

RESEARCH PROJECTS PATH-SAFE Phase 1 Evaluation Report

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#### FSA Research and Evidence

#### Executive summary

This report describes the findings of an evaluation of the PATH-SAFE programme from its inception in 2021 to March 2024. PATH-SAFE is a crossgovernmental pilot programme focused on the surveillance of foodborne pathogens (FBPs) and antimicrobial resistance (AMR) in the UK. The programme consists of four workstreams focused on multiple aspects of surveillance, including sampling and sequencing activities, data infrastructure, methods development, and the generation of knowledge about FBPs, AMR and surveillance practices. It aims to influence a range of public health and economic outcomes related to FBPs and AMR. PATH-SAFE is coordinated by the Food Standards Agency (FSA), working with Food Standards Scotland (FSS), the Department of Health and Social Care (DHSC), the Department for Environment, Food and Rural Affairs (Defra), UK Health Security Agency (UKHSA), the Environment Agency (EA) and the Wales and Northern Ireland governments. PATH-SAFE received £19.2 million from His Majesty's Treasury (HMT) through the Shared Outcomes Fund (SOF) from 2021-2024, and continuation for an additional year until March 2025; however, this report is focused only on the first round of funding.

#### Methods

We were commissioned by FSA (on behalf of PATH-SAFE) to conduct a process and outcome evaluation of the PATH-SAFE programme. The process evaluation focused on the resources for PATH-SAFE, its governance structures, and process by which it facilitated cross-government collaboration, data sharing and linkages to the wider surveillance community in the UK. The outcome evaluation, which looked at preliminary outcomes achieved by the PATH-SAFE programme, adopted a contribution analysis approach. The outcomes were identified in collaboration with the PATH-SAFE management team and delivery stakeholders, through the development of a theory of change (ToC) and contribution statements that briefly described the outcomes and impacts PATH-SAFE aimed to achieve, and the mechanisms by which they would be accomplished. The evaluation then looked at the degree to which PATH-

SAFE contributed to the following outcomes: encouraging interactions across the surveillance community; influencing national policymaking; and contributing to improvements in surveillance practice.

To gather information for this evaluation, we reviewed documentation from PATH-SAFE and conducted desk research to understand PATH-SAFE's organisation and structures, the activities it had undertaken, and the outcomes of these activities. We also conducted interviews with stakeholders involved in delivering PATH-SAFE (n=41, across two time points) and a policy workshop with 20 stakeholders involved in surveillance across sectors and devolved nations in the UK. The workshop focused on PATH-SAFE outputs, the outcomes and impacts it aimed to produce, and what is needed to achieve them.

Along with reviewing and collecting information about the PATH-SAFE programme, we also reviewed information about the wider surveillance landscape through desk research. This information was used to conduct a gap analysis, which assessed the degree to which PATH-SAFE is affected by wider challenges related to surveillance, and the degree to which the programme addressed gaps in the surveillance system. Based on this analysis and information gathered throughout the evaluation, we developed recommendations for PATH-SAFE to improve its contribution to outcomes and impacts, as well as recommendations around the feasibility of the outcomes and impacts specified in the programme's ToC.

#### Key findings from the process evaluation

- Funding allocation: PATH-SAFE received sufficient funding for the activities it planned to undertake. However, the short-term funding distribution model of one-year periods was not optimal to strategically plan and resource a large, multi-year programme. Short-term funding contributed to challenges in recruiting staff and procuring services.
- Governance structures: Overall, the PATH-SAFE programme had appropriate governance and management structures, which was highlighted as a strength of the programme. The programme was organised under different workstreams and projects, and there were meetings and reporting structures to collect information on progress and share findings across projects. However, some reporting and monitoring requirements were viewed as overly time intensive.
- **Cross-government collaboration processes:** Coordination and collaboration across the PATH-SAFE programme was fostered by the central management team, and often involved shared

meetings and events. There was also strong collaboration across specific PATH-SAFE workstreams and projects, although this varied.

- Data sharing processes: PATH-SAFE has led to data-sharing agreements between partners delivering specific workstreams projects within the programme, enabled through and consultations, negotiation (e.g. regarding metadata requirements) and hiring a data fellow. However, the programme faced challenges related to data sharing (e.g. privacy concerns, commercial sensitivities, inconsistencies in metadata) that are common across surveillance programmes and could not be resolved at a programme level within PATH-SAFE (e.g. it was not feasible to implement a programme-wide data-sharing agreement in the context of PATH-SAFE). Issues with data sharing slowed delivery in some areas, and potentially contributed to duplication of work as data issues were solved by each project independently. In some areas, projects were also unable to gain access to anticipated clinical data.
- Linking with the wider surveillance community: The PATH-SAFE programme counts key organisations involved in surveillance in the UK among its partners, facilitating alignment with other programmes and strategies. PATH-SAFE is also connected to other UK surveillance programmes and has connected with the wider surveillance community through presentations, workshops, conferences and webinars.

#### Key findings from the outcome evaluation

- The outcomes from PATH-SAFE are not yet known: PATH-SAFE has made good progress in several key areas, as summarised below and described throughout this report. However, as a pilot programme that is still ongoing, it has not yet led to changes in policy or sustained changes in surveillance practices. While PATH-SAFE has generated useful outputs, it will require further time and effort to ensure that the insights produced by PATH-SAFE lead to improved surveillance practices in the UK. This report suggests actions that may be necessary to transform PATH-SAFE's outputs into tangible changes to surveillance practice in the UK.
- Interaction and collaboration across the surveillance community: PATH-SAFE is in a good position to bring wider surveillance stakeholders across the UK together and has facilitated

collaboration in delivering specific projects. However, collaboration at a programme level to bring together insights from across PATH-SAFE has been more limited.

- National policymaking: PATH-SAFE has contributed to the national debate around surveillance in the UK and aligns with national strategies and objectives. PATH-SAFE has been cited in recent policy and has influenced other programmes related to surveillance, but the long-term policy impacts from the programme are not yet known.
- Surveillance practices: PATH-SAFE has generated new knowledge about tools, technologies and methodologies for the surveillance of foodborne pathogens and AMR. It has also generated new knowledge that can help improve future pilots and programmes in surveillance, including on data sharing and coordination between partners within and outside government. The programme has also generated new questions and lines of inquiry which would benefit from further investigation and investment prior to deciding whether new techniques should be incorporated into business-as-usual (BAU) surveillance, some of which are being explored using the continuation funding that PATH-SAFE received. Despite all these achievements having the potential to influence future surveillance practices, it is not yet known whether new knowledge and insights will lead to changed surveillance practices in the long term.

#### Conclusion

Process evaluation findings indicate that PATH-SAFE has been successful in setting up robust structures for governance and oversight, collaboration and linking with the wider surveillance community. Although there are signs that PATH-SAFE is well-positioned to influence surveillance practices within the UK, outcome evaluation findings indicate that PATH-SAFE has not yet achieved its overall aims of influencing UK surveillance practices in a sustainable way (i.e. beyond the period of funding for PATH-SAFE). PATH-SAFE has produced knowledge about surveillance, AMR and FBPs that can subsequently lead to improved surveillance practices, but additional activities are needed to achieve lasting impact on surveillance practices in the UK. It is worth noting that PATH-SAFE has been funded for an additional year, which may result in sustained changes to practices within the UK. During this time, we will continue to assess progress towards the intended outcomes and impacts of PATH-SAFE.

Overall, PATH-SAFE has developed good processes for delivering projects and coordinating across workstreams. It has strong management and governance arrangements, and a wide range of stakeholders involved in coordination and delivery, which have helped the programme generate insights about surveillance and link with other stakeholders within the surveillance community. The programme has been successful in facilitating coordination across departments and delivery partners in the context of specific projects and has created structures and process to share progress and findings across the programme.

While PATH-SAFE has facilitated coordination and data sharing between partners, there remain challenges at a system level. PATH-SAFE is well positioned to develop recommendations to improve how coordination and data sharing is approached, given the programme's experience conducting a large, cross-government surveillance pilot, but there is limited evidence that it has, so far, generated better coordination or data sharing in the overall surveillance system outside immediate delivery of the programme. Additionally, although PATH-SAFE has generated useful insights across different areas, there is no evidence that PATH-SAFE has led to changes in surveillance practices beyond the programme, which is in part due to the timing of the pilot programme (having only just completed and moving into an additional year of funding). Additional action is required for PATH-SAFE to accomplish sustained outcomes and impacts beyond the lifecycle of PATH-SAFE funding (see below for recommended actions).

#### Recommendations

Below, we identify areas where PATH-SAFE can improve its contribution to the realisation of outcomes and impacts.

 Consolidation of evidence at a programme-level: PATH-SAFE should consolidate evidence from across its individual projects and workstreams on what has been learned through the pilot programme. These insights can then inform the development of specific recommendations around activities that should, or should not, be incorporated into wider surveillance practices in the UK, areas where additional investigation or evidence is needed, and where investment in surveillance could be beneficial in the future. Insights generated through PATH-SAFE may stem from both individual projects and workstreams delivered through PATH-SAFE, and knowledge gained from coordinating a large pilot programme across government departments. To consolidate learnings from across the programme, PATH-SAFE will likely need to create processes to promote more programme-level thinking, to avoid siloes between workstreams, project outputs and dissemination. For example, this may be accomplished through engaging with the Strategic Board, identifying key actionable

insights from across the workstreams and identifying where sustained action is needed – for example on the maintenance of the data platform.

- Tailoring insights to decision makers: For PATH-SAFE to influence surveillance practices in the UK, it must generate actionable insights for decision makers. Given the range of stakeholders involved in surveillance who could benefit from insights generated through PATH-SAFE, the programme should tailor dissemination activities to specific decision makers in the surveillance system. To do this, PATH-SAFE should engage with decision makers to understand their specific evidence needs, and create short, tailored outputs based on the evidence generated that address these needs wherever possible. Developing more specific aims for PATH-SAFE and the precise mechanisms by which the programme will influence outcomes and impacts may be helpful in targeting communications to specific decision makers and stakeholder groups.
- Benefits realisation plans: By better understanding the potential for each PATH-SAFE activity to generate specific outcomes and impacts, PATH-SAFE can identify gaps and additional investment required to ensure outcomes and impacts are achieved. To assist with this, PATH-SAFE should develop a benefits realisation plan to prioritise activities and subsequent investments. PATH-SAFE aims to influence surveillance practices and to influence a range of public health and economic outcomes, and a plan can help prevent the programme from becoming too dispersed to create lasting impact. In prioritising further action and funding, PATH-SAFE should consider which aspects of its outputs could benefit from being scaled up and implemented, as well as its impact on specific aspects of surveillance and decision making.
- Improving coordination and addressing wider issues in surveillance: PATH-SAFE well-positioned develop is to recommendations to address wider issues in surveillance that are beyond its scope and ability to directly address without action from others. For example, PATH-SAFE faced challenges related to data sharing, harmonisation and coordination, which are common across not just PATH-SAFE but other surveillance initiatives as well. These types of issues require wider action and coordination. PATH-SAFE may consider taking on a convening or advocacy role within the surveillance system to improve how wider issues requiring collaboration and additional action are addressed. For example, this could take the form of events for surveillance stakeholders (similar to those PATH-SAFE has already conducted),

position statements and recommendations to government, and coordination with other surveillance initiatives around areas of common interest.

### Abbreviations

AMR	Antimicrobial resistance
APHA	Animal and Plant Health Agency
BSAC	British Society for Antimicrobial Chemotherapy
Col	Communities of interest
Cefas	Centre for Environment, Fisheries and Aquaculture Science
DAG	Data Advisory Group
Defra	Department for Environment, Food and Rural Affairs
DHSC	Department of Health and Social Care
EA	Environment Agency
EARS-Net	European Antimicrobial Resistance Surveillance Network
ECDC	European Centre for Disease Prevention and Control
ECOSS	Electronic Communication of Surveillance in Scotland
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ESBL	Extended spectrum beta lactamases
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
ESS EU	Environmental surveillance system European Union
FBD	Foodborne disease
FBP	Foodborne pathogen
FSA	Food Standards Agency
FSS	Food Standards Scotland
FY	Financial year
GDPR	General Data Protection Regulation
HMT	His Majesty's Treasury
LAMP	Loop-mediated isothermal amplification
NAP	National action plan
NBN	National Biosurveillance Network
NCBI	National Center for Biotechnology Information
OECD	Organisation for Economic Cooperation and Development
OHEJP	One Health European Joint Programme
OHSS	One Health Surveillance System
PATH-SAFE	Pathogen Surveillance in Agriculture, Food and Environment
PHA NI PII	Public Health Agency Northern Ireland Personal identifiable information
RASCI	Responsible, accountable, supportive, consulted, informed
SAG	Scientific Advisory Group
SGSS	Second Generation Surveillance System
SOF	Shared outcomes fund
SRO	Senior responsible officer
ТоС	Theory of change

UK	United Kingdom
UKHSA	UK Health Security Agency
VMD	Veterinary Medicines Directorate
WARP	Welsh Antimicrobial Resistance Programme
WGS	Whole genome sequencing
WHO	World Health Organisation
WS	Workstream

## 1. Introduction

This chapter introduces foodborne pathogens (FBPs), antimicrobial resistance (AMR), the PATH-SAFE programme and the focus of this evaluation.

# 1.1. Introduction to foodborne pathogens and AMR in the UK

Foodborne diseases (FBD) pose a major public health risk and create a significant burden on health services and economies worldwide. Most human diseases are caused by just a few pathogens that predominantly enter the food chain from farmed animals or the environment (FSA, 2022). Moreover, these foodborne pathogens (FBP) can also develop antimicrobial resistance (AMR), which is a naturally occurring process but is made worse by the misuse of antimicrobials, including in the food system. Holistic surveillance is critical for mitigating risks caused by foodborne pathogens and AMR across the food chain and environment.

Surveillance across any one aspect of the health system, agriculture or environment is not sufficient given the interconnectedness of these systems and the transmission pathways of pathogens. Governments across the world, as well as international organisations, have included a One Health approach in their strategies. One Health is a coordinated and multi-sectoral approach that recognises the links between human health, animal health and the environment (WHO et al., 2022).

The UK government has been actively pursuing the One Health approach to surveillance for pathogens and AMR. Its 2019-2024 AMR national action plan (NAP) followed One Health principles and is now being updated to develop a new action plan for 2025-2029. The UK also published its Biological Security Strategy in June 2023, which featured: the launch of a real-time Biothreats Radar to monitor threats and risks as and when they appear; regular domestic and international exercises to better examine effective responses to biological threats with policymakers across UK, devolved, and local governments (CEPI, 2022); and the creation of a UK Biosecurity Leadership Council to work with businesses and organisations on the ground (HM Government, 2018).

# 1.2. Introduction to the PATH-SAFE programme

PATH-SAFE is a pilot programme that aims to develop surveillance of FBPs and AMR in all four nations of the UK. It started in 2021 with funding of £19.2 million from HM Treasury (HMT) through the Shared Outcomes Fund (SOF) lasting until 2024 (HM Treasury, 2020b). Continuation funding amounting to £2.2 million from the SOF and £2.5 million in match funding from government and academic delivery partners has extended the programme for one year, until March 2025. However, the focus of this report is on the phase 1 funding that was provided to PATH-SAFE prior to the continuation funding (up to May 2024). A separate evaluation report will be produced looking at the additional continuation activities from March 2024 to March 2025 as a second phase 2.

PATH-SAFE is a cross-governmental collaboration, coordinated by the Food Standards Agency (FSA), working with Food Standards Scotland (FSS), the Department of Health and Social Care (DHSC), the Department for Environment, Food and Rural Affairs (Defra), the UK Health Security Agency (UKHSA), the Environment Agency (EA) and the Wales and Northern Ireland governments.

It consists of four workstreams (WS), briefly described below. The programme focuses on multiple aspects of biosurveillance, including sampling and sequencing activities, data infrastructure, methods development and the generation of knowledge about FBPs, AMR and surveillance practices. An overview of the PATH-SAFE workstreams can be found in 7.

- 1. **WS1a:** This workstream is focused on working with academic colleagues and major pathogen and surveillance data government stakeholders to create a user-friendly platform for the rapid interrogation of genomic data from databases like PubMLST and Enterobase.
- 2. WS1b and WS2: WS1b is focused on understanding the source attribution, infection threat and level of AMR of *E. coli* in Scotland using whole genome sequencing (WGS), with samples isolated from a range of reservoirs across Scotland. WS2 is focused on providing high granularity WGS data from regular, multilocation sampling of wastewater and food products to capture AMR and FBP data.

- 3. **WS3:** This workstream investigates the technology readiness levels (TRLs) of existing and new portable diagnostics. The results of these studies will inform options for in-field testing and development at scale.
- 4. **WS4:** The overall aim of this workstream is to create an evidencebased understanding of the nature and extent of AMR in the environment and the drivers that influence it. This pilot aimed to deliver an agreed and tested methodology for environmental AMR surveillance, as well as an environmental IT platform to enable scaled-up AMR surveillance across the environment.

#### 1.3. Focus of the evaluation

FSA has commissioned RAND Europe to conduct an evaluation of the PATH-SAFE programme to assess the effectiveness and appropriateness of processes underpinning its design and delivery, and its contribution to improving surveillance in the UK. The evaluation consists of a process evaluation as well as an initial outcome evaluation of the programme. The evaluation approach and the evaluation framework were published in a report (Zakaria et al., 2023), which outlines the evaluation questions for each aspect of the evaluation. This report presents the findings from the first phase of PATH-SAFE, considering the period from inception to May 2024. The evaluation will also continue throughout PATH-SAFE's second phase of funding, and results from this will also be made publicly available in 2025.

The process evaluation and outcome evaluation frameworks in Annex E and Annex F serve as the underlying structure of the report, with each chapter covering a set of evaluation questions grouped according to the following themes:

- Chapter 2 provides a summary of the methods used in this evaluation.
- Chapters 3-4 address programme-level questions relating to processes (e.g. resourcing, governance, collaboration and data sharing) and respective outcomes and impacts of PATH-SAFE.
- Chapters 5-8 cover workstream-level developments, including progress with the national genomic data platform (WS1a, Chapter 5), multilocation sampling and surveillance projects (WS1b and WS2, Chapter 6), assessment of technologies for onsite pathogen testing (WS3, Chapter 7), and the pilot national AMR surveillance system (WS4, Chapter 8).

