DEVELOPMENT AND VALIDATION OF FOOD POISONING OUTBREAK COSTING TOOL (MyFPO-CT) AND COST ANALYSIS OF FOOD POISONING OUTBREAK INVESTIGATION MANAGEMENT

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Form

А	JePEM Ethical Approval
В	NMMR Ethical Approval
С	Permission Letter to used Health Facility
D	Pre- testing call letter
Е	MyFPO-CT costing tool
F	Patient Informed Consent Form

LIST OF ABBREVIATIONS

AEHO	Assistant Environmental Health Officer		
АРНО	Assistant Public Health Officer		
CBA	Cost Benefit Analysis		
CDCIS	Communicable Diseases Control Information		
	System		
CEA	Cost Effective Analysis		
CHEERS	Consolidated Health Economic Evaluation		
	Reporting Standards		
CUA	Cost Utility Analysis		
DHO	District Health Office		
EHRN	Eurasian Harm Reduction Project		
FSO	Food Safety Officer		
FSQ	Food Safety Quality		
HPP	Health Policy Project		
ISDR	the Integrated Surveillance and Disease Response		
MO	Medical Officer		
NCD	Non-Communicable Disease		
My FPO-CT	My Food Poisoning Outbreak Costing Tool		
GA	General Assistant		
PHS	Public Health Specialist		
SHD	State Health Department		
UN	United Nation		
USAID	United State Agency for International Development		

WHO World Health Organization

LIST OF SYMBOLS

Symbols	Description
%	Percentage
CI	Confidence Interval
SD	Standard Deviation

ABSTRAK

PEMBENTUKAN DAN VALIDASI ALAT PENGUKURAN KOS WABAK KERACUNAN MAKANAN DAN ANALISIS KOS PENYIASATAN DAN KAWALAN WABAK KERACUNAN MAKANAN

Pengenalan

Penyiasatan dan pengurusan wabak keracunan makanan yang dijalankan oleh pihak berkuasa kesihatan awam memerlukan sumber yang tinggi. Maklumat analisis kos dapat membantu pihak berkuasa kesihatan awam menentukan perancangan serta intervensi yang maksimum. Terdapat keperluan mendesak untuk maklumat kos data yang tepat bagi penyiasatan dan pengurusan wabak keracunan makanan. Sebuah alat pengukuran kos yang mampu mencerminkan situasi sebenar di lapangan oleh pihak berkuasa kesihatan awam adalah diperlukan bagi tujuan pengiraan kos dan pengiraan budget.

Objektif

Kajian ini bertujuan untuk membangunkan dan mengesahkan alat pengukuran kos wabak keracunan makanan (MyFPO-CT) serta menjalankan kos analisis penyiasatan dan pengurusan wabak keracunan makanan.

Kaedah

Kajian ini mengandungi dua fasa di mana fasa satu adalah untuk membentuk dan mengesahkan alat pengukuran kos dan fasa dua melibatkan analisis kos penyiasatan dan pengurusan wabak keracunan makanan. Rangka Kerja Pengekosan Perkhidmatan Kesihatan untuk Pembayaran Pembekal daripada " Jaringan Pembelajaran Bersama untuk Akses Kesihatan Sejagat" telah disesuaikan untuk memandu proses pembentukan. Microsoft Excel 2016 dipilih sebagai platform berikutan cirinya yang bersesuaian serta mesra pengguna. Pertemuan pakar yang terdiri daripada ahli epidemiologi, ahli ekonomi kesihatan, ahli statistik diadakan bagi tujuan menyelaras rekabentuk dan pembentukan MyFPO-CT. Pemerhatian secara langsung diadakan semasa penyiasatan dan pengurusan keracunan makanan di Kelantan untuk menentukan penggunaan sumber, andaian kos, tempoh masa, bentuk serta proses kerja. Unit kos diperolehi daripada garis panduan Kementerian Kesihatan Malaysia dan dokumen perolehan kerajaan. Simulasi di lapangan dilaksanakan dan penambahbaikan reka bentuk dan susun atur dilaksanakan. Pengesahan kandungan dilaksanakan oleh tiga pakar kesihatan awam dan tiga ahli ekonomi kesihatan. Pengesahan muka dilaksanakan oleh dua pegawai perubatan epidemiologi, tiga penolong pegawai kesihatan persekitaran kanan serta lima penolong pegawai kesihatan persekitaran. Fasa dua melibatkan pengukuran serta analisis kos penyiasatan pengurusan wabak keracunan makanan dengan mengunakan MyFPO-CT. Sebanyak enam wabak keracunan makanan dianalisis dengan menggunakan MyFPO-CT.

