The Chatham House Sustainable Laboratories Initiative

Prior assessment tool

David R Harper, Emma Ross and Ben Wakefield

Canada

CHATHAM HOUSE
The Royal Institute of International Affairs

Contents

Introduction

Laboratories are critical for supporting effective infectious disease surveillance and outbreak response, and lack of adequate laboratory capacity is a global challenge. As part of global health security initiatives, cooperative threat reduction efforts and international development programmes, sophisticated laboratories have been provided to mitigate biological threats and bolster a country's capacity for detection, diagnosis and storage of high-consequence pathogens. Very often, these use the assumptions, standards and templates applied in high-income countries. However, it can be difficult or even impossible to sustain these facilities in low-resource environments. There can sometimes be limited local technical capacity and capability, which can result in a high reliance on imported expertise, skills, equipment and other resources. Sustainability can therefore be hard to achieve. In addition, when a funding partner withdraws, the laboratories can become disused, foundering without the trained personnel and financial resources to sustain them.

To help address this situation, a proposal gaining increasing support internationally is to adopt an approach based on a local risk assessment, whereby laboratories are appropriately and optimally tailored to the local risks and to the resources available, both in the short and longer term, without compromising biosafety and biosecurity.

A Chatham House workshop was convened in Abuja, Nigeria, in 2018 to explore what West African countries would find most appropriate in terms of building laboratory capacity, what the main challenges have been so far, and what needs to be done to improve the sustainability of laboratories in the region. It emerged that there was a need for a more structured conversation between the funding partner and recipient country early in the process – prior to embarking on the detailed planning phase for the establishment or repurposing of a laboratory. This should involve careful consideration and an assessment of existing and planned capacity, needs and contextual issues, together with proposals for how to address the issues revealed, so that any ensuing laboratory demonstrably supports the national strategy and therefore flourishes.

The purpose of this tool

This tool aims to provide a structure for such a conversation. Developed in close collaboration with international experts and West African stakeholders, it seeks to increase local ownership and help partners ensure they have given due attention to all the relevant aspects, including risks and benefits, that need to be considered at an early stage. It should provide clarity on what is needed and improve the sustainability of any laboratory project that might result from the discussions. The tool can be applied when a new laboratory is being considered, or when an existing laboratory is to be repurposed or strengthened. It is also appropriate for use with public health, veterinary and environmental laboratories. Although the tool was developed in the context of high-consequence pathogens in Africa, it is anticipated that it will find global application.

It should support recipient countries to take stock of their capacities and capabilities, identify gaps, conduct an analysis of their needs and to develop the business case that can assist in seeking the necessary political and financial support for the laboratory. Meanwhile, it should facilitate the process of due diligence for the funding partner and provide a better understanding of what the recipient country perspective and realities are, and what the scale and nature of any investment might be.

When and how to use the tool

The tool is designed to be used throughout the process of an early conversation; this conversation can reasonably be paused and then resumed to allow questions to be answered and points to be addressed in the interim. The partners should agree the process, and who should be involved in it. It is recommended that partners assign someone to act as their focal point for the process. However, to answer some of the questions, those with expertise in the specific areas covered should be involved, along with a broader group of national participants from other relevant sectors. It is also recommended that the tool be used in advance to prepare for the main conversation in which the issues covered will start to be considered. It is envisioned that the partners will collaborate in answering some of the questions, and the tool has been constructed in a way that provides scope for the funding partner, or others, to support any capacity building the recipient country identifies as being necessary to answer some of the questions posed in it.

Structure of the tool

The tool is built around the essential elements of a business plan, tailored to a laboratory context, and takes the partners on a journey through the key issues that need to be discussed, encouraging situation analysis, needs assessment and identification of solutions where necessary.

It opens with a map illustrating the tool's structure to aid navigation. This is followed by questions relating to national strategic engagement. This section seeks to understand the proposed laboratory's strategic role for the country, and explores political support for, and national commitment to, the project – including consideration of roles and responsibilities, and which key actors are to be involved in the conversation guided by this tool.

It then takes the partners towards defining the general framing for the laboratory, exploring what specific need it will meet, what kind and volume of work will be done in it, and how it will fit into the existing and planned national laboratory network.