- Chapter 5 focuses on the results of a gap analysis for the overall programme (to explore the gaps between PATH-SAFE's current outputs and intended outcomes and impacts) and an impact feasibility assessment (to understand the feasibility of achieving and measuring these impacts).
- Chapter 6 discusses the results of the overall evaluation and presents a set of recommendations for PATH-SAFE based on evaluation findings.
- Annexes A-D provide findings about specific WSs within PATH-SAFE.

## 2. Methods

This chapter details our overarching evaluation approach and the methods frameworks utilised in conducting the theory-based evaluation. We conducted two types of assessment: a process evaluation and an outcome evaluation based on contribution analysis methodology. The sections below provide more information on the aims of each assessment.

#### 2.1. Overall approach

#### 2.1.1. Process evaluation

The process evaluation establishes how well the programme is working, whether it is progressing as intended, and identifies any lessons learned that can be applied to ongoing programmes as well as their future iterations. The evaluation methodology follows the HMT Magenta Book (HM Treasury, 2020a). We focused the evaluation on assessing whether the intervention incorporates needs of stakeholders and considering the wider context of surveillance.

This process evaluation is based on the PATH-SAFE ToC, focusing on the inputs, activities and the resulting outputs of the PATH-SAFE programme and its workstreams. It assesses the mechanisms and structures in place to deliver key programme outputs. This ToC was used to create a process evaluation framework (0), outlining indicators for each process-oriented question asked in this evaluation. Our process evaluation comprises three main components: undertaking desk research to map existing AMR and FBP surveillance mechanisms and assess the relevance and coherence of the PATH-SAFE programme; a documentary review of the PATH-SAFE programme structure and governance documents to date; and interviews with the central programme management team, delivery partners and strategic government stakeholders. These approaches are described in detail below.

#### 2.1.2. Outcome evaluation

The outcome evaluation is focused on whether the programme and its workstreams have realised the changes expected at a given point in time and determining the mechanisms through which the changes may or may not have occurred. The goal of the outcome evaluation was not to attribute outcomes exclusively to PATH-SAFE but rather to provide evidence-based explanations of whether and how the programme contributed to the outcomes of interest alongside other external factors through undertaking contribution analysis (CA), as explained below. Given the programme only began in early 2022, most outcomes are unlikely to have emerged at the time of writing this report. The outcome evaluation used the lens of the OECD evaluation criteria of effectiveness<sup>1</sup> in assessing if PATH-SAFE is progressing towards accomplishing its objectives. The outcome evaluation framework is provided in Annex F.

#### 2.1.3. Contribution analysis

To help attribute causality in a programme of this size and complexity, this evaluation used the contribution analysis methodology on the data collected. Contribution analysis is a method for assessing causal claims that examines the contribution of an intervention to observed results. It provides a framework for testing working hypotheses and establishing a case to explain and validate the contribution made by PATH-SAFE. We followed a method adapted from the approach outlined in Mayne (2011), which consisted of developing contribution stories based on the ToC and assessing evidence collected during the evaluation to ascertain the strengths and weaknesses of the claim. The contribution claims below were developed by reviewing the ToC and consulting with the PATH-SAFE leadership team on the central hypothesis of the pilot in terms of how it would achieve outcomes and impacts. In consultation with the PATH-SAFE team, we arrived at the three main claims listed below, which were at the time considered the main contributions of PATH-SAFE. We did not revise these claims to create a more credible contribution story or to revise the ToC, which will be proposed as PATH-SAFE enters its year of extended funding to March 2025. The ToC is a live output, and as such will be modified prior to evaluating the second phase of PATH-SAFE (funding March 2024-2025).

The three contribution claims based on the programme ToC that are assessed in Chapter 4 are as follows:

https://www.oecd-ilibrary.org/sites/543e84ed-en/1/3/4/index.html?itemId=/content/ publication/543e84eden&\_csp\_=535d2f2a848b7727d35502d7f36e4885&itemIGO=oecd&itemContentType=b ook#section-d1e3395

- The processes established in the PATH-SAFE programme led to cross-government collaboration on FBP and AMR surveillance due to increased transparency and engagement across departments through the work on interrelated workstreams.
- The data platform developed by PATH-SAFE leads to easier data sharing across government departments through data sharing-agreements and the programme's user engagement activities.
- The collective outputs of PATH-SAFE workstreams lead to the establishment of a nationally connected and improved FBP and AMR surveillance approach through multilocation sampling, novel testing tools and an interconnected data platform.

In the tables outlining the results of the contribution analysis in this report, we both assess the claim qualitatively, and assign a green, amber or red rating based on the extent to which the claim has been met. We also assess the consistency of the evidence (i.e. Did different sources tell the same story about the contribution claim?) and its credibility (i.e. are the sources of evidence for the claim robust? Were claims backed up by sources not directly involved in PATH-SAFE?). We placed greater weight on findings stemming from multiple data sources, to ensure that assessment against the contribution claims is robust.

#### 2.2. Desk research

#### 2.2.1. Phase 1

We conducted a web-based search to find existing AMR and FBP surveillance networks and activities already in place within the UK, Europe and globally using the following high-level search string: "pathogen surveillance" OR "AMR" OR "AMR surveillance" OR "pathogen tracking" OR "foodborne pathogens" OR "biosurveillance" AND Europe OR UK OR global OR international OR US. The search covered the period from 2015 to 2023. The first 50 hits were reviewed and screened based on the criteria of either being UK, Europe and globally relevant mentions of initiatives, platforms or networks for surveillance. We excluded anything that was primary research focused on scientific or technical developments in the field. We included 24 sources and used a snowballing approach to find further relevant information about the initiatives and networks identified (meaning that we looked for sources cited in the articles already identified and reviewed these sources if they were relevant). This was a high-level scoping search and intended to provide an exemplar suite of initiatives to assess linkages with PATH-SAFE, if any, and identify opportunities for learning and collaboration. Primarily, this was also an exercise to assess the broader context within which PATH-SAFE is situated in order to develop a qualitative assessment of the programme's coherence and relevance to the wider sector. We developed search terms to find key literature on AMR and FBP surveillance activities, which were the basis of the desk research.<sup>2</sup> A template was developed using Microsoft Excel to draw out key information about the activities, scale and setting of these networks or programmes and so identify how their scope and focus aligned with the PATH-SAFE programme. We also aimed to identify opportunities for learning and future linking up. The outputs of this scoping can be found in Annex J.

#### 2.2.2. Phase 2

We conducted desk research to identify and review academic and grey literature outputs that may be fully or partly attributable to PATH-SAFE. We reviewed outputs from PATH-SAFE's work provided by the PATH-SAFE team (although the number of outputs available at the time of writing this report were limited). To help fill gaps and identify additional outputs from PATH-SAFE and mentions of PATH-SAFE in the wider literature, we also searched for academic and grey literature using Google, Google Scholar and PubMed. The search strategy was targeted, and included search terms related to PATH-SAFE, FSA, biosurveillance, AMR and FBP. For each search string, we reviewed the first 100 hits and any article that covered topics of relevance to PATH-SAFE in a UK context. We also searched through the citations of recent relevant academic and policy documents, as well as the documents that cited known PATH-SAFE outputs. Our search covered the period from January 2021 to March 2024. We only searched Englishlanguage sources.

#### 2.3. Documentary review

We completed a documentary review of selected PATH-SAFE programme governance and workstream documentation, Strategy and Delivery Board papers and internal management information, to better understand governance arrangements, links with existing surveillance and monitoring approaches, as well as the extent to which cross-sector collaboration had occurred. The documents made available on or before 31<sup>st</sup> January 2024 were reviewed and information was extracted using an Excel template in relation to the evaluation questions for the overall programme and for each workstream. To update our findings, we reviewed workstream and sub-workstream closure reports in June 2024. Not all closure reports were available at this time, and some were available in draft form only.

<sup>&</sup>lt;sup>2</sup> Search terms used for the desk research were *"UK AMR surveillance; NBN programme; Pathogen surveillance initiatives Europe; Foodborne pathogen tracking Europe; AMR surveillance Europe; GenomeTrackr USA; Quadripartite AMR; Pathogen surveillance global".* 

#### 2.4. Data collection

#### 2.4.1. Interviews

We conducted interviews at two time points (marked as 'Phase 1' and 'Phase 2' in this report to distinguish between time periods). We conducted 25 interviews with key individuals across the delivery of the programme in June-July 2023 (Phase 1). At this time, four interviewees belonged to the central programme management team, 15 interviewees were delivery partners of the programme and six were strategic government stakeholders.<sup>3</sup>

We conducted 16 interviews with key individuals across the delivery of the programme from October 2023 to January 2024 (Phase 2). Some of these individuals had also been interviewed during Phase 1 interviews (above), while some were interviewed for the first time during Phase 2. Two interviewees belonged to the central programme management team, 10 were delivery partners of the programme and four were end users.

Interview guides were developed for each stakeholder group, tailored to their role (see Annex I). Interview questions aimed to gain high-level understanding of the process and governance mechanisms underpinning the programme, to reveal the extent to which these mechanisms and resourcing are fit for purpose, and to identify any changes or progress since the previous round of interviews. Phase 2 interviews also sought to understand programme outcomes realised to date and the encompassing workstreams. The interview guide was based on the process and outcome evaluation framework questions presented in Annex E and Annex F. We developed an analytical synthesis template using Microsoft Excel and used the evaluation framework questions to extract key themes from the interviews.

#### 2.4.2. Policy workshop

A workshop was conducted in March 2024, with five members of the research team and 20 external stakeholders in attendance. These stakeholders covered a broad range of expertise and experience from across the devolved nations, sectors relevant to the One Health approach and surveillance generally. The workshop focused on several aspects, including discussion of PATH-SAFE outputs and what is needed to achieve impact. The first session in the workshop, on PATH-SAFE outputs, included discussion around tools and methodologies, data, infrastructure and knowledge to improve analysis and insights. The second discussion, on

<sup>&</sup>lt;sup>3</sup> Of these six, one was interviewed as a delivery partner, and one submitted answers via e-mail.

actions needed to meet impact, considered coordination, prioritisation and capacity. Insights gleaned from this workshop were written up as full workshop notes, analysed, and incorporated into this report.

#### 2.5. Case studies

Four case studies were developed, with two focused on process and two focused on outcomes of the programme. The specific topics of the case studies were selected in consultation with the PATH-SAFE programme team and the broad topic areas were derived from mapping to the contribution claims so that, where evidenced, they could serve as illustrative examples of progress made on these claims.

The evidence to support each case study consisted of interview data (from the interviews described above), desk research and a documentary review around the specific case study, as well as a short written questionnaire with open questions, which was distributed to up to four key stakeholders with knowledge of each case study topic (see Annex H). We received information from 11 respondents. This approach was taken in lieu of an interview to reduce the burden on stakeholders of participating in the evaluation.

# 2.6. Identifying surveillance system needs, gaps and feasibility of outcomes and impacts

#### 2.6.1. Wider landscape analysis

We conducted a brief, targeted review of the wider surveillance landscape in order to inform our understanding of gaps and challenges in the surveillance space. The purpose of this exercise was to help us understand how these gaps and challenges affect PATH-SAFE's ability to realise outcomes and impacts as specified in the ToC, and how PATH-SAFE can help fill priority gaps in surveillance.

We identified articles to review by searching PubMed for articles published since 2020, using keywords related to AMR, foodborne diseases and surveillance, along with a previously published landscape review of the international surveillance space conducted by RAND Europe (Parkinson et al., 2023). We prioritised articles that were reviews, and those that summarised challenges relating to key areas of PATH-SAFE's work (e.g. surveillance of foodborne diseases and AMR, One Health surveillance systems, integrating different sources of data, environmental and wastewater surveillance, genomic surveillance). In total, 13 sources were reviewed at this stage.

Researchers extracted information from included articles using an Excelbased extraction template, with sections to reflect the current state of surveillance systems (e.g. related to data collection, technology, data sharing, integration, collaboration/coordination, analysis and prediction, evidence-based decision making, efficiency and other areas), gaps/ challenges in surveillance, and who would need to take action to resolve these issues. Researchers also extracted information on interim actions and outcomes that would help fill gaps, and reflected on the relevance of information about the wider surveillance landscape to PATH-SAFE's ToC.

Following this exercise, the study team held an internal workshop to analyse and synthesise information on the wider surveillance system and its relation to PATH-SAFE. Challenges identified in this analysis were categorised into different groups (scientific and knowledge gaps, processlinked challenges and gaps, and capacity gaps). Results from this analysis are described in Section 5.2 of this report.

#### 2.6.2. Gap analysis

Using information gathered throughout the evaluation and wider landscape analysis, we then conducted a gap analysis. The purpose of this exercise was to consider what gaps and challenges in the wider surveillance landscape mean for PATH-SAFE's ability to accomplish outcomes and impacts, to identify actions PATH-SAFE could take to improve impact and fill gaps in the surveillance system, and to identify what other, external changes would be necessary for PATH-SAFE to address challenges.

We held an internal analysis workshop, drawing on results from the wider landscape analysis. During the workshop, we used a framework to help us link gaps and challenges in the surveillance system to PATH-SAFE (see Section 5.3). Finally, we looked at the actions we had identified to help improve impact (both within PATH-SAFE and in the external environment) and produced recommendations on what is needed to improve PATH-SAFE's impact, based on factors in the wider surveillance landscape.

## 2.7. Limitations

This evaluation was conducted throughout the PATH-SAFE programme's delivery thus far and has benefited from multiple data collection points and ongoing observation of PATH-SAFE's progress through regular meetings and communication with the PATH-SAFE team. It has gathered evidence both from within PATH-SAFE – for example by reviewing reports and outputs from projects and consulting with delivery partners – and from the wider landscape to contextualise PATH-SAFE's activities and contributions. However, there are key limitations that should be considered in utilising the findings from this evaluation.

First, much of this evaluation relies on information provided by interview and workshop participants. While the evaluation team made every effort to encourage participation, in the second round of interviews there were gaps in participation among strategic government stakeholders outside of FSA and UKHSA. These strategic government stakeholders would be among the projected end users of PATH-SAFE, in that they would use outputs and information from PATH-SAFE to make decisions about ongoing surveillance practices in the UK. However, there was good participation in the policy workshop in March 2024, which helped gather perspectives from members of this stakeholder group at a key point in PATH-SAFE's delivery as the first phase of funding concluded. It is possible that we would have found additional results if we had spoken to more stakeholders, or different stakeholders, which is a limitation of this study. Additionally, there is a risk that those who agreed to engage with the evaluation team may hold different views from those that did not – for example, they may have had more positive feelings about PATH-SAFE or, conversely, they may have had more negative associations with the programme.

The timing of this evaluation in relation to the timeline of PATH-SAFE presents an additional limitation. There was a significant delay at the outset of PATH-SAFE, meaning that many activities were delayed (for more details, see Section 3.1). The evaluation is completed as PATH-SAFE's first phase of funding concludes, meaning there has not been sufficient time for some of PATH-SAFE's intended outcomes and impacts to materialise. As such, where no evidence has been identified to support an impact, this does not necessarily mean that impact will not occur in the future. However, there will be additional evaluation for the continuation phase of PATH-SAFE, with a report describing findings made publicly available after this round of funding ends in May 2025.

Lastly, while the evaluation has reviewed evidence on the wider surveillance landscape and drawn on evidence from previous reviews of gaps and challenges in the surveillance system, this review was not comprehensive. The recommendations were formulated using frameworks to consider how gaps in the surveillance system relate to PATH-SAFE's ToC and intermediate outcomes that would need to be achieved to accomplish PATH-SAFE's goals. While these methods are structured, they also require judgement, and it is possible that other researchers implementing these frameworks would arrive at different recommendations for PATH-SAFE.

## 3. PATH-SAFE programme processes

This chapter presents the findings of the process evaluation conducted as part of this study, and reflects on PATH-SAFE resourcing, governance and end user engagement, as well as the wider surveillance ecosystem within which the pilot programme is operating. The process evaluation looked at the effectiveness and appropriateness of the structures underlying PATH-SAFE and the processes by which the programme is delivered. Findings from the outcome evaluation and evidence around the extent to which PATH-SAFE has accomplished intended outcomes and impacts are provided in the following chapter.

#### 3.1. PATH-SAFE resourcing

#### Evaluation questions

• How appropriately has PATH-SAFE been resourced throughout the stages of inception, design and implementation?

Summary of key findings

- PATH-SAFE received sufficient funding for the activities it planned to undertake.
- The short-term funding model was not found to be optimal for strategic planning and resourcing of a large-scale, multi-year programme.
- Staffing and procurement were challenging for PATH-SAFE, in part due to required procurement processes and short-term funding model.

PATH-SAFE received £19.2 million in 2021 from the Shared Outcomes Fund (SOF) established by HMT, with this funding planned to conclude on  $31^{st}$ 

March 2024.<sup>4</sup> The programme has now obtained continuation funding of  $\pm 4.7m$  – comprising  $\pm 2.2m$  from SOF and  $\pm 2.5m$  from programme delivery partners – to extend the programme by an additional 12 months. The focus of this report is on the funding until March 2024 only.

In 2021/2022 to 2023/2024, funds for PATH-SAFE flowed from HMT to FSA, which distributed funding to FSS, UKHSA and Defra, based on the respective workstreams these partners are responsible for, as illustrated in Figure 1 below.<sup>5</sup> Since Defra is the parent department of the Centre for Environment, Fisheries and Aquaculture Science (Cefas), the Veterinary Medicines Directorate (VMD), the Animal and Plant Health Agency (APHA) and EA, it is in charge of allocating funds across these organisations. Similarly, FSA distributes funds to the Public Health Agency Northern Ireland (PHA NI), which is in charge of WS2c.

