CICER
Tacaíocht don Treoirlíne Chliniciúil
Clinical Guideline Support

PROTOCOL

Development of a tool for the collection of costs attributable to infectious disease outbreaks in public acute hospitals

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Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

NATIONAL CLINICAL EFFECTIVENESS COMMITTEE

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About CICER

In 2016, the Department of Health requested that the Health Research Board (HRB) fund an evidence synthesis service to support the activities of the Minister-appointed National Clinical Effectiveness Committee (NCEC). Following a competitive process, HIQA was awarded research funding spanning the period from 2017 to 2024 to produce the evidence to support the development of National Clinical Guidelines. This funding was renewed through a competitive process to support the work of the Centre in Ireland for Clinical guideline support and Evidence Reviews (CICER) from 2024 to 2028. CICER comprises a dedicated multidisciplinary research team supported by staff from the Health Technology Assessment team in HIQA, the Discipline of Public Health and Primary Care in the School of Medicine in Trinity College Dublin, as well as national and international clinical and methodological experts.

With regard to clinical guidelines, the role of the CICER team is to independently review evidence and provide scientific support for the development, by guideline development groups (GDGs), of National Clinical Guidelines for the NCEC. The CICER team undertakes systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines, as well as estimating the budget impact of implementing the guidelines. The CICER team also works closely with the GDGs and provides tailored training sessions; assists in the development of clinical questions and search strategies; performs systematic reviews of international clinical guidelines and supports the assessment of their suitability for adaptation to Ireland; and supports the development of evidence-based recommendations informed within the National Clinical Guidelines.

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Table of contents

About CICER **2**

Table of contents **3**

List of figures **4**

List of tables **5**

List of abbreviations that appear in this report **6**

1 Introduction **7**

2 Work package 1: Investigate the processes for recording and reporting outbreaks and their resource use in public acute hospitals in Ireland **12**

3 Work package 2: Systematic review of costing tools used to estimate resource utilisation attributable to outbreaks in acute hospitals **18**

4 Work package 3: Develop and pilot an outbreak costing tool for use by healthcare workers in public acute hospitals **24**

5 Quality assurance process **29**

6 Ethical considerations **29**

7 Reporting and dissemination **29**

References **31**

Appendix 1. Irish public acute system **35**

Appendix 2. Discussion guide (Costing researcher) **36**

Appendix 3. Costing items **37**

Appendix 4. Search strategy **39**

Appendix 5. Tool to critically appraise costing tools **41**

Appendix 6. Example of the data extraction form **43**

Appendix 7. Usability and feasibility measures **44**

List of figures

Figure 2.1 Cost items attributable to outbreaks in hospital settings in Ireland 15
Figure 2.2 Example of swimlane for costing item: Bed closures 17

List of tables

Table 2.1 Approaches to scoping meetings with key informants and primary stakeholders .14
Table 3.1 PIC for research question.....18
Table 3.2 Grey literature sources.....20
Table 3.3 Inclusion and exclusion criteria.....21

List of abbreviations that appear in this report

ADON	Assistant Director of Nursing
AMR	antimicrobial resistance
AMRIC	Antimicrobial Resistance and Infection Control
CPE	carbapenemase-producing Enterobacterales
DON	Director of Nursing
EAG	Expert Advisory Group
HPSC	Health Protection and Surveillance Centre
CICER	Centre in Ireland for Clinical guideline support and Evidence Reviews
HSE	Health Service Executive
iNAP	Ireland's National Action Plan for Antimicrobial Resistance
IPC	infection prevention and control
NCEC	National Clinical Effectiveness Committee
OCT	outbreak control team
OH-SMART	One Health Systems Mapping and Analysis Resource Toolkit
PIC	Population, Interest and Context framework
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	The International Prospective Register of Systematic Reviews
SUS	System Usability Scale

1 Introduction

Hospital outbreaks of infectious diseases are caused by microorganisms such as bacteria, fungi and viruses. The Health Protection and Surveillance Centre (HPSC) states that an outbreak is "an infection or foodborne illness that may be defined as two or more linked cases of the same illness, or the situation where the observed number of cases exceeds the expected number, or a single case of disease caused by a significant pathogen (for example, diphtheria or viral haemorrhagic fever)".[1]

Hospital outbreaks are an ongoing challenge for the healthcare system due to longer hospitalisation, prolonged illness, or mortality for infected individuals.[2] Managing and containing these outbreaks consumes substantial funds and resources.[3] Given the breadth of staff involved (including clinical, support and administrative staff) as well as the complexity of management, outbreaks can be costly.

Furthermore, antimicrobial resistance (AMR) is increasing, making it more challenging to treat hospital infections.[4-6] Outbreaks of infections caused by AMR microorganisms in acute hospitals pose an additional threat to services because they further increase the length of stay for affected patients in standard medical wards and intensive care units.[7, 8] This can result in other hospital services such as elective surgery or planned procedures being postponed or cancelled, in turn escalating resources required and overall costs attributable to hospital outbreaks. These hospital-acquired infections can also have a significant impact on the welfare and finances of patients and their families.

1.1 Costing outbreaks in Ireland

In Ireland, there is little data available on the cost of outbreaks, as the specific costs associated with outbreaks in the clinical setting are not routinely recorded or reported.[9] However, from the limited available literature, it was reported that in 2015, a carbapenemase-producing Enterobacterales (CPE) outbreak in University Hospital Limerick resulted in 60 cases and cost the Health Service Executive (HSE) €4 million.[10] In the same year, another outbreak of CPE in Limerick affected 27 patients and cost just under €1.4 million: costs included anti-infectives, screening, contact precautions, ward monitors and hydrogen peroxide vapour decontamination, along with 473 lost bed-days. CPE outbreaks in Tallaght University Hospital

in 2016-2017 were estimated to have cost €2 million, with 700 operations postponed as a direct consequence of the outbreak.[10]

Despite the significant impact outbreaks can have on hospital resources, there is currently no agreed-upon approach to assessing the costs of outbreaks in Irish acute hospitals. A thorough understanding of these financial impacts is crucial for effective resource allocation and to inform further investments in infection prevention and control (IPC) measures.[3, 11]

1.2 Background to the request

In 2021, at the request of the Department of Health and in line with one of the strategic objectives of Ireland's One Health National Action Plan on Antimicrobial Resistance (iNAP1), HIQA published an analysis of the hospital costs associated with AMR.[12] The analysis estimated the additional costs associated with eight selected pathogens of public health concern (as defined by the European Centre for Disease Prevention and Control) in the public acute hospital setting in Ireland. This study estimated that it cost the HSE an additional €12 million to treat patients with selected resistant infections in public acute hospitals in 2019. This figure is a conservative estimate as it only reflects the additional cost due to excess length of stay for a selected number of resistant pathogens.

