governments (Harrison, 2010). This contrasts with a recommendation of 3% for LMIC in a reference case commissioned by the Bill and Melinda Gates Foundation (Wilkinson et al., 2016). High discount rates put increased pressure on projects to deliver benefits in the short term as longer-term benefits are worth relatively less. In the case of investments in biosafety and biosecurity, the benefits are likely to take place over the longer term so this should be reflected in the choice of discount rate. A range of rates should be considered, bearing in mind it should also take into account the local market conditions of the particular country or region (Marsh et al., 2017).

Table 1. Numeric outputs of a cost-benefit analysis and their interpretation.

Output metric	Definition	Interpretation
Benefit-cost ratio	Total present value of benefits/Total present value of costs	Values over 1 indicate the total benefits of a project outweigh the total costs, with higher values indicating increasing returns
Net present value	Total present value of benefits – Total present value of costs	Positive values indicate present value of benefits exceeds the present value of costs
Internal rate of return	Discount rate at which the NPV is equal to zero.	Indicates the yield required by an alternative investment to provide better value for money

For a cost-benefit analysis, a comparison is made between a baseline and intervention(s). The baseline scenario may vary over time depending on current policies. Uncertainty in both the baseline and intervention can be reflected using a stochastic model, where probabilities of various model parameters are allowed to vary in different simulations. The output of a stochastic simulation will reflect the underlying uncertainty and variability in the model, giving ranges of outcome and standard errors around the outputs defined in Table 1 (Marsh et al., 2017). A sensitivity analysis will indicate parameters where further data collection is required to refine the model and improve outputs. Another approach might be to use different scenarios. For any analysis, only the costs and benefits that would be expected to vary between the baseline and intervention scenarios need to be quantified.

Economic analyses are sensitive to the **time** over which any intervention is applied. It should also be considered that the baseline scenario may also change over time. For laboratory investments, this should be based on the expected timeline over which the intervention has its primary effect (in the current context that would be on reducing the risk of laboratory escapes to an acceptable level). **Inflation** should also be incorporated into this calculation using “real” rather than “nominal” prices.

A CBA approach has been used previously for assessing investments in biosecurity and biosafety, notably for the construction of the new National Bio and Agro Defense Facility in the U.S. focussing on accidental release of Foot and Mouth Disease virus, a major pathogen of concern in this context (Pendell et al., 2015). However, studies involving investments in laboratories in LMIC where PVS Sustainable Laboratories missions typically occur are lacking. Based on experience from these missions, this is due to an absence of the required data, which was apparent in a previous CBA project funded by OIE that was unable to complete the analysis.

## Estimating benefits

The benefits from laboratory interventions can be very broad due to the number of benefit streams that may come from the work of a laboratory (see Annex C of the final report). Improvements in biosafety and biosecurity may be considered to have benefits that are direct (related to a reduced risk of escape of pathogens and other potentially harmful materials) or indirect (related to other improvements in the laboratory system that occur because of the intervention). An example of an indirect benefit might be that improved biosafety and biosecurity leads to increased use of a quality management system, with more reliable test results, higher domestic and international credibility, and an increased use of the laboratory's services.

**Direct benefits** from improved biosafety and biosecurity will come from *averted losses* that would occur in the event of a laboratory "escape". To quantify these benefits, the baseline risk needs to be estimated for each potentially harmful pathogen or substance being used or stored both in terms of escape (or release) and exposure to susceptible animals or people (OIE, 2010, 2016, 2018). In this context, risk refers to both the probability and impact of an escape. For the former, an expert assessment would be needed on the annual probability of an escape. For the latter, the impact of outbreaks would need to be estimated which is likely to be extremely variable and uncertain for an individual pathogen depending on numerous factors including but not limited to:

- Disease status of the area surrounding the laboratory (free of infection, endemic)
- Presence or absence of appropriate vectors (ticks, fleas, and others)
- Availability of effective treatments or other containment methods
- Existing trade benefits from the pathogen being absent from circulation in the resident population
- Sensitivity of surveillance systems for early detection of escapes
- Control policy and access to resources to effect control
- Competencies of the veterinary services
- Production systems present, their spatial distribution and associated practices that may affect exposure risk
- Changes in consumer surplus (the difference between what consumers are willing to pay for a product and the market price) in response to a disease event or intervention (Marsh et al., 2017)
- Changes in producer surplus (the difference between the total revenue and production costs) related to trade benefits being lost, changes in productivity and variable costs (Marsh et al., 2017)

Various scenarios could be considered for a particular pathogen depending on the country context. Simulation modelling of disease outbreaks could be utilised, although it is unlikely that this will be possible for all pathogens present in a laboratory. It is likely that any impact assessment will rely heavily on assumptions, but the availability of field data would strengthen confidence in any analyses. It also needs to be considered that both the probability of escape and level of impact for the baseline scenario may vary over time, for example if equipment or facilities depreciate, or the disease status of the country changes. A time-effective approach might be to do an initial qualitative risk assessment followed by a

quantitative risk assessment if the former produces a result over a defined threshold (OIE, 2010).