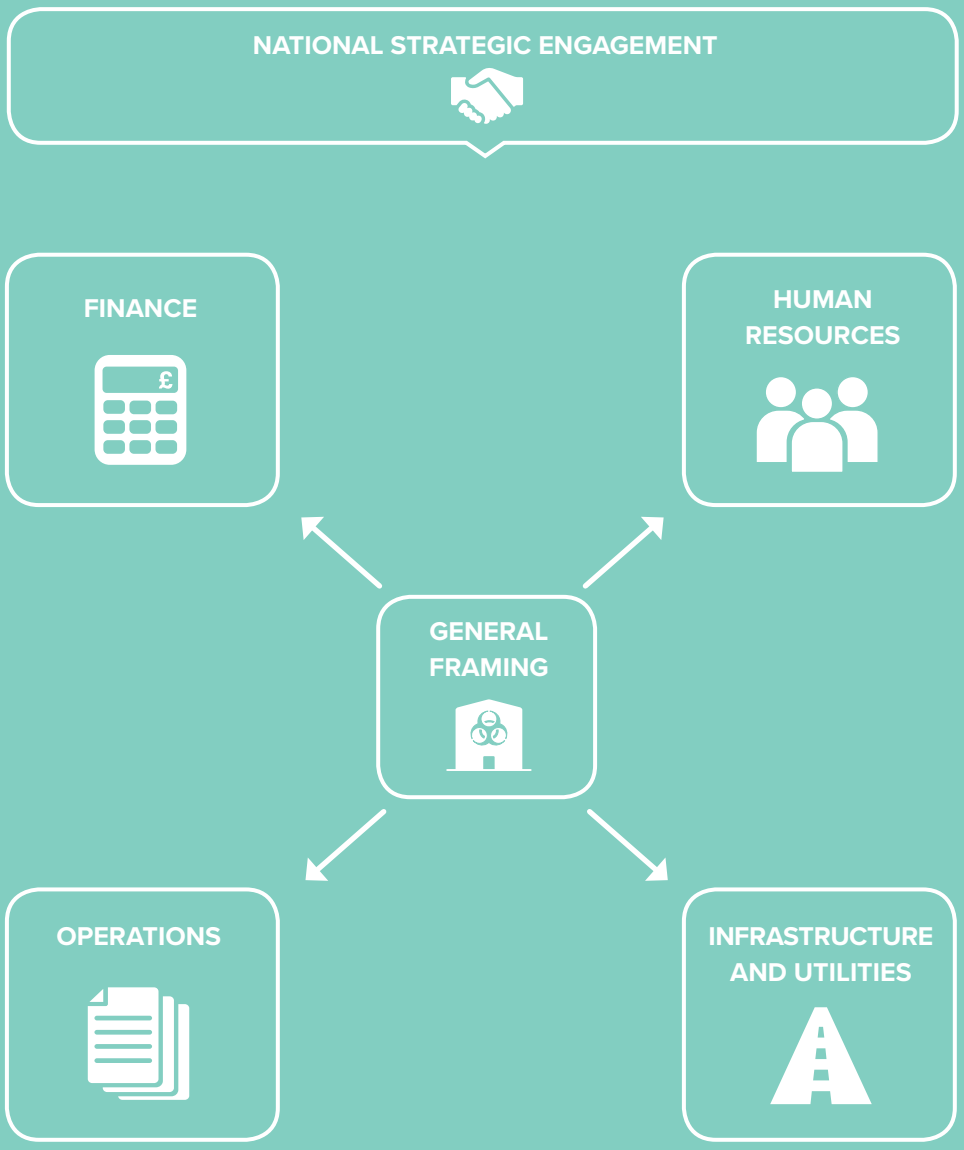
The tool then presents four topic sections that cover essential functional aspects that should be considered prior to embarking on establishing or repurposing a laboratory. These are finance, human resources, operations, and infrastructure and utilities. The four topic sections can be explored in any order, depending on the context.

There is some intentional overlap between the sections, as some aspects need to be discussed in more than one context. Similarly, some issues raised in one section are interdependent with those in one or more other sections. The sections of the tool are designed to be considered in parallel, or in a non-linear manner, when this is appropriate.

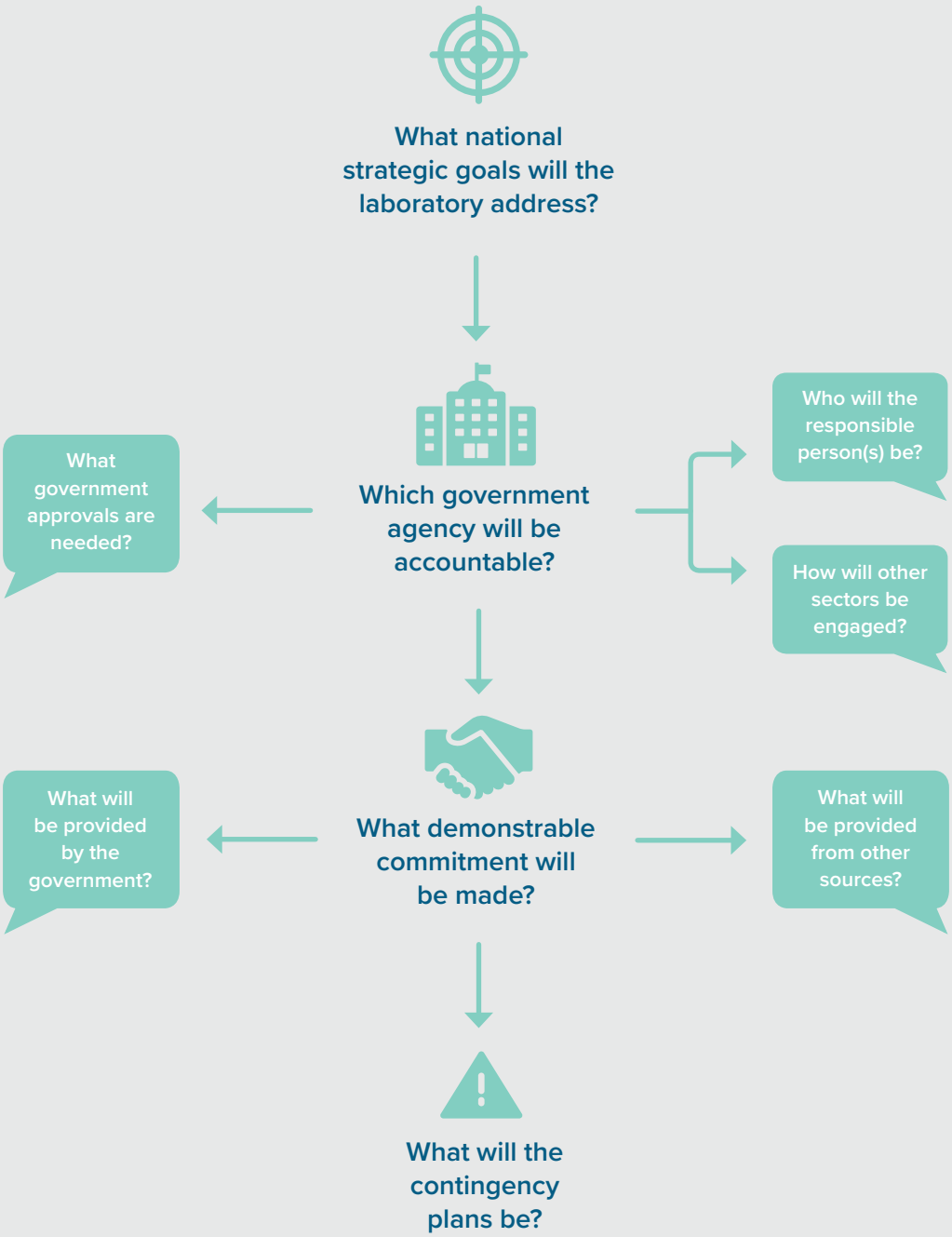
Each section begins with an overview to contextualize the conversation that follows, and is structured around a set of thematic questions that set out the main, higher-order questions, and then follow-on questions related to each main question. The main questions and some of the follow-on questions are presented in the form of a graphic at the start of each section. The follow-on questions are designed to be a deeper layer to help answer the main question or to explore more detailed, related considerations. The tool shows a blank box at the end of each sub-section – these boxes are not designed in any way to limit the answers to the space provided, they simply signpost the recommendation to answer the questions by sub-section. Each section also contains a box at the end for noting other key issues on the topic.