The HIQA analysis suggested surveying acute hospital staff on the management of outbreaks. Ascertainment of accurate costs of outbreaks is an important research gap that is critical to informing future IPC policy as set out in iNAP2.[13]

Building on iNAP1, iNAP2 was published in 2021; it outlines over 150 new actions to address the threat of AMR in Ireland.[13] In line with strategic objective 5-07 of iNAP2, CICER at HIQA has been requested to:

> "Develop a tool to collect a core data set and collection, and or survey methodology for the collection of costs attributable to AMR at a point in time, to initially consider public healthcare perspective."

1.3 Scope of this study

There are important considerations related to the development of a costing tool to estimate the cost of infectious disease outbreaks in public acute hospitals in Ireland. These include the:

1. **Definition of an infectious disease outbreak:** As stated by HPSC, an outbreak "may be defined as two or more linked cases of the same illness, or the situation where the observed number of cases exceeds the expected number, or a single case of disease caused by a significant pathogen (for example, diphtheria or viral haemorrhagic fever)".[1]

2. **Costs to be considered within acute hospital settings:** This costing tool will collect costs from the public healthcare perspective. Costs associated with the patient perspective and broader societal costs outside of the public healthcare system are outside the scope of this study.

   These healthcare related costs will include direct, indirect and opportunity costs. In accordance with the HIQA economic guidelines:[14]

   - **Direct costs** include the fixed and variable costs of all resources consumed in the management of an outbreak as well as any consequences of the outbreak such as adverse effects or goods or services induced by the outbreak. These include direct medical costs and direct non-medical costs of treating affected patients such as medication, additional length of stay and laboratory services.[14]

   - **Indirect costs** include the cost of time lost from work and decreased productivity due to the outbreak.[14, 15] This includes productivity losses owing to sick leave for healthcare employees.

   - **Opportunity costs** include the value of opportunity forgone because the resource is not available for its best alternative use as a result of engaging those resources in the management of the outbreak (that is, displaced care).[12, 14] Examples include bed closures and elective surgery cancellations.

3. **Causative microorganisms associated with outbreaks:** This costing tool will focus on infectious disease outbreaks caused by any microorganism (not only AMR microorganisms), and will provide an opportunity to include a range of causative organisms (for example, norovirus, influenza, verotoxigenic *Escherichia coli,* meticillin resistant *Staphylococcus aureus* and CPE).

1.4 Aims and objectives

The overarching aim of this study is to develop and pilot a costing tool that can be used to estimate the key cost implications of resources used during outbreaks from a public healthcare perspective.

The specific objectives of this study are to:

- investigate the processes for reporting outbreaks in public acute hospitals in Ireland, to ascertain the types of data routinely collected and the method(s) of data collection (work package 1)
- identify feasible ways to measure unit costs and resource utilisation in the management of outbreaks in acute hospitals in Ireland, from the public healthcare perspective (work package 1)
- conduct a systematic review of tools that have been developed internationally to measure cost and or resource utilisation attributable to outbreaks in acute hospitals, from the healthcare perspective (work package 2)
- develop an outbreak costing tool for use by healthcare workers to collect a core data set to estimate the key unit costs and resources used during outbreaks in public acute hospitals in Ireland (work package 3)
- pilot the outbreak costing tool with healthcare workers who manage outbreaks in public acute hospitals in Ireland, considering its usability, feasibility, reliability, and adaptability in measuring actual outbreak costs and resource utilisation (work package 3).

1.5 Establishment of the Expert Advisory Group

An expert advisory group (EAG) will be convened for this project, comprising representation from key stakeholders including clinical experts, policy-makers, service providers, public and patient representatives, and methodological experts. The role of the EAG will be to inform the process and provide expert advice. Input from the EAG will inform the development and piloting of the outbreak costing tool.

The Terms of Reference for the EAG will be to:

- Contribute to the provision of high-quality research by CICER.
- Contribute fully to the work, debate and decision-making processes of the group by providing expert guidance, as appropriate.
- Be prepared to provide expert advice on relevant issues outside of group meetings, as requested.
- Provide advice to CICER regarding the scope of the research.
- Provide advice on how to access available data sources.
- Support the Evaluation Team led by CICER during the research process by providing access to pertinent data, as appropriate.
- Review the project protocol and advise on priorities, as required.
- Review the draft report from the Evaluation Team and recommend amendments, as appropriate.
- Contribute to CICER's development of its approach to evidence synthesis.

1.6 Methods overview

A mixed methods research design will be used to guide the development of the outbreak costing tool.[16] Using a purposive sample of key stakeholders, scoping meetings will be conducted to explore the processes for recording and reporting outbreaks in public acute hospitals in Ireland and feasible methods for collecting key resources used and costs incurred during outbreaks (work package 1). A systematic review will be conducted to identify costing tools for use by healthcare workers that have been developed to measure unit costs and resource utilisation attributable to outbreaks in acute hospital settings (work package 2). Informed by the key findings from work packages 1 and 2, an outbreak costing tool will be developed and piloted in specific public acute hospitals in Ireland (work package 3). The piloting will collect early implementation outcomes as identified by Proctor et al., including acceptability, usability and feasibility.[17] The final costing tool will enable hospitals to collect a core dataset that can be used to estimate the key cost implications of resources used during outbreaks from a public healthcare perspective.

2 Work package 1: Investigate the processes for recording and reporting outbreaks and their resource use in public acute hospitals in Ireland

The overall aim of work package 1 is to investigate the processes for recording and reporting outbreaks (as defined by the HPSC)[1] in public acute hospitals in Ireland and to measure unit costs and resource utilisation attributable to outbreaks. This work package will be conducted in parallel with work package 2 (systematic review): both work packages 1 and 2 will inform work package 3 (development and piloting).

The current processes in public acute hospitals in Ireland for recording and reporting the type and quantity of resource use attributable to outbreaks are varied, complex, and setting-specific, involving several stakeholders and systems across multiple levels. Process mapping is a systems-thinking approach that has been applied in many settings, including healthcare, to understand, analyse, and optimise processes within complex systems.[18-20] In this study, process mapping will be used to describe the various processes for recording and reporting outbreaks in acute hospitals in Ireland. This will allow the research team to identify the types of data routinely collected, the methods of data collection, how and where the data is stored, the key stakeholders involved and the feasibility of collecting specific data across all acute hospitals using a standardised approach.

The process mapping approach will be guided by the One Health Systems Mapping and Analysis Resource Toolkit (OH-SMART), which adapts a swimlane system mapping.[21] The OH-SMART is a process that can be used to map and analyse an existing complex process or system that requires interdisciplinary collaboration. OH-SMART has been previously used in similar systems mapping projects — for example, by the Centers for Disease Control and Prevention and the United States Department of Agriculture, to illustrate interagency interactions during outbreak investigation and response.[22] The OH-SMART steps will be adapted to meet the purposes of this study: specifically, we will (1) identify the relevant network, (2) meet with relevant informants and stakeholders, (3) map the system, and (4) analyse the system. These are described in sections 2.1- 2.4.

