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The Politics of Reporting Reportable Diseases: A Methodological Review of the State-Researcher Clash[114]

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Abstract

In December 2016 the media in Tanzania was preoccupied with questions on the presence or not of the Zika virus in Tanzania. The debate was sparked by a National Institute of Medical Research (NIMR) report which pointed out that traces of the Zika virus had been identified in Tanzania. Within a short time, the government refuted the report and asked NIMR to retract the findings, arguing that the reporting process did not follow established procedures. Two central questions demand a close review: first, why did the government demand that the report be retracted? Second, what are the procedure that should have been followed? In this methodological review of the reporting of reportable diseases, an attempt will be made to examine the raison d'etre for the tag of war between the two sides and highlight the procedures that the announce of such findings should have followed. The review concludes with a methodological note to researchers and reporting of findings in health-related studies.

Key words: Reportable disease, reporting politics, Tanzania, Zika, methods.

[114] This article is the second in the author's series on research methods. The first one was: "2016 Killing of Researchers in Tanzania: Towards a Conceptual Safety Protocol".

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Introduction

In his 1999 article, Kevin De points out that the portrayal of disease and treatment commonly characterise conflicts between the state and medical professionals (Dew 1999). What this suggests is that a certain portrayal of disease alone could lead into a disagreement between parties due to the image painted by such a portrayal. In December 2016, the trending news, in Tanzania, was the presence of traces of the Zika virus in the country. A team of researchers from the National Institute of Medical Research (NIMR) had declared that traces of the Zika virus had been found in the country, a position vigorously disputed by the state, which ideally, is keen to defend its interest (Goodsell 2017).

Although the news about the presence of the Zika virus in Tanzania started small, in less than 48 hours the news had spread widely and became a politically sensitive issue. There were press briefings, debriefings, summons, press conferences and breaking news episodes. While the dust has finally settled, the central issue that needs to be interrogated by researchers and methodologists in particular, is that the drama was generated by a report of research findings, being 'challenged by the state'. This is a matter which calls for a critical reflection from a methodological perspective because reporting of research results is a methodological issue. Further, the event provides a 'rare opportunity' for methodologists to argue with an actual case at hand on the significance of sticking with the research protocol throughout the stages of a research including admission, validation and dissemination of results.

The Zika episode, as it unfolded in Tanzania, helps to illuminate that the research process does not end with the collection of data, analysis and writing of a report. The processes and methods used throughout the study matter if the findings have to hold and remain valid for possible application.

The conflict that emerged between the state and the NIMR team was to do with the reporting of study findings and not the scientific approach of the study. This is no small issue when it comes to research methods and has implications to a number of issues. It is an event that warrants a methodological review since reporting of research findings is a methodological issue. In order for researcher findings to be beneficial to research users, there is a need to closely reflect on what happened, highlight critical issues that characterised the clash between the parties and finally chart out ways in which such clashes could be avoided in future.

Although the focus of this case is on health research, the episode serves to provide insights beyond health fields as it applies to all disciplines. This is exemplified by another 2017 debate in Tanzania on the consumption of sunflower oil and its safety, emanating from another research conducted in the country

that pointed out that the sunflower oil on the market contained high levels of aflatoxins (Mmongoyo et al. 2017). Similar to the case of Zika, the findings on the safety of sunflower oil were challenged by the Tanzania Food and Drug Administration (TFDA) and consumers of sunflower edible oil were advised to continue using the oil because it was safe.116 A press release issued by the TFDA had nine points and two of them warrant attentions of researchers or methodologists. These are, first, a caution to researchers conducting studies on safety and quality of food, drugs, cosmetics, and medical supplies to involve TFDA officials as the main stakeholder. The second issue was on media units which were called upon to seek the opinion of TFDA before publishing any research findings in order to get the correct interpretation of those results.

A common methodological problem in the two cases is 'reporting of the findings'. Dew (1999) argued that media outlets tend to present findings produced by medical and public health researchers passively because they do not have the knowledge base to scrutinize the information. This is debatable because media houses have multiple ways available to them through which they can crosscheck the validity of what they are reporting. In addition, there are ethics and procedural requirements of reporting findings of such studies. According to Dew (1999), media present views of experts as sound, scientific and requiring neither analysis nor questioning. On the one hand, this suggests that researchers need to be aware of media weakness and how such weakness may damage their good work and hence design ways in which to guide the reporting of their study findings. On the other hand, consumers of media reports need to be aware of media shortcoming as well as they are not able to digest what was presented and or question researchers on the depth of their findings.

The Issue

The main issue under review in this work, is the clash between NIMR team which claimed that there were traces of the Zika virus in Tanzania, on the one hand, and the state which refuted the claim. At the centre of the clash was the reporting of the study outcomes which led to the dispute. While NIMR researchers argued that traces of Zika viruses had been found in Tanzania and thus the country need to take measures,[117] the government rejected the findings were not sufficient to lead to such a conclusion.[118] Reading in between the lines, the state was not saying that there were no traces of the Zika virus

[116] See Press Release by TFDA: "Taarifa Kwa Umma: Ufafanuzi Kuhusu Usalama wa Mafuta ya Alizeti". Issued by the Director General on 24 April 2017. http://www.tfda.or.tz/index/?q=taarifa_kwa_umma_mafuta_ya_alizeti accessed 25 April 2017.