Keputusan

Hasilnya, alat pengukuran kos MyFPO-CT mengandungi enam domain, 21 subdomain, dan 83 item, dibentuk dengan menggunakan perspektif penyedia kesihatan untuk mengukur satu episod wabak keracunan makanan dari sudut mikro costing bawah ke atas. Tahap skala indeks pengesahan kandungan, purata pengiraan (S-CVI/ Ave) dan tahap skala indeks pengesahan muka, purata pengiraan (F-CVI/ Ave) adalah

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memuaskan. Analisis kos yang dijalankan menggunakan MyFPO-CT mendapati purata bagi setiap wabak adalah RM 5295.10. Kos personel (55.25%) dan kos makmal (38.63%) merupakan penyumbang terbesar kos keseluruhan. Purata dari analisis boostrap 10,000 adalah RM 5280.30 (95% CI 4090.30- 6391.20). Analisa sensitiviti yang dijalankan mendapati perubahan 83.07% dan 106.48% pada kos keseluruhan apabila peningkatan kos 150% pada kos personal dan makmal.

Kesimpulan

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MyFPO-CT adalah alat yang sah untuk mengukur kos penyiasatan dan pengurusan wabak keracunan makanan, membolehkan analisis kos untuk dijalankan. Analisis kos menunjukkan penyiasatan dan pengurusan wabak keracunan makanan adalah mahal dengan kos personal menyumbang lebih dari separuh kos keseluruhan.

Kata kunci: alat pengukuran kos, kos analisis, ekonomi kesihatan, wabak keracunan makanan

ABSTRACT

DEVELOPMENT AND VALIDATION OF FOOD POISONING OUTBREAK COSTING TOOL AND COST ANALYSIS OF FOOD POISONING OUTBREAK INVESTIGATION MANAGEMENT

Background

Food poisoning outbreak investigation management carried out by public health authorities require extensive resources. Information on cost analysis may assist public health authorities determine optimal intervention and plan management. There is a need for cost assessment of food poisoning outbreak investigation management. A costing tool that reflects an actual process of field investigation and outbreak management by public health authorities is needed for costing and budgeting purposes.

Objectives

This study aims to develop and validate a food poisoning outbreak costing tool (MyFPO-CT) and carry out program cost analysis of food poisoning outbreak investigation management.

Methodology

The study consists of two phases which Phase 1 developed and validated a new costing tool, meanwhile, Phase 2 involved cost analysis of food poisoning outbreak investigation management. The development of the MyFPO-CT was guided by the Costing of Health Services for Provider Payment framework from the Joint Learning Network for Universal Health Coverage. Microsoft Excel was the chosen platform due

to its feasibility and user-friendly features. Content expert meetings among epidemiologists, health economists, and statisticians were held to oversee the design and development process of MyFPO-CT. Direct observations were performed during food poisoning outbreak investigations in Kelantan to determine work pathways, patterns, duration, resource consumptions, and costing assumptions. Unit costing values were imputed based on the Ministry of Health national guidelines and government procurement documents. Field simulation was carried out and improvements in the design and content arrangement were made. Content validation of the MyFPO-CT and relevancy was completed by three public health specialists and three health economists. Face validation from users' perspectives was carried out involving two epidemiology medical officers, three senior assistant environmental health officers, and five assistant environmental health officers. Phase 2 involve cost analysis of food poisoning outbreak investigation management using a new validated MyFPO-CT costing tool. A total of six food poisoning outbreaks were analyzed using newly validated MyFPO-CT.

Result

The final validated MyFPO-CT spreadsheet consists of six domains, 21 subdomains, and 83 items, developed from a provider perspective to capture one episode of outbreak investigation and control management using a bottom-up micro-costing methodology. Scale level content validation index, averaging calculation method (S-CVI/Ave) and scale level face validation index, averaging calculation method (S-FVI/Ave) were acceptable. Cost analyses carry out using MyFPO-CT found that the the mean cost per outbreak was RM 5295.10. Personnel cost (55.25%) and laboratory cost (38.63%) contributed to a large portion of the total cost. Mean outbreak from

bootstrap 10 000 was RM 5280.30 (95% CI 4090.30- 6391.20). Sensitivity analysis shows that changes 83.07 % and 106.48% of total cost when personnel cost and laboratory cost varied by 150%.

Conclusion

The newly developed MyFPO-CT is a valid tool to capture resource consumption in food poisoning outbreak investigation management. The cost analysis shows that food poisoning outbreak investigation was costly with personnel cost contributing more than half of the total cost.

Keywords: costing tool, cost analysis, health economics, food poisoning outbreak

CHAPTER ONE INTRODUCTION

1.1 Overview of food poisoning

1.1.1 Epidemiology of food poisoning

Food poisoning is a public health burden contributing to significant mortality and morbidity worldwide, especially in developing countries. It is an important public health concern that requires immediate attention by the local health authorities.