2.1 Identify network

A network identification exercise will be undertaken to identify individuals involved in the multi-level network of local, regional and national reporting processes for outbreaks in public acute hospitals in Ireland. This exercise will be guided by national outbreak management guidance documents and protocols.[23-25]

2.2 Conduct scoping meetings with key informants and primary stakeholders

The aim of these scoping meetings is to understand local, regional and national recording and reporting processes around outbreaks. The scoping meetings will examine the perspective of both national and regional "key informants" (for example, policymakers and researchers) and hospital-based "primary stakeholders" (for example, IPC leads, hospital finance staff and surveillance scientists) identified during step 1 (see section 2.1).

Beginning with a high-level approach, scoping meetings will be conducted with a purposive sample of approximately 12 key informants (see Table 2.1).[26] Key informants will be selected on the basis of having one or more of the following:

- knowledge and or experience of the current outbreak reporting processes in Ireland
- an active leadership role within health departments and organisations such as the regional Departments of Public Health, Department of Health, HSE, HPSC, Antimicrobial Resistance & Infection Control (AMRIC) and IPC Ireland
- an involvement in national data collections relevant to outbreaks
- an involvement in economic evaluations of outbreaks in Ireland.

Table 2.1 Approaches to scoping meetings with key informants and primary stakeholders

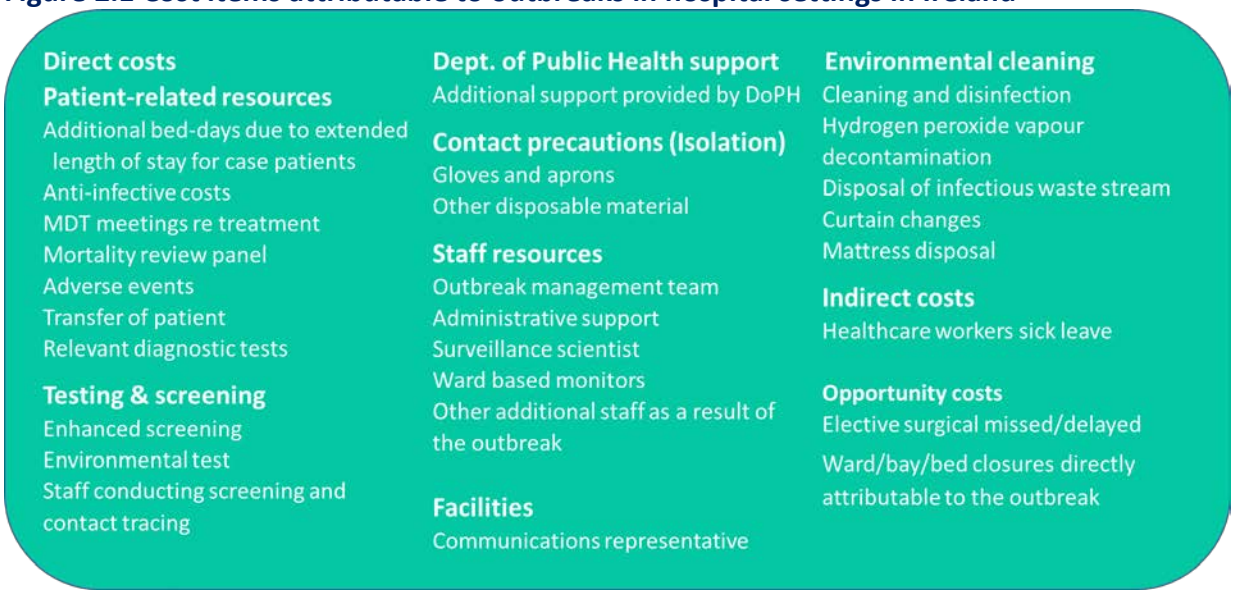
	Key informants	Primary stakeholders
Roles	National and regional: DoPH, DoH, HSE, HPSC, AMRIC and IPC Ireland, national data collections, and outbreak researchers.	Hospital-based: Surveillance scientists, DON, ADON, IPC leads, finance team.
Aim	Identify multi-level outbreak recording and reporting processes and data sources at the regional and national level.	▪ Identify sources for routinely collected data within hospitals and determine the processes for recording and reporting data ▪ Identify variation in data collection practices by hospital group.*
Number of informants	Approximately 12	Approximately 6
Sampling approach	Purposive sample	Snowball sample identified from the key informant scoping meetings, ideally one per hospital group.
Focus of discussions	National and regional data collection systems, accessibility of resource and cost data, reporting requirements, patterns of outbreaks, key actors.	Hospital data collection systems, accessibility of resource and cost data at hospital level, reporting requirements, outbreak management processes, key actors.
Outcome	▪ Identify key cost items from national/regional sources, including their location, purpose and method of data collection ▪ List of primary stakeholders to attend scoping meetings.	Identify key cost items at the hospital level, their corresponding location and alternative locations, purpose and method of data collection and key actors involved.

Key: ADON – Assistant Director of Nursing; AMRIC – Antimicrobial Resistance & Infection Control; DoH – Department of Health; DoPH – Department of Public Health; DON – Director of Nursing; HPSC – Health Protection Surveillance Centre; HSE – Health Service Executive; IPC – Infection Prevention Control.

** Irish public acute system includes 49 hospitals, across six HSE Health Regions, ranging from Model 2 to Model 4, and operating in a statutory or voluntary capacity (see Appendix 1.* Irish public acute system*).*

See Appendix 2. Discussion guide (Costing researcher) for an example of a scoping meeting agenda for an outbreak costing researcher. Other key informants may be identified and invited to meet using a snowball sampling method.[26] These scoping meetings will focus on national and regional perspectives on management of outbreaks, with a particular focus on the availability of relevant high-level data and identifying key actors in outbreak reporting and management. Based on the key cost categories listed in Figure 2.1, we will explore with key informants how national and or regional data could be leveraged to measure key costs associated with outbreaks.