<sup>&</sup>lt;sup>4</sup> Information from PATH-SAFE management documents

<sup>&</sup>lt;sup>5</sup> Information from PATH-SAFE management documents



Figure 1. Flow of funding for PATH-SAFE to government departments Source: 2021/2022–2023/2024 PATH-SAFE funding flow

# PATH-SAFE received sufficient SOF funding for the activities it planned to undertake

Central programme management interviewees agreed that PATH-SAFE was well-resourced,<sup>6</sup> and multiple stakeholders mentioned that the projects funded through PATH-SAFE would be difficult to fund from other sources.<sup>7</sup> The structure of funding from SOF also was reported to have helped encourage cross-government working within PATH-SAFE. An interviewee from the delivery team commented that the funding mechanism via the SOF permitted novel ways of working, and that the fluidity of the funding between workstreams enabled cross-government work, especially for smaller projects where extra capacity was needed at times.<sup>8</sup> However, as would be expected, partners involved in delivering PATH-SAFE also emphasised that additional funding would allow them to extend their activities to create more impact.<sup>9</sup>

As of February 2024, PATH-SAFE has received continuation funding from SOF and delivery partners to extend activities for an additional year. This funding covers an expansion of the data platform developed through

<sup>6</sup> Phase 1 interviews

<sup>7</sup> Phase 2 interviews

<sup>8</sup> Phase 1 interviews

<sup>9</sup> Phase 2 partners and the central delivery team interviews

PATH-SAFE (described in Annex A), continued investigation of transmission routes and AMR development and spread (described in Annex B), further development of on-site diagnostics (described in Annex C) and an extension of PATH-SAFE's activities to facilitate linkages between stakeholders and government departments and support data-sharing approaches. This funding does not cover the AMR surveillance system work (described in Annex D); PATH-SAFE's continuation proposal did not seek funding to continue this workstream (WS4). Funding has been secured to cover £4.67m in costs, 48% of which is provided by HMT through the SOF, and 52% by matched funding from external partners involved in delivering PATH-SAFE, such as Defra, FSS, PHA NI, Bangor University, Queens University Belfast and Oxford University.<sup>10</sup> This additional year of funding is not covered in the scope of this evaluation, although it is anticipated that the evaluation will be extended to generate insights about this additional year of funding.

#### The short-term funding model was not found to be optimal for strategic planning and resourcing of a large-scale, multi-year programme

Central programme management and strategic stakeholder interviews indicated that while the total funds allocated across the programme were sufficient, government requirements and procedures relating to how and when they can be used contributed to difficulties. For example, interviewees mentioned significant problems with the ringfencing of the budget per financial year. According to most interviewees, HMT's guidelines to spend annual allocations within each financial year meant that delays in procurement and implementation had a knock-on effect as any unspent funds had to be handed back to HMT.<sup>11</sup>

A key struggle in relation to financial resources stemmed from the initial delay of the programme itself. Funding for the project was received in spring 2021, but work could only begin in Q4 of that financial year (FY 21/22) due to postponement of ministerial approval for kick-off and procurement delays.<sup>12</sup> The initial late start to the programme resulted in delays to hiring staff for workstreams, which caused an underspend in the first and second financial year of the programme. Due to the budgetary ringfencing, the extra funds could not be used in subsequent years.<sup>13</sup>

<sup>&</sup>lt;sup>10</sup> PATH-SAFE SOF: Continuation Funding Bid (January 2024). Provided by PATH-SAFE central management team.

<sup>11</sup> Phase 1 interviews

<sup>12</sup> Information from HMT Year 2 summary

<sup>&</sup>lt;sup>13</sup> Information from PATH-SAFE Strategic Board report (March 2023)

There is evidence that the short-term nature of funding is a wider challenge within surveillance, rather than unique to PATH-SAFE. For example, participants in the November 2023 Innovation in Biosurveillance Conference cited funding constraints and the short-term financing of projects as general issues that can inhibit progress in biosurveillance. During the workshop, RAND Europe conducted a root cause analysis<sup>14</sup> and found that insufficient and short-term funding inhibited stakeholders from addressing known challenges in biosurveillance, limited stakeholder engagement within the biosurveillance community, and prevented data owners from engaging effectively with end users. Participants called for more reliable and better-coordinated funding, as well as clearer indications of the government's direction of travel, to help surveillance stakeholders better understand priorities in biosurveillance.

# Staffing and procurement were challenging within PATH-SAFE, in part due to required procurement processes and short-term funding

In addition, the annual ringfencing of funding for PATH-SAFE contributed to some difficulties in recruiting staff for multi-year projects, since funds were not guaranteed for future years and staff were contracted on an annual basis.<sup>15</sup> Among delivery partners, there were mixed views and experiences regarding the usefulness of temporary contracts – which were necessary due to the temporary nature of the funding – across the programme. One interviewee from this group mentioned that over-reliance on recruitment through temporary contracts caused delays due to lack of continuity. However, others said the flexibility to hire temporary staff to help their team with project management work and with clearing a backlog of tasks during busy periods (e.g. for six months) was helpful.<sup>16</sup>

Hiring appropriate delivery partners and staff also proved difficult due to governmental requirements for recruitment and procurement. Several stakeholders across central programme management and delivery partners cited government procurement frameworks and sign-off procedures as a cause of delay, and said these frameworks were not appropriate for sourcing scientific and technical knowledge.<sup>17</sup> Other

<sup>&</sup>lt;sup>14</sup> High-level systemic challenges/barriers were provided to attendees, and they had to identify underlying conditions and sequence of events that led to the barriers. They categorised the underlying causes into broad categories of human, physical/technical and organisational.

<sup>15</sup> Phase 1 and Phase 2 interviews

<sup>16</sup> Phase 1 interviews

<sup>17</sup> Phase 1 interviews, Information provided by SOF Q1 return questionnaire

challenges mentioned included open market tenders yielding inadequate bids and lengthy contract negotiations.<sup>18</sup> Interviews with partners and the central delivery team towards the end of PATH-SAFE's initial round of funding attributed the projected underspend of PATH-SAFE to delays in procurement and slow processes within government.<sup>19</sup>

Procurement for the specific PATH-SAFE workstreams pertaining to the data platform (WS1a) and AMR surveillance (WS4) were particularly challenging, according to central programme management and delivery partner interviewees.<sup>20</sup> In the case of WS1a, the niche product required was eventually procured through direct award since the necessary supplier could not be appointed through open procurement based on the quality and suitability of proposals submitted in the open call.<sup>21</sup>

#### 3.2. PATH-SAFE governance

#### Evaluation question

- How effective and appropriate is the governance in place to support delivery of PATH-SAFE? Summary of key findings
- PATH-SAFE governance is facilitated using appropriate and relevant bodies and forums.
- The programme management team was described as a strong resource for PATH-SAFE.
- There were mixed views regarding reporting on and monitoring requirements.
- Participant engagement in governance meetings varied.

Two boards – the Strategic Board and Delivery Board – and two advisory groups – the Scientific Advisory Group and the Data Advisory Group – make up the key oversight structures of the PATH-SAFE programme. The core responsibilities of the boards and groups are summarised in

<u>Table 1</u> below using responsible, accountable, supportive, consulted, informed (RASCI) definitions.

Figure 2 illustrates the programme governance structure.

- 20 Phase 1 interviews
- 21 Phase 1 interviews

<sup>18</sup> Information provided by SOF Q1 return questionnaire

<sup>19</sup> Phase 2 interviews

#### Table 1. Key responsibility matrix for PATH-SAFE

Responsibilities	Strategic Board	Delivery Board	Programme manager	Workstream leads	Partner departments
Approvals	А	С	R	S	I
Setting strategy	A	С	R	С	С
Finances	А	С	R	R	R
Project delivery	С	С	A	R	R

RASCI is a project management framework used to determine all stakeholder roles and responsibilities on a given project (Brulotte, 2021)

Source: PATH-SAFE management information



Figure 2. PATH-SAFE governance structure Source: PATH-SAFE management information

The Strategic Board is ultimately accountable for PATH-SAFE's strategy, financing and decision making. HMT delegated responsibility for providing overarching guidance, including oversight of assurance and evaluation, to the Strategic Board. It meets bi-monthly and comprises senior governance and management representatives from UK government bodies relevant to PATH-SAFE (e.g. Cefas, EA, FSA, FSS, Defra, UKHSA, APHA, etc.), including chief scientific advisers.

The Delivery Board's core membership are the delivery partners, including programme evaluators who provide monthly delivery-focused updates. The programme management team are also represented on the Delivery Board in a directing capacity, as are finance and benefits management personnel from an assurance perspective. The board's responsibilities include timely project delivery, oversight of workstream budgets and overall activities, as well as providing methodological and technical direction. The project management team for PATH-SAFE sits within FSA. The Senior Responsible Officer (SRO) reports on delivery of programme benefits to the Strategic Board. The programme manager ensures delivery of programme outcomes are aligned to maximise realisation of benefits. Project managers, senior project managers and support officers are engaged in the day-to-day running of the programme.

Figure 3 below illustrates the central programme management team structure.



Figure 3. PATH-SAFE central programme management team structure Source: PATH-SAFE management information

Along with these governance structures, PATH-SAFE has several advisory groups who provide guidance to ensure its alignment with existing crossdepartmental and devolved administration priorities, strategies and surveillance activities. The Scientific Advisory Group (SAG) advises on the relevance and robustness of the programme's scientific methods and approaches. It consists of programme fellows and academic leaders in the fields relating to PATH-SAFE.

The Data Advisory Group (DAG) advises on alignment with government data policy, data integration, transparency, open data and data sharing across relevant government bodies.<sup>22</sup> DAG does not cover data science,

<sup>22</sup> Information from PATH-SAFE management documents

which is part of SAG's remit. Membership of the DAG includes the data advisory group chair, programme fellows and data representatives from each relevant government organisation.

#### The programme management team was described as a strong resource for operational support of PATH-SAFE

PATH-SAFE's central management team within FSA was described favourably by nearly all interviewees.<sup>23</sup> One delivery partner described the central programme management team as a "tour de force" and "the lynchpin," noting that it was particularly effective in ensuring delivery teams and their milestones were not impacted by cross-government or interdepartmental politics regarding the scope and priorities of biosurveillance and AMR.<sup>24</sup> Feedback was also positive on the central management team's handling of sensitivities around sampling and publishing,<sup>25</sup> which included developing a cross-government publications framework that takes into account commercial and other sensitivities of all delivery partners.<sup>26</sup>

In summer 2023, the central programme management team introduced process efficiencies based on learnings from the programme. Strategic Board meetings changed from monthly to bi-monthly, with the board receiving written updates from the central programme management team on a monthly basis – which is reported to have improved attendance and engagement.<sup>27</sup> Similarly, the Delivery Board's monthly meetings were made shorter and reporting became based on exception, due to the steady state of the projects.<sup>28</sup> The Delivery Board's reporting templates were also modified, which a central management interviewee said improved consistency in reporting across the programme and therefore led to better insights on the projects.<sup>29</sup>

- 24 Phase 1 interview
- 25 Phase 2 interviews
- <sup>26</sup> Information from PATH-SAFE management documents
- 27 Phase 2 interviews
- 28 Phase 1 interviews
- 29 Phase 1 interview

<sup>23</sup> Phase 2 interviews

## There were mixed views on reporting and monitoring requirements

The monthly reporting required of all projects entailed detailing progress against milestones with red, amber or green ratings depending on completion timeline, detailed financial accounts and risk registers. Delivery partners' perceptions of monthly reporting requirements were mixed.<sup>30</sup> While most viewed the requirements as appropriate and not too onerous, especially when compared to European projects of this nature and scale,<sup>31</sup> a smaller proportion of partners felt them to be burdensome with negative impacts on day-to-day work.<sup>32</sup> One government stakeholder also viewed PATH-SAFE as more management-heavy than most research programmes they had experienced in the health space.<sup>33</sup>

## Participant engagement in governance meetings varied

The Delivery Board was generally seen as a useful forum characterised lively engagement and discussion, and helpful in building networks and fostering cross-government collaboration. Interviewees reported that making the meetings shorter and adopting 'reporting by exception' – meaning only issues were reported, rather than all progress and operational details for each workstream – helped make meetings more interactive.<sup>34</sup> However, interviewees across central management and delivery partners indicated that Delivery Board meetings focused heavily on outputs and milestones, leaving little room for knowledge exchange.<sup>35</sup>

A small number of interviewees perceived the Strategic Board as less active.<sup>36</sup> This view was formed in the early phase of the programme, in part due to reportedly low attendance at meetings and the seniority of its members, who lack time to engage with programme outputs.<sup>37</sup> This is reported to have improved in later stages of PATH-SAFE, when Strategic

- 31 Phase 1 and Phase 2 interviews
- 32 Phase 1 and Phase 2 interviews
- 33 Phase 1 interview
- 34 Phase 2 interviews
- 35 Phase 1 interviews
- 36 Phase 1 interviews
- 37 Phase 1 interviews

<sup>30</sup> Phase 2 interviews

Board meetings were made less frequent.<sup>38</sup> One delivery partner described Strategic Board meetings as helpful a forum to discuss strategy as distinct from immediate delivery of the programme.<sup>39</sup>

Advisory groups were generally seen as helpful in guiding the direction of PATH-SAFE, although engagement and perceptions of meeting efficacy were mixed. One delivery partner suggested that while SAG meetings have served a clear, useful purpose and provided a meaningful sense check for the programme, engagement was challenging at times due to meetings being very information heavy. To address this, the central management team has changed the format of the meetings, replacing information-heavy oral updates with written points, which focus only on key points for discussion and are circulated in advance. Similarly, a central management interviewee described the DAG as a welcome forum for those navigating data-focused challenges across the programme, but said it initially struggled to find its role and engage government.<sup>40</sup> This may be due to the bottom-up nature of the group's management, whereby the leadership and priorities of the DAG were not pre-determined.

### 3.3. Collaboration within PATH-SAFE: crossgovernment engagement, workstream collaboration and communities of interest

Evaluation questions

• How is PATH-SAFE enabling and conducting cross-government interaction?

Summary of key findings

- The central programme management team has fostered cross-government activity, which was viewed as effective.
- Collaboration across different workstreams provided value, but varied and was largely conducted through formal events and channels.
- Communities of interest were viewed positively, although members suggested ways to improve utilisation.

<sup>38</sup> Phase 2 interviews

<sup>39</sup> Phase 2 interviews

<sup>40</sup> Phase 1 interviews

#### The central programme management team has fostered cross-government activity, which was viewed as effective

Interviews indicated that the central programme management team had played a key role in facilitating cross-government activity.<sup>41</sup> Numerous interviewees across delivery partners and strategic government stakeholders spoke positively of PATH-SAFE team's efforts to promote cross-government collaboration, including through cross-agency meetings, workshops and conferences, as well as the central management team's general promotion of collaboration across One Health areas.<sup>42</sup> They praised the team's strong project management and chairing, describing meetings and other cross-workstream collaboration activities led by the PATH-SAFE team as helping to build a sense of community and establish robust linkages between interdepartmental R&D teams.<sup>43</sup> Overall, Delivery Board and Strategic Board meetings were also viewed as useful for building networks across government.<sup>44</sup>

PATH-SAFE also organised webinars and other events to share learning across the wider biosurveillance community, including an in-person biosurveillance workshop in November 2023 and a conference in February 2024. These events, alongside board meetings and other formal meetings, provided opportunities to connect across workstreams and the wider sector.

#### Collaboration across different workstreams provided value, but varied and was largely conducted through formal events and channels

Despite positive feedback on facilitation of collaboration by the central PATH-SAFE team, opinions on how effective PATH-SAFE was at encouraging collaboration and learning across different workstreams was divided, indicating variation across the programme. This could be due to the number and type of stakeholders involved in the delivery of each workstream or the different focuses of workstreams, as well as variation in the quality of relationships across workstreams.

- 43 Phase 1 interview
- 44 Phase 1 interviews

<sup>41</sup> Phase 2 interviews

<sup>42</sup> Phase 2 interviews

For some workstreams, cross-government collaboration was reported as strong. For example, WS2 reportedly benefitted from interactions both within the workstream and with other workstreams. Stakeholders involved in WS2 cited the flexibility to move funds between Defra agencies as conducive to collaboration and helpful in enabling the transfer of extra sequencing capacity from one project to another within WS2.<sup>45</sup> WS2 staff also described tapping into expertise from researchers working on other, complementary PATH-SAFE workstreams and forging new connections with institutions (e.g. the Moredun and Quadram Institutes) across different workstreams.<sup>46</sup>

However, some interviewees remarked that, on the whole, there was little interaction among workstream delivery teams outside formal meetings and events.<sup>47</sup> Interviewees said partners sometimes lacked understanding of the structures and functions of other organisations, and that collaboration was also affected by siloed working and a lack of holistic and systems thinking.<sup>48</sup> Some interviewees also said that communication from the central team could have better facilitated collaboration at a programme level (as opposed to within workstreams), and a small number wanted more clarity around how different workstreams could share information outside formal collaboration events.<sup>49</sup>

Interviewees also had contrasting opinions on the effectiveness of interactions between stakeholders across devolved nations. One delivery partner reported that bodies in devolved nations were not included in programme design at the onset of PATH-SAFE, contributing to a view that devolved nations were not sufficiently integrated into PATH-SAFE, despite workstreams now running in Scotland and Northern Ireland. Conversely, one strategic stakeholder highlighted the programme as a successful example of agencies from across the four nations working cohesively.<sup>50</sup> This may reflect devolved nations' carrying levels of participation in different stages of PATH-SAFE's design, inception and implementation.