The described approach might be satisfactory for laboratories with clear needs for investment in biosafety and biosecurity. However, in situations where both the probability and impact of adverse events have a large degree of uncertainty, another approach which integrates uncertainty within the method might be more appropriate. State-contingent analysis (SCA) has been proposed as an appropriate platform for situations like this, and has been suggested as an approach to be used for evaluating investments in preparedness for animal health emergencies (Adamson et al., 2020). The approach considers a series of “states of nature” (for example: no release, release of endemic pathogen, release of non-endemic pathogen, release of zoonotic pathogen, etc.) with a subjective probability assigned to each, alongside management solutions which have an ascribed cost represented by the benefit in terms of averted losses. The approach is flexible and can group pathogens together in different categories and can be updated or refined as more information becomes available. For these reasons, the SCA is the recommended approach for estimating direct benefits according to the aims of the PVS Sustainable Laboratories missions (Box 1).

The **indirect** benefits that might come from the investment will depend on the changes that are required to improve biosafety and biosecurity and how they may impact the specific benefit streams from a laboratory (Figure 1). For a particular intervention, the relevant benefit streams need to be identified and quantified under both baseline and intervention scenarios. Some of these benefits may be specific to the laboratory, such as increased use of their services and subsequent generation of revenue (or increased subsidy), whereas others may be relevant to different parts of the animal health system such as facilitating improved disease management or facilitation of trade in livestock or livestock products. Although these indirect benefits might be considerable and make a large difference to any investment appraisal, they are often difficult to estimate and may require collection of field data and a process of stakeholder consultation.

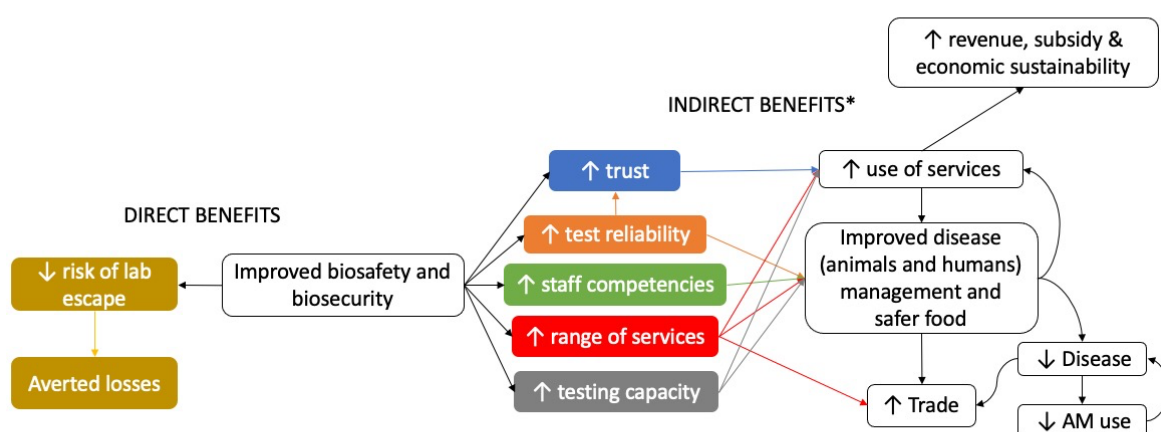


Figure 1. Diagrammatic representation of the possible benefits coming from investments in biosecurity and biosafety for a laboratory network. \*Indirect benefits will vary depending on the specific intervention(s) which might include implementing a quality management system, improved infrastructure, and staff training.

The collective impacts of disease for animal and human health can be broadly categorised into health losses (both visible and invisible) and losses from expenditure and reaction. (Figure 2). Whereas most animal health impacts can be monetarised, impacts on public health are more challenging to monetarise. For any human disease, the economic burden of illness can be estimated based on direct (paying for medical services and other associated costs) and indirect (lost productivity time) costs. Another approach is to estimate disability-adjusted life years (DALYs) which are a measure of the loss of health due to illness, accounting for premature death and disability (WHO, 2021). For a cost-benefit analysis, human health and life may need to be monetarised, a process which incorporates a subjective assessment of value that would vary with the context (Zweifel et al., 2009). Another approach would be to create a mixed measure using DALYs as the denominator for a cost-effectiveness analysis reported alongside a CBA metric.