Figure 2.1 Cost items attributable to outbreaks in hospital settings in Ireland



Source: Adapted from Morel et al. A one health framework to estimate the cost of antimicrobial resistance and HIQA Economic burden of antimicrobial resistance: An analysis of additional costs associated with resistant infections.[12, 27]

Scoping meetings will then be conducted with a group of primary stakeholders who manage outbreak-related resources and costs at the hospital level, specifically members of the hospital finance team, surveillance scientists or those in IPC leadership roles. At least one stakeholder from each of the six hospital groups (see Appendix 1. Irish public acute system) will be invited to meet (see Table 2.1). From the key cost categories listed in Figure 2.1, the meetings will explore how routinely collected outbreak data at the hospital level could be leveraged to measure key costs of outbreaks (see also

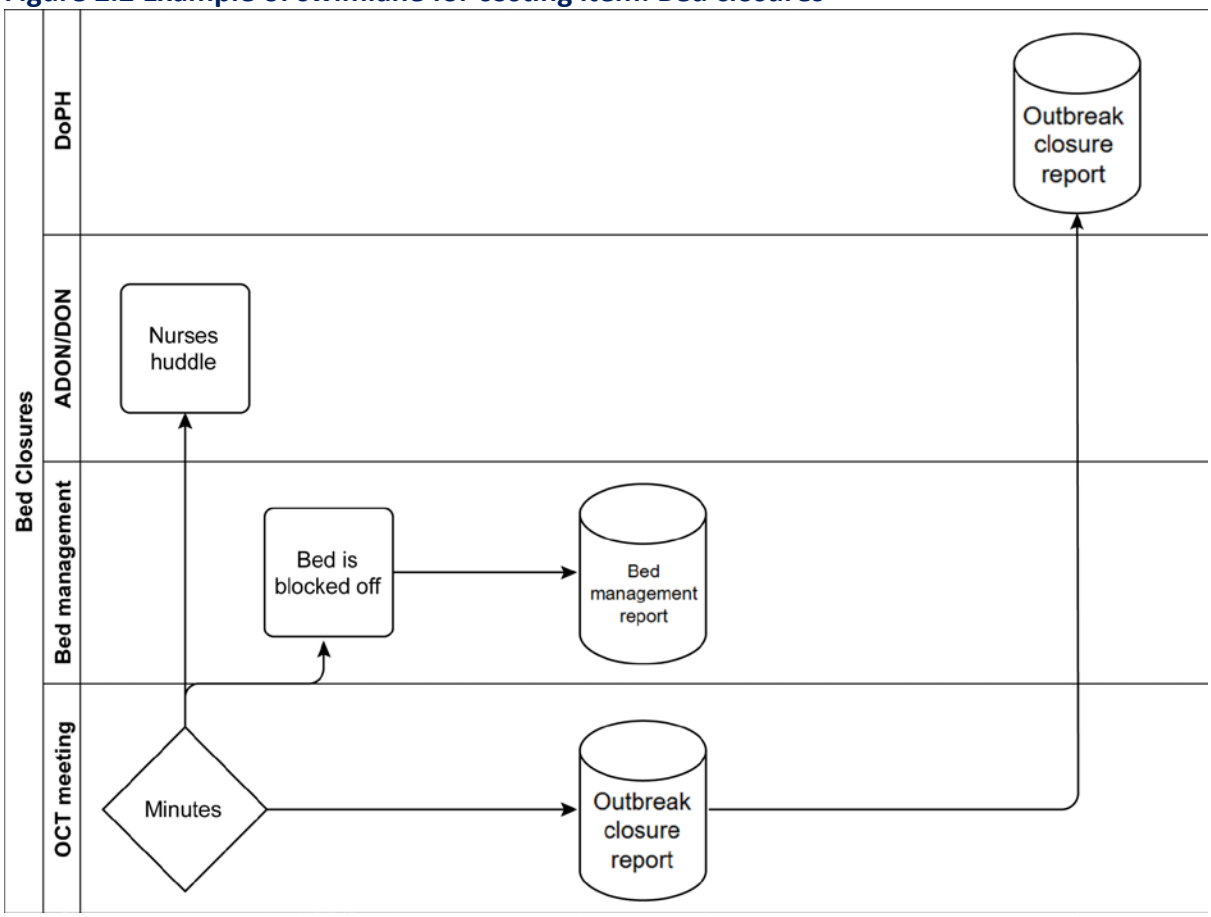
Appendix 3. Costing items). We will request permission to shadow data collection processes (in-person or virtually) where this may aid in understanding how data is collected and retrieved in a real-world hospital setting.

Combined, these meetings will allow us to identify feasible ways of operationalising and accessing key resources and cost items from national, regional and local hospital sources.

2.3 Map system

Based on the outcomes of the scoping meetings, the research team will develop swimlanes for each of the key cost items. The swimlane will visually outline the flow of information, including details on when it is collected, who collects it, the method of collection, how it is stored, and whether and how it is shared. Methods of collection may include meeting minutes, records, routine reports and databases. Figure 2.2 shows an example of a swimlane for one costing item, bed closures. For example, the number of bed closures may initially be reported by the outbreak control team (OCT) in their meeting minutes and later in their final outbreak closure report. In parallel with this process, the bed manager closes the affected beds, which is later reported in the bed management report, and the Assistant Director of Nursing or Director of Nursing (ADON/DON) reports the closure at the nurse's huddle each morning.

Figure 2.2 Example of swimlane for costing item: Bed closures



Key: ADON – Assistant Director of Nursing; DON – Director of Nursing; DoPH – Department of Public Health; OCT – outbreak control team.

2.4 Analyse system and identify opportunities

The swimlanes will be reviewed and analysed by the research team to (1) establish a detailed understanding of how key cost items could be operationalised and accessed across different acute settings, (2) ascertain where reporting is consistent across all acute settings and identify where variation exists, and (3) identify gaps where relevant data on key cost items is not available, or routinely collected data is difficult to access. In combination with work package 2, this work will inform the content and guidance of the costing tool developed in work package 3.

3 Work package 2: Systematic review of costing tools used to estimate resource utilisation attributable to outbreaks in acute hospitals

This systematic review will be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement[28] and the protocol will be registered on the International Prospective Register of Systematic Reviews (PROSPERO).[29]

3.1 Purpose of this systematic review

The purpose of this review is to identify costing tools that have been developed for use by healthcare workers to measure resource utilisation attributable to outbreaks in acute hospitals, from the healthcare perspective. If identified, these tools will be assessed for suitability for the Irish context and will be adopted, adapted and or inform the development of the costing tool in work package 3.

3.2 Research question

This review will consider the following research question:

- What costing tools have been developed for use by healthcare workers to measure resource utilisation (and or cost data) attributable to outbreaks in acute hospitals from the healthcare perspective?

The review question was formulated in line with the Population, Interest and Context (PIC) framework, as presented in Table 3.1

Table 3.1 PIC for research question

Population	Infectious disease outbreak (for example, two or more linked cases of the same illness, or where the observed number of cases exceeds the expected number). ▪ Outbreaks of specific pathogenic organisms. ▪ Outbreaks of any pathogenic organisms.
Interest	Costing tools, completed by healthcare workers, used to collect resource utilisation and or cost data attributable to outbreaks. For example: ▪ Online, paper-based or template-based. ▪ Conducted at a single point in time or post-outbreak or any other frequency and interval. ▪ Focused on a single or multiple outbreaks. ▪ Collects micro-costing (bottom up) and or macro-costing (top down) data.
Context	▪ Acute hospital setting or must be able to disaggregate costs for acute hospital setting.