Food poisoning occurs when a person consumes a contaminated food product that contains hazardous pathogens, the pathogens proliferate in the intestinal tract and cause illness. Symptoms can range from minor to severe and can last anywhere from a few hours to several days, depending on the virus, organism, or toxin. A food poisoning outbreak is defined as the occurrence of two or more cases of a similar illness resulting from the ingestion of common food (MOH, 2006, Kearney et al., 2018).

Cross-contamination of foods and food handlers, lack of hygiene, globalisation, antibiotic-resistant bacteria, and climate change are all factors that contribute to the rise of food poisoning. Poor food handling practices and a lack of public knowledge are significant elements contributing to the high rates of foodborne diseases (Salleh et al., 2017).

In 2015, the WHO Foodborne Disease Burden Epidemiology Reference Group released the first report on foodborne disease incidence, mortality, and disease burden. The diarrheal disease was responsible for 3% of global mortality. Children under the age of five (who account for 40% of the overall burden despite accounting for only 9% of the global population) and people in low-income countries are the most vulnerable groups affected by the foodborne disease. Other vulnerable groups include pregnant women, the elderly, and those with compromised immune systems (WHO, 2015). It is estimated that over one-tenth of the world's population, or 600 million people, become unwell after eating contaminated food each year, resulting in 420,000 deaths. Consequently, an estimated 33 million healthy life years (DALY) have been lost due to food poisoning (WHO, 2015). The 2018 World Bank report the annual cost of treating foodborne illnesses is estimated at US\$ 15 billion. In addition, US\$110 billion is lost each year in productivity and medical expenses resulting from unsafe food in low- and middle-income countries.

Food poisoning is still a public health issue in Malaysia, as implied by the incidence rate of 45.171 per 100,000 people with a mortality rate of 0.02 in 2018, and the incidence rate of 50.90 per 100,000 people in 2019 with a mortality rate of 0.03. It also ranked among the top five communicable diseases in Malaysia (MOH, 2020).

Epidemiological data of food poisoning is very limited, especially in underdeveloped countries. Even the most apparent foodborne outbreaks are frequently unnoticed, unreported, or investigated, and are only made public if they have significant public health or economic impact (WHO, 2015). Large outbreaks, such as food poisoning in schools, are easily discovered, but diffused outbreaks are frequently overlooked (Soon

et al., 2011). The actual burden of food poisoning has been unknown due to the lack of reporting of the incidents, especially in the community and rural areas. Hence, the true incidence could be higher.

Identifying epidemiologic characteristics of food poisoning is critical since epidemiological data is crucial for developing more effective national policies to prevent recurrent outbreaks (Moon et al., 2014). During outbreaks, epidemiologist seeks to identify and implement effective complex public health interventions to control disease spreads (Li et al., 2019). The action taken by the local health authority would include the deployment of personnel and resources to define the case, screen all potentially exposed individuals to determine the magnitude of the outbreak, characterize the demographics of the patients, place, and time, sampling procedure to identify the source, disinfection and closure of premise to break chains of infection. These public health responses require many resources and can be time-consuming.

1.1.2 Outbreak investigation management of food poisoning in Malaysia

All food poisoning outbreak investigation management are carried out by the Ministry of Health via District Health Offices as the main implementer and oversaw by the State Health Department. The *Garis Panduan Pengurusan Wabak Keracunan Makanan FWBD/KRM/GP /001* (Pindaan 2016) was used as the standard operating procedure to guide health care worker carrying out outbreak control activities. Several units within the District Health Office such as the CDC (Centre Disease Control) Epidemiological Unit, and the Food Safety Quality (FQC), Legislative and inspectorate Unit (UIP) and the Health Promotion Unit are mobilized to investigate food poisoning and to implement appropriate control measures to identify the source and break the chain of

infection. The sequence of food poisoning outbreak investigation management were summarized as in Figure 1.1. However, in an actual outbreak investigation, the listed components rarely occur in a linear fashion, and some may even occur concurrently (Kearney et al., 2018).



Figure 1.1 Sequence of food poisoning outbreak investigation management, adapted from *Garis Panduan Pengurusan Wabak Keracunan Makanan FWBD/KRM/GP /001* (Pindaan 2016)

The notification of food poisoning is sent either from a local health clinic or private clinic to CDC Epidemiological Unit via phone within 24 hours followed by official notification. via an electronic reporting system called the Communicable Diseases Control Information System (CDCIS) (Soon et al., 2011). The rapid Respond Team consist of a small number of assistant environmental health officer are mobilised to conduct a preliminary investigation in order to verify the existence of an outbreak, and if the criteria are met, an outbreak will be declared by the district epidemiologist. A field investigation will be conducted at the scene by a team of investigators comprised of personnel from the CDC Epidemiology unit, FSQ unit, and UIP unit.