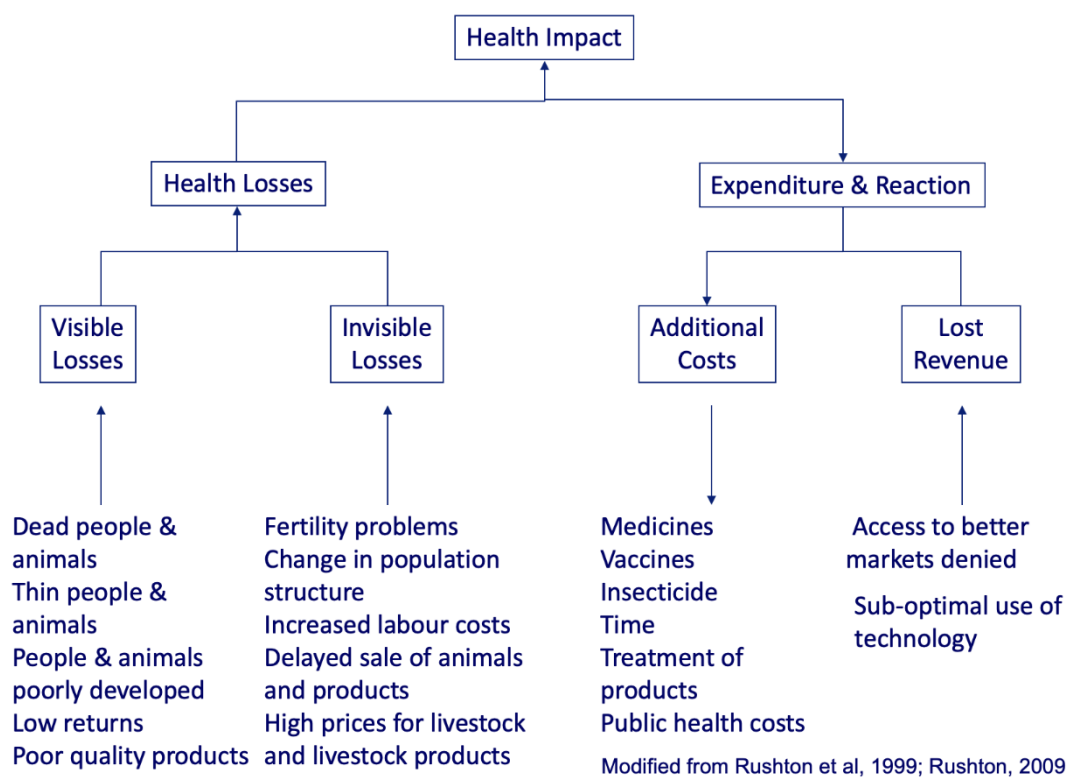


Figure 2. One Health losses from disease (modified from Rushton et al., 1999)

Box 1. An example of using SCA for estimating direct benefits of reducing the risk of laboratory escape.

Previous analysis of WAHIS data (Gilbert et al., 2020) showed that outbreaks of infectious disease follow an extreme value distribution with a strong positive skew in terms of the proportion of the total population at risk which is exposed (Figure 3).

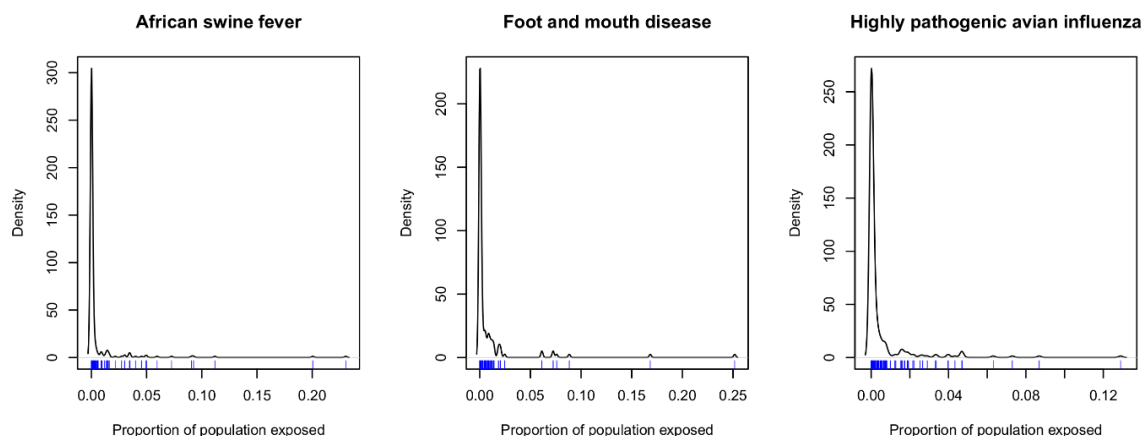


Figure 3. Disease outbreak size, as proportion of at-risk population exposed, for three viral diseases affecting the major livestock species (Gilbert et al., 2020).