The tool concludes with a blank space for those involved in the conversation to distil their overall conclusions and to highlight risks, opportunities, challenges and the next steps.

Navigating the tool



National strategic engagement



National strategic engagement

A clear vision for the laboratory's role in addressing national strategic goals is fundamental. Political support for the project and demonstrable commitment from the relevant government agency are essential for embedding the laboratory in the country's systems and strategies, and for the ongoing support that the laboratory will need to be sustainable. National strategic engagement is an overarching requirement for success. It entails the participation of the full range of necessary stakeholders. A primary agency should be designated to deliver the laboratory, and an appropriate person assigned to lead the project. The support of a champion within the government should be secured to ensure sustainable funding and facilitate troubleshooting. To address some of the questions in this section, it might be necessary for discussion to move to other sections of this tool in order to build the business case to secure demonstrable government commitment.

- **What national strategic goals will the laboratory address?**

  Consider, for example, goals related to:
  - National laboratory network
  - Surveillance programme
  - Emergency plan

COMMENTS

- **Which government agency will be accountable?**
- Who will the responsible person(s) be?
- Which other agencies or other key actors need to be involved in the process?

  Consider, for example:
  - Agriculture
  - Finance
  - Environment
  - Trade
  - Customs
  - National security

- How will other sectors be engaged?
- What government approvals are needed?

COMMENTS

- **What demonstrable commitment will be made?**
- What will be provided by the government?

  Consider, for example:
  - Finance
  - Human resources
  - Materials
  - Timeframe

- What will be provided from other sources?

  Consider, for example:
  - Other national governments
  - International agencies
  - Private sector

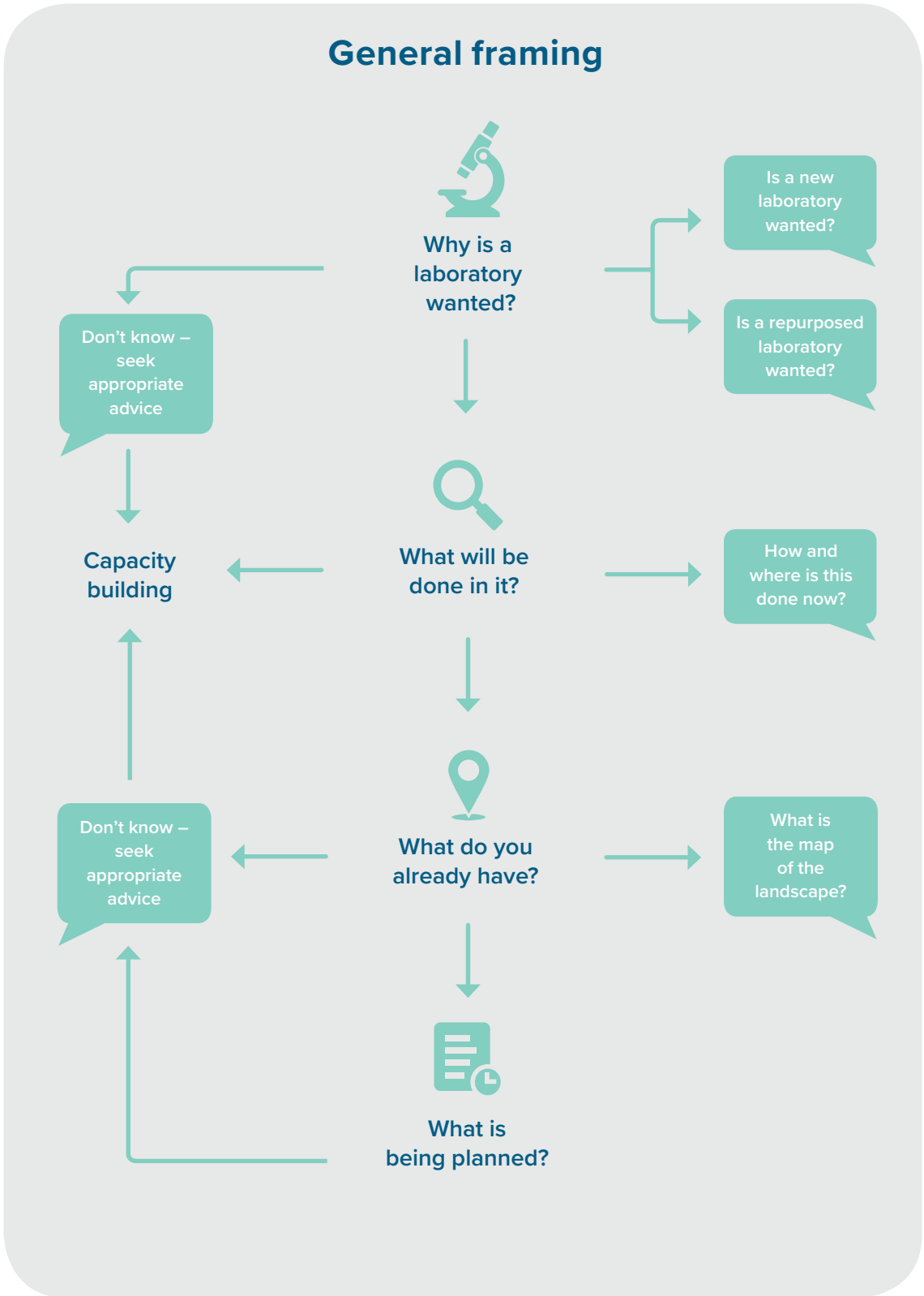
COMMENTS

- **What will the contingency plans be?**

  Consider, for example:
  - Change in government priorities or policy
  - Lack of national funding
  - Lack of engagement from other sectors

COMMENTS

OTHER KEY ISSUES


General framing
Why is a laboratory wanted?
Is a new laboratory wanted?
Is a repurposed laboratory wanted?
What will be done in it?
How and where is this done now?
What do you already have?
What is the map of the landscape?
What is being planned?
Capacity building
Don't know – seek appropriate advice
Don't know – seek appropriate advice

General framing

Defining what the laboratory's purpose is and what unmet needs it will address is an essential starting point. Also important is how it will fit into the local, national, regional and global systems, including surveillance programmes and laboratory networks. This involves taking stock of what laboratories exist or are already planned, as well as taking account of current and forecast disease profiles and priorities. Such an assessment will help determine what type and volume of work will be done in the laboratory. Answers to the questions in this section are critical in shaping the discussion of requirements for human resources, finance, operations, and infrastructure and utilities.