<sup>45</sup> Phase 1 interviews

<sup>46</sup> Phase 1 interviews

<sup>47</sup> Phase 1 interviews, Phase 2 interviews

<sup>48</sup> Phase 2 interviews

<sup>49</sup> Phase 2 interviews

<sup>50</sup> Phase 1 interviews

#### Communities of interest were viewed positively, although members suggested ways to improve utilisation

The central programme management team created discrete communities of interest (CoIs) to provide a space for projects' technical leads to share updates across the programme.<sup>51</sup>

For example, the Wastewater for AMR and FBD Surveillance (WaFAS) Col meets bi-monthly with 20 members representing all workstreams, and has focused on increasing awareness of events relevant to the community, providing feedback on engagement strategies with stakeholders and helping foster collaboration.<sup>52</sup> There is also a Col on Data Analysis and Bioinformatics (DAaBs), which has 31 members, including representatives from workstreams 1, 2 and 4.<sup>53</sup>

Feedback from programme partners when scoping the potential of Cols was reportedly positive.<sup>54</sup> While the Col are seen as a good potential platform for reviewing work done in other workstreams, interviewees felt the communities would be better utilised in exchanging technical notes on techniques and methods, rather than sharing project updates.<sup>55</sup> Delivery partners also spoke of a degree of hesitancy to share information prematurely through the platform, which one interviewee saw as counterintuitive to the purpose of the community.<sup>56</sup>

## 3.4. Linking to wider surveillance efforts

#### Evaluation questions

- How is PATH-SAFE linked to existing and/or developing surveillance programmes? Summary of key findings
- PATH-SAFE's partners include key organisations responsible for surveillance, facilitating alignment with other programmes, strategies and plans in the UK.
- PATH-SAFE connects with the wider surveillance community through presentations, workshops,
  - conferences and webinars, as well as wider community-building events.
- <sup>51</sup> Information from PATH-SAFE wastewater for FBD and AMR surveillance Community of Interest (WaFAS) meeting minutes (March 2023)
- <sup>52</sup> Information provided by PATH-SAFE cross government wastewater group planning discussion; wastewater Col meeting in Dec 2023.
- <sup>53</sup> Information provided by Data Analysis and Bioinformatics Col Lead Members database
- 54 Information from wastewater activities summary document (March 2023)
- 55 Phase 1 interviews
- 56 Phase 2 interviews

#### PATH-SAFE's partners include key organisations responsible for surveillance, facilitating alignment with other programmes, strategies and plans in the UK

Interviewees across delivery partners and strategic stakeholders said that PATH-SAFE aligns closely with the UK government's ambition to scale up surveillance and build connections across the One Health space.<sup>57</sup>

There is evidence that partners involved in PATH-SAFE are considering how to align activities undertaken as part of their wider remit and knowledge gained during the PATH-SAFE pilot. For instance, Defra's Storm Overflows Discharge Reduction Plan references PATH-SAFE's potential to strengthen understanding of AMR in the environment, including by improving understanding of the sensitivity of different surveillance techniques, and by monitoring the impacts of intervention and regulation in the water industry (Defra, 2022). Defra's Environmental Improvement Plan 2023 also references PATH-SAFE's aim to improve understanding of the sources of AMR (HM Government, 2023), which may inform future iterations of the environmental plan. PATH-SAFE is also linked with UKHSA and Cabinet Office efforts around the development of the National Biosurveillance Network (NBN).<sup>58</sup>

There are a number of anticipated national policies, strategies and frameworks within the same focus area as PATH-SAFE that programme partners will contribute to, providing further opportunities for alignment and influence. These include the AMR National Action Plan 2024-2029 (discussed in more detail below), UKHSA's development of improved AMR indicators, future funding decisions of the UK's Global Antimicrobial Resistance Innovation Fund (GAMRIF), UKRI's Tackling Infections Programme, and future phases of the International Health Regulations (IHR) Strengthening Project.

PATH-SAFE has also acted as a convenor responding to calls in other parts of the government. For example, PATH-SAFE has produced a cross-government concept note and gathered several networks in response to the UKRI's transdisciplinary call to tackle AMR.<sup>59</sup>

<sup>•</sup> PATH-SAFE is connected to other surveillance initiatives in the UK.

<sup>57</sup> Phase 1 interviews

<sup>58</sup> Phase 1 interviews

<sup>&</sup>lt;sup>59</sup> Information from PATH-SAFE Strategic board report (Jul 2023)

#### PATH-SAFE connects with the wider surveillance community through presentations, workshops, conferences and webinars, as well as wider community-building events

Phase 2 interviewees reported that PATH SAFE was an effective host of new relationships between many teams within and beyond government. They saw one of PATH-SAFE's main routes to future impact through community building, bringing in funding and continuing to take a strategic role across the UK.<sup>60</sup>

PATH-SAFE uses presentations, workshops, conferences and webinars to forge links with the wider surveillance community beyond its programme partners.<sup>61</sup> These activities have mostly involved PATH-SAFE partners providing information and discussing the programme's progress. For example, PATH-SAFE partners have presented at external events including: the board meeting of the Responsible Use of Medicines for Agriculture (RUMA) initiative; the Advisory Committee on Antimicrobial Prescribing, Resistance and Healthcare Associated Infection (APRHAI); the Wales Animal and Environment AMR Delivery Group Meeting (FSA, 2023); UK Food Safety Research Network;<sup>62</sup> Civil Service Environment Network Offshoot Talks; the Cattle Antibiotic Guardian Group meeting; and the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR). PATH-SAFE also sent a summary of the programme to the Advisory Committee on the Microbiological Safety of Food in 2022 and presented the programme to the Committee in February 2024.<sup>63</sup> PATH-SAFE has also organised its own events to facilitate collaboration and knowledge exchange, including a workshop in November 2023<sup>64</sup> and a conference in February 2024, as reported in the sections above.

The private sector includes key stakeholders in detection, diagnostics and analysis of AMR and FBPs, and PATH-SAFE has made efforts to engage with them. For instance, PATH-SAFE has engaged with the Pet Food Industry body, National Milk Laboratories, the Agricultural Industries Confederation

<sup>60</sup> Phase 2 interview

<sup>&</sup>lt;sup>61</sup> Information from PATH-SAFE strategic board meeting minutes (Jun 2023), and Phase 1 interview

<sup>62</sup> Information provided by PATH-SAFE management team

<sup>&</sup>lt;sup>63</sup> Information from advisory committee note on the microbiological safety of food.

<sup>64</sup> Information from PATH-SAFE strategic board report (March 2023)

(AIC) and the Association of Meat Inspectors.<sup>65</sup> <sup>66</sup> Private sector stakeholders have also been involved in delivering aspects of PATH-SAFE: the National Milk Laboratories and AIC supported the delivery of WS2b.4 and WS2b.5, for example.

Learned societies and academic groups working in the field of FBPs and AMR have also been important forums for PATH-SAFE to link with the wider surveillance community: for example, PATH-SAFE has linked with the Microbiology Society, including through the society's annual conference in April 2024.<sup>67</sup> PATH-SAFE-linked academic experts have participated in consultations on human and animal pharmaceuticals and other policy proposals, providing further opportunities for knowledge from PATH-SAFE to inform policy processes and the discourse around FBPs and AMR.<sup>68</sup>

Along with engagement at a programme level, there have also been linkages between individual workstream teams and stakeholders in the wider surveillance space. Instances of this type of linkage include WS4 describing progress at UKHSA Board meetings, the Society for Environmental Toxicology and Chemistry<sup>69</sup> and other events and conferences; WS2a and WS3 attending the Testing the Waters (Zhugen Yang, 2023) conference to present work from the programme;<sup>70</sup> and WS2a presenting at the Antimicrobial Resistance Research Interest Group networking event at Bangor University and at the Better Water Quality for Wales Conference.<sup>71</sup>

## PATH-SAFE has emerging connections across the UK surveillance initiatives

A scoping search was conducted to identify the broader ecosystem PATHSAFE is situated within. A list of initiatives identified in this evaluation is provided in Annex J. We recognise that international connectivity is beyond the scope of PATH-SAFE funding – however, it is important to highlight the breadth of infrastructure and networks across Europe and beyond, to identify points of learning and reflection that can inform PATH-SAFE's relevance in the broader sector.

<sup>65</sup> PATH-SAFE Association of Meat Inspectors Sept 2023

<sup>&</sup>lt;sup>66</sup> Information from PATH-SAFE delivery board meeting and presentation (May and July 2023)

<sup>67</sup> Phase 1 interviews

<sup>68</sup> Phase 1 interview

<sup>69</sup> Information from PATH-SAFE delivery board presentation (May 2023)

<sup>&</sup>lt;sup>70</sup> Information from PATH-SAFE strategic board report (March 2023)

<sup>71</sup> Information from PATH-SAFE delivery board presentation (July 2023)

We reviewed a range of initiatives in the UK, the European Union, the United States and globally and found that there is much activity in the surveillance of pathogens and AMR, with some clear connections emerging between PATH-SAFE and a selection of the wider initiatives, all within the UK. Some notable engagements include informing the AMR National Action Plan (NAP). PATH-SAFE has contributed to the 2019-2024 NAP by developing collaborative approaches to surveillance and has influenced FSA's contribution to the development of the next NAP.<sup>72 73</sup>

NBN is part of the new UK Biological Security Strategy. This strategy references the aims of PATH-SAFE to improve the detection of AMR and FBPs, with emphasis on rapid detection and identification of disease outbreaks. PATH-SAFE outputs are likely to be relevant for future iterations of this strategy (HM Government, 2018). Further details about this potential influence are described in Chapter 4 in relation to PATH-SAFE's impact on surveillance systems.

The breadth of PATH-SAFE delivery partners includes those embedded within various UK initiatives and networks, such as the UK-wide EU-harmonised surveillance, Scotland's Rural College Veterinary Services and Capital Diagnostics (SRUC) surveillance system, and the Genomics for Animal and Plant Diseases Centre (GAP-DC) project.<sup>74</sup>

While there is no evidence of influence on international policy, PATH-SAFE has been highlighted at international forums such as the G7 High-Level Technical Meeting on One Health, which took place in October 2023. The US EPA visited PATH-SAFE partners in November 2023 and discussed synergies between PATH-SAFE and EPA's current work.<sup>75</sup> There are also reports of connections being established with stakeholders involved in the WHO, UN and African Union for collaboration opportunities, and ongoing conversations with GenomeTrackr programme in the United States.<sup>76</sup>

#### 3.5. Data sharing within PATH-SAFE

- 74 Information from PATH-SAFE delivery board meeting (July 2023)
- 75 Information provided by PATH-SAFE programme internal comms log
- 76 Information provided by PATH-SAFE programme internal comms log

**Evaluation questions** 

<sup>•</sup> How is data being accessed and shared between relevant stakeholders and departments?

<sup>72</sup> Information provided by PATH-SAFE AMR review meeting presentation, Phase 1 and 2 interviews

<sup>73</sup> Information provided by PATH-SAFE Welsh AMR Delivery Group meeting (June 2023)

• Has PATH-SAFE enabled and improved access, sharing and use of data for FBP and AMR across government departments?

#### Summary of key findings

- Individual partners and workstreams within PATH-SAFE have set up data-sharing agreements.
- There is no programme-level data-sharing agreement for the whole of PATH-SAFE.
- Despite some successes in setting up data-sharing agreements between individual partners involved in PATH-SAFE, the programme has faced multiple challenges related to data sharing.

# Multiple partners within PATH-SAFE have set up data-sharing agreements

As part of the PATH-SAFE programme, agreements have been set up between partners to facilitate data sharing within workstreams. This has been done on an ad hoc basis by individual partners and workstreams, rather than at a programme level for the whole of PATH-SAFE.

For example, catalysed by the work under WS1b, a data-sharing agreement was set up between FSS and multiple other government organisations, which allowed sharing of real-time datasets for organisations within the agreement. This led to data linkages and enhanced analytics, reduced administrative burdens, and further horizon scanning for surveillance data.<sup>77</sup> Data-sharing agreements have also been set up within WS2, which delivery partners view as useful for feeding into the predictive modelbased elements under the workstream and building a more comprehensive picture of AMR.<sup>78</sup> More specifically, WS2b.5 developed a collaborative relationship with Agricultural Industries Confederation (AIC), which provided access to import data for informing sampling, insights into feed production, and access to a feed mill for sampling. In WS2c, data on norovirus concentrations will be integrated into the SARS-CoV-2 wastewater dashboard, which is available to all Northern Ireland government departments, in consultation with colleagues in PHA.<sup>79</sup> Project partners under WS2 were seen to be utilising existing interagency relationships to enable data access and sharing within government,<sup>80</sup> while data sharing with non-government stakeholders was done on a case-bycase basis.<sup>81</sup>

<sup>77</sup> Information provided from FSS data-sharing agreement with local authorities

<sup>78</sup> Phase 1 interviews

<sup>79</sup> Information from WS2e project brief

<sup>80</sup> Phase 1 interviews

<sup>81</sup> Phase 1 interview
Below, we provide a case study of how data sharing has been enabled within PATH-SAFE. As described above, the process for establishing datasharing agreements has depended on the specific requirements of each workstream and partner. Although data access and data-sharing requirements varied across the programme and workstreams, templates and guidelines on developing appropriate agreements to facilitate data sharing could have been more beneficial than the ad hoc approach taken by individual partners and projects.

Case study 1. Data sharing in pathogen surveillance

#### Context

Data sharing is a perpetual challenge in the biosurveillance community, in part due to limited central resources mapping the surveillance landscape of initiatives, data sources, databases and data-sharing agreements. This results in a disjointed ecosystem and missed opportunities for alignment and learning.<sup>a</sup> Some projects within PATH-SAFE provide recent examples of how data sharing can be improved across the community. In this case study, we focus on the efforts of WS2a and WS4 (see Annexes for additional information on what each of these workstreams aimed to accomplish with respect to data sharing). Within these workstreams, PATH-SAFE attempted to develop infrastructure to share insights from whole genome sequencing, and to develop a pilot system for sharing insights between One Health areas to better understand AMR.

WS2a was successful due to active stakeholder outreach and aligned priorities within the workstreams, but WS4 had mixed experiences; personally identifiable data (PII) under the General Data Protection Regulation (GDPR) could not be shared in certain cases, and issues with the IT system were reported, as well as delays in the data-sharing process. Conversely, there is evidence to suggest that WS4 enabled the sharing of diverse and previously siloed datasets to some extent, which provides some useful lessons for the sector.

#### Data sharing in action

In WS2a, Cefas was able to set up effective data-sharing agreements with academic, government and other public sector partners for environmentally sourced data, but not clinical data. For example, Cefas shared *Salmonella* genomic sequence data for the Scottish Salmonella Reference Laboratory to use in its bioinformatic pipeline.<sup>b</sup> While obtaining clinical data was more challenging, researchers were guided to publicly available clinical data, which they used.

The team delivering WS4 appears to have had mixed experiences of data sharing. Some individuals involved in delivering WS4 viewed data sharing as simple (so long as no PII was involved), while others described it as difficult and noted particular challenges to sharing data between government and industry partners due to use of different platforms.<sup>C</sup> Creating data infrastructure to handle large volumes of data between organisations was highlighted as a novel and potentially beneficial solution, but the platform was not developed as planned and did not ultimately function in a way that would allow interoperability (see Annex D on WS4 for more information).

#### Enablers of data-sharing

WS2a benefitted from active stakeholder outreach. The workstream created new working relationships allowing stakeholders to draw on the expertise from organisations. For example, they formed links with a wide range of catchment-based stakeholders (e.g. the North Devon Biosphere Reserve, the EA and The Rivers Trusts) to gather information on sources and pathways of pathogen transport. There was also an indication of hosting stakeholder workshops to gather information from experts.<sup>d</sup>

At the programme level, a dedicated data scientist was employed to support the programme and help navigate technical issues.

#### Challenges to data sharing

For both workstreams, barriers appeared to be structural. Obtaining clinical data and PII was a structural barrier for WS2a and WS4. WS4 also grappled with a government IT system that did not allow the sharing of data with private contractors. Moreover, there appears to have been limited understanding across organisations and partners of the types of data needed and rationale, creating further challenges to data sharing.

Learning for the wider programme and surveillance sector It is critical to specify, at a granular level, the data requirements and rationale for every workstream and project, as well as how and why data should be shared between teams. This would allow data-sharing pipelines and approval processes to be developed prior to project commencement, sufficient funding resources to be allocated, and clear roles to be established for people sending and receiving data. Specific roles such as data coordinators and data scientists may also be helpful.

<sup>a</sup> Biosurveillance Conference Summary

<sup>b</sup> Information provided by respondent to short questionnaire for case study.

<sup>c</sup> Information provided by respondent to short questionnaire for case study

<sup>d</sup> Information provided by respondent to short questionnaire for case study

## Despite some success in setting up data-sharing agreements between PATH-SAFE partners, the programme has faced multiple challenges related to data sharing

These challenges are consistent with data-sharing challenges in the wider surveillance landscape and are not necessarily unique to PATH-SAFE. They include issues with the interoperability of specific data platforms and formats, metadata granularity and levels of user access.

Some criticisms of PATH-SAFE's facilitation of data sharing were raised. Some interviewees across central programme management and delivery partners said they would have received the same data without PATH-SAFE, and stressed that the programme must engage with other external stakeholders to better allow data sharing and connection.<sup>82</sup> Common themes included: determining an appropriate level of access and granularity in terms of what data should be openly accessible, and what should be provided only to certain users<sup>83</sup>; balancing transparency over commercially sensitive information against risk to industries; privacy concerns around linking individual-level data with clinical datasets; and individual delivery partners impeding data sharing to protect their own interests.<sup>84</sup>

For instance, PATH-SAFE aimed to bring together diverse datasets and data streams (e.g. clinical, climate, hydrological, tidal, animal and temperature data) within single data systems, and attempted to develop processes for obtaining and formatting data to achieve this goal. However, there were inconsistencies in how metadata was shared amongst partners,<sup>85</sup> making it difficult to integrate different datasets and understand data in their appropriate context.