As such, a state-contingent approach aimed at quantifying the cost of laboratory security breaches and the benefits of averting them could explore three disease scenarios:

1. No biosecurity breaches
2. A biosecurity breach with limited exposure (for example, median of distribution)
3. A biosecurity breach with widespread exposure (95<sup>th</sup>, 97.5<sup>th</sup>, 99<sup>th</sup> percentile, for example)

Once this categorisation has been decided, the next step is to quantify the costs of each state of nature within the country or region of interest. In this regard, a full or partial impact assessment can be developed according to the disease impact framework illustrated in Figure 2 utilising available data (Table 1). These estimates can then be compared to the “No disease” state, to estimate the net change resulting from a disease outbreak.

Table 2. Example of cost items to include for a partial avian influenza impact estimate in intensive poultry systems.

Species	Chickens
Component of disease impact estimated	Reduced volume of production
	Cost of replacement stock
	Carcass disposal costs
	Vaccination costs
	Lost revenue from reduced sale price
	Lost revenue from downtime

To weight investment costs against a beneficial reduction in risk presents a challenge because risk is difficult to measure, and the precise degree to which risk changes between scenarios is hard to quantify. In this case, one approach is to take the dimensions for which there can be certainty, i.e., the budget that can be allocated to risk reduction, and determine what the break-even point for return on investment is when risk is variable. This can be done by any preferred method. To illustrate the concept, the outcome of a decision-tree analysis is presented.

Considering a simulated outbreak of highly pathogenic avian influenza, a minor to major outbreak ratio can be estimated from WAHIS data, in this case 20:1. Using this assumption, an expected median outbreak size can be calculated, and a monetary value estimated. The probability of a laboratory escape with and without intervention can then be estimated, and the change in probability with and without intervention given a value by calculating the product with outbreak cost. The outcome of this calculation, presented as a dollar value per % reduction in risk of escape (considering only avian influenza impact) is presented in Table 3. This relatively simple model can then be challenged with sensitivity analysis around the core probability assumptions.

Table 3. Results of decision tree analysis for interventions to reduce the risk of laboratory pathogen escape for select countries having previously had a PVS Sustainable Laboratories Mission.

	<b>Median of Major outbreak (US\$)</b>	<b>Median of Minor outbreak (US\$)</b>	<b>Expected cost of single outbreak</b>	<b>US\$/% reduction in annual risk (±95% Prediction interval)</b>
<b>Cote d'Ivoire</b>	\$82,745,900	\$67,595	\$4,004,657	<b>\$40,047(±\$13,349)</b>
<b>Senegal</b>	\$64,406,527	\$51,361	\$3,115,893	<b>\$31,159(±10,386)</b>
<b>Lao PDR</b>	\$83,578,519	\$66,253	\$4,043,028	<b>\$40,430(±\$13,477)</b>
<b>Myanmar</b>	\$619,510,209	\$513,619	\$29,989,647	<b>\$299,896(±\$99,964)</b>
<b>Uganda</b>	\$20,403,276	\$16,306	\$987,114	<b>\$9,871(±\$3,290)</b>
<b>Republic of Tanzania</b>	\$35,417,148	\$30,477	\$1,715,556	<b>\$17,156(±\$5,718)</b>

## Estimating costs

Costs can be broadly defined as fixed and variable. **Fixed costs**, such as rent of a facility, do not vary with the level of activity, and will only generally change in the long term. In the context of a laboratory network, some of these costs may be shared between laboratories. By contrast, **variable costs**, such as consumables and reagents, electricity, and water costs, etc., will vary with the level of activity and are specific to the laboratory (i.e., do not cover non-related departments or activities – if they do, they should be considered as fixed costs). This distinction is critical when considering investment in laboratories and both would be expected to behave differently over time. Fixed costs have a major influence over the thresholds when interventions become economic (Tisdell and Adamson, 2017) and high levels will require relatively more activity to become economically sustainable. Upfront fixed costs from an intervention may need to be followed by subsequent outlays (fixed and variable) which are needed so that future benefits (both direct and indirect) are realised. For example, failure to upgrade or maintain equipment may add to the operational costs when repairs are needed, and down-time means services that contribute benefits cannot be provided. Further examples of fixed and variable costs for a laboratory are presented in Table 4.

High fixed costs of individual laboratories are likely to favour a smaller network with lower levels of activity required to justify their place economically. Minimising fixed costs may allow more labs to exist, which may increase revenue from services. A balance needs to be struck and a CBA may be helpful for comparing laboratory network scenarios.

Table 4. Fixed and variable costs that should be considered for a laboratory when undertaking a cost-benefit analysis.