3.3 Search strategy

Data for this review will be identified through searching of databases for peer-reviewed articles and of grey literature. The search strategy will be developed by a HIQA librarian and peer reviewed by a HSE librarian using the PRESS checklist.

3.4 Databases

The following five databases will be searched for peer-reviewed articles (see Appendix 4. Search strategy for an example of the search terms for Embase) and supplemented with manual reference searches of all included articles:

- Medline (EBSCO)
- CINAHL (EBSCO)
- Embase (Ovid)
- The Cochrane Library (Wiley)
- PsycINFO. (EBSCO)

3.5 Other sources

Lenus, Google and Google Scholar (first five results pages) will be searched.

3.6 Organisations

A grey literature search will be informed by the Grey Matters checklist, which was developed for searching health-related grey literature from health-related institutions globally.[30] Websites of the organisations listed in Table 3.2 will be searched for relevant documents containing information about costing tools used in outbreaks to estimate resource usage. These national and international organisations were chosen as they were considered the most relevant agencies and their documentation is available in the English language.

When costing tools are described but not available to view online, the organisation will be contacted (via email) to request the costing tool. Other relevant organisations identified during the searching process will also be included and searched.

Table 3.2 Grey literature sources

Organisation name	Organisation URL
Centers for Disease Control and Prevention	https://www.cdc.gov/
Centre for Health Economics and Policy Analysis	https://www.universityofgalway.ie/health-economics/
Cost Effectiveness Analysis Registry	https://cevr.tuftsmedicalcenter.org/databases/cea-registry
Database of Instruments for Resource Use Measurement	https://www.dirum.org/
Department of Health, Ireland	http://health.gov.ie
European Centre for Disease Prevention and Control	https://www.ecdc.europa.eu/en
Health and Social Care in Northern Ireland	https://online.hscni.net/
Health Information and Quality Authority (HIQA)	https://www.hiqa.ie/
Health Protection Surveillance Centre (HPSC) Ireland	https://www.hpsc.ie/
Health Research Board (HRB) Ireland	https://www.hrb.ie/
Health Service Executive (HSE), Ireland	https://www.hse.ie/
Health Technology Assessment International (HTAi) portal	https://www.inahta.org/hta-tools-resources/
Institute of Health Economics (Alberta, Canada)	https://www.ihe.ca/
National Institute for Health and Clinical Excellence (NICE), England and Wales	http://www.nice.org.uk
NHS Evidence Database	https://library.nhs.uk/
Organisation for Economic Co-operation and Development (OECD)	https://www.oecd.org
Public Health Agency, Northern Ireland	https://www.publichealth.hscni.net/
Public Health England	https://www.gov.uk/government/organisations/public-health-england
The Grey Literature Report	http://www.greylit.org/about
The National Health Service – National Services Scotland	https://www.nss.nhs.scot/
The National Health Service – Wales	https://www.nhs.wales/
The Rand Corporation	https://www.rand.org/research.html
The World Health Organisation	https://www.who.int/
The World Bank	https://www.worldbank.org/en/research
UK Health Security Agency	https://www.gov.uk/government/organisations/uk-health-security-agency

3.7 Eligibility criteria

The inclusion and exclusion criteria for this review are provided in Table 3.3.

Table 3.3 Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
Reports of costing tools for use by healthcare workers for measuring resource utilisation and or estimating unit cost values attributable to outbreaks in acute hospitals from the healthcare perspective.	▪ Reports that do not sufficiently describe the costing tool to allow adaptation for the Irish context ▪ Tools that are not available after contacting the corresponding author ▪ Costing tools that do not include the healthcare perspective. ▪ Costing tools designed for non-acute or community settings ▪ Reports that were published before 2014* ▪ Reviews, editorials or commentaries ▪ Reports and or costing tools that are not available in English.

* Due to improvements in infection, prevention and control practices in acute settings, the most relevant tools will most likely to be found in studies published within the last 10 years (2014 onwards).

When outbreak costing studies mention using a costing tool, a request will be made by email to the corresponding authors. The email will request additional information on the complete costing tool, the development process, accompanying guidance and or the approach taken to validate it. Additionally, authors of the ten AMR outbreak costing studies[3, 31-39] identified in the HIQA report[12] on the economic burden of AMR will be contacted to request further details on any costing tools mentioned in the studies.

3.8 Selection of eligible publications

All citations identified from the search strategy (see Appendix 4. Search strategy) will be exported to EndNote (Version X20) for reference management, where duplicates will be identified and removed. Using Covidence (www.covidence.org), two reviewers will independently screen the titles and abstracts of the remaining citations against the eligibility criteria (see Table 3.3). The full texts of articles progressing through title and abstract screening will be obtained and independently evaluated by two reviewers against the

eligibility criteria. Where disagreements occur, discussions will be held to reach consensus and, where necessary, a third reviewer will be involved. Citations excluded during the full-text review stage will be documented, alongside the reasons for their exclusion, and summarised in the PRISMA flow diagram.

3.9 Quality appraisal

The quality of the identified costing tools and their relevance to the Irish context will be assessed using an adapted version of the quality appraisal for cost-of-illness studies listed in Appendix 5. Tool to critically appraise costing tools. This cost-of-illness quality appraisal tool, used in the previous HIQA work and by the Welsh Public Health Observatory, is derived from an original tool developed by Larg et al.[40]

The initial focus will be on the relevance and usability domain (that is, the first two quality appraisal questions). This relevance and usability assessment will be conducted independently by at least two reviewers for the first three studies, and thereafter will be completed by one reviewer and verified by another. If, based on this domain, a study is deemed not relevant or not applicable to the Irish healthcare system, it will be excluded at this stage — that is, it will not undergo any further quality assessment or proceed to the data extraction phase. Studies that are deemed relevant and applicable will undergo a full quality appraisal by one reviewer, with the assessment double checked by a second reviewer, and third party arbitration if required.

3.10 Data extraction and management

Data will be extracted from peer-reviewed articles and grey literature by one reviewer and checked for accuracy and omissions by a second. Where disagreements occur, discussions will be held to reach consensus and, where necessary, a third reviewer will be involved. Data extraction will be conducted in Microsoft Excel, using a purposefully designed data extraction form (Appendix 6. Example of the data extraction form). The data extraction form will be piloted and refined as necessary. Examples of relevant data to be extracted include: perspective of study; questions on resources utilisation; causative agent of the outbreak(s); cost items assessed; costing method (for example micro-costing and or macro-costing); costing tool development process; costing tool validation process; and number of items in

costing tool. Where authors describe limitations or challenges in applying the costing tool or any modifications made, these will be recorded.