The investigation and control process is divided into three distinct phases, which are epidemiological investigation, environmental assessment, and laboratory investigation (Kearney et al., 2018). Active case detection, screening of all individual potentially exposed to a source of infection, detailed food history for three days is used in epidemiological investigations to ascertain the true magnitude of the outbreak. The process of evaluating the cleanliness rating of a facility also was carried out as part of environmental assessment. Food samples, holding samples, proxy samples, and/or environmental/operator swab samples all be collected and sent to the laboratory for analysis.

The closure of the premises and the directive to cease production and handling of food were immediately implemented as part of the control activities by adopting the CDC act 1988. Additionally, disinfection procedures were carried out. Health education campaigns are conducted to increase food handlers' and community awareness. The Outbreak Operations Room is activated to coordinate all activities related to epidemic control and investigation. To determine the source of the outbreak, epidemiological analysis was conducted. The respective officers are responsible for documenting and finalising preliminary and final outbreak reports, as well as conducting an investigation based on the HACCP concept. The operation room is closed and the outbreak declared over when there is no increase in cases after two incubation periods of the last case.

1.1.3 The cost of food poisoning investigation management

Outbreaks are costly, the cost of not identifying an outbreak would even be more substantial and economic benefits resulting from intervention will vary by the outbreak (Roberts, 2000). It is critical for decision-makers in prevention science to be aware of intervention costs in order to allocate scarce resources effectively (Charles et al., 2013a).

Assessing outbreak costs, including costs of response activities by public health authorities, can help in planning for future outbreaks and in optimizing the allocation of public resources (Suijkerbuijk et al., 2015). Failure to consider the cost of intervention may result in public health authorities choosing an effective but expensive intervention, leading to suboptimal decision-making by over or underestimating the management outcome.

Therefore, policymakers need to make important decisions on the use of public funds, optimizing the use of resources during public health response (Baltussen and Niessen,

2006). Form a stand-point policymaker, information about cost analysis that captures how much resource consumption and utilization could improve unit per investment, aiding public health authority to determine the optimal intervention and plan management effort. Accurate data on the burden of food poisoning is required to adequately inform policymakers and allocate appropriate resources for food safety regulation and intervention programmes (WHO, 2015).

Despite increased international awareness of foodborne pathogens as a serious threat to human health and socioeconomic growth, food safety is still neglected. The lack of accurate data on the actual scope and cost of foodborne infections, which would allow policymakers to determine public health priorities and allocate resources, is a key impediment to appropriately addressing food safety concerns (WHO, 2015).

There is a growing appeal of the use of applications of economic evidence in public health. The Institute of Medicine committee on Public Health Strategies to Improve Health and its Board on Population Health and Public Health Practice in 2012 issued a call to action for public health practitioners to embrace economic evidence. Among the suggestions were 1) develop a model chart of accounts for use by public health agencies to facilitate tracking of the resource associated with programme outputs and results across agencies, 2) develop data systems and methodologies for the collection of high-quality research on the costs of essential public health programme, and 3) develop and validate approaches for evaluating the costs and benefits of alternative population health programmes (Rabarison et al., 2015).

1.1.4 The need of a costing tool for food poisoning

Globally, the incidence of food poisoning, associated with outbreaks and food contamination that raise international concern continue to be reported (WHO, 2014). In the absence of a systematic and comprehensive cost assessment, the true program cost of food poisoning outbreak investigation remains unclear.

Developing, identifying, and scaling interventions that effectively prevent and manage healthcare resources is a critical component of controlling healthcare costs. Decisionmakers- faced with limited public resources, are increasingly requesting information on the economic costs and benefits of health interventions in order to make evidencebased programming and resource allocation decisions (Crowley et al., 2018).

Access to precise and reliable cost data for health services can be beneficial for a variety of purposes, including discussions about economics and financial sustainability, budgeting, cost-effectiveness, and cost-benefit analysis (Stenberg et al., 2018). The distribution of resources should be based on a thorough cost and benefit. As a result, it is crucial that national and local governments, as well as the international community, increase their efforts to collect, analyse, and use data on health system resource allocation (Stenberg et al., 2018). The available data collection techniques and methods utilised to perform costing studies have been restricted, with an emphasis on clinical settings and health technology, with public health interventions receiving less attention (Chapel and Wang, 2019).