Cost category	Fixed	Variable
Human resources	Permanent staff (all costs including fringe benefits and training)	Casual/temporary staff
Sample testing	Equipment maintenance, calibration, and depreciation; quality assurance and proficiency testing	Consumables, reagents
Building and facilities including vehicles and IT	Rent, maintenance and repairs, depreciation	Electricity, gas, fuel, petty cash needs, capital investments

## Cost benefit analysis and the current PVS Sustainable Laboratories Tools

The PVS Sustainable Laboratories mission has numerous aims including:

1. Analysis of the current and prospective demand for veterinary laboratory analysis and services;
2. Estimation of the cost of diagnostic laboratory analysis or provision of such services;
3. Determination of the financial, human, physical, and other tangible resources needed by the national laboratory network;
4. Evaluation of the pertinence of the national laboratory network structure and its economic viability in its national context; and
5. Assistance to decision makers relating to the structure, funding, and management of the national laboratory network.

These mission aims are achieved using tools to assist in the collection and analysis of data related to laboratory management and economics. The data collection tool has been streamlined for an improved user experience and enhanced with economic key performance indicators for laboratory sustainability. Many of these data would be useful in undertaking a cost-benefit analysis for investments in biosafety and biosecurity. Table 5 includes those variables that might be useful for estimating the fixed and variable costs in the baseline scenario, and that potentially vary with interventions. Table 6 shows more detailed budget information used during the mission to estimate the real costs of the laboratory diagnostic service, which may also vary with different operating scenarios. For a CBA, only those costs that are thought to change with the intervention need to be estimated, which should reduce the data needs depending on the specific intervention being evaluated.

Table 5. PVS Sustainable Laboratories variables and data that could be used as part of a cost-benefit analysis, either for the baseline scenario or changed through some intervention.

Category	Variable
Human Resources	Sex and age of employees
	Employment status
	Type of position (management, technician, etc.)
	Level of education
	Field of work in laboratory
	Continuing education status
Equipment Inventory	Name, location, make, model, specifications, ID number
	Category (freezer, centrifuge, etc.)
	Field of use (virology, feed safety, etc.)
	Year acquired
	Acquisition value
	Present day cost (cost to replace)
	Condition
	Maintenance/calibration status
Equipment Management	Maintenance/calibration programmes, service providers, and in-house competencies
	Annual cost of contracts
	Temperature monitoring systems
	Procurement procedures

Category	Variable
Transport	Field activities of lab (sampling, surveys, outbreak investigation)
	Vehicles present (type, age, and equipment)
Premises	Surface area by BSL status for different lab types
	Unit cost and value of premises by BSL status
	Refrigeration equipment
	Communications (phones, internet, intranet)
	Water supply, treatment, and disposal
	Power supply and backup
	Waste disposal
	IT (computers, photocopiers, LIMS)
Quality Assurance	Programme and staff presence
	Standard used, manuals, accreditation status, proficiency test participation, formal documentation by topic
Activities: Demand	Number of clients using lab
	Submissions/samples/tests by client type (Import control, Export certification, AH/VPH programmes, Request of client, Undetermined purpose)
Activities: Tests	Number of tests/year by agent/disease and test type
	Official test price, and cost of test as estimated by lab
Activities: Prospects	Human and animal population for area served by lab (farms/animals)
	Industry types served by lab (abattoirs, food processing plants, import/exports, etc.)
	List of useful analyses not performed (technique, potential clients, and number)
Budget	Actual expenditures over previous 3 years (capital investments, salaries including Continuing Education, operating costs [building maintenance, power, etc.])
	Real budgetary resources over previous 3 years (initial budget, supplementary budget, exceptional allocations, external funding)
	Revenue from activities in previous 3 years (charge to clients by private/public sector or service/research contracts)
	Accounting systems
	Renumeration of staff by type of employment (management, etc.)

Table 6. Laboratory network budget used in the PVS Sustainable Laboratories Mission.

Category	Variable	Unit Cost	Number	Renewal Rate	Annual Budget
Capital Investment	Buildings and Premises		-	0.05	
	Vehicles			0.2	
	IT and Office Equipment			0.33	
	Telecommunication Equipment			0.2	
	Refrigerators & Deep Freezers (-20°C & -80°C)			0.1	
	Laboratory Equipment			0.2	
	Other Equipment			-	0.2

Category	Variable	Unit Cost	Number	Renewal Rate	Annual Budget
Salaries and Remuneration	Veterinarians and Other Professionals			-	
	Laboratory Technicians			-	
	Support Staff			-	
	<i>Per diem</i> and travel allowance in the country			-	
	<i>Per diem</i> and travel allowance abroad			-	
Operating Costs	Continuing Education (short courses, etc.)	Salaries	5%	-	
	Administrative Expenditures (office supplies, etc.)	Salaries	30%	-	
	Reagents and Consumables			-	
	Maintenance, Calibration, and Metrology	Laboratory Equipment	20%	-	
	External Services (Reference Laboratory, External Analysis, Transport, etc.)			-	
	Other			-	