<sup>82</sup> Phase 1 interviews

<sup>83</sup> Phase 1 interviews, information provided by PATH-SAFE WS1 delivery board slides

<sup>84</sup> Phase 1 interviews

<sup>85</sup> Phase 1 interviews

In addition, PATH-SAFE faced challenges related to commercial sensitivities and GDPR. Interviewees spoke of industry concerns around sharing data with government stakeholders,<sup>86</sup> particularly as advancements in genomic data analysis have raised fears of tracing of infectious pathogens back to retail/farm origins. Metadata related to isolates could be difficult to anonymise, adding to these concerns.<sup>87</sup> These sensitivities created barriers to recruiting and gathering data from stakeholders such as sheep abattoirs and the cattle industry. Aggregated data may be helpful in allaying some of these concerns, although this must be balanced against the benefits of granularity in terms of understanding specific contexts and arriving at insights relevant for surveillance. This aggregated approach has been taken within WS2 to address industry concerns and improve commercial engagement in data sharing by making it impossible to trace data back to individual companies, lessening the risk of data being used inappropriately or damaging business for individual companies where samples are collected.88

There were also challenges with access to clinical data. A delivery partner reported facing difficulty trying to access data from hospitals, including prescription data on antibiotics and data on hospital C-difficile strains – likely due to concerns around GDPR compliance and clinical teams being overstretched.<sup>89</sup> One interviewee in Phase 2 attributed challenges to inconsistent guidelines for data sharing between departments, concerns around the risk of potentially harmful uses of the data, general bureaucracy and red-tape.<sup>90</sup>

Surveillance initiatives in the UK and internationally commonly face these types of challenge, which are not unique to PATH-SAFE. For instance, surveillance initiatives often face challenges related to privacy, security, consistency of data collection, data management and data collation (Parkinson et al., 2023). While PATH-SAFE has taken steps to address some of these challenges, pervasive data challenges across the surveillance community will likely need to be addressed by wider sector stakeholders collectively. The PATH-SAFE central team, along with other programmes that have experienced similar challenges and the wider biosurveillance community, have been engaging with the Cabinet Office on improving data sharing, which was also a topic discussed at the November 2023 workshop. A PATH-SAFE data fellow has also been appointed to enable

- 88 Phase 1 interviews
- 89 Phase 1 interview
- 90 Phase 2 interview

<sup>86</sup> Phase 1 interviews

<sup>87</sup> Phase 1 interviews

smoother sharing between agencies/strands and to clarify data use and access concerns, which programme interviewees welcomed as a positive addition to the programme.<sup>91</sup>

## 4. PATH-SAFE programme outcomes

In the previous chapter, we reflected on the effectiveness and appropriateness of PATH-SAFE's underlying structures and the processes by which the programme is delivered. In this chapter, we focus on evidence for the extent to which PATH-SAFE has accomplished its intended outcomes and impacts. We break this down into three sections, focusing on the degree to which PATH-SAFE has promoted interaction across the surveillance community, the degree to which it has contributed to national policymaking, and the degree to which it has contributed to an improved surveillance system in the UK.

It is important to note that many of the outcomes and impacts PATH-SAFE hoped to influence are ambitious, long-term and require input from multiple stakeholders across the surveillance community and beyond. Where PATH-SAFE has not achieved outcomes and impacts as planned, this does not necessarily indicate that the programme's activities were not worthwhile or important steps to achieving outcomes and impacts.

Results of the contribution analysis and assessment of the strength of evidence against each contribution claim are incorporated throughout this chapter. In this analysis, we consider the state of evidence as of early March 2024, rather than potential future outcomes and impacts that may be realised.

While this evaluation did not set out to assess the degree to which PATH-SAFE completed all planned activities, specific activities are discussed in relation to the delivery of PATH-SAFE workstreams and projects (Annex A to Annex D). We also have summarised sample collection, processing and sequencing from across the PATH-SAFE programme, drawing on data provided by the PATH-SAFE leadership team through the programme's 'Pathogen Tracker'<sup>92</sup> in

Figure 4 to Figure 7 below. Please note that although the programme as a whole exceeded its targets for sample collection, targets in several key areas were not met, which is discussed in Annex A to Annex D below.

<sup>91</sup> Phase 1 interview

<sup>92</sup> Downloaded on 16 May 2024



Figure 4. Total number of samples collected by PATH-SAFE (planned versus actual)



Figure 5. Number of samples collected by PATH-SAFE by source type



Figure 6. Number of samples collected by PATH-SAFE by pathogen



## Figure 7. Number of samples collected, processed and sequenced, by novel versus routine sampling<sup>a</sup>

<sup>a</sup> Novel sampling refers to new samples that would not have been collected without PATH-SAFE involvement. PATH-SAFE's value-add for novel sampling is collecting the new samples plus subsequent analysis and sequencing. Routine sampling refers to samples that would have been collected without PATH-SAFE involvement, but would not have been analysed for target pathogens. PATH-SAFE's value-add for routine sampling is analysis and subsequent sequencing.

# 4.1. Interaction across the surveillance community

### Evaluation question:

• How (if at all) has PATH-SAFE enabled a community of decision makers and practitioners to cooperatively inform and act on surveillance of FBPs and AMR?

### Summary of key findings

- PATH-SAFE has facilitated collaboration between key surveillance partners on specific projects.
- Key stakeholders view PATH-SAFE as well positioned to bring stakeholders together.
- Cross-workstream collaboration at a programme level within PATH-SAFE was more limited.
- PATH-SAFE has not led to data-sharing capabilities being realised to their full extent.

# PATH-SAFE has facilitated collaboration between key surveillance partners on specific projects

Many interviewees described PATH-SAFE as a step in the right direction in terms of encouraging collaboration between delivery partners.<sup>93</sup> PATH-SAFE has provided concrete and active forums for collaboration, which was also helped by the multiple partner organisations involved in the delivery of the programme itself. Interviewees reported new interactions facilitated through PATH-SAFE and instances of current and future collaborations between government teams enabled by PATH-SAFE.<sup>94</sup> These include, for example, the EA team informing Defra's redevelopment of environmental monitoring and PATH-SAFE's involvement in maintaining the wastewater surveillance community following the Covid-19 pandemic and enabling a community around AMR in EA.<sup>95</sup>

Below, we provide a case study on how collaboration has been facilitated within and between specific workstreams of PATH-SAFE.

Case study 2. Cross-community collaboration in pathogen surveillance

#### Context

Collaboration within the UK biosurveillance community can be challenging due to limited coordination of remit, scope and policy priorities between organisations; limited knowledge sharing; and the complex landscape of biosurveillance, which prevents easy access to relevant stakeholders.<sup>a</sup> PATH-SAFE provides valuable lessons for improving collaboration across the community. In this case study, we focus on some examples of collaboration in WS2 and WS4. While WS2 offers an example of fruitful coordination and its enablers, WS4 provides learning opportunities on how coordination opportunities could be maximised.

#### Collaboration in action

WS2 participants described positive collaboration among government departments/agencies, third

- 93 Phase 2 interviews
- 94 Phase 2 interviews
- 95 Phase 2 interview

sector organisations, academia and industry on expansive sampling, sequencing and analysis as well as collection, monitoring and processing. For instance, Bangor University coordinated with the Welsh government to align sample collection with the ongoing Welsh government wastewater monitoring programme, and Cefas worked with water industry company South West Water to collect wastewater samples. This collaboration increased the number of samples that could be utilised and processed and the types of analysis that could be performed, which led to cost efficiencies.<sup>b</sup>

Collaboration within WS4 was built into the project, given its multiple strands on surveillance in the environment and the building of a blueprint for an environmental surveillance system. Each partner of the workstream – EA, UKHSA, Defra – had ownership of a particular project task, meaning coordination and engagement were clear and well defined.<sup>C</sup> There were other areas, however, where collaboration between WS4 and other workstreams was more challenging. For example, collaboration between WS4 and WS1a was not defined in the scope of the respective workstreams, and timelines did not align between the projects, which made collaborating and sharing data challenging. However, despite not planning for collaboration and data sharing up front, some outputs from each workstream (WS1a and WS4) appear to have been shared between projects.

#### Enablers of collaboration

Factors that facilitated collaboration were mainly structural. The flexibility of the funding system – which allowed easy re-allocation across multiple agencies without lengthy procurement exercises – and the existence of pre-existing networks (Environmental Monitoring for Health Protection Programme for monitoring of SARS-CoV-2 from wastewater) emerged as the most supportive variables.<sup>d</sup> Regular coordination meetings (e.g. Delivery Board, Col groups) were mentioned as helping collaboration, and the operational effectiveness of the central PATH-SAFE management team – including their 'can-do' ethos – was also highlighted as a critical enabler.<sup>e</sup>

### Challenges/Barriers in collaboration

As above, barriers to collaboration were mostly structural. The consequences of major delay to the start of some aspects of the programme, which caused staggered operationalisation, appear to have been the biggest barrier.<sup>f</sup> This impacted stakeholder mapping and timely identification of collaborators across the programme. The WS4 and WS1a dynamic illustrates this challenge: by the time WS1finally started 'in earnest', WS4 was finalising its outputs.<sup>g</sup> Aside from staggered timelines, differences in the priorities of different government agencies and delivery organisations also impeded collaboration, as did a lack of connectivity built into the scope of the respective workstreams.<sup>h</sup>

#### Learning for the wider programme and surveillance sector

Reflecting on the enablers and barriers of collaboration, it appears to be beneficial to establish collective aims of work packages with other stakeholders as early as possible through an established coordination structure. Moreover, it is critical to assign dedicated time/resources to do this prior to the start of project work, and to build projects using relevant existing networks within a given sector.<sup>i</sup>

<sup>a</sup> Biosurveillance Conference Summary (Nov 2023)

<sup>b</sup> Information provided by respondent to short questionnaire for case study

 $^{\rm c}$  Information provided by respondent to short questionnaire for case study

 $^{\rm d}$  Information provided by respondent to short questionnaire for case study

<sup>e</sup>Information provided by respondent to short questionnaire for case study

<sup>f</sup> Information provided by respondent to short questionnaire for case study

 $^{\rm g}$  Information provided by respondent to short questionnaire for case study

<sup>h</sup> Information provided by respondent to short questionnaire for case study

 $^{\mathrm{i}}$  Information provided by respondent to short questionnaire for case study

## Cross-workstream collaboration at a programme level was limited

While collaboration on projects and within workstreams was described as strong, some delivery partners have expressed reservations over the degree to which collaboration across workstreams at a programme level have been facilitated. One delivery partner reported that programme-level collaboration could have been improved with dedicated funding to encourage interaction across government (outside of workstreams), and another said that the focus on workstream delivery limited time available for wider interactions.<sup>96</sup>

Interviewees mentioned that some connections built through these activities are likely to continue independently, while others would benefit from ongoing central support. As PATH-SAFE's original funding phase comes to an end, dedicated structures to help maintain relationships established through PATH-SAFE could support joined-up working practices, as discussed in the November 2023 workshop. Attendees at this workshop said coordination and collaboration across workstreams and with surveillance efforts beyond PATH-SAFE were required for long-term outcomes to be realised.

Participants in the March 2024 policy workshop also reported that to surveillance facilitate collaboration between efforts. additional coordination is needed at a national level - which would be beyond the scope of PATH-SAFE to provide. They highlighted that coordination at this level could help improve harmonisation of efforts, reduce duplication and increase capacity across the system in a sustainable way by consolidating knowledge and capacities developed in the context of temporary pilot programmes such as PATH-SAFE. Some participants argued that wider, or whole-system, approach would improve capacity to absorb new information learned from PATH-SAFE (and other programmes) and incorporate this into standard practice. However, participants highlighted that there is no clear option or agreement on who would be suited to lead national coordination efforts.

## PATH-SAFE has not led to data-sharing capabilities being realised to their full extent

The challenges associated with data sharing described in Section 3.5 have prevented PATH-SAFE from successfully addressing the fundamental barriers to sharing data between government departments, which would be important to smooth and effective collaboration between relevant stakeholders beyond the immediate delivery of specific projects within PATH-SAFE.

Looking more closely, PATH-SAFE activities' success in improving data sharing has been mixed. While PATH-SAFE has made substantive efforts on data integration and analytics through the development of its WS1a data platform, multiple stakeholders questioned the continued maintenance

<sup>96</sup> Phase 2 interviews

and viability of the platform.<sup>97</sup> PATH-SAFE also led to feasibility testing of a system to bring together different sources of data around AMR in the environment, which was populated by data from UKHSA, the Environment Agency and the Quadram Institute.<sup>98</sup> However, implementing this system would require more consistent wastewater surveillance for AMR, which is currently not available. To achieve this project's aims requires more funding, which has been sought outside of PATH-SAFE and the SOF rather than being included in PATH-SAFE's bid for continuation funding.<sup>99</sup>

There are also opportunities for PATH-SAFE to improve the longevity of progress made on data sharing in the context of specific workstreams and project. For instance, participants in the March 2024 policy workshop discussed the need for ongoing maintenance and clear ownership of assets such as data platforms and systems, which they argued are often overlooked when new data systems are developed. To maintain effective, worthwhile assets emerging from PATH-SAFE, participants highlighted the need for funding and clear ownership in the long term.

## Key stakeholders view PATH-SAFE as well positioned to bring stakeholders together

As explained above, PATH-SAFE has successfully brought together stakeholders in the context of specific projects, although challenges remain. In the longer term, stakeholder perceptions of PATH-SAFE's place in the surveillance system provide evidence of its ability to act as a convenor in this space. Key surveillance stakeholders in the UK have asserted that PATH-SAFE is making valuable contributions to improving coordination for surveillance. For example, PATH-SAFE has been identified in reports, board documents and academic outputs as a key initiative improving cross-government and cross-disciplinary collaborative work and data sharing (Bottery et al., 2023; Muloi et al., 2023; Nicholls et al., 2023; UK Health Security Agency, 2023c, 2023a; VMD & APHA, 2023). This has been facilitated by PATH-SAFE's alignment with the AMR NAP and One Health objectives, putting PATH-SAFE is a good position to inform future surveillance efforts.

External stakeholders also viewed PATH-SAFE's coordination efforts favourably. For example, participants in the November 2023 Innovation in Biosurveillance workshop explained that the programme was well placed to coordinate between government departments and between different

<sup>97</sup> Phase 1 interviews

<sup>98</sup> PATH-SAFE management information

<sup>99</sup> Phase 2 interviews

types of stakeholders (e.g. academia, industry, government), in part due to its strong programme management across government departments. Participants in this workshop identified three ways in which PATH-SAFE could help coordinate within the surveillance system: networking facilitation, relationship management and knowledge brokering. Workshop participants also discussed the potential role of PATH-SAFE in incentivising further work on areas such as data terminology standardisation and improved data-labelling practices, which can also support coordination between surveillance efforts and improve integration. However, participants in the policy workshop in March 2024 highlighted that an overarching coordination function would require additional national-level support beyond PATH-SAFE.

# Overall assessment of collaboration and data sharing

There is evidence that PATH-SAFE has facilitated interaction between stakeholders in the surveillance community through the activities and processes described in Sections 3.3-3.5 and above. However, there remain challenges related to data sharing that can make collaboration difficult. Based on the evidence surfacing during the evaluation, we have measured the extent to which the programme has realised its main contribution claims. Two of the contribution claims relating to interaction among stakeholders and developed in Phase 1 of the evaluation are evaluated in Table 2 below. For more information on how these claims were developed and assessed, and how we assessed the consistency and credibility of the evidence, please see the Methods section of this report (Chapter 2).

Table 2. Contribution claim and robustness of evidence for cross-government collaboration and data sharing

Claim	Synthesis	Source of evidence	Consistency of evidence	Credibility of evidence	Assessment of claim based on state of evidence		
Processes established within the PATH- SAFE programme led to cross- government collaboration on FBP and AMR surveillance due to increased transparency and engagement between departments through work on interrelated workstreams.	<ul> <li>PATH-SAFE has led to cross-government collaboration, which was accomplished through project delivery, engagement via forums and events, rather than through increased transparency.</li> <li>In particular, we noted nurturing of collaborations through bottom-up engagement efforts and interpersonal connections.</li> <li>Increased transparency does not therefore appear to be the core mechanism at play. It is likely that transparency could have been intended as a much wider catch-all term to indicate more open communication between government departments, which has indeed occurred.</li> </ul>	Primary: Partners involved in PATH- SAFE that sit within government departments Secondary: Analysis of PATH- SAFE documents and desk research	High	Strong	Claim has been almost entirely met with clear evidence of PATH- SAFE facilitating cross-government collaboration during the programme. However, the causal mechanism for this was not as anticipated: collaboration was not accomplished by increasing transparency, but rather through project delivery and bottom-up engagement via interpersonal connections and networking.		
The development of the data platform in PATH-SAFE leads to easier data sharing between government departments due to data-sharing agreements put in place and user engagement efforts.	Some data-sharing agreements have been put in place to facilitate delivery of PATH-SAFE across government departments. Data fellow was appointed, which appears to have alleviated some burdens by providing a point of contact on data challenges. Data sharing was challenging for many workstreams and projects within PATH-SAFE. PATH-SAFE has not addressed overarching challenges that would make it easier to share data. There remain challenges related to privacy concerns, GDPR and differences in departmental policies that likely require wider action beyond PATH-SAFE.	Primary: Partners involved in PATH- SAFE within government departments and policy stakeholders across government departments Secondary: Analysis of PATH- SAFE documents and desk research	High	Moderate	Claim has not fully materialised. While PATH-SAFE has led to data-sharing agreements and the sharing of knowledge between government departments, it has not addressed fundamental challenges that make data sharing difficult within the context of this programme.		

## 4.2. Contribution to national policymaking

## Evaluation question:

• How and to what extent (if at all) has PATH-SAFE evidence contributed to national policies and frameworks for improved public health?

## Summary of key findings

- PATH-SAFE has contributed to the national debate around surveillance and aligns with UK interests and objectives in this area.
- The long-term policy impacts of PATH-SAFE are not yet known. However, PATH-SAFE has been cited in recent policy and its operational model has influenced other programmes.

## PATH-SAFE has contributed to the national debate around surveillance and aligns with UK interests and objectives in this area

There is evidence that PATH-SAFE has contributed to the national debate around surveillance. For example, it has been referenced in the House of Lords,<sup>100</sup> and was frequently cited by partners involved in PATH-SAFE in interviews and in publicly available documents as an important aspect of government departments' efforts to address AMR and FBPs. Its alignment with the AMR NAP and One Health objectives in the UK are frequently cited, indicating that the programme is in a position to influence policy.<sup>101</sup> Additionally, PATH-SAFE represents a significant investment in surveillance within the UK and operated in a period when the government was also undertaking other activities related to improving surveillance (see NBN case study below), indicating interest in this area within the UK government.

According to interviewees, awareness of FBPs and AMR is perceived to have increased across the UK government and externally, but not all interviewees were certain that this was entirely attributable to PATH-SAFE.<sup>102</sup> Interviewees who asserted that PATH-SAFE increased awareness cited the volume of work conducted through PATH-SAFE, the breadth of stakeholders involved and the degree of cross-government interaction. To increase awareness of PATH-SAFE and build awareness of FBP and AMR surveillance, one interviewee suggested a dedicated communications function to disseminate programme learnings.<sup>103</sup>

<sup>100</sup> Information from PATH-SAFE delivery board meeting (Nov 2023)

<sup>101</sup> Phase 2 interview

<sup>102</sup> Phase 2 interview

<sup>103</sup> Phase 2 interview

## The long-term policy impacts of PATH-SAFE are not yet known. However, PATH-SAFE has likely achieved soft influence and its operational model may have influenced other programmes

National policies are influenced by many factors, and it is difficult to trace precise contributions to the actions of any one organisation or network. Given that PATH-SAFE activities are ongoing at the time of the writing of this report, the long-term impacts of PATH-SAFE on national policy are not yet known. PATH-SAFE aimed to create a more connected and improved FBP and AMR surveillance system at a national level, and one pathway to do this would be through policy impact.