- **Why is a laboratory wanted?**
- Is a new laboratory wanted?
- Is a repurposed laboratory wanted?

  Consider, for example, strengthening:
  - Diagnostic capability
  - Surveillance programmes
  - Research capability
  - Sample storage (biobanking)

- At what level will the laboratory operate?
  - Local
  - National
  - Regional
  - Global
  - Biosafety measures
  - Biosecurity measures

COMMENTS

- **What will be done in it?**
- What type and volume of work will be done in the laboratory?

  Consider, for example:
  - Origin of samples
  - Sample throughput
  - Current and future disease profiles

- Where is this work done now?
- Will this work be transferred to the new laboratory?

COMMENTS

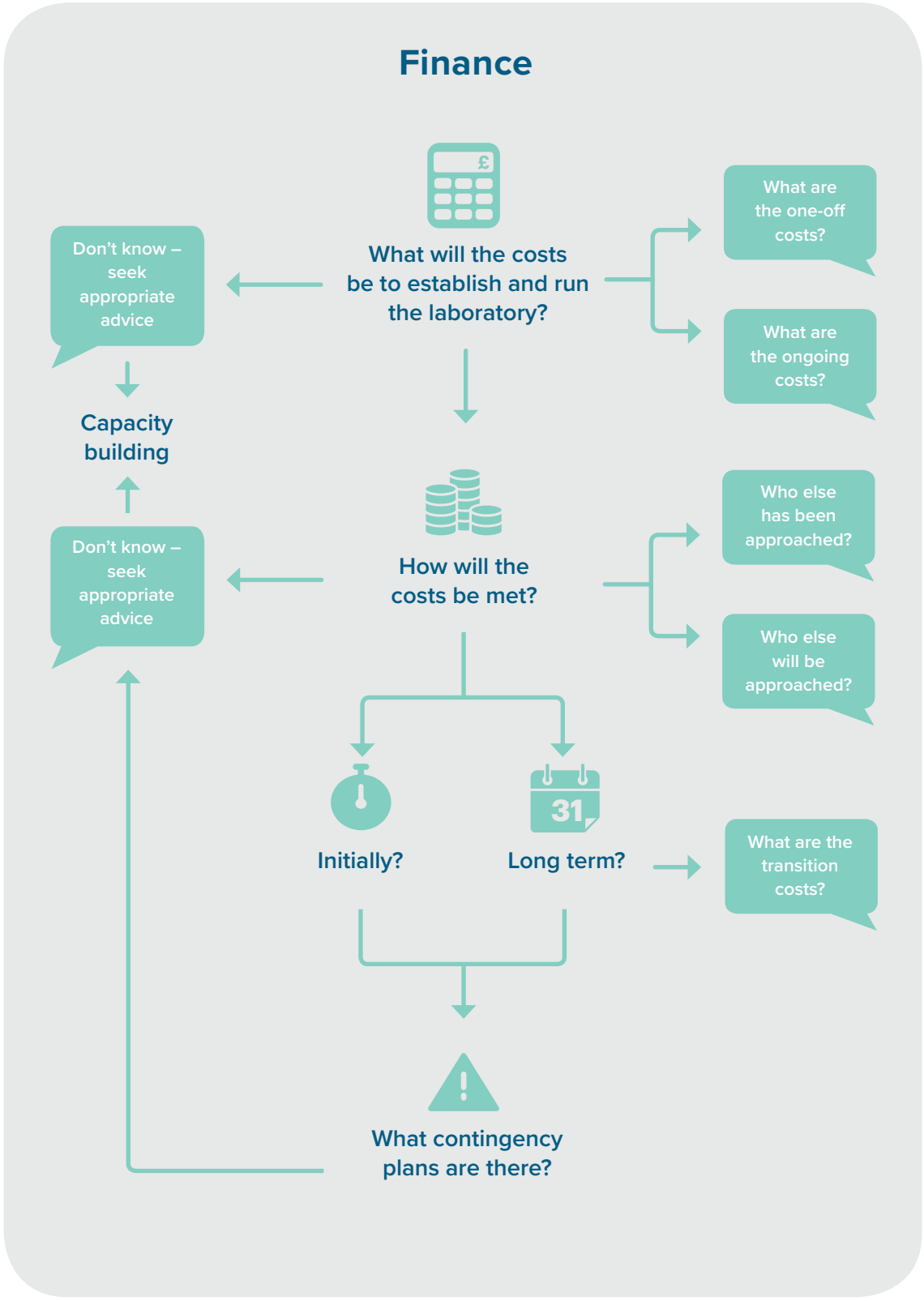
- **What do you already have?**
- How many laboratories are there (in your network)?
- Where are they located?
- What do they do?
- Are any suitable for repurposing?

COMMENTS

- **What is planned?**
- What other laboratories are planned?
- Where will they be located?
- What will they do?
- What is the source of funding?

COMMENTS

OTHER KEY ISSUES


Finance
What will the costs be to establish and run the laboratory?
What are the one-off costs?
What are the ongoing costs?
Don't know – seek appropriate advice
Capacity building
How will the costs be met?
Who else has been approached?
Who else will be approached?
Don't know – seek appropriate advice
Initially?
Long term?
What are the transition costs?
What contingency plans are there?