## Cost-benefit analysis and Key Performance Indicators for Economic Sustainability of Laboratory Networks

Key Performance Indicators (KPIs) for economic sustainability of laboratory networks have been proposed, falling into three categories: financial, services, and resources (see Annex H of the final report). These KPIs may be useful for a CBA in the following ways:

1. Investment Areas: Indicate areas that may require investment such as improving infrastructure or services
2. Magnitude of Benefits: Demonstrate the potential magnitude of indirect benefits in particular categories and areas
  - a. Laboratory networks that have low values for KPIs may indicate a large potential for improvement and therefore better targeting interventions
    - i. For example, a laboratory network that scores poorly on catchment area potential and test availability may have scope for an increase in the use of their services, so investments in the laboratory network and official animal health programmes and surveillance could lead to increased revenue and enhanced economic sustainability.
    - ii. Relevant targets and benchmarking groups for different countries still need to be developed,
  - b. Conversely, some factors may limit the potential gains from any investment
    - i. For example, if the laboratory network scores high in particular KPIs, there may be little scope for making such gains. Therefore, it is suggested that when the potential benefit streams are identified, an appraisal of the current KPIs be used to inform the areas where potential gains can be made.
3. Evaluating Investment: Provide a framework for assessing the broader impact of investments on economic sustainability of the laboratory network (not just those specific to the investment itself)

Table 7 indicates the connections between the final recommended list of KPIs (see Annex H of the final report) and these three aspects of the CBA.

Table 7. Mapping of KPIs for economic sustainability of laboratory networks and cost-benefit analysis.

KPI Category	KPI Name	Investment Areas	Magnitude of Benefits	Evaluating Investment
Financial	Public investment in labs by biomass		X	X
	Public investment in labs by livestock outputs		X	X
	Public investment in labs by veterinary services		X	X
	Donor contributions		X	X
	Private sector contributions			X
	Subsidy per overall activity		X	
	Operating expense ratio	X		
	Staff income	X		
Services	Catchment area potential	X	X	X
	Client satisfaction	X	X	X
	Test completion	X		
	Test availability	X	X	
	Quality assurance	X		
	Test training support	X		
	Test capacity (equipment)	X		
	Test capacity (staff)	X		
Resources	Staff retention rate			X
	Workforce time		X	
	Representativeness			X
	Reagent supply		X	
	Local reagent sourcing		X	
	Equipment maintenance	X		
	Equipment calibration	X		
	Equipment maintenance availability		X	
Equipment calibration availability		X		

## Methodological steps for conducting a CBA for biosafety and biosecurity in animal health laboratories

The steps required for undertaking a CBA for investments in biosafety and biosecurity in animal health laboratories are represented in Figure 4 and Table 8.