3.11 Data synthesis

Data extracted as part of this review will be descriptive in nature and a narrative synthesis of included studies will be produced. Results will be presented in tables and discussed with reference to applicability in the Irish context. The unit of analysis will be a costing tool and therefore if more than one record is identified that relates to the same costing tool, these records will be analysed as one unit.

4 Work package 3: Develop and pilot an outbreak costing tool for use by healthcare workers in public acute hospitals

Leveraging the process mapping of key cost items (work package 1) and any existing costing tool(s) from the international literature (work package 2), the third work package will focus on developing and piloting an outbreak costing tool for healthcare workers in public acute hospitals.

There will be three tasks involved in work package 3:

1. Develop an outbreak costing tool for use by healthcare workers to collect a core data set to estimate the key unit costs and resources used during outbreaks
2. Pilot the outbreak costing tool in eligible acute settings with healthcare workers
3. Consider the reliability, usability and adaptability of the outbreak costing tool.

The content and modality of the tool will depend on the outcomes of work package 1 and work package 2; therefore the process outlined here represents our anticipated approach and is subject to review and updating following completion of work packages 1 and 2.

4.1 Development

If a relevant costing tool is identified during work package 1 scoping meetings or the work package 2 systematic review, it will be adapted to suit the purposes of the current study.

If no suitable costing tool is identified, an outbreak costing tool will be developed based on the findings of work package 1 and informed by the learnings from work package 2. This will be done using a micro-costing approach to collect a core data set to estimate the key costs of resources consumed during outbreaks in public acute hospitals.[41, 42] Macro-costing approaches may be required if there are feasibility restraints to estimating some resource costs using micro-costing.[12]

The development of the outbreak costing tool will proceed as follows:

1. Based on data sources identified in work package 1, develop the outbreak costing tool, including clear and precise questions to quantify the resources allocated and estimated unit costs for the key resource inputs, attributable to a single outbreak in acute hospitals.

This step will include the development of clear guidance on how to use the tool and common sources of relevant data.

2. Internal testing:

   - Research group: All questions and respective guidance within each section of the outbreak costing tool will be iteratively developed by the core research group and reviewed by additional members of the research group and members of the HTA Directorate, as required.

   - Primary Stakeholders and EAG members: Each question and respective guidance within the outbreak costing tool will be user-tested with selected primary stakeholders (who attended a scoping meeting in work package 1) and select EAG members. The purpose of conducting these checks is to ascertain that the costing tool is fit for purpose.

3. Pilot the costing tool and its guidance with a purposive sample of Irish public acute hospitals applied to actual outbreaks to evaluate whether it is reliable, usable 'on the ground' and adaptable under real world circumstances.

4.2 Design of outbreak costing tool

The outbreak costing tool will likely be divided into the following sections:

- Details of the setting – for example: model and type of hospital, hospital group, number of beds, stakeholder role responsible for completing the costing tool, other stakeholders involved in collecting the necessary data.

- Details of the outbreak – for example: hospital outbreak code, date when outbreak was declared, date when outbreak was declared over, causative agent of the outbreak, total number of cases and number of wards affected.

- Resource usage and estimated costs for the key cost drivers.

  - Direct costs – examples may include:

    - Patient-related resources: Additional bed-days due to extended length of stay for cases, anti-infective costs (for example, antivirals, antibiotics, antifungals,

Centre in Ireland for Clinical guideline support and Evidence Reviews (CICER) etc.), multidisciplinary team meetings regarding treatment, mortality review panel, adverse events, transfer of patients, relevant diagnostic tests (for example, microbiological diagnostics or imaging).

- Testing and screening: Enhanced screening, environmental test, staff resources for screening (for example, staff conducting screening and screening of staff) and contact tracing.
- Staff resources directly attributable to the outbreak: Outbreak management team time, time allocated to administrative support, surveillance scientist, ward-based monitors, other additional staff as a result of the outbreak.
- Department of Public Health support: Additional support provided by the Department of Public Health (as reported in outbreak control team meetings).
- Contact precautions (isolation): Gloves and aprons, other disposable materials.
- Environmental cleaning: Cleaning and disinfection, hydrogen peroxide vapour decontamination, disposal of infectious waste stream, curtain changes, mattress disposal.

o Indirect costs – examples may include: Sick leave for healthcare workers attributable to the outbreak.

o Opportunity costs – examples may include: Elective and emergency surgeries missed or delayed, and ward, bay, and or bed closures directly attributable to the outbreak.

- Outcomes:

o The primary outcome will be the total cost in euros for a single outbreak from the public healthcare perspective (total direct, indirect and opportunity costs will also be reported). The duration of the outbreak will be defined as from the date of declaration of outbreak to the date of closure of the outbreak.

- The secondary outcome will be the key resources attributable to the outbreak — for example, additional length of stay, bed days lost, surgeries cancelled.

- As well as traditional reports, other outputs may include graphs or infographics of the estimated costs for users to support implementation of the outbreak costing tool and understanding of the total costs.

4.3 Costing tool use

The costing tool will be available electronically using survey software such as RedCap (REDCap) or a purposefully designed Excel or pdf document. Ideally, the costing tool will be completed at the end of an outbreak by a lead user such as a DON, ADON, IPC lead and or relevant member from the finance team. The lead user might use a variety of data sources to fill out the costing tool, such as financial records, report documents, meeting minutes, surveillance systems, and consultation with other staff. It may be necessary to have more than one lead user owing to the varied and setting specific reporting processes. Guidance notes will be developed and shared with participants with instructions on how to complete the costing tool.

4.4 Piloting and evaluation

The costing tool and guidance notes will be piloted with a purposive sample of approximately five public local and regional acute hospitals across a variety of infectious diseases types. A study by Virzi et al. suggests that 80% of usability problems are detected with four or five subjects.[43] Antimicrobial Resistance and Infection Control (AMRIC) will be approached to nominate acute settings that have strong but varied outbreak reporting practices in place, across local and regional settings. The costing tool will be completed by individuals who are working within these public acute hospitals and have experience in managing outbreaks (for example DON, ADON, IPC Lead) and or by individuals with experience in costing activities within acute settings. We will request two individuals to independently test the costing tool at each site, focusing on an outbreak whose investigation has closed so that the costing reflects the full duration of the outbreak. Further sites may be identified based on variations in reporting practices identified in work package 1. The research team will be available to

answer participants' questions and support completeness in their responses. We will employ the following measures:

- **Usability**: The System Usability Scale (SUS) (10-item instrument; Appendix 7. Usability and feasibility measures) will be employed to quantify usability perceptions of both the costing tool and the guidance with a widely accepted measure.[46] Scores above 80/100 on the SUS are generally considered to represent good usability.[47] We will also gather open-ended qualitative feedback from participants on the tool's usability.