Some interviewees said that PATH-SAFE was unlikely to have a major impact on national policies and strategies during its lifetime, given the timescale.<sup>104</sup> Further to this, discussion at the policy workshop in March 2024 highlighted that it is difficult to conclude or comment on PATH-SAFE's policy impact at this time, as it is largely still in the pilot stage or because outcomes are yet to be published.

Despite the short timescale, the influence of PATH-SAFE on the delivery, logistics and choice of data sources for other programmes was discussed by interviewees. For example, interviewees pointed to the AMR NAP and NBN as specific examples of PATH-SAFE's soft influence, especially as many of the same stakeholders are involved across these programmes of work.<sup>105</sup> PATH-SAFE's operational model may have also influenced how other government initiatives have been structured. For an example of how this has been applied, see the case study below on the influence of PATH-SAFE on the NBN. This demonstrates PATH-SAFE's potential influence on other programmes, despite a lack of concrete policy influence to date.

Case study 3. Influence of NBN

## Context

The National Biosurveillance Network (NBN) is a government initiative supported by the Cabinet Office and brought about by the re-evaluation of the biosecurity risk landscape, which considers the evolving priorities since Covid-19 and rapid advances in science and technology. In 2023, the UK government updated its biological security strategy (HM Government, 2018) and a significant objective of this is to develop a network that enables effective detection of biological risks and subsequently respond to them. The NBN is a direct response to this need. While investment in biosecurity, science and technology remains high across government departments, there are challenges to building a connected network around these programmes that enables the fast detection of threats in our environment as and when they occur. UKHSA wants to understand the picture across government, where the gaps are and how to fill them to create a coherent network delivering functional biosurveillance (UK Health Security Agency, 2022).

Phase 2 interviewsPhase 2 interviews

Highlighted in the UK biological security strategy, the NBN shares priorities with the PATH-SAFE programme, as both aim to establish cross-governmental action to tackle threats to public health, and specifically threats of a biological nature. The NBN aims to assess biosecurity programmes across government, of which PATH-SAFE is one such programme of relevance. One similarity between the programmes is that they span all four nations of the UK and endeavour to enable and address challenges to cross-governmental action. While the NBN focuses on a much broader scope of bio surveillance than PATH-SAFE does, there are opportunities for learning on data sharing across government bodies, technical expertise to identify threats, and strategies to mitigate these threats and contribute to the development of a UK-wide solution to biosecurity threats.

#### Influencing in action

The NBN aims to build a connected, cross-government, cross-industry, cross-UK network to ensure threats are detected and responded to more effectively. The PATH-SAFE team have been able to contribute to this aim by inputting into the NBN at strategic points, from the discovery to alpha phase. This has primarily been through participation in discussions as part of the NBN's programme of activities, as well as separate and specific conversations around programme learnings and sharing of materials, as many of the PATH-SAFE technical outputs are relevant to what the NBN aims to assess and identify.<sup>a</sup> The PATH-SAFE programme has also helped support the NBN by providing operational insights, sharing learning and helping the NBN understand how to work with HMT and SOF financing.

#### Enablers of influencing the NBN

The UK Biological Security strategy (HM Government, 2018) has set out a top-down mandate for working, collaborating and sharing learnings, which has been an enabler for the PATH-SAFE programme to influence and support the NBN in a strategic manner. This has also been complemented by the bottom-up approaches led by key individuals across FSA, UKHSA and the Cabinet Office, creating a shared space for cross-government collaboration and learning at an operational level. Evidence suggests that professional relationships between various government organisations have been a major enabler of influence, as have opportunities to network enabled by conferences that actively engage stakeholders working in this space and across government, subsequently strengthening buy-in from individuals within the various organisations.<sup>b</sup>

#### Challenges in influencing the NBN

Challenges to further enhancing support for the NBN are mainly structural and derive from circumstances such as the two programmes being at different stages of development. The PATH-SAFE programme began in 2020 and is due to end in 2024, while the NBN is still in early stages of development. This may pose challenges to real time-shared learning – although lessons from PATH-SAFE would still be useful to inform NBN operationalisation. Another key challenge relates to people and funding. For successful collaboration across these programmes and its various organisations, resources will need to be made available to encourage collaboration and discourage siloed working. Due to the evolving nature of the programme, as well as limited resources and potential staff turnover experienced in government departments, this poses a challenge to enabling effective influence and support.

#### Learning for the wider programme and surveillance sector

The NBN is ongoing and in the early stages of its development, while the PATH-SAFE programme is in its final stages, with some of its outputs still being developed. Nevertheless, there is significant opportunity to incorporate lessons learned from the PATH-SAFE programme into the NBN's programme of work. Communication across government, trying to break out of silos, and connecting people and data, are of major importance and a significant determinant of the success of both programmes. A combination of top-down and bottom-up efforts can be effective – indicating that government buy-in and individual engagement are both crucial factors in determining success. Early engagement is helpful: given the NBN has not yet been operationalised, this represents an effective opportunity for input and influence. These insights can also be applied to other areas of the PATH-SAFE programme to ensure that learning from the workstreams and projects feed into any new workstreams or additions that develop, and directly counteract siloed working and other challenges to shared learning. Insights gleaned on data infrastructure, data requirements and data sharing will be particularly critical to enabling NBN to effectively navigate potential challenges that may emerge.

<sup>a</sup> Information provided by respondent to short questionnaire for case study <sup>b</sup> Information provided by respondent to short questionnaire for case study

# 4.3. Contribution of PATH-SAFE to surveillance efforts

## Evaluation questions

- How (if at all) have collective source-detection efforts and the use of novel technology translated to improved surveillance of FBP and AMR?
- What (if at any) strategies and operations have been enhanced, enabled or influenced through the surveillance activities?
- To what extent have pilot efforts exemplified practice and enhanced national surveillance capability? Summary of key findings
- Whether PATH-SAFE will lead to long-term impacts in the overall surveillance system is not yet known. Additional activities will need to be undertaken to achieve long-term impacts.
- PATH-SAFE has generated new knowledge of tools, technologies and methods for surveillance of FBP and AMR.
- PATH-SAFE has led to new knowledge about surveillance and coordination around AMR and FBPs.

## More time and further activities will be required for PATH-SAFE's outputs to lead to long-term impacts in the overall surveillance system

PATH-SAFE's long-term contributions to surveillance efforts are not vet known. This was highlighted by interviewees in Phase 2, who said that PATH-SAFE had generated insights, but these insights yet to be incorporated into business-as-usual surveillance functions.<sup>106</sup> Interviewees felt that PATH-SAFE is unlikely to have a major impact on public health outcomes during its lifetime, and that academic publications will not have resulted in immediate impact.<sup>107</sup> Policy workshop attendees in March 2024 reported similar views, noting that since there have been few outputs, the full contribution of PATH-SAFE is yet to be seen. To achieve the ultimate aims of PATH-SAFE (improving public health outcomes), insights from PATH-SAFE would first need to be incorporated into surveillance practices, which would in many cases require additional activity (e.g. additional collation and dissemination of key insights from the programme). Therefore, whether PATH-SAFE achieves public health outcomes will depend on its activities going forward, and the degree to which its outputs are incorporated into standard surveillance practice.

<sup>106</sup> Phase 2 interviews

<sup>107</sup> Phase 2 interviews

Discussion in the workshop highlighted that work so far has largely been around specific use cases, which is helpful, but that new solutions have yet to be fully developed, communicated and incorporated into practice. Participants also highlighted that PATH-SAFE is a pilot, and for any pilot programme to achieve long-term impact it would need to be associated with commitment, resources and mechanisms to implement successful aspects of the programme more widely. Additionally, attendees highlighted that to achieve long-term impact, PATH-SAFE outputs would need to fit the needs of end users across One Health disciplines, including surveillance stakeholders who have not been involved in project delivery.

Below, we discuss outputs and knowledge that PATH-SAFE has produced and reflect on the extent to which these outputs can be expected to contribute to longer-term outcomes and impacts related to the surveillance system in the UK.

# PATH-SAFE has generated new knowledge of tools, technologies and methods for surveillance of FBP and AMR

PATH-SAFE has advanced knowledge related to tools, technologies and methods for surveillance of AMR and FBPs. For example, work by PATH-SAFE partners has led to new knowledge in:

- The readiness and real-world applicability of novel diagnostic tests for in-field diagnostic testing for AMR and FBPs;
- Wastewater surveillance, including knowledge to help detect new *Salmonella* variants and predict outbreaks (see case study below); understand pathways, seasonal influences and 'hotspots'; and track norovirus in specific locations (i.e. care homes);
- Laboratory techniques, for example to analyse samples from livestock feed;
- Machine learning methods for source attribution and how these can be applied to surveillance and rapid diagnostics;
- Evidence to support business cases for different use cases of surveillance approaches; and
- Genomics, including sequencing techniques and algorithms to assess AMR.

Specific insights generated by PATH-SAFE that can improve surveillance tools, technologies and methods were mentioned by interviewees in Phase 2. For example, one interviewee said PATH-SAFE showed that while in-

field diagnostics may become more feasible, there is a need to further investigate whether in-field testing improves FBP and AMR surveillance compared to centralised diagnostic capacity, through more formal costbenefit analysis. Another interviewee mentioned that PATH-SAFE had identified real-time monitoring use cases, such as bathing water monitoring, and that this may improve surveillance practices in the future.<sup>108</sup>

Below, we provide one example of how partners in the PATH-SAFE programme have approached developing new tools, technologies and methods for surveillance, focusing on the genomic data platform developed in WS1 (see Annex A). This case study illustrates how this workstream approached end user consultation to understand needs, and how this was incorporated into tool development. As well as the potential impact of this tool, this case study also highlights challenges to using this tool to its full potential (e.g. data sharing and cross-government coordination).

Case study 4. PATH-SAFE's development of a novel tool for surveillance

#### Context

This case study builds on information gathered from our evaluation of WS1, described in Annex A.

The WS1a data platform broadly aims to enhance the value of surveillance data across agencies through a partnership model that brings together existing expertise in molecular epidemiology, surveillance and engineering.<sup>a</sup> The success of the UK's Covid-19 genomics consortium (Marjanovic et al., 2022) at delivering combined analytics and deepening understanding of genome clusters in a standardised manner to identify new emerging variants and risk mutations was taken as a model and adapted to foodborne pathogens under PATH-SAFE through the WS1a platform.<sup>b</sup> *Salmonella* is used as an exemplar pathogen in the WS1a platform, paving the way for the development of a process that can be rolled out to other pathogen species. The 1a platform allows for the integration of sample data with other existing data sources to create new knowledge to inform surveillance. The platform presents a standardised way of bringing this information together and analysing it, in contrast to ad hoc and often incompatible approaches taken across different agencies. As of January 2024, the platform was at the end user testing stage, with training materials being developed (FSA, 2024) and plans to improve the richness of metadata over time. The key challenges going forward would be arriving at an appropriate governance structure to ensure stakeholder buy-in to share data and use the platform to inform surveillance decisions.

## Development in action

WS1a brought together expertise across various UK institutions who were partners on this project: the CLIMB secure cloud environment by University of Birmingham hosted the platform; PubMLST developed by the University of Oxford brought in nomenclature standards and bacterial analytical capabilities; Enterobase by the University of Warwick delivered collation and contextualisation of genomics through availability of historic data; and Pathogen Watch by the CGPS provided rapid delivery of risk prediction, clustering and reporting in a manner appropriate for end users and informing surveillance (FSA, 2024). A standard software engineering approach of building a programmatic API to ensure platform interoperability was taken from the outset, ensuring the diverse platform components could 'speak to each other', as reported by the WS1a delivery team in interviews.<sup>C</sup>

A consultative, end user focused approach was taken to ensuring expertise across the surveillance landscape was incorporated into building the platform through technical advisory groups along multiple strands, including on antimicrobial resistance, analytics/bioinformatics and foodborne data standards, as well as a group on international interaction.<sup>d</sup>

Bringing these elements together, the platform aims to provide centralised capability to characterise genomes, complementing local approaches, providing contextual information that increases the value of the data across agencies, identifying trends and ultimately informing triggered investigations to improve surveillance. The platform and its potential capabilities have also garnered wider interest – for example, its genomics analysis capabilities are of interest to the UK Microbial Forensic consortium, which is looking to establish a mechanism across government departments to detect threats at their source (as reported by interviews).<sup>e</sup>

#### Enablers of tool development

A consultative and combined approach to building existing sets of expertise into an operational system was a key enabler of the platform. This was done both technically by combining the knowledge-generation powers of various data platforms and systems, as well as by ensuring expert opinion and end user needs are incorporated into the design and delivery of the platform. As the platform has not yet entered its delivery stage, final remarks on the efficacy of this approach may need to be updated.

The delivery team for this project were also considered a positive enabler in the delivery of this platform; their flexibility and effective programme management was seen as especially helpful in bringing together the diverse agencies and stakeholders involved in the WS1a platform.<sup>f</sup>

#### Challenges of tool development

Going forward, the main challenges facing the 1a platform are data sharing and platform governance. Different government agencies have competing priorities and interests to safeguard in the context of data sharing and have often been hesitant to share information via a centralised platform – an insight that surfaced in both interview cycles of the evaluation.<sup>g</sup> The WS1a team also encountered this challenge and were able to increase buy-in from agencies at the later stages of the programme.<sup>h</sup>

While government agencies showed increased engagement and interest in the platform following initiatives by the team to showcase the platform's collective value, the next step would be to arrive at a governance mechanism that enables utilisation of the data and for insights emerging from the platform to inform surveillance.

It was highlighted that industry stakeholders' reticence to share data might prove the final barrier, with commercially sensitive information on the line.<sup>i</sup> Effective resolution of this challenge is still to be arrived at for the larger surveillance community, and in turn for the WS1a platform.

#### Learning for the wider programme and surveillance sector

Given the need for cross-sectoral engagement to inform robust decision making for surveillance, having a dedicated resource for this early in programme delivery would be helpful. Effective communication with stakeholders on the benefits and uses of a given initiative is often as important as its successful creation. The demonstration of the WS1a platform across multiple agencies in late 2023 was a useful exercise in this vein and was able to engage and demonstrate the value of the platform for multiple stakeholders, helping shift the narrative from hesitance to share data to one of maximising the value of collective data across agencies, as reported in interviews. <sup>J</sup> The importance of framing cross-sectoral surveillance initiatives in this positive light and ensuring early engagement and co-creation of priorities are useful lessons for the wider ecosystem.

<sup>a</sup> Information provided by WS1a demonstration video

- <sup>b</sup> Information provided by WS1a demonstration video
- <sup>c</sup> Phase 2 interviews
- <sup>d</sup> Phase 2 interviews
- <sup>e</sup> Phase 2 interviews
- <sup>f</sup> Phase 2 interviews

<sup>g</sup> Phase 1 and Phase 2 interviews (has been a common point across many interviews)

- <sup>h</sup> Phase 2 interviews
- <sup>i</sup> Phase 2 interviews
- <sup>j</sup> Phase 2 interviews

The knowledge PATH-SAFE has produced on tools, methods and technologies has been made available in project reports, at conferences and through other means of dissemination. However, many outputs from PATH-SAFE are not yet publicly available. Moreover, even after they are made publicly available, it will take time for them to be accessed, for

knowledge from them to be incorporated into existing knowledge, and for outputs to achieve impact. This can be facilitated through active consolidation and dissemination of knowledge from the PATH-SAFE programme.

Policy workshop attendees in March 2024 reflected that it is difficult to comment on the added value and contribution of these tools and methodologies, as they are not yet publicly available. Attendees noted that it is important to get these outputs into the public domain for benefits to be realised. Also, different user groups and contexts will have different needs of these outputs, which is something to be considered when assessing their potential contribution and added value to the system. As such, it would be important for PATH-SAFE to ensure awareness of the outputs being developed among those who may benefit from them.

Another important reflection shared by workshop attendees relates to maintenance of tools and infrastructure. Time and resources will likely be required to maintain systems and tools developed by PATH-SAFE, which may require central support. Similarly, input may be needed to ensure that PATH-SAFE outputs are compatible with existing tools and systems, including on technological considerations.

## PATH-SAFE has led to new knowledge about AMR and FBPs surveillance and coordination.

PATH-SAFE activities generated data and insights from sequencing activities, the wastewater surveillance pilot and activities around genomic and environmental surveillance platforms, as discussed in Annexes A-D. This generated knowledge – for example on resistance profiles and the transmissibility of resistance, and on the prevalence and diversity of pathogens in wastewater samples.<sup>109</sup> As a pilot programme, its contribution to surveillance has primarily been through the capabilities it enabled and knowledge produced on surveillance methods, rather than information that would be directly relevant to public health decision making in the short term or in isolation. If PATH-SAFE contributes to improved surveillance practices and data sharing capabilities in the longer term, this may also contribute to knowledge on AMR and FBPs in the future.

One PATH-SAFE's key contributions has been knowledge generated on coordinating surveillance efforts between government departments and other stakeholders.<sup>110</sup> Specifically, it has generated knowledge on the

<sup>&</sup>lt;sup>109</sup> PATH-SAFE management information

<sup>110</sup> Phase 1 and 2 interviews, and November 2023 conference

process of conducting a pilot programme, developing governance and management structures, coordinating on project-based work, and building data platforms that suit the needs of multiple partners. As the UK further invests in One Health surveillance, this type of coordination will be necessary to improve the surveillance system.

Interviewees in Phase 2 suggested several ways to disseminate learnings from PATH-SAFE, including manuals and briefings for policymakers and other outputs that would attract ministerial interest.<sup>111</sup> Similarly, participants in the policy workshop in March 2024 highlighted the need for additional activities to pull together the learnings from across PATH-SAFE so they can be incorporated into other surveillance efforts and surveillance strategies in the UK. Regarding coordination, workshop attendees reflected that there should be a centralised group to coordinate across programmes at a national level in the UK, with one participant calling this 'coordination of coordination'. This would reduce fragmentation and the risk of duplication within UK surveillance systems. According to participants, there would need to be a dedicated team to drive the effort forward, either through PATH-SAFE or elsewhere in the system. Along with questions over who would be suited to leading this effort, there are also questions over the level at which coordination should occur. For example, participants questioned whether coordination should be done for all surveillance activities, or only surveillance outputs. There are also guestions over how to overcome institutional boundaries and siloed funding mechanisms that disincentivise overarching coordination. Some form of incentive - for example through pooled funding mechanisms – would likely be beneficial to supporting coordination between organisations and reduce current silos and fragmentation across working groups.