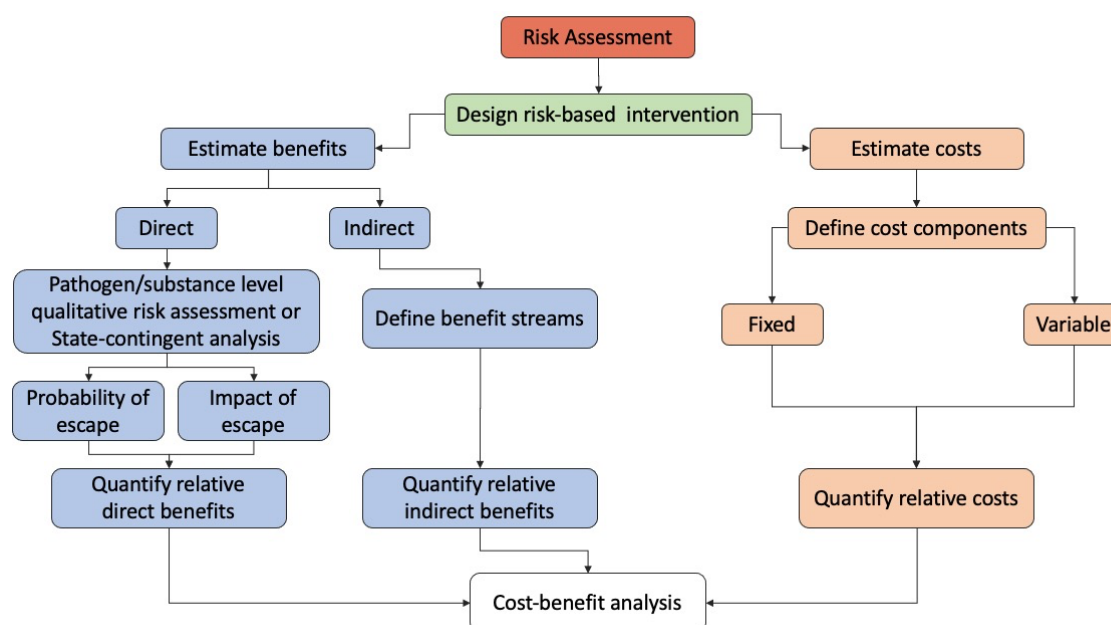


Figure 4. Methodological framework for conducting a cost-benefit analysis appraising interventions in biosafety and biosecurity of animal health laboratories. See Table 8 for a description of the steps.

Table 8. Description of methodological steps for conducting a cost-benefit analysis appraising interventions in biosafety and biosecurity of animal health laboratories.

Step Number	Name	Description
1	Conduct Risk assessment	Risk assessment for current biosafety and biosecurity standards to identify any problems at the laboratory level.
2	Design risk-based intervention	Based on the risk assessment, decide the improvements needed to reach a satisfactory risk level including the time over which they would be expected to have an effect.
3a	Estimate benefits - Direct	Undertake a qualitative risk assessment of the baseline probability and impact of a lab escape for each pathogen or substance of concern held by the laboratory. Depending on the nature of the initial risk assessment, this step may not be necessary. Alternatively, a SCA is performed where various scenarios are considered relevant to pathogens and substances that are kept in the laboratory. Each scenario is assigned a probability and the management costs are estimated to reflect the direct benefits of investment.

3b	Quantify relative direct benefits	For risks identified in Step 1 as above a defined threshold, a quantitative estimate is made for the baseline scenario (of no intervention), and with the designed intervention over the expected time period that the intervention would be expected to have a benefit. Inputs and outputs from the PVS Sustainable Laboratories mission should be appropriately utilised.
3c	Estimate benefits - Indirect	Identify the indirect benefit streams that will be affected (positively and negatively) by the investment.
3d	Quantify relative indirect benefits	For identified benefit streams, the relative benefits need to be estimated under the baseline (of no intervention) and with the designed intervention. The timeline should be the same as that used in the direct estimate, the assumption being that at the end of those benefits, a new intervention would be required.
4a	Estimate costs – Define cost components	Identify the fixed and variable costs components that will be affected by the investment.
4b	Quantify relative costs	For affected cost components, relative costs need to be estimated under the baseline (of no intervention) and with the designed intervention utilising inputs and outputs from the PVS Sustainable Laboratories mission. The timeline should be the same as that used for the direct benefits, the assumption being that at the end of those benefits, a new intervention would be required with new costs.
5	Cost-benefit analysis	Comparison made between benefits and costs using an appropriate discount rate and time-period previously specified. Uncertainty and variability in parameters should be accounted for using probability distributions as part of a stochastic model, or various scenarios could be considered, or both.

## Conclusions

Cost-benefit analysis is a powerful economic tool to effect change and could be a useful approach to justify private and public investments in improved and sustainable biosecurity and biosafety of animal health laboratories. The approach is potentially very complex and can take several months or more to complete due to the heavy data requirements and the use of economic assumptions. Moreover, the differences between animal health laboratory networks mean custom models need to be created to reflect the individual circumstances and types of data available. Indirect benefits are likely to vary widely due to the diverse benefit streams from different laboratories.

The approach outlined in this document provides a practical yet thorough framework for the analysis, drawing on risk assessment methodologies as a foundation, and focussing only on data that are required. It provides a background to decision makers and laboratory personnel on the challenges and usefulness of a CBA. If a CBA is being considered for a host country, discussions should involve an economist, or someone familiar and experienced in CBA methodologies in the early stages and it may be worthwhile having their presence during or in preparation for a PVS Sustainable Laboratories missions to determine whether a CBA is plausible and of likely benefit to the host country in supporting their advocacy for investments in biosafety and biosecurity. It should be highlighted that *ex-ante* assessments should be followed by *ex-post* evaluations to test the original assumptions and produce updated analyses of the costs and benefits as the investments are implemented.