- **Feasibility**: This refers to the extent to which respondents believe that the outbreak costing tool could be successfully used within a given acute setting. Feasibility will be examined using the Feasibility of Intervention Measure (FIM) (Appendix 7. Usability and feasibility measures).[48] Using a 5-point ordinal scale that ranges from "completely disagree" to "completely agree", respondents will be asked if the outbreak costing tool seems implementable, possible, doable and easy to use. Scores above 4/5 on the FIM (indicating respondents "agree" with positive statements) will be considered to represent good perceived feasibility.

- **Reliability**: Two or more respondents will be asked to independently complete the costing tool in relation to the same outbreak. Instances where raters differ substantially (for example, by more than 15% on the same item for the same outbreak[49]) will be assessed; we will identify whether the issue was likely attributable to the rater's role (and information available to them) or to the item itself.

- **Adaptability/completeness:** The outbreak costing tool will be tested across a range of acute settings and outbreaks of different causative agents to ascertain if the tool is adaptable. Items that are left incomplete by more than two respondents will be noted. Respondents will have the opportunity to document the reasons for incompletion. Any withdrawals or non-response of a hospital or team after agreement to pilot will also be noted.

An iterative approach will be taken. Thresholds described above, which were derived from the literature where available and team consensus otherwise, will be set for the various measures. These thresholds are 80/100 on the SUS, 4/5 on the FIM, less than 15% difference

between raters for reliability, and two or fewer respondents leaving the same item incomplete. If the thresholds are not reached, improvements will be made to the costing tool based on feedback and discussion with the EAG; items may be amended, added or removed, or additional guidance may be drafted. If substantial changes are made, the new version of the question or tool will be re-piloted with the same sites. Quantitative data will be presented using descriptive statistics, alongside normative data where available.[47] Open-ended qualitative data will be analysed using inductive content analysis and will be integrated with quantitative data in the results report.

Informed by the quality of the pilot data, we will assess the feasibility of creating a core data set to estimate the key costs and resources attributable to outbreaks. A reasonable unit cost value will be assigned to specific resource inputs if there are restraints to estimating costs using micro-costing.

5 Quality assurance process

The work packages will be undertaken in accordance with the HIQA HTA Directorate's Quality Assurance Framework and led by an experienced member of the team. All outputs will be reviewed by a member of the senior management team and the CICER Director and Clinical Director, to ensure processes are followed and quality is maintained.

6 Ethical considerations

The research team has received approval from the HSE Research Ethics Committee for Midlands and HSE Corporate Services Committee for the pilot-testing of a tool for the collection of costs attributable to infectious disease outbreaks in public acute hospitals.

7 Reporting and dissemination

The evidence gathered for this project, as outlined in sections 2 to 4, will be synthesised in one report to be published in the CICER area of the HIQA website. However, the findings and outputs of each work package will be prepared as work is completed. The results of the pilot of the costing tool in work package 3 will likely be reported in line with the quality appraisal tool listed in Appendix 5. Tool to critically appraise costing tools. This tool is the same tool that is proposed for the systematic review in work package 2; this cost-of-illness quality

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appraisal tool was used in the previous HIQA work and by the Welsh Public Health Observatory.[12, 40]

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Appendix 1. Irish public acute system

Type	HSE Dublin & South East - UCD	HSE Dublin & North East - RCSI	HSE Dublin & Midlands - TCD	HSE South West - UCC	HSE Midwest - UL	HSE West & North West - UG	Children's Hospital Group
Model 4	St. Vincent's* Waterford	Beaumont & St. Joseph's* Mater Misericordiae*	St. James's* Tallaght*	Cork	Limerick	Galway	-
Model 3	St. Luke's Tipperary Wexford	Connolly Our Lady of Lourdes Cavan & Monaghan Our Lady's	Naas Tullamore Portlaoise Mullingar	Mercy* Kerry	-	Portiuncula Mayo Letterkenny Sligo Roscommon	-
Model 2	St. Columcille's St. Michael's*	Louth County Monaghan	-	Bantry Mallow South Infirmary Victoria*	St. John's Ennis Nenagh	-	-
Model 1	-	-	-	-	-	-	-
Specialist	Royal Victoria Eye & Ear* National Rehabilitation*	National Orthopaedic, Cappagh	St Luke's	Kilcreene Orthopaedic	Croom Orthopaedic	-	Connolly Crumlin Tallaght Temple St.
Maternity	National Maternity*	Rotunda*	Coombe Women & Infants*	-	Limerick	-	-

Key: * denotes a voluntary hospital, all other hospitals are statutory.

Appendix 2. Discussion guide (Costing researcher)

Date: **Location:** **Time:**
Attendees:
Introductions:

Thanks for taking the time to meet with us this morning. As mentioned in our email, we are currently working on a project for the Department of Health. In line with strategic objective 5-07 of Ireland's second One Health National Action Plan on Antimicrobial Resistance 2021-2025 (iNAP2), the rationale for this project is to develop and pilot a costing tool to collect resource and cost data to estimate the costs of outbreaks in public acute hospital settings from the public healthcare perspective. The tool will ideally focus on the key cost drivers.

We are reaching out to researchers in this field with experience of costing outbreaks in Irish hospitals.

1. Can I ask you about your experiences with data collection for the costing outbreak study in question (and any other similar outbreak studies you conducted) please?
2. What do you see as the key cost drivers of outbreaks in Irish hospitals?
3. What would be a feasible approach to collecting these key cost drivers at a hospital level?
4. Are there any recent developments in terms of routine data collection, surveillance, costing data?
5. Who are the main hospital stakeholders that provided you with access to this data?
6. Is there anyone else that comes to mind that we should contact in relation to our project? Other researchers or hospital stakeholders, especially in the Irish context.
7. Did we miss anything in the discussion that you would like to bring up?
8. We would like to thank you most sincerely for your time here today. If we have further questions, can we follow-up with you?