There is an urgent need for accurate cost data in public health response against high burden communicable disease such as food poisoning. In particular, a standardized disease-specific costing tool, with the ability to capture direct and indirect resource utilization and consumption, conduct cost analysis, budgeting, and scale-up, is necessary for this purpose (Gustafsson-Wright et al., 2017). Determining the most appropriate costing tool for each case requires knowledge of the costing tool applicability (Gurowka and Lawson, 2007).

Epidemiologically effective intervention may not be optimal if it is operationally hard and highly technical to implement or economically expensive. Public health response requires interventions tools that are cheap, user-friendly, less technical, operationally feasible and effective (Li et al., 2019). The platform needs to be universally accessible, available and extensively used by all partner institutions, and easy for non-economist to understand (Batura et al., 2014a). The use of user-friendly platforms such as MS Excel software is the most suitable for this purpose. It can be used to facilitate the implementation of a new costing tool, as most assistant environmental health officer are familiar with its application.

Due to the absence of a costing tool suitable for local use, past economic evaluation studies on public health intervention against food poisoning in Malaysia had to rely on multiple cost data from multiple sources. Ideally, these cost data should be independently calculated to provide more accurate findings. However, to our knowledge, a costing tool for Malaysia has yet to exist. It is therefore the aim of the study to develop and validate a costing tool that can be used to capture resource consumption and utilization during an outbreak investigation of food poisoning outbreak and carry out cost analysis at the same time. Costing of intervention strategies means estimating the physical resource required for their implementation and valuing these resources in monetary terms (Hendriks et al., 2014a). As such, costing is an integral part of the strategic planning process, and cost estimates are normally part of action plans that support the strategy implementation. Costing is the first and most important step in a strategic financial management cycle To prioritise resource allocation, governments require high-quality scientific evidence (McLaughlin et al., 2014). The lack of accurate data on the actual scope and cost of foodborne infections, which would allow policymakers to determine public health priorities and allocate resources, is a key impediment to appropriately addressing food safety concerns (WHO, 2015).

1.2 Problem statement

Despite the various costing tools available worldwide, the use of these tools may not be suitable in the local context. The existing costing tools do not address the public health response for food poisoning outbreak investigation management. A costing tool for public health response for a communicable disease that is in line with the Malaysian context, national policies and resources, the scope of practice of local health service is currently not available.

The traditional method of measuring costs is highly technical and difficult to conduct for untrained personnel. Since there is no standardized costing tool, the quality of measured cost is questionable and may vary in methodology. Obtaining the cost of public health intervention for communicable disease is difficult due to unavailability of cost measurement for outbreak management and public health response. The lack of accurate data on the cost of food poisoning may in turn delay resource allocation and made it difficult for policymakers to improve current policies or regulations (Salleh et al., 2017).

1.3 Study rationale

Public health professionals must also consider restrictions such as resource capacity and funding in deciding areas to focus on. The cost and benefit analysis of public health interventions provides information for public health experts and decision-makers in deciding which initiatives are successful and efficient (Rabarison et al., 2015).

Estimating the costs of health interventions is critical for policymakers for a variety of reasons, one of which is that the data may be used to evaluate and improve the performance of health system Furthermore, cost data on public health intervention is essential for replication planning and scale-up of interventions that have been proven to be successful and efficient. Transitioning from more controlled research settings to real-world implementation requires a detailed understanding on the cost of an intervention.

There is a significant need to develop a new costing tool for public health response to capture cost in communicable disease response. Consideration is given to local evidence, specific health questions related to specific needs, legislation, policies and resource, the scope of practice within local health service and fit with the existing model of delivery. The development of a validated costing tool that is based on the Ministry of Health guidelines will allow policymakers to capture the actual costs of public health response in communicable disease control and enable a more systematic resource allocation.

Incorporating principles of health economics into the field of epidemiology also enable the selection of effective intervention. An appropriate costing methodology guided with the right framework allows compressive food poisoning costing tools to be developed. Thorough content development for item identification and assigning value for the costing tool to reflect the actual field cost of food poisoning outbreak investigation management enable the costing tool to yield accurate cost results.

In addition, provider cost data is extremely useful for cost-effectiveness, cost-benefit and cost-utility analysis. This new costing tool will provide the cost data required by these studies, enabling more economic evaluations to be conducted in the future. Furthermore, this will encourage evidence-based decision making, particularly in health technology assessment.

1.5 Research questions

- 1. Is the MyFPO-CT a valid costing tool in measuring the cost of food poisoning outbreak investigation management?
- 2. What is the cost of food poisoning outbreak investigation management?

1.5 Objectives

General:

To develop and validate the MyFPO-CT and to measure the cost of food poisoning outbreak investigation management from provider perspective.

Specific:

- To develop and validate the MyFPO-CT in measuring the cost of food poisoning outbreak investigation management from provider perspective.
- 2. To estimate the cost of food poisoning outbreak investigation management from provider perspective.