## References

- Adamson, D., W. Gilbert, K. Hamilton, D. Donachie, and J. Rushton. 2020. Preparing for animal health emergencies: considerations for economic evaluation. *Rev. Sci. Tech.* 39:625–635 Available at <http://www.ncbi.nlm.nih.gov/pubmed/33046914>.
- Anderson, I. A. 2008. Foot and mouth disease 2007: A Review and Lessons Learned.
- Gilbert, W., D. Adamson, and J. Rushton. 2020. Building resilience against agro-terrorism and agro-crime: A cost-benefit analysis of investing in emergency management. Paris, France.
- Harrison, M. 2010. Valuing the future: the social discount rate in cost benefit analysis.
- Howe, K. S. 2017. The allocation of resources for animal health. *Rev. Sci. Tech.* l’OIE 36:35–48 Available at <https://doc.oie.int/dyn/portal/index.seam?page=alo&alold=34614>.
- Marsh, T. L., D. Pendell, and R. Knippenberg. 2017. Animal health economics: an aid to decision making on animal health interventions – case studies in the United States of America. *Rev. Sci. Tech.* l’OIE 36:137–145 Available at <https://doc.oie.int/dyn/portal/index.seam?page=alo&alold=34638>.
- OIE. 2010. Introduction and Qualitative Risk Analysis.in Handbook on Import Risk Analysis for Animals and Animal Products.
- OIE. 2016. Risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in animals. *Terr. Anim. Heal. Code*:1–6 Available at [http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre\\_antibio\\_risk\\_ass.htm](http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_antibio_risk_ass.htm).
- OIE. 2018. Biosafety and biosecurity: Standard for Managing Biological Risk in the Veterinary Laboratory and Animal Facilities. Pages 48–63 in *Terrestrial Manual*.
- Pendell, D. L., T. L. Marsh, K. H. Coble, J. L. Lusk, and S. C. Szmania. 2015. Economic assessment of FMDv releases from the National Bio and Agro Defense Facility. *PLoS One* 10:1–22.
- Rushton, J. 2009. The economics of animal health and production. *Econ. Anim. Heal. Prod.*:1–364.
- Rushton, J., P. K. Thornton, and M. J. Otte. 1999. Methods of economic impact assessment. *Rev. Sci. Tech.* 18:315–42 Available at <http://www.ncbi.nlm.nih.gov/pubmed/10472671>.
- Sangula, A. K., H. R. Siegismund, G. J. Belsham, S. N. Balinda, C. Masembe, and V. B. Muwanika. 2011. Low diversity of foot-and-mouth disease serotype C virus in Kenya: evidence for probable vaccine strain re-introductions in the field. *Epidemiol. Infect.* 139:189–96 Available at [http://www.journals.cambridge.org/abstract\\_S0950268810000580](http://www.journals.cambridge.org/abstract_S0950268810000580) (verified 8 July 2012).
- Siengsan-Lamont, J., and S. Blacksell. 2018. A Review of Laboratory-Acquired Infections in the Asia-Pacific: Understanding Risk and the Need for Improved Biosafety for Veterinary and Zoonotic Diseases. *Trop. Med. Infect. Dis.* 3:36.
- The World Bank. 2010. *Cost-Benefit Analysis in World Bank Projects*. The World Bank, Washington D.C.
- Tisdell, C. A., and D. Adamson. 2017. The importance of fixed costs in animal health systems. *Rev. Sci. Tech.* l’OIE 36:49–56 Available at <https://doc.oie.int/dyn/portal/index.seam?page=alo&alold=34616>.
- United States Government Accountability Office. 2008. *High-Containment Biosafety Laboratories: DHS Lacks Evidence to Conclude That Foot-and- Mouth Disease Research*

Can Be Done Safely on the U.S. Mainland.

- USDA-APHIS. 1994. Foot-and-mouth Disease: Sources of Outbreaks and Hazard Categorization of Modes of Virus Transmission. :42 Available at [http://www.fao.org/fileadmin/user\\_upload/eufmd/USDA\\_\\_1994.pdf](http://www.fao.org/fileadmin/user_upload/eufmd/USDA__1994.pdf).
- Valarcher, J. F., Y. Leforban, M. Rweyemamu, P. L. Roeder, G. Gerbier, D. K. J. MacKay, K. J. Sumption, D. J. Paton, and N. J. Knowles. 2008. Incursions of foot-and-mouth disease virus into Europe between 1985 and 2006. *Transbound. Emerg. Dis.* 55:14–34.
- WHO. 2021. Disability-adjusted life years (DALYs). Available at <https://www.who.int/data/gho/indicator-metadata-registry/imr-details/158>.
- Wilkinson, T., M. J. Sculpher, K. Claxton, P. Revill, A. Briggs, J. A. Cairns, Y. Teerawattananon, E. Asfaw, R. Lopert, A. J. Culyer, and D. G. Walker. 2016. The International Decision Support Initiative Reference Case for Economic Evaluation: An Aid to Thought. *Value Heal.* 19:921–928 Available at <http://dx.doi.org/10.1016/j.jval.2016.04.015>.
- Zweifel, P., F. Breyer, and M. Kifmann. 2009. Economic Valuation of Life and Health. Pages 17–74 in *Health economics*.