Appendix 3. Costing items

	Is this routinely collected? Yes/No	**Data collection method** How is it collected? Paper/spreadsheets/ reporting system/lab system, for example, APEX	**Role** Who collects it?	**Location** Where is it stored?
Direct costs: Patient related resources				
Additional bed-days due to extended length of stay for case patients (by bed type)				
Anti-infective costs (for example, antivirals, antibiotics, antifungals etc.)				
MDT meetings re treatment				
Mortality review panel				
Adverse events				
Transfer of patient				
Relevant diagnostic tests (for example, microbiological diagnostics or imaging)				
Testing & screening				
Enhanced screening				
Environmental test				
Staff conducting screening				
Contact tracing				
Staff resources directly attributable to the outbreak				
Outbreak management team				
Administrative support				
Surveillance scientist				
Increased resources (not already covered) as a result of the outbreak				
Ward-based monitors (to ensuring hand hygiene, and environmental and equipment cleaning are being conducted				

properly)				
Other additional staff as a result of the outbreak				
DoPH support				
Additional support provided by DoPH				
Contact precautions (Isolation)				
Gloves and aprons				
Other disposable materials				
Facilities				
Communications representative				
Environmental cleaning				
Cleaning and disinfection				
Hydrogen peroxide vapour decontamination				
Disposal of infectious waste stream				
Curtain changes				
Mattress disposal				
Indirect costs				
Sick leave for healthcare workers				
Opportunity costs				
Elective surgical missed/delayed				
Ward/ bay/ bed closures directly attributable to the outbreak				

Appendix 4. Search strategy

Search strategy for Embase (via Ovid)

#	Searches	Results
1	exp epidemic/	134407
2	exp pandemic/	197450
3	(outbreak* or pandemic* or epidemic*).ab,ti.	506885
4	1 or 2 or 3	573246
5	exp hospital/	1469598
6	exp cross infection/	21171
7	*health care facility/	26797
8	(ward or wards).ab,ti.	116348
9	"Hospital*".ab,ti.	2641983
10	(acute adj3 setting*).ab,ti.	26601
11	(Healthcare adj3 infection*).ab,ti.	10908
12	(HAIs or nosocomial).ab,ti.	51458
13	5 or 6 or 7 or 8 or 9 or 10 or 11 or 12	3378061
14	*information processing/	39188
15	exp health survey/	280696
16	exp questionnaire/	965821
17	"survey*".ab,ti.	1119454
18	"Questionnaire*".ab,ti.	1004601
19	(resource adj2 (utiliz* or utilis* or measure*)).ab,ti.	30251
20	((data collection or cost*) adj3 (tool* or instrument*)).ab,ti.	17335
21	14 or 15 or 16 or 17 or 18 or 19 or 20	2278681

22	(cost* or cost benefit analys* or health care costs).mp.	1383837
23	21 and 22	149584
24	4 and 13 and 23	1357
25	(cost? adj2 (illness or disease or sickness)).tw.	7987
26	(burden? adj2 (illness or disease? or condition? or economic*)).tw.	93046
27	quality adjusted life year/	37014
28	"cost of illness"/	21595
29	exp "health care cost"/	350487
30	(out-of-pocket adj2 (payment? or expenditure? or cost? or spending or expense?)).tw.	10320
31	(expenditure? adj3 (health or direct or indirect)).tw.	14784
32	((adjusted or quality-adjusted) adj2 year?).tw.	44465
33	25 or 26 or 27 or 28 or 29 or 30 or 31 or 32	489328
34	4 and 13 and 33	4165
35	24 or 34	5039
36	limit 35 to (english language and yr="2014 -Current")	3967
37	limit 36 to (conference abstract or conference paper or "conference review" or editorial or letter)	1325
38	36 not 37	2642

Appendix 5. Tool to critically appraise costing tools

This tool developed by the Welsh Public Health Observatory was based on Larg et al. 2011 (Cost of illness studies: a guide to critical evaluation).[40]

The tool was used in the previous HIQA report on the economic burden of AMR and has been further modified to meet the aims of the current project.[12]

A. Is the Cost-of-illness study likely to be relevant and usable (what costs should have been measured)?

	Yes	Can't tell	No
1. Is the costing tool described in enough detail to replicate?			
2. Are some or all of the cost inputs relevant to an Irish setting?			
3. Is the necessary data likely to be available in Ireland?			

Is it worth continuing? (delete as appropriate) YES/NO/Discuss

Only complete the next section if the answer to the question above was 'Yes'

B. Methodology and data: how well were resource use and cost items measured?

	Yes	Can't tell	No
4. Was an appropriate method(s) of quantification used, such that: (i) additional, or excess, costs were measured? (ii) only costs specific to (caused by) the outbreak(s) were included (confounders controlled)? (iii) all important effects were captured? (iv) the required level of detail could be provided?			
5. Was the resource quantification method(s) well executed? (i) Were cost allocation methods, data and assumptions valid? (ii) For person-based studies, were appropriate statistical tests performed and reported? (iii) Were data representative of the study population? (iv) Were there any other relevant resource quantification issues?			
6. Was the performance of the costing tool evaluated in a real world setting?			

Is it worth continuing? (delete as appropriate) YES/NO/Discuss

Only complete the next two sections if the answer to the question above was 'Yes'

C. What did they find (analysis and reporting)?

	Yes	Can't tell	No
7. Did the analysis address the study question?			
8. Was a range of estimates presented?			
9. Were the main uncertainties identified?			
10. Was a sensitivity analysis performed on: (i) important (uncertain) parameter estimates? (ii) key assumptions? (including the counterfactual) (iii) point estimates? (based on confidence or credible intervals)			
11. Was adequate documentation and justification given for cost components, data and sources, assumptions and methods?			
12. Was uncertainty around the estimates and its implications adequately discussed?			
13. Were important limitations discussed regarding the cost components, data, assumptions and methods?			
14. Were the results presented at the appropriate level of detail to answer the study question (cost components; causative pathogens; subpopulation groups; parameters of the outbreak, for example, number of units/hospitals; cost bearers)?			

Appendix 6. Example of the data extraction form

Authors (year) Country	Study design	Causative agent of the outbreak(s)	Cost items assessed	Costing method (for example micro-costing and or macro-costing)	Costing tool development process	Costing tool validation process	Number of participants/sites and characteristics piloted (tool test)	Method of administration (for example, mode, main user)	Time horizon (cost assessment)	Completion time	Limitations in cost assessment

Appendix 7. Usability and feasibility measures

System Usability Scale (Brooke, 1994)

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
I think I would like to use this tool frequently.	☐	☐	☐	☐	☐
I found the tool unnecessarily complex.	☐	☐	☐	☐	☐
I thought the tool was easy to use.	☐	☐	☐	☐	☐
I think that I would need the support of a technical person to be able to use this system.	☐	☐	☐	☐	☐
I found the various functions in this tool were well integrated.	☐	☐	☐	☐	☐
I thought there was too much inconsistency in this tool.	☐	☐	☐	☐	☐
I would imagine that most people would learn to use this tool very quickly.	☐	☐	☐	☐	☐
I found the tool very cumbersome to use.	☐	☐	☐	☐	☐
I felt very confident using the tool.	☐	☐	☐	☐	☐
I needed to learn a lot of things before I could get going with this tool.	☐	☐	☐	☐	☐

Feasibility of Intervention Measure (Weiner et al., 2017)

	Completely Disagree	Disagree	Neither Agree nor Disagree	Somewhat Disagree	Completely Agree
The outbreak costing tool seems implementable.					
The outbreak costing tool seems possible.					
The outbreak costing tool seems doable.					
The outbreak costing tool seems easy to use.					

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