The PATH-SAFE central management team reported that there are activities planned to synthesise overall learnings from PATH-SAFE that would be relevant at the national level. For example, this may include recommendations on approaches to cross-government coordination, collaboration across One Health areas, and resource requirements and business cases for multilocation sampling. Another potential activity suggested by policy workshop attendees was the development of a toolkit to improve knowledge of what tools, systems, methods and data are available to surveillance stakeholders.

## Overall assessment of surveillance efforts

It is not yet known the degree to which PATH-SAFE will lead to long-term improvements in surveillance practices and outcomes in the UK. One of the contribution claims developed in Phase 1 of the evaluation related to overall surveillance efforts in the UK and is evaluated in

<u>Table 3</u> below. This assessment is based on the evidence described immediately below.

Table 3 Contribution claims and robustness of evi	idence for nationally connected	and improved surveillance approach
	idence for nationally connected	and improved surveinance approach

Claim	Synthesis	Source of evidence	Consistency of evidence	Credibility of evidence	Assessment of claim based on state of evidence
The collective outputs of PATH- SAFE workstreams leads to the establishment of a nationally connected and improved FBP and AMR surveillance approach due to multilocation sampling, novel testing tools and an interconnected data platform	<ul> <li>PATH-SAFE has not yet led to a nationally connected surveillance approach. There is some evidence that PATH-SAFE has influenced other surveillance programmes in the UK, and that it is well positioned to contribute to the national debate around surveillance. However, it has not yet influenced national policymaking and additional coordination would be required to establish a nationally connected approach.</li> <li>PATH-SAFE has not yet led to improved approaches to surveillance, although it has generated knowledge, tools and methodologies that, if incorporated into surveillance practices, could potentially contribute to improved surveillance in the future.</li> <li>As a pilot programme, PATH-SAFE would be expected to generate knowledge that would then require additional action to support long-term impact.</li> <li>Not all outputs from PATH-SAFE are publicly available yet, and there is not yet evidence that learning has been consolidated and communicated at a programme level.</li> </ul>	Primary: External policy stakeholders and desk research on national policy Secondary: Partners involved in PATH-SAFE and desk research on PATH-SAFE outputs	Moderate	Moderate	Claim has not materialised. However, PATH-SAFE has led to new knowledge, surveillance tools and methods, which may contribute to this aim in the longer term. Additional action would be required to achieve this long-term aim.

# 5. Wider landscape review, gap analysis and impact feasibility assessment

In this chapter, we assess the gaps, both in the wider biosurveillance sector and those that exist between the outputs delivered by PATH-SAFE and the outcomes and impacts it aims to contribute to. We identify actions that could be taken by the PATH-SAFE programme and the broader community to maximise impact and propose feasible short-term and long-term outcomes that could result from these actions.

# 5.1. PATH-SAFE's positioning in the biosurveillance landscape: policy workshop findings

We conducted a policy workshop in March 2024 focused on understanding the gaps between PATH-SAFE's current outputs and what would be needed to achieve its long-term outcomes and impacts as envisioned in the ToC. The goal of this workshop was to discuss of PATH-SAFE outputs and what is needed to achieve impact from the pilot programme with a wide range of policy stakeholders from across One Health areas. The key themes from the workshop are summarised below.

## Summary of key findings

- PATH-SAFE is a pilot programme, and despite generating potentially useful knowledge and insights, it is too early to know whether it has led to improved surveillance practices or public health outcomes in practice.
- Developing more specific aims for PATH-SAFE and the precise mechanisms by which it will influence outcomes and impacts may help clarify where PATH-SAFE fits within the surveillance system and target insights and outputs to specific decision makers.
- The UK surveillance system needs additional coordination, which can help government departments collaborate on surveillance initiatives and ensure there is clear ownership and leadership of specific areas.
- PATH-SAFE may benefit from additional prioritisation of actions that would have the biggest impact on improving surveillance and health outcomes.

## Timing and stage of PATH-SAFE

There was a general view at the workshop that it is too early to discuss and draw conclusions about PATH-SAFE's impact, and therefore too early to know how it has contributed to surveillance. When the outputs – including tools, technologies and methodologies – are available in the public domain,

the trajectory of the programme's impacts will be clearer, as will areas where further work is needed to influence surveillance practices and achieve outcomes and impacts.

There was a consensus that PATH-SAFE does, however, present an opportunity for learning as it progresses. Attendees at the policy workshop recommended that ongoing initiatives, including PATH-SAFE, should actively learn from one another as they progress, rather than learning reflectively after completion. Gaps could then be accounted for and addressed during the programme, rather than at the end. There is evidence to suggest that this is occurring to some extent in PATH-SAFE, where emerging lessons are being actively shared with other programmes and departmental units such as NBN, AMR NAP, GAPDC and the UK Microbial Forensics group at DSTL. Similarly, one attendee commented that evaluation periods are often limited to the delivery timeframes of a given programme, whereas meaningful impact often emerges further down the line. This speaks to the need to continue to monitor outcomes and impacts beyond the lifespan of pilot programmes.

## Specificity of the programme

To fully understand the impact of PATH-SAFE and determine any gaps in realising outcomes and impacts, workshop attendees suggested that there is a need to clearly specify how, precisely, PATH-SAFE aims to improve surveillance. For example, it could aim to improve efficiency and reduce duplication of efforts, fill long-term knowledge gaps to improve insights in the future, or provide information that is immediately useful to decision making. Importantly, each of these goals would require different activities, even though they all fall under the broader aim of improving the surveillance system. End goals must be clarified, not only for those involved in PATH-SAFE but also for those who intend to use the outputs. While PATH-SAFE's broad aims are clear – and reflected in the programme-wide ToC - the workshop findings suggest that PATH-SAFE should define more specific aims. It was suggested that PATH-SAFE could be more effective if the programme aimed to fully accomplish more specific, modest aims, rather than trying to improve all aspects of surveillance in the UK, but in a less focused way.

This framing and specificity of aims will also impact how the outputs are developed and disseminated. For example, more clearly defined aims can allow stakeholders delivering PATH-SAFE to consider PATH-SAFE outputs' specific end users, such as specific departments, policymakers and types of company in the private sector, and target communication strategies to specific use cases for these audiences. Some audiences may be more tuned into comparative data, while other stakeholders may be more familiar with thinking about risk data and analytics. With this in mind, PATH-SAFE should clearly define the outputs it intends to develop and have a clear dissemination plan so that relevant stakeholders can engage in the most appropriate ways based on their needs. Relatedly, there is a need for PATH-SAFE to have a good gauge on activities and challenges of the surveillance landscape to target outputs, develop successful dissemination strategies and affect change. This will prevent intervening for intervention's sake, as one attendee noted, and/or duplicating efforts already being addressed by other stakeholders/programmes, leaving other critical gaps unaddressed. This, of course, also requires good communication and engagement from other stakeholders within the surveillance system.

## Coordination

Coordination was a key issue raised by workshop attendees. There is a risk that PATH-SAFE will be one effort within a very busy landscape (see Annex J for a non-comprehensive list of other programmes relating to surveillance), and that it won't result in improvements to the overall surveillance system because there is no mechanism for it to augment or replace existing practices. There is a need to coordinate across programmes at a national level in the UK (one participant said called this "coordination of coordination") and it is unclear who would be suited to lead this. There are also outstanding questions over the level at which coordination should occur (do you coordinate all activities or just outputs of surveillance?) and how to overcome institutional boundaries/funding mechanisms that disincentivise overarching coordination. Coordination would also allow ongoing learning opportunities from other sectors, organisations and initiatives, illuminating shared understandings and highlighting gaps or areas for change.

One participant noted SOF's relevance as a way of organising and bringing together different government departments to work together. This could act as a continued way to encourage collaborative working and ensure priorities are aligned, while maintaining the momentum of PATH-SAFE and other initiatives (although not all relevant initiatives are funded by the SOF). Other participants noted issues of ownership hindering collaboration efforts, as there are some grey areas, and future action will need to consider who owns different parts of the surveillance and One Health agenda going forward. Another individual noted inertia between departments when funding, or another driving factor, stops. Funding structures and governance will be key in future efforts.

## Prioritisation

Workshop attendees highlighted that PATH-SAFE could generate more focused impact by prioritising its actions and aligning its efforts to plug into known challenges and gaps. Prioritisation will require external horizon scanning and consultations with surveillance user groups to determine what is being done in the system and understand where PATH-SAFE can improve the status quo. In prioritising, the 'so what' should be a primary focus – workshop attendees highlighted that data itself does very little if it cannot be analysed to produce insights that are meaningful beyond the immediate context of where the data was collected.

While PATH-SAFE did consider what is needed within the surveillance system at the outset of the programme, this suggestion from the policy workshop suggests a need to do this on an ongoing basis. It also points to the need (outside of PATH-SAFE) to provide funding for projects that address specific priority needs within the surveillance system in an applied way.

# 5.2. Gaps in surveillance: insights from a wider landscape review

To gather evidence of the wider surveillance landscape's needs and understand how PATH-SAFE fits into the wider system, we conducted a brief review of literature on gaps and challenges in the wider landscape of AMR and FBP surveillance. Below, we briefly summarise evidence of gaps prevalent in the wider surveillance landscape to contextualise the challenges PATH-SAFE is attempting to address. This overview is by no means exhaustive and presents a high-level summation of three types of challenge or gap: scientific, process and capacity.

## Summary of key findings

- There are challenges and gaps in the wider surveillance system that are not unique to PATH-SAFE but influence its ability to accomplish outcomes and impacts.
- There are scientific and knowledge gaps related to how resistance is transferred, baseline levels of FBPs in different contexts, and the best ways to conduct surveillance and analyse data.
- Process-related challenges have also led to gaps in surveillance systems. For instance, political will
  and long-term funding are necessary for surveillance but not always present. There are also frequent
  challenges related to lack of coordination among surveillance stakeholders, and issues around
  sharing and integrating data across sources. Process issues can also limit the degree to which
  surveillance insights are used in decision making on an ongoing basis.
- Capacity constraints also limit surveillance activities. In many settings, there is a lack of infrastructure for surveillance and challenges related to workforce and skills. These affect low-resource settings especially, but high-resource settings also face issues.

## 5.2.1. Scientific and knowledge gaps

## Knowledge about AMR and foodborne pathogens

Firstly, there are scientific gaps affecting all AMR and foodborne pathogen surveillance initiatives. In particular, there are gaps in evidence of the mechanistic causes and pathways for AMR, especially in terms of how resistance is transferred in the environment and in water, and how this contributes to public health outcomes (Nguyen et al., 2021). It is also unclear what concentrations of antibiotics and other chemical agents promote resistance selection (Bengtsson-Palme et al., 2023), and what baseline levels of AMR and foodborne illnesses exist in different settings, which is a challenge to effectively identifying and responding to threats. For example, there are gaps and inconsistencies in the way priority FBP are categorised/speciated, notified and monitored across different countries (Giessen et al., 2021), which make it difficult to understand baseline levels in different areas.

## Knowledge about surveillance methods

There are also gaps in knowledge of best practices in surveillance methodologies, especially for wastewater surveillance and genomic surveillance. It is not always clear what sampling techniques are best for different settings, or how to use metagenomic surveillance and other pathogen-agnostic techniques to identify novel threats (Wheeler et al., 2023). For example, there are gaps in how to ensure that genomic surveillance results generated by different laboratories are comparable (NIHR Global Health Research Unit on Genomic Surveillance of AMR, 2020), and gaps regarding the appropriate detection cut-off values for wastewater surveillance (Nguyen et al., 2021).

Along with technical and operational challenges in sharing and linking data, there are also knowledge gaps that prevent integrated surveillance from being used at scale. For example, there is a lack of evidence on what types of integrated surveillance lead to the most timely and efficient insights, and how new surveillance approaches compare with the status quo in different contexts and applications (Baker et al., 2023), (Muloi et al., 2023). There are also evidence gaps around cost-effective ways to incorporate resource-intensive surveillance into business-as-usual surveillance practices (Wheeler et al., 2023). To enable better use of data sources in surveillance, there is a need to better assess the value of surveillance information for different use cases and clarify the capabilities of tools in different environments and use cases.

## Data science and analysis

Analysis is another area where there are gaps in best practice. To produce public health impacts, surveillance must be timely and efficient. However, there are currently gaps in how to analyse certain types of data, including genomic data for metagenomic surveillance, at speed and scale (Wheeler et al., 2023), (Parkinson et al., 2023). Moreover, despite some progress in developing predictive models using surveillance data, these models are not yet mature enough to be used to inform specific decisions (Parkinson et al., 2023). With advancements in Al, it may be possible to train predictive models to become more accurate in the future.

## 5.2.2. Process linked challenges and gaps

## Political will and long-term funding

Political buy-in and strong, sustained commitment from key stakeholders and decision makers are instrumental to a robust surveillance system. While political buy-in and commitment for surveillance have been strong in the aftermath of the Covid-19 pandemic, there are questions around the long-term buy-in and investment in public health and surveillance, given that other political priorities will likely arise, competing with public health, infectious diseases and pandemic preparedness for resources and political prioritisation (Parkinson et al., 2023). Concerns have been raised, for instance, on the level of support environmental metagenomics is receiving from decision makers, with some experts calling for greater political buy-in of this technology (Wheeler et al., 2023).

Although there is funding available for surveillance, current funding structures tend to be based on short-term cycles, which can create challenges in meeting long-term surveillance needs to maintain robust surveillance architecture (Parkinson et al., 2023).<sup>112</sup> To create benefit from short-term investments, strategies on how to integrate knowledge into existing surveillance practices and targeted dissemination to communicate insights to relevant stakeholders can be helpful.

## Coordination and fragmentation

Coordination is an important part of conducting surveillance at many different levels (i.e. local, national, regional, international). For example, coordination and collaboration are needed across geographic areas and across different disciplines (e.g. health, environmental science), sectors and government departments (Bordier et al., 2020).

However, globally, surveillance is fragmented and complex, with separate initiatives and efforts that do not systematically coordinate with one another (Baker et al., 2023; Giessen et al., 2021; Parkinson et al., 2023). Even at a national level, collaboration and coordination can be challenging, for example due to competing departmental priorities and interests.<sup>113</sup> Creating national surveillance systems can be challenging, because

<sup>112</sup> PATH-SAFE workshop, November 2023

<sup>113</sup> PATH-SAFE workshop, November 2023

different parties may wish to use surveillance systems for different purposes, and there is a lack of coordination between them to identify areas of overlap and trade-offs (Parkinson et al., 2023).

## Integrated surveillance using multiple data sources

Recently, there has been a greater focus on integrating surveillance systems, including linking data sources, and establishing coordination across actors, institutions and decision makers (Djordjevic et al., 2024; NIHR Global Health Research Unit on Genomic Surveillance of AMR, 2020). Progress in the field of health data science is a key factor affecting the shift towards integrated surveillance systems (NIHR Global Health Research Unit on Genomic Surveillance at the surveillance of AMR, 2020), and a focus on interoperability and semantic consistency has been reflected in the integration approaches taken by health systems (George et al., 2020).

However, there are still gaps related to coordinating integrated surveillance and incorporating new surveillance techniques into practice. For instance, siloed data streams and a lack of coordination between surveillance initiatives contribute to challenges in sharing and linking data across settings (Baker et al., 2023; Benis et al., 2021).<sup>114</sup> A lack of shared standards in data formats and storage (Liguori et al., 2022), systems that are not interoperable, varying case definitions, poor and varying data quality, a lack of metadata, and poor data-management practices, can all create difficulty in linking data and conducting integrated surveillance (George et al., 2020; Parkinson et al., 2023; Wheeler et al., 2023).

## Insights and decision making

For surveillance to generate public health, economic, and other types of impact, insights need to be used to inform decision making. However, there is sometimes a lack of clear follow-up actions or recommendations on what should be done (e.g. by public health agencies, governments and other stakeholders) in response to signals from surveillance systems. This can be particularly true for aggregated data sources, including insights from environmental surveillance, and data that is used continuously or in real time a to inform public health decision making (rather than event-based surveillance or quarterly/yearly updates) (Parkinson et al., 2023). In the UK and internationally, there is a lack of agreement and clarity around the thresholds for investigation or action, and around the plausible and available actions for common and rare signals (Giessen et al., 2021). To address this, best practice would need to be developed on the most appropriate responses to surveillance signals both for public health response/mitigation and for wider biosecurity actions.

<sup>114</sup> PATH-SAFE workshop, November 2023

## 5.2.3. Capacity gaps

## Data collection, storage and sharing

A surveillance system requires robust infrastructure and capacity for data collection, storage, and sharing. However, there are gaps and logistical challenges that limit capacity, especially in low-resource settings (although capacity issues also affect high-resource settings). For example, the lack of use of diagnostic tests within healthcare settings limits the availability of clinical data in these settings, and the scarcity of Electronic Health Records (EHRs) adds to the data gaps in this area (Parkinson et al., 2023). A lack of infrastructure, including laboratory capacity (especially for more specialised techniques such as genomic surveillance) and healthcare infrastructure for confirming diagnoses, affects the ability to conduct surveillance across different settings (Parkinson et al., 2023). There are opportunities to address capacity challenges through more efficient surveillance methods, such as those that draw on aggregated data. However, there are still gaps related to how to effectively use these methods in a way that increases efficiency, and how to integrate insights from this type of surveillance into business as usual (Parkinson et al., 2023).

The availability of skilled workers to conduct surveillance also affects capacity to collect, analyse and share data in the surveillance system. This is particularly true for certain types of surveillance that require specialised skillsets, for example genomic surveillance (Parkinson et al., 2023). Surveillance requires a wide set of skills, including frontline healthcare workers, scientists (e.g. biomedical and clinical scientists, data scientists and modelling experts), epidemiologists, and public health and policy experts. These skills require building in the UK, and are being addressed through strategies from UKHSA to help up-skill relevant stakeholders and provide training (UK Health Security Agency, 2023b).