Finance

Attention to financing issues and early awareness of the costs are key to laboratory sustainability, and discussion of finance is likely to run throughout the conversation, across the other sections of this tool. These questions help identify what needs to be considered in determining the cost of establishing, operating and maintaining the laboratory, and in planning for sustainable financing. It is important to take account of the relative contribution that each partner is able or prepared to make at various stages of the laboratory's life course, to minimize the risk of a 'cliff-edge' when a transition to national financing occurs.

- **What will the costs be to establish and run the laboratory?**
- What are the one-off costs?

  Consider, for example:
  - Scoping
  - Design
  - Construction/repurposing
  - Commissioning
  - Site (e.g. analysis, acquisition and preparation)
  - Equipment (e.g. purchase)
  - Project management

- What are the ongoing costs?

  Consider, for example:
  - Staff (e.g. recruitment, retention, and ongoing training)
  - Utilities (e.g. power, water, waste treatment and disposal)
  - Laboratory maintenance
  - Servicing and calibration of equipment
  - Consumables and reagents
  - Repair and replacement of equipment
  - Regulatory requirements (e.g. customs clearance, waivers and exemptions)

COMMENTS

- **How will the costs be met?**
- How will the costs be met initially?
  - What will the sources of funding be?
- How will the costs be met in the long term?
  - What are the plans for transition to sustainable national funding?
- Has the appropriate government funding authority been engaged?
  - What costs will be built into government budgets?
- Are there opportunities for public-private partnerships?
- What income-generating activities might be feasible?
- Who else has been or will be approached?
  - Which governments?
  - Which private sector organizations?
  - Which philanthropic organizations?
- Are there opportunities for additional partnerships or other cost-sharing arrangements?

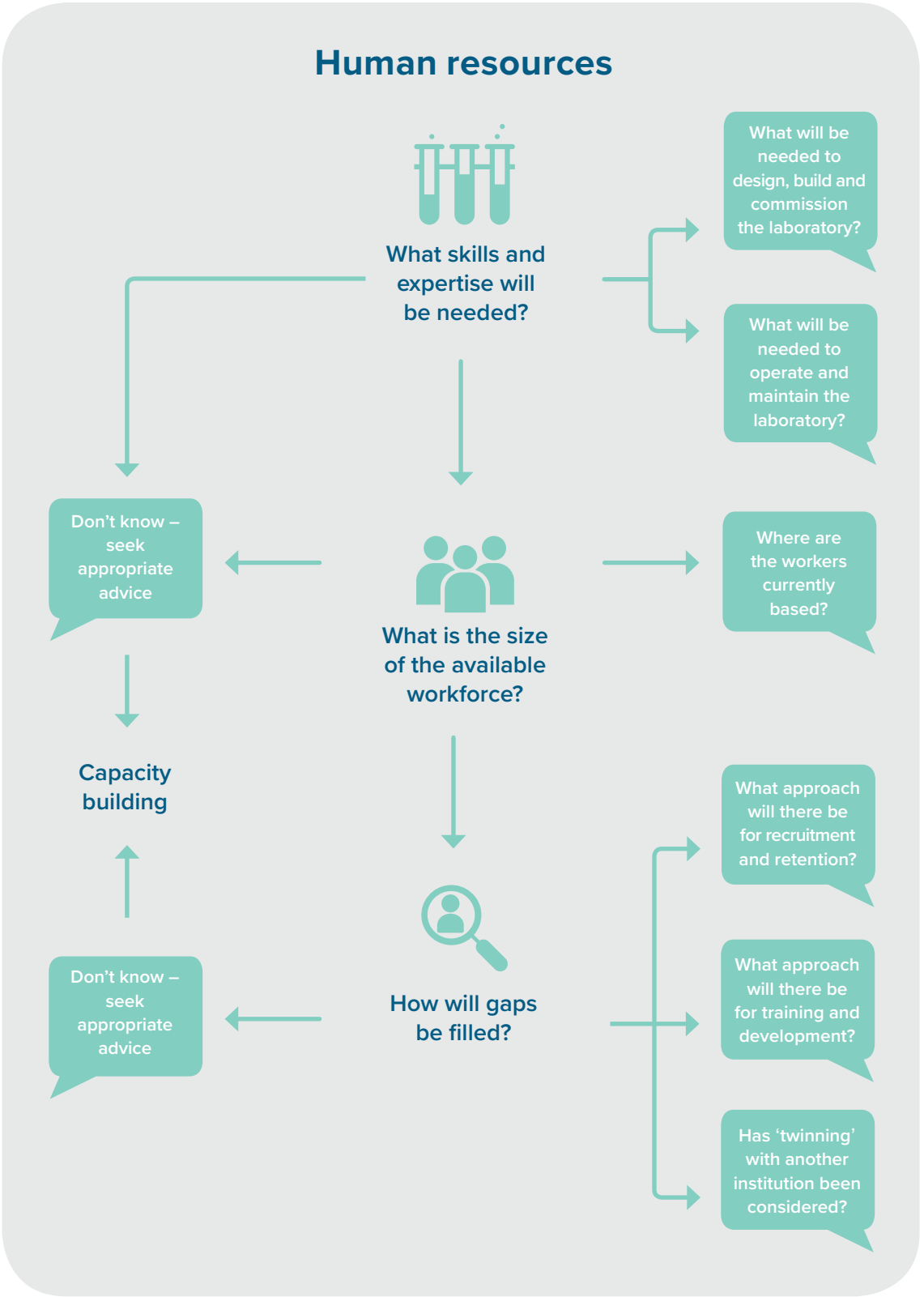
COMMENTS

- **What contingency plans are there?**
- What are the financial risks and related contingency plans?

COMMENTS

OTHER KEY ISSUES

Human resources



Human resources

Consideration should be given to the human resource needs, including where the full range of workers (such as scientists, administrators and maintenance workers) will come from, and how surge capacity can be accommodated. These needs are interdependent with the proposed programme and volume of work, and with financing. Thought should be given to which roles could or should be filled by staff, and which would be better outsourced. Related considerations include skills development and staff retention, as well as succession planning. 'Twinning' with another laboratory or institution – a partnership in which, for example, staff, expertise and quality assurance standards are shared – can also enhance sustainability.

- **What skills and expertise will be needed?**
- What will be needed to design, build and commission the laboratory?

  Consider, for example:
  - Design/architecture
  - Project management
  - Construction
  - Engineering
  - Commissioning
  - Support staff (e.g. administrative and contracts)
  - How many people this will involve

- What will be needed to operate and maintain the laboratory?

  Consider, for example:
  - Laboratory (e.g. scientific, technical and management)
  - Equipment calibration
  - Engineering
  - Support (e.g. administrative and cleaning)

COMMENTS

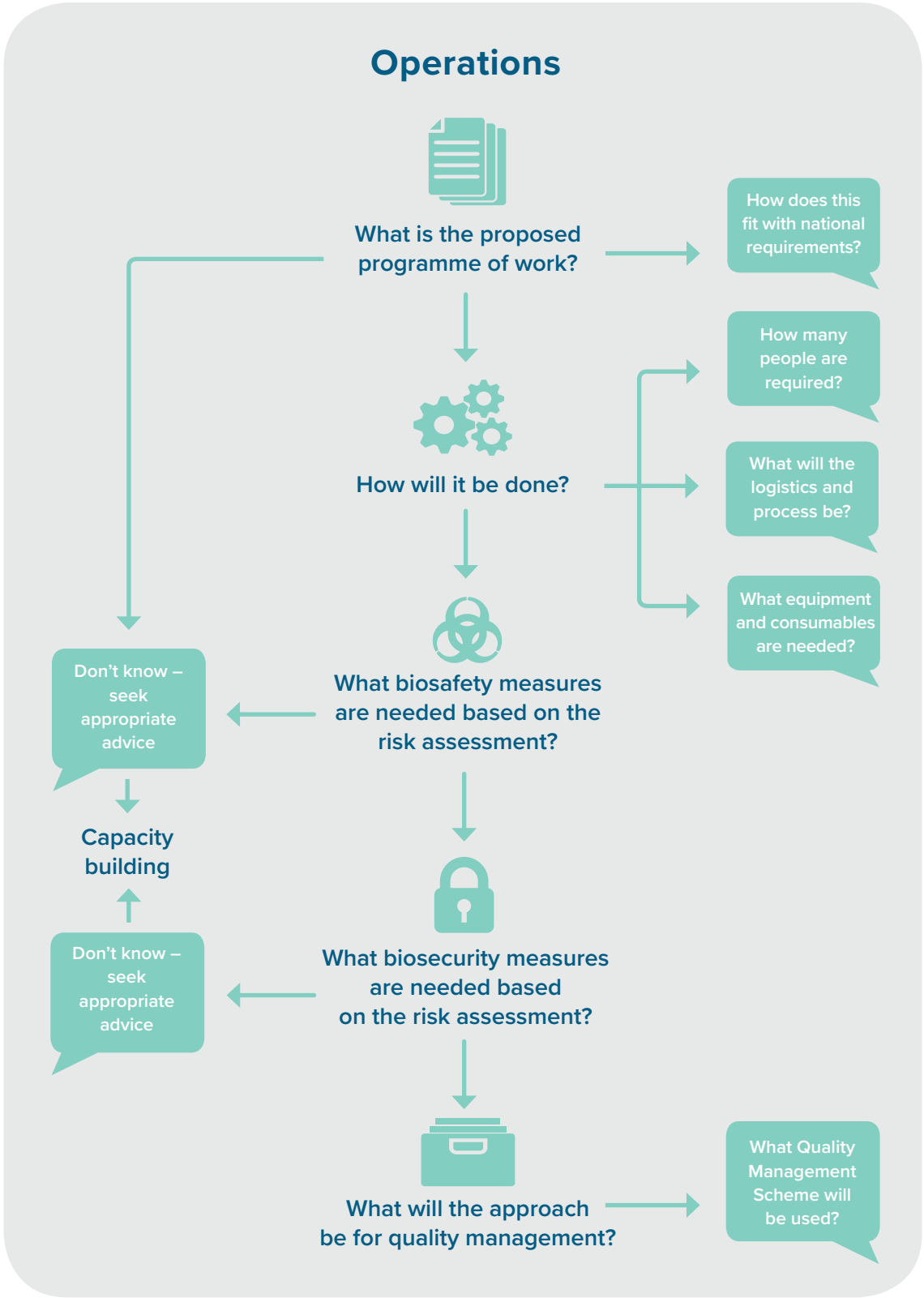
- **What is the size of the available workforce?**
- Where are the workers currently based (e.g. locally or remote)?
- Will the workers move to the new laboratory?
- What training have the workers received?
- Which workers have experience in high-biocontainment laboratories (e.g. scientists, technicians, maintenance workers and support staff)?
- Is there a human resource shortfall?

COMMENTS

- **How will gaps be filled?**
- What approach will there be for recruitment and retention?
- What skills need improving?
- What approach will there be for training and development?
- Is ‘surge’ capacity available?
- Has ‘twinning’ with another laboratory or institution been considered?

COMMENTS

OTHER KEY ISSUES


Operations
What is the proposed programme of work?
How does this fit with national requirements?
How will it be done?
How many people are required?
What will the logistics and process be?
What equipment and consumables are needed?
What biosafety measures are needed based on the risk assessment?
Don't know – seek appropriate advice
Capacity building
What biosecurity measures are needed based on the risk assessment?
Don't know – seek appropriate advice
What will the approach be for quality management?
What Quality Management Scheme will be used?

Operations

Operational aspects need to be considered early if the laboratory is to be fit for purpose and accurately costed. This involves having a vision for what activities will be undertaken, how they will be done and what the workflow will be. The opportunities and risks of using emerging technologies should be taken into account. Operational considerations include how many samples the laboratory will be expected to process over a given time period, how many people will need to be accommodated at the bench at any particular time, what systems will be used to ensure smooth operation of the laboratory, and what the appropriate biosafety and biosecurity measures will be. These issues all affect the cost, and therefore are interdependent with the discussion on financing. They are also linked to issues covered in the other thematic sections of this tool. The appropriate level of biosafety and biosecurity should be determined by a robust risk assessment.

- **What is the proposed programme of work?**
- What is the purpose of the programme?

  Consider, for example:
  - Diagnostics
  - Surveillance
  - Research
  - Biobanking

- What capabilities does the laboratory need to have?

  Consider, for example:
  - Microbial culturing
  - Molecular testing
  - Serological testing
  - Testing samples of unknown origin

- How does this fit with local, national and regional requirements?
- Would the laboratory play a role in an outbreak?
- What will the source of the samples be (e.g. the health system)?
- What are the expected organisms?
- What is the expected type and number of samples?

COMMENTS

- **How will it be done?**

  Consider, for example:

- People
  - How many people will need to be accommodated in the laboratory?
  - How much space will be needed?
  - What partners might need to be engaged (e.g. for development/delivery of programme)?

- Logistics
  - How will samples be transported to, and received by, the laboratory?
  - How will samples be despatched?
  - How close is the site to transport links?

- Process
  - How will samples be handled on receipt?
  - How will samples be tested?
  - What biocontainment issues are there?
  - How will samples be stored?
  - How will results be communicated?

- Equipment
  - What will be needed?
  - How will it be procured?
  - How will it be operated?
  - What will the approach be to maintenance/disposal (e.g. in-house or outsourced)?

- External engagement
  - What will the relationship be with local, national, regional or global laboratory networks (e.g. for external quality assurance)?
  - Could resources be shared with other laboratories?

COMMENTS

- **What biosafety measures are needed based on the risk assessment?**

  Consider, for example:
  - Facility design
  - Safety equipment (e.g. personal protective equipment)
  - Laboratory principles, practices and techniques
  - Administrative controls

COMMENTS

- **What biosecurity measures are needed based on the risk assessment?**

Consider, for example:

- Physical security
- Personnel security
- Material control and accountability
- Transport security
- Information security
- Programme management

COMMENTS

- **What will the approach be to quality management?**
- What Quality Management Scheme (QMS) will be used?

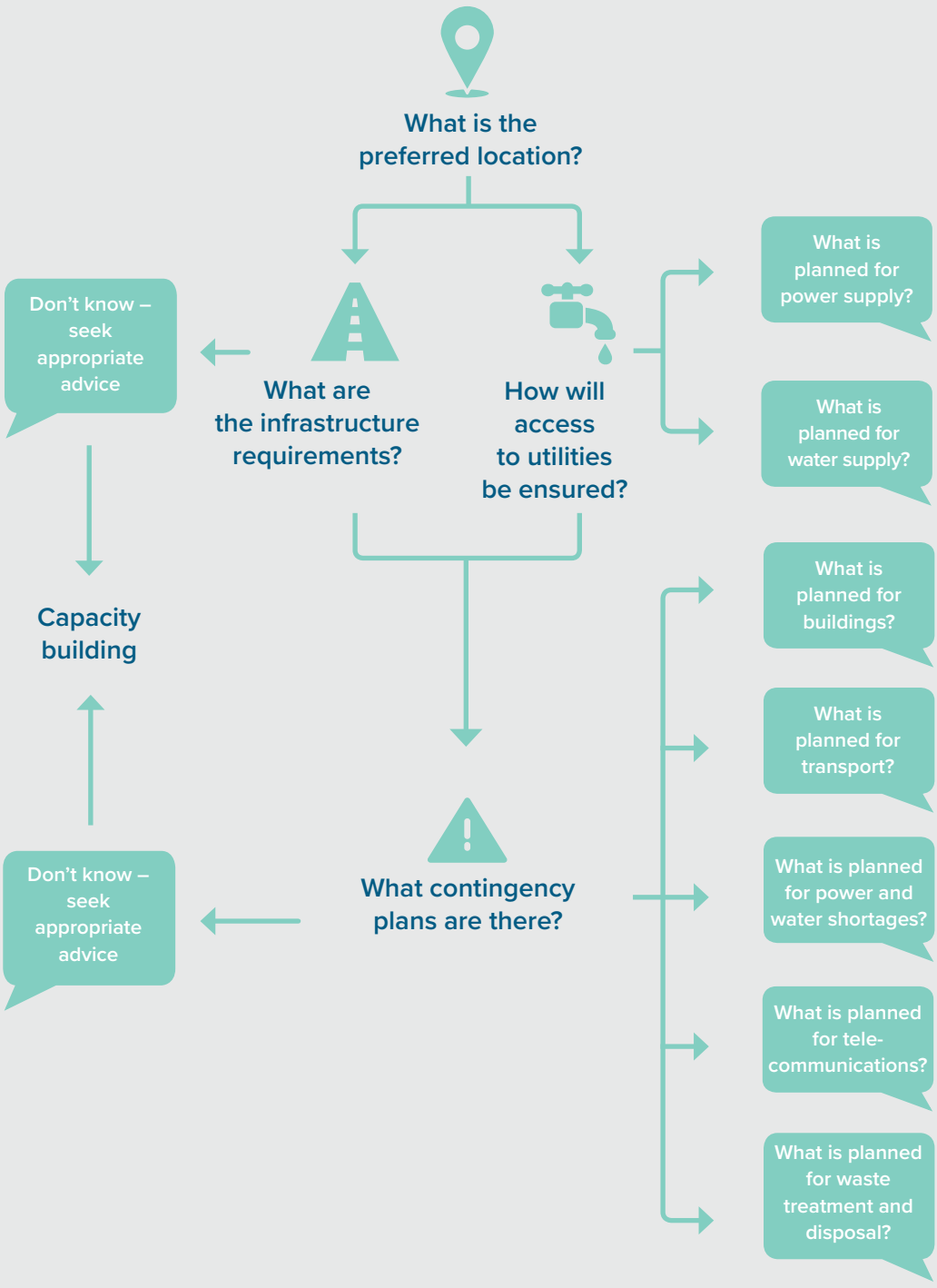
Consider, for example, the ISO 9001 concept of Quality Management:

- Recognize interested party requirements including licences to trade, guidelines, customer requirements and the chosen management system standard(s)
- Ensure that all requirements have been met
- Confirm that employees receive applicable training in the quality system requirements
- Determine processes, their interaction, inputs and outputs
- Produce records or evidence that system requirements have been met
- Measure, monitor and report the performance of the QMS
- Plan changes to the QMS, and take actions to address risks and opportunities as a result of changes
- Perform internal audit to analyse the QMS and correct nonconformities
- Continually improve the QMS

COMMENTS

OTHER KEY ISSUES

Infrastructure and utilities



Infrastructure and utilities

Suitable infrastructure and adequate access to utilities are fundamental requirements for laboratory sustainability. Consideration should be given to the most suitable location for the laboratory, what security measures need to be in place, and what the main risks are in terms of power supply, access to water, transport links and buildings, and environmental conditions, as well as what measures can be taken to mitigate such risks. Reviewing how other appropriate laboratories manage these risks can be helpful in determining how best to approach this aspect of sustainability early in the planning process. Identifying the challenges in this area will also inform accurate costing and aid financial planning. Contingency planning in this area may require collaboration across government.

- **What is the preferred location?**

  Consider, for example:
  - Repurposing or new laboratory
  - Environmental impact
  - Community engagement
  - Accessibility (e.g. proximity to transport networks)
  - Security
  - Land ownership
  - Requirement for licences
  - Size of the plot

COMMENTS

- **What are the infrastructure requirements?**
- Are there adequate transport links?
- Are the roads appropriate?
  - Are they suitable for use by the necessary vehicles?
  - Do new roads need to be built?

- What buildings are needed for the site?

  Consider, for example:
  - Laboratory and bench space
  - Administrative and office space
  - Storage

- What security measures are necessary?

  Consider, for example:
  - Setbacks
  - Fencing
  - Gates
  - Locks

- What is required for waste treatment and disposal?
  - What incinerator services are available?

COMMENTS

- **How will access to utilities be ensured?**
- What is planned for power supply?
  - How reliable will access to power be?
  - What is the quality of the power?

Consider, for example:

- Brownouts
- Blackouts
- Surges
- Voltage instability
- What source will be used?

Consider, for example:

- Sustainable energy sources (e.g. wind or solar power)

- What is planned for water supply?
  - How reliable will access to water be?
  - What is the quality of the water?
  - What source will be used?

COMMENTS

- **What contingency plans are there?**
- What is planned for transport?

Consider, for example:

- Alternative routes

- What is planned for buildings?

Consider, for example:

- Specific site security implications of the buildings (e.g. high occurrence of theft)

- What is planned for power and water shortages?

Consider, for example:

- Backup generators
- Fuel cost, supply and storage
- Environmental context (e.g. effects of dust, humidity, salt, heat, winds, proximity to coast or other topography issues)
- Storage of emergency water supplies (e.g. method and volume)

- What is planned for telecommunications?

  Consider, for example:

  - Availability of a satellite phone
  - Mobile data

- What is planned for waste treatment and disposal?

  Consider, for example:

  - Emergency maintenance/repair contracts
  - Storage facilities

COMMENTS

OTHER KEY ISSUES

Overall conclusions

COMMENTS

Acknowledgments

We are grateful to all those who have provided insight and review through participation in the Abuja workshop and subsequent roundtable in Accra, through the project advisory group, telephone interviews or in other contexts since February 2018. Such contributors we would like to thank specifically include Mohammed Abdulaziz, Adedeji Adebayo, William Adu, Anthony Ahumibe, Emmanuel Allegye-Cudjoe, William Amanfu, Kingsley Amoako, Martin Antonio, Ama Appiah, Franklin Asiedu-Bekoe, Joseph Awuni, Julie N. Bergmann, Cynthia Boateng, Kofi Bonney, Waqo Boru, Brad Brooks, Nancy Connell, Heba Diab, Daniel Duvall, Mike Ebie, David Elliott, Maureen Ellis, Amma Fenny, Julie Fischer, Damilola Graham-Douglas, Keith Hamilton, Nurudeen Hussain, Jide Idris, Chikwe Ihekweazu, Tony Joannis, Rame Khasawneh, John Klena, Kwadwo Koram, Jennifer Lasley, Zibusiso Masuku, William Addo Mills-Pappoe, Dhamari Naidoo, Nick Nwankpa, Edward Nyarko, Dennis Odai Laryea, Theophilus Odoom, Adebola Olayinka, David Opare, Djibril Sangare, Emmanuel Sarkodie, David Shamaki, Heather Sheeley, Trevor Smith, Nataly Spears, Richard Suu-Ire, Ikuo Takizawa, Yuriya Teragaki, Ken Ugwu, Sacha Wallace-Sankarsingh and Dorothy Yeboah-Manu.

Our thanks also go to the Chatham House editorial team for their work in finalizing this tool, and to Autumn Forecast at Soapbox for her interpretation of our design concept for the tool and her production of not only the final product but also the earlier conceptual storyboards that we created to develop and test the tool with African stakeholders and our advisory group. This work was funded by the Weapons Threat Reduction Program, Global Affairs Canada.

About the Centre on Global Health Security

The Centre on Global Health Security seeks to generate ideas for enhancing global health security by conducting independent research and analysis and by convening the relevant communities to stimulate discourse in the internationally recognized, politically neutral forum of Chatham House and in countries that are the focus of its work.

The Centre examines key global health challenges and how they manifest themselves as problems of international affairs and global politics. It seeks to inform policy by translating evidence into options for decision-makers around the world to consider that would improve national and global health security. A hallmark of its approach is the engagement at all stages of its projects with those in the countries where the outcome of the work would be implemented.

Chatham House, the Royal Institute of International Affairs, is a world-leading policy institute based in London. Our mission is to help governments and societies build a sustainably secure, prosperous and just world.

Design by Soapbox, soapbox.co.uk

ISBN 978 1 78413 341 2

Independent thinking since 1920

The Royal Institute of International Affairs
Chatham House
10 St James's Square, London SW1Y 4LE
T +44 (0)20 7957 5700 F +44 (0)20 7957 5710
contact@chathamhouse.org www.chathamhouse.org
Charity Registration Number: 208223