1.6 Hypothesis

The newly developed MyFPO-CT costing tool is a valid tool to measure the cost of food poisoning outbreak investigation management in Malaysia.

CHAPTER TWO

LITERATURE REVIEW

2.1 Food Poisoning Outbreak Investigation management in Malaysia

In Malaysia, the present method of investigating food poisoning outbreaks is a multistage procedure. The process starts with receiving notification to District Health Office by the local medical officer. After receiving a notification, the assistant environmental health will inform the case to Medical Officer of Health, and verification of the incident will be done. An initial investigation can begin once the information has been verified (MOH, 2006).

The three primary components of a food poisoning outbreak investigation are the epidemiologic investigation, laboratory investigation, and environmental investigation. Without these three components, which are often performed simultaneously, an outbreak investigation cannot be conducted. Field investigation is a critical component of epidemiological research, with the primary goal of identifying the source of a problem based on suggestive evidence or information gathered throughout the process (Jroundi and Belarbi, 2016). Laboratory investigation and environmental investigation that was carried out together with epidemiological investigation provide further information in the identification of causative agent of the outbreak. Therefore, it is important that each of these components works together and communicates to complete the goals and objectives for a successful investigation (Kearney et al., 2018).

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The initial report must be submitted to State Health Department within 20 hours and the Ministry of Health within 24 hours from the time of outbreak is declared. In the initial report, the outbreak control team must identify the suspected source of the food poisoning outbreak, which is the contaminated food most likely to have contributed to the occurrence of the outbreak.

Whether or not the comprehensive investigation into the source of the problem has been completed, preventive action and control measures will be implemented on the ground. The operational room is activated to regulate outbreak control activities until the outbreak was declared over. The outbreak was declared over if no new case was reported within two incubation periods. Most cases of food poisoning involve a short incubation period.

How quickly public health acts and begins collaboration across many entities determines the essential strength of an epidemic investigation (Simone et al., 2014). A more efficient field investigation technique would lead to a faster and easier adoption of preventative and control measures, breaking the outbreak's transmission in less time. Finally, within one month after the outbreak's declaration, a final report must be sent to the State Health Department.

2.2 Available Costing Tool

Costing is a process to identify the resources required to produce goods or deliver a service that are valued in monetary terms (Stenberg and Rajan, 2016). In healthcare,

costing tools are useful to monitor cost of resources used and service operation to enable rational resource planning and financial management. There are several costing tools available worldwide which are explained in below sections.

2.2.1 OneHealth Costing Tool

The OneHealth costing tool was developed by an inter-agency working group consisting of costing experts from World Health Organization (WHO) and other United Nations (UN) agencies to inform sector-wide national strategic health plans and policies. This tool incorporates planning and costing of human resources, facilities, equipment and transportation, medicines and supply chains, health management information systems, monitoring and evaluation, and governance activities.

This tool also provides planners with scenario analysis, costing, health impact analysis, budgeting and financing of strategies for all major diseases and health system components (WHO, 2013). The OneHealth costing tool can be very useful to health agencies, however, the process of developing and using this costing tool requires extensive data and various information for analysis purposes.

2.2.2 Harm Reduction Costing Tool

This program-specific costing tool was developed by the USAID-funded Health Policy Project (HPP) in collaboration with the Eurasian Harm Reduction Network (EHRN) to estimate in-country unit costs per client per year for opioid substitution therapy and needle and syringe exchange services. The tool was intended to help civil society organizations in the Eastern Europe and Central Asia to push for additional financing towards harm reduction agenda such as the HIV prevention strategy. The findings will aid evidence-based decision-making by filling a data gap on the costs of delivering harm reduction in various countries throughout the region.

Developed from a societal perspective, the initiative intends to improve civil society advocacy, including drug users, for sufficient, strategic, and long-term investments in harm reduction. Using Microsoft Excel (MS Excel) as the platform, the average annual unit cost was disaggregated by program, level of priorities, direct and indirect cost and also cost categories (personnel, equipment, medical commodities and others). Cost categories included in this costing tool were staff times, medical commodities, medical equipment, non- medical equipment, site overhead and other direct cost not included under commodities and equipment. The limitation of this costing tool was the need to save multiple versions of the tool across different service delivery scenarios and packages of service.