There are also challenges related to sharing data, in all resource settings. These include logistical challenges, such as a lack of interoperability between data platforms, as well as challenges in navigating regulations such as GDPR (Muloi et al., 2023), and balancing commercial sensitivities around sharing data that can be useful to surveillance.<sup>115</sup> At an international level, political pressure can result in reluctance to share data, or under-reporting of cases, and there are sensitivities around the sharing of physical samples and genetic data across borders (Wheeler et al., 2023). In some areas, there is a lack of consensus on best practices and guidelines for sharing data (e.g. recoverability of identifiable genetic material from different sample types) (Parkinson et al., 2023).

<sup>115</sup> PATH-SAFE workshop, November 2023

## 5.3. Gap analysis

Recommendations for PATH-SAFE based on gap analysis findings:

- Consolidate knowledge from PATH-SAFE and develop clear implications (supported by evidence) on how insights should be incorporated into surveillance practices
- Take a cross-workstream approach particularly when consolidating learning and prioritising areas to take forward from the pilot programme – to avoid siloes between separate PATH-SAFE projects and workstreams
- Consider the evidence needs of end users of surveillance in terms of what types of insights are most impactful in improving surveillance practices and outcomes
- Think about implementation, scale-up and impact when considering priority areas and communicating insights from the programme
- Based on PATH-SAFE's experience, develop recommendations to address data sharing, harmonisation and coordination challenges based

Recommendations for wider system, based on gap analysis findings:

- Actions to address coordination and data-sharing challenges (e.g. coordinated funding streams, identification of leads and mechanisms for coordination)
- Prioritisation of gaps in evidence and knowledge that consider needs across surveillance partners, and long-term funding to support work in these priority areas
- Consideration of dissemination activities, adoption, implementation and scale-up in funding for pilot programmes

We conducted an internal workshop with members of the evaluation team to analyse how gaps in the surveillance system relate to PATH-SAFE and could affect achievement of outcomes and impacts in the PATH-SAFE ToC. This analysis was based on gaps in the surveillance system identified in the March 2024 policy workshop and the wider landscape review undertaken as part of the evaluation (See sections 5.1-5.2). During the workshop, we also developed recommendations on what actions PATH-SAFE can take, bearing in mind the programme scope and remit, to help fill key gaps in the surveillance system. Crucially, we also discussed wider actions beyond PATH-SAFE's scope and sphere of influence that other surveillance actors need to address systemic challenges.

This section should be understood as the analysis that brings together data from within and outside of PATH-SAFE to generate recommendations on what is needed to achieve impact from the programme. It considers:

• The overall results of the evaluation, described in the process and outcome evaluation Chapters of this report;

- The policy workshop, which engaged key policy stakeholders within and beyond PATH-SAFE to discuss the degree to which PATH-SAFE's activities and outputs can be expected to lead to outcomes, and gaps that need to be filled for outcomes to be achieved; and
- The wider landscape analysis, which looked beyond PATH-SAFE to identify gaps in surveillance systems.

By combining information from these disparate sources, we generated recommendations that consider both what is happening within the programme and what is needed within the wider surveillance system.

Below, we present the results of this gap analysis (see Boxes below for summary, and the section following these Boxes for a narrative description of the findings). The Boxes show our work in terms of how the evaluation team considered gaps in the surveillance system, how these relate to PATH-SAFE, and what, therefore, both PATH-SAFE and the wider system should do to address gaps. As per the wider landscape analysis (described above), we have structured the gap analysis thematically across scientific and knowledge gaps, process gaps, and capacity gaps.

Box 1. Results of gap analysis – Scientific and knowledge gaps



#### Theme: Scientific and knowledge gaps

- Engage with end users of surveillance insights and consider the relevance of activities in terms of implementation, scale-up and impact, including in comparison to the status quo, at the start of projects and throughout the pilot programme.
- Consolidate new knowledge on mechanisms of resistance, AMR, foodborne pathogens, genomic surveillance, wastewater surveillance and data analysis approaches.
- Develop clear statements on implications of new knowledge generated through PATH-SAFE in terms of remaining gaps in evidence and surveillance practices, with a focus on how to identify threats and improve outcomes.
- Publish outputs that are tailored to decision makers in surveillance (e.g. public health, environment, food stakeholders).
- Look for opportunities to build consensus around best practice, including by connecting with other initiatives and playing a convening role within the UK.

What else needs to happen in the wider community and through government stakeholders

- Identification of priority evidence gaps that need filling to improve surveillance practices and health/ economic outcomes (e.g. analytical gaps, gaps in best practice, areas of uncertainty).
- Funding for research to fill priority evidence gaps in order to improve surveillance practices and outcomes, including around the mechanistic understanding of AMR.
- Funding that prioritises implementation, scale-up, timeliness of insight and impact on surveillance practices and outcomes, with a focus on specific areas of application (e.g. through challenges).
- Building expertise in data science and modelling in the surveillance community.
- Structures to support more timely analysis pipelines so surveillance insights can inform response strategies.

### Box 2. Results of gap analysis – Process gaps

#### Theme: Process

#### Gaps/challenges in the surveillance system and relationship to PATH-SAFE ToC

- Lack of coordination between surveillance stakeholders, including government departments, largescale studies and projects, and public/private sector.
  - PATH-SAFE encouraged collaboration around specific projects between government stakeholders, and coordination was one of its key goals.
- Lack of standardised/interoperable methods and data, including a lack of standards around metadata. This limits the ability to share data and conduct integrated, timely surveillance.
  - PATH-SAFE has created a platform to help integrate insights from surveillance data, and data standardisation is one of its key goals.
- Concerns around privacy and security, and a lack of best practice in this area, particularly for genomic data. This contributes to conservative data sharing.
  - PATH-SAFE stakeholders discussed concerns around privacy and security and how these affect the ability to share data. Individual data-sharing agreements have been established between PATH-SAFE partners in the context of specific projects, but discussions to resolve this at a programme level are ongoing.
- Lack of long-term funding for surveillance, which makes it difficult to address long-term issues and to implement insights from short-term programmes into surveillance practices.
  - Many of PATH-SAFE's aims will take a long time to materialise and incorporating insights into surveillance practices will require further investment.

#### **Theme: Process**

- However, the funding of PATH-SAFE, and other programmes such as the NBN, is a sign of political will within government, which influences levels of public investment.
- · Challenges converting insights into actions that improve surveillance practices.
  - PATH-SAFE has broad aims and, given that it is still in an early stage of maturity, insights are yet to be consolidated to impact the surveillance system or outcomes. It is a pilot programme, and the goal is for its knowledge and insights to lead to long-term impacts.

#### Actions PATH-SAFE can take to fill gaps

- Attempt to address data-sharing concerns at a programme level, or conduct work to identify what types of agreement would need to be in place to facilitate data sharing between multiple partners.
- Coordinate with other initiatives to improve data sharing and harmonise with other programmes in the UK and internationally.
- Advocate for action to address data-sharing and coordination challenges at a higher level, both in the UK and internationally.
- Consolidate knowledge and conduct work to understand the costs and benefits of potential follow-up actions from PATH-SAFE, considering realistic long-term expectations of what can be taken forward from the pilot programme.
- Prioritise items that should be taken forward based on the learning from across PATH-SAFE, rather than considering each workstream separately.
- Engage with decision makers to understand evidence is required to increase the value of what PATH-SAFE offers.

What else needs to happen in the wider community and through government stakeholders

- Incentivise and support coordination and consensus building, including around methods, and collecting and sharing data and metadata.
- Coordinate funding streams to incentivise coordination between government departments (reduce siloed funding streams).
- Address data-sharing and coordination issues, for example by providing a framework for sharing data between multiple government departments within surveillance frameworks that consider risks (e.g. privacy/security) and benefits.
- Identify leads who can coordinate surveillance in the UK at a national level.
- Long-term funding to build coordinated surveillance across government departments in an efficient and effective way, including funding for implementation, scale-up and recruitment of long-term staff.
- Recognise the long-term and wide-ranging impacts of surveillance in order to conduct cost-benefit analyses and prioritise potential actions.
- Resources for adoption, implementation and scale-up of pilot programmes to make the most of investments in short-term surveillance programmes.

#### Box 3. Results of gap analysis – Capacity gaps

#### Theme: Process

## Gaps/challenges in the surveillance system and relationship to PATH-SAFE ToC

Capacity and infrastructure gaps that limit the collection, storage, sharing and analysis of data.

• As a pilot programme, PATH-SAFE has temporarily increased capacity for certain types

of data collection, storage, sharing and analysis.

#### Theme: Process

• PATH-SAFE's technology assessment activities also provide additional capacity, and knowledge from this can be used in future assessments.

## Actions PATH-SAFE can take to fill gaps

- Develop evidence-based business cases to take forward successful aspects of the pilot programme with a long-term outlook, and identify areas that should not be taken forward.
- What else needs to happen in the wider community and through government stakeholders
- Investment in capacity building for priority areas, potentially including genomic and wastewater surveillance (depending on results of pilot studies). Investment can include technical capabilities, infrastructure and workforce, among other areas.

Looking across the actions PATH-SAFE can take to address key gaps in the surveillance system and achieve the outcomes and impacts specified within the ToC (described in the Boxes above), there are several common themes. These are described in narrative form below.

# PATH-SAFE could consolidate knowledge across the programme and provide actionable, tailored insights to end users, along with prioritised recommendations from the pilot programme

The PATH-SAFE ToC includes outcomes related to generating new knowledge on how to expand existing surveillance mechanisms and where to invest in new technologies for surveillance. While this knowledge can lead to impact on surveillance practices, this can only occur if the knowledge is effectively consolidated and communicated to those who can act on it. As a pilot programme, it will be important for PATH-SAFE to consolidate the knowledge generated and develop clear ideas around the implications of these insights on surveillance practices. Without clear statements around implications, it will be more challenging for stakeholders outside PATH-SAFE to use insights to inform their practices and decision making, and for best practice to be formed. In developing and communicating these implications, PATH-SAFE should consider the evidence needs of end users in terms of insights generated through the pilot programme and what types of communication would be most useful and impactful for this audience.

Where PATH-SAFE has not yet generated actionable insights, it may be useful to conduct additional activities to arrive at suggestions for surveillance practices. For instance, assessing the readiness level of technologies in a particular context for in-field diagnostics is useful, but not enough to guide a commissioning decision, which is likely to require a more complete business case, including the full costs (including staff time) and economic viability of the proposed process. PATH-SAFE could consult with
relevant decision makers/bodies and consider the additional requirements for remote diagnostics when communicating outputs and planning future iterations.

While individual projects have generated considerable insights in specific areas, it may be useful to take a programme-wide approach to consolidating and communicating insights, to give a sense of priority insights across the whole PATH-SAFE programme. Not all areas tested in the pilot programme will be suitable for wider scale implementation and scale-up, which should also be considered when developing implications and recommendations from the programme.

Lastly, while many gaps in surveillance will require further action beyond PATH-SAFE (e.g. challenges in data sharing, harmonisation and coordination), it may be worthwhile for PATH-SAFE to develop recommendations based on experience of the programme, and to advocate for these to be taken up by wider stakeholders. For example, challenges related to data sharing proved a key barrier within the PATH-SAFE programme. Addressing issues around data sharing more systematically across the surveillance landscape in the UK would require additional action at a national level beyond PATH-SAFE. However, PATH-SAFE can help contribute to this by consolidating knowledge on data sharing generated by the programme, advocating for changes that would allow for easier data sharing, and developing tools to help other initiatives approach data sharing in a more sensible way. Similarly, although it may be beyond the scope of the programme to produce best practice statements, PATH-SAFE could identify opportunities to host, facilitate or contribute to these discussions

#### Challenge or mission-oriented funding and sustainability focused funding could be beneficial for the surveillance sector

There are also important actions that can be taken to fill gaps in the surveillance system that are outside PATH-SAFE's scope and immediate sphere of influence. For example, challenges around data sharing, coordination and harmonisation within the surveillance system are common, but beyond the power of any one initiative to address. Actions to address these issues, such as more harmonised funding streams (e.g. that set requirements around the compatibility or interoperability of outputs from funded projects) and mechanisms for coordination across government departments outside of individual projects (e.g. clear leadership for issues around data sharing), may be helpful. Additionally, actors within the wider surveillance system – including the government departments involved in surveillance among PATH-SAFE partners – can help improve the impacts of surveillance initiatives by identifying priority

areas that would make the biggest impact in terms of improving surveillance practices and outcomes. Considering these priority areas when conducting and funding programmes related to surveillance may facilitate a more coordinated approach to improving surveillance. Lastly, when funding pilot programmes, there should be consideration of the long-term sustainability of outputs and impacts, including clear plans and requirements for implementation and scale-up where possible, to maximise the impact of investments in surveillance.

# 6. Conclusion and recommendations

### 6.1. Conclusion

Process evaluation findings indicate that PATH-SAFE has been successful in setting up robust structures for governance and oversight, collaboration and linking with the wider surveillance community. Although there are signs that PATH-SAFE is well positioned to influence surveillance practices within the UK, outcome evaluation findings indicate that PATH-SAFE has not yet achieved its overall aims of influencing surveillance practices in the UK. PATH-SAFE has produced knowledge about surveillance, AMR and FBPs that can subsequently lead to improved surveillance practices, but additional activities are needed to achieve these goals.

Overall, PATH-SAFE has developed good processes for delivering projects and coordinating across workstreams. It has strong management and governance arrangements, and a wide range of stakeholders involved in coordination and delivery, which have helped it to generate insights about surveillance and link with other stakeholders within the surveillance community. The programme has been successful in facilitating coordination across departments and delivery partners in the context of specific projects and has created structures and process to share progress and findings across the programme.

While PATH-SAFE has facilitated coordination and data sharing between partners, there remain challenges with this at a system level. PATH-SAFE is well positioned to develop recommendations to improve how this is addressed more widely, but there is limited evidence that it has generated better coordination or data sharing across the overall surveillance system so far. Additionally, although PATH-SAFE has generated useful insights across different areas, there is little evidence that PATH-SAFE has led to changes in surveillance practices outside the programme, aside from potential changes to the business-as-usual practices of delivery partners.<sup>116</sup>

<sup>&</sup>lt;sup>116</sup> Based on closure report from WS2b.1, the VMD will reportedly compare future isolates from caecal surveillance with historical isolates as part of business as usual.

This is in part due to the timing of the pilot programme (having only just completed and moving into an additional year of funding) and because additional action is required for PATH-SAFE to accomplish its outcomes and contribute to the impacts it aims to influence. For example, the programme will need to collate insights generated from across the programme, prioritise key areas of learning, and disseminate these findings to decision makers in surveillance in a way that meets their needs, in order for this information to influence surveillance practices and for longer-term impacts (e.g. improving responses to outbreaks and public health outcomes).

## 6.2. Recommendations

Although PATH-SAFE has generated useful insights that can inform surveillance of foodborne pathogens and AMR, additional action is required for PATH-SAFE to accomplish sustained outcomes and impacts by influencing surveillance practices in the UK. In the next stages of PATH-SAFE, it will be important for the programme to consolidate knowledge and insights from across projects and workstreams, and to develop a clear set of implications and recommendations targeted at different decision makers within the surveillance system. This would help the programme influence surveillance practices and contribute to national policies, agenda-setting and funding practices, as is feasible in the context of a large-scale pilot.

· Consolidation of evidence at a programme-level: PATH-SAFE should consolidate evidence from across its individual projects and workstreams on what has been learned through the pilot programme. These insights can then inform the development of specific recommendations around activities that should, or should not, be incorporated into wider surveillance practices in the UK, areas where additional investigation or evidence is needed, and where investment in surveillance could be beneficial in the future. Insights generated through PATH-SAFE may stem from both individual projects and workstreams delivered through PATH-SAFE, and knowledge gained from coordinating a large pilot programme across government departments. To consolidate learnings from across the programme, PATH-SAFE will likely need to create processes to promote more programme-level thinking, to avoid siloes between workstreams, project outputs and dissemination. For example, this may be accomplished through engaging with the Strategic Board, identifying key actionable insights from across the workstreams and identifying where sustained action is needed - for example on the maintenance of the data platform.

- Tailoring insights to decision makers: For PATH-SAFE to influence surveillance practices in the UK, it must generate actionable insights for decision makers. Given the range of stakeholders involved in surveillance who could benefit from insights generated through PATH-SAFE, the programme should tailor dissemination activities to specific decision makers in the surveillance system. To do this, PATH-SAFE should engage with decision makers to understand their specific evidence needs, and create short, tailored outputs based on the evidence generated that address these needs wherever possible. Developing more specific aims for PATH-SAFE and the precise mechanisms by which the programme will influence outcomes and impacts may be helpful in targeting communications to specific decision makers and stakeholder groups.
- Benefits realisation plans: By better understanding the potential for each PATH-SAFE activity to generate specific outcomes and impacts, PATH-SAFE can identify gaps and additional investment required to ensure outcomes and impacts are achieved. To assist with this, PATH-SAFE should develop a benefits realisation plan to prioritise activities and subsequent investments. PATH-SAFE aims to influence surveillance practices and to influence a range of public health and economic outcomes, and a plan can help prevent the programme from becoming too dispersed to create lasting impact. In prioritising further action and funding, PATH-SAFE should consider which aspects of its outputs could benefit from being scaled up and implemented, as well as its impact on specific aspects of surveillance and decision making.
- Improving coordination and addressing wider issues in well-positioned surveillance: PATH-SAFE is to develop recommendations to address wider issues in surveillance that are beyond its scope and ability to directly address without action from others. For example, PATH-SAFE faced challenges related to data sharing, harmonisation and coordination, which are common across not just PATH-SAFE but other surveillance initiatives as well. These types of issues require wider action and coordination. PATH-SAFE may consider taking on a convening or advocacy role within the surveillance system to improve how wider issues requiring collaboration and additional action are addressed. For example, this could take the form of events for surveillance stakeholders (similar to those PATH-SAFE has already conducted), position statements and recommendations to government, and coordination with other surveillance initiatives around areas of common interest.

PATH-SAFE Phase 1 Evaluation Report



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## Supplementary Materials

#### **Key Findings Summary**

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#### Annexes

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