[117] See NIMR Director General's press conference; clip available online http://millardayo.com/zika01/ Accessed 22nd December 2016

[118] See The Ministry of Health's press release of December 16th 2016 where the Minister explains that the presence Zika virus claims are unfounded and Tanzanians should ignore them.

in the country, instead it pointed out that the findings were not adequate to confirm the existence of the disease in the country. These differing positions of the two parties led to the issuance of statements in the media with conflicting messages that came with the potential to confuse the general public.

Objective and Significance of this Review

The objective of this review work is to he researchers and research users to reflect on the episode with a view to understanding methodological perspectives and the likely impact they can have on findings. It is a 'rare actual case' that provides a good learning opportunity for a review example, which should be exploited positively in order to strengthen the conduct and reporting of research findings. Reflections of this nature, further provide an opportunity to learn not only from the literature on research protocols, but also from policies and regulations that are in place to guide research activities. More, it avails a learning opportunity on how to deal with situations where study findings lead to public controversy.

This reflection is intended to serve as a resource for researchers, instructors, students, policy makers, journalists and the community on the significance of research protocols including reporting of findings, which is a central methodological consideration in any research project. The focus is on methodology since it affects outcomes of research, in a fundamental way, if it is not followed. The strength and completeness of research methodology is what determines a study's credibility and shortcomings.

Moreover, a deeper reflection on this clash would help to illuminate the need to have a clear research method for every study, staying the course and the importance of correct reporting of findings. A study conducted without following acceptable methods may lead to disappointment for different parties and head-on collision of parties. Besides, the findings would not have the intended impact if methods were not approved. The findings must be correctly communicated and should not misrepresent the truth to the general public. Finally, this essay will help to illuminate the place and importance of 'systematic review and meta-analysis in these kinds of studies which are common in health and development research'.

This is significant because it allows different actors in the research process to see the importance of established procedures starting from the design stage to reporting of findings. It helps to open eyes of researchers to carefully examine all steps in the research process in order to accomplish their intended goals. To instructors of research methodology, this case helps to remind them to consider using existing policies in the course of teaching. There are different requirements, for example,

of reporting findings of rare animals, plants, insects, marine resources, contaminated food, medicines, toxic chemicals and material artefacts to mention but a few. In some instances there could be executive orders and requirements that direct and specify when and how the reporting should be done. Such reporting requirements must be known in advance to avoid clashes and miss reporting.

It is important to note the difference between avenues of sharing research results with peer scientists and public reporting. These avenues are not the same and they have different requirements. While researchers need only to publish their work for other scientists to note, critique and or do further studies; reporting to the general public has different politics and requirements. Scientists may correctly interpret the meaning of concepts such as significant cases, adequate number, sporadic cases, outbreak of disease and similar concepts but the general public may not comprehend these concepts in the same way. Researchers need to be aware of this when it comes to sharing results through the two avenues.

Approach

This is a review of a case, as pointed out above, and it is an actual event that happened. It has been reviewed on a step by step basis and reflections are arrived at in relation to the literature, established policies, and procedures. To begin with, the episodes will be re-mounted so as to provide a levelled field for a good understanding and thereafter proceed to review the requirements of reporting reportable diseases. This would allow readers to be able to follow the discussion as well as expose them to policies and regulations governing such reporting. The last part of the article provides some reflections aimed at giving insights into cases of this nature.

Review of the Episode

The Director General of the National Institute of Medical Research (NIMR) on 15 December 2016, spoke to the press on the findings of a research on the Zika virus in Tanzania.[119] In her remarks, she pointed out that NIMR had conducted a research to establish whether Tanzanians had been affected by the virus since the country had an environment similar to countries which were then affected by it. The virus is spread by mosquitoes and Tanzania being a tropical country where mosquitoes are common it was at risk.[120]

According to the Minister's press briefing, studies of this nature are crucial to the country in order to know if the country is safe or not and if not, to take the necessary measures. She went further at length to point

[119] See NIMR Director General's press conference; clip available online http://millardayo.com/zika01/ Accessed 22nd December 2016.

[120] Although it is popularly known that Zika is a vector-borne disease, reports from CDC indicate that Zika is spread via sexual contact through vaginal intercourse, anal sex, oral sex and sharing of sex toys. Prevention methods are similar to those for HIV/AIDS. See: "Basics of Zika virus and sex" https://www.cdc.gov/zika/transmission/sexual-transmission.html Accessed 22 December 2016.

out that it does not help anything to remain silent when there is a disease of that nature in the country. According to the findings, she presented to the public, she indicated that out of 533 people screened 15 per