2.2.3 SurvCost

The SurvCost is a spreadsheet costing tool developed by the World Health Organization in collaboration with United State Agency for International Development (USAID) and Centre Disease Control (CDC) used for the Integrated Surveillance and Disease Response (ISDR) in the African regions (Irurzun-Lopez et al., 2016). This costing tool includes physical infrastructure, human resources, tools of activities that were measured in multiple core capacities. This costing tool guide users on the data collection of resources used, including capital (one-time investment) and recurrent (on-going) items. The capital items include building infrastructure, vehicles, equipment, and furniture. The recurrent items included personnel (salaries and benefits of surveillance officers, data managers, physicians, nurses), rent (rent, utilities, operation, and maintenance), office and laboratory supplies, transportation, and public awareness campaigns (Somda, 2007). The limitation of SurvCost is that diseases included in this costing tool are unique to Africa, such as trypanosomiasis, yellow fever, onchocerciasis, and neonatal tetanus which do not pose public health burden in Malaysia.

2.2.4 Malaria Strategic and Operational Plan Costing Tool

This disease-specific costing tool is designed to assist countries in estimating costs of the Malaria Strategic Plan and to support the development and alignment of the annual budget for the Malaria Annual Work Plan with the national annual budget cycles. It relates country funding priorities to the needed resources. Built on the MS Excel platform, the tool also provides a dashboard for tracking year-on-year implementation of the Malaria Annual Work Plan activities and resource use. It is a user-friendly tool, developed based on a practical costing and budgeting framework.

Out of 12 worksheets, only seven require data entry, which are primary datasheet, malaria strategic plan sheet, malaria annual work plan and budget sheet, development partner resource mapping sheet, annual work plan tracking sheet, objective costing sheets (for seven objectives), annual budget summary sheet. The sheets throughout the tool are linked to each other so that data entered on one sheet appears in the appropriate sections on other linked sheets. However, the tool required users to have a detailed

knowledge on the cost consumption, unit cost and country-specific budget chart account (WHO, 2019).

2.2.5 Value TB Costing Tool

This disease-specific costing tool was developed by the WHO in collaboration with the London School of Hygiene, University of Cape Town, Global Health Cost Consortium and Value TB. It was developed from the provider perspective, encompasses all costing aspects for a variety of TB interventions that countries needed to adapt to accommodate country-specific context. The *Value TB Costing Tool* has been organized via a MS Excel spreadsheet to allow data collection and calculation of unit costs of TB service delivery at the facility level. It supports both top-down and bottom-up costing, economic and financial cost approaches, different methodologies for measuring staff time (interviews, observations and timesheets) and disaggregated by key input categories.

The Value TB Costing Tool Suite allows costing in different platforms (such as outpatient and inpatient care and facility outreach services) but is currently limited to the facility level. However, the Value TB Costing Tool Suite is limited in the sense that it does not measure adverse events related to TB treatment and a list of monitoring tests are required (Cunnama et al., 2020). Table 2.1 summarizes the available costing tool as discussed above.

	OneHealth Costing Tool	Harm Reduction Costing Tool	SurvCost	Malaria Strategic and Operational Plan Costing Tool	Value TB Costing Tool
Developer	WHO and other UN Agencies	USAID	USAID CDC	WHO	WHO, London School of Hygiene, University of Cape Town, Global Health Cost Consortium and Value TB
Disease Specific/ Broad Sector	Broad sector	Program specific	Disease Specific	Disease Specific	Disease Specific
Platform	Specific Software	MS Excel	MS Excel	MS Excel	MS Excel
Element	 Personnel Facilities equipment Transportation Medicine Supplies chain Health Management Information system Governance Activities 	 Site staff Medical commodities Medical equipment Other direct costs not included under commodities and equipment Non- medical equipment Site overhead 	 Capital items building, vehicles, equipment, and furniture. Recurrent items included personnel rent, utilities, office and laboratory supplies, transportation, and public awareness campaign 	 Cost assumption for each activity and per activities Timeline of each activity over 5 years Quantities per annum of each activity 	 Building Vehicle Equipment and furniture Training Personnel Drug Diagnostic test
Limitation	Required extensive information	Need to save multiple versions of the tool across different service delivery scenarios and packages of service.	Diseases unique to Africa	Required users to have a detailed knowledge on the cost consumption, unit cost and country- specific budget chart account	Not measure adverse events related to TB treatment and list of monitoring tests required

Table 2.1: Summary available costing tool

2.2.6 Availability of costing tool in Malaysia

Review of the literature did not find any costing tool being developed in Malaysia specific for calculating costs for public health activities. However, the DRG casemix have been widely implemented in the clinical field. The Malaysian DRG casemix system that was piloted in 2010 and currently used in 49 hospitals is used to determine cost of medical care for provider payment and funding purposes (Saizan et al., 2020).

2.2.7 Limitations of the available costing tools

A critical analysis of the literature on the available costing tool revealed several gaps and shortcomings. Firstly, a costing tool developed according to specific purposes in addressing the needs of other countries may not be suitable for use in the Malaysian setting. Harrison et al. (2010) stated that consideration should be given to local evidence, specific health questions related to specific needs, legislation, policies and resource, the scope of practice within local health service and fit with the existing model of delivery. Hence, the existing costing tool needs to be developed and customized to fit the local context.

In addition, other costing tools may not reflect the actual field process, and key stakeholders were not involved during its development stage i.e., planning, design, and definition of purpose and objectives. Hence it lacked the scope of the costing exercise and failed to identify existing cost data and end-user gaps (Özaltın and Cashin, 2014). Moreover, certain costing tool was not based on the workflow process occurring at the national and local level, thus failing to identify costs associated with the implementation of a complex program to reduce the cost gap (Chungong et al., 2014). Therefore, the development of a costing tool must be in line with the national guidelines and based on actual activities and responses to reflect the true situation in the field. To overcome this problem, key stakeholders must be involved in the development of the costing tool so that the above issues can be addressed.

As mentioned by Gurowka and Lawson (2007), different methodologies work for different situations and determining the most appropriate tool for each situation involves knowing about the applicability of each costing tool. It is important for a costing tool to generate accurate cost estimation of healthcare services and intervention for efficient administration of healthcare systems and research (Chapko et al., 2009). Precise information on the cost analysis of health services is crucial for financial sustainability, budgeting, cost-effectiveness and cost-benefit analysis. A well-designed costing tool must fulfil the internal and external validity which means the estimate is appropriate for the study question and the measurement is well-founded (Špacírová et al., 2020a).

2.3 Determining the approach

The majority of healthcare organisations adopt either the top-down or bottom-up approaches to cost accounting (Chapko et al., 2009, Özaltın and Cashin, 2014, Negrini et al., 2004). Both approaches have trade-offs between precision, accuracy, applicability, and time horizon of research. The decision between top-down and bottom-up has implications for resource item identification and resource utilization measurement. The primary distinction between the two approaches is that the bottom-up strategy focuses on comprehensive costing of service, whereas the top-down approach relies on average costing. The top-down approach assumes equal distribution of resources between patients. More accurate results would be obtained by the bottom-up method, even if the process is laborious and expensive (Negrini et al., 2004).

Current guidelines for conducting economic evaluations provide no specific recommendations regarding which costing approach should be utilized to inform economic evaluations (Clement et al., 2009). The methodology chosen affects cost estimates and can alter the outcome of a study (Chapel and Wang, 2019). The application of a standardised methodology enables the cost estimates to be comparable across interventions and situations (Johns et al., 2003).

2.3.1 Top-down approach

The top-down approach (also known as gross or average costing approach) is widely used due to its feasibility and simplicity. This technique estimate mean costs for the entire collection of products and services (cost items) generated by the organization during a specified time (Špacírová et al., 2020a). The top-down method breaks down health care intervention and service into significant large components. The top-down technique begins with the total cost of the institution, then breaks it down into departments, and finally into individuals by dividing total costs by the number of discharged patients (Özaltın and Cashin, 2014). In top-down costing, the total expenditure is divided by the total output to obtain the average value (Negrini et al., 2004).

Due to the feasibility of the top-down approach, this method was widely used by hospital administrators and accountants to estimate costs within the hospital (Negrini et al., 2004). In addition, a top-down approach is suitable to be used for long term run average cost. However, a top-down approach is less detailed and less accurate compared to the bottom-up costing.

2.3.2 Bottom-up approach

The bottom-up micro-costing is a technique that enables precise calculation of resources utilized to deliver a given intervention or health service (Negrini et al., 2004, Cunnama et al., 2020). It is particularly useful for calculating true costs to the health system, society and interventions with high provider variability. Reliable costs of an intervention at the micro-level are essential to perform accurate further economic analysis such as cost-effectiveness or cost-benefit analysis. (Charles et al., 2013a). Whenever cost data are available, micro-costing should be the preferred strategy in all fields of health and medicine as it is becoming a more popular tool for policy purposes (Xu et al., 2021).

Bottom-up approaches typically follow three phases in sequence: resource identification, measurement, and valuation (Špacírová et al., 2020a). It also involved identifying detailed service delivery process from the inventory, measuring each necessary item and breaking it down into discrete components which are analyzed separately (Mogyorosy and Smith, 2005b).

Studies that used bottom-up micro-costing can be used to estimate the cost of novel technologies or community-based therapies, as well as to provide estimates in nonmarket item research and to explore cost variation within processes (Frick, 2009a). Hendriks et al. (2014a) suggested that bottom-up micro-costing has better accuracy in the identification and valuation of the resource. Needy et al (2003) recommended bottom-up micro-costing, as it may provide more information for the operating organization. Ruger and Reiff (2016a) mentioned that micro-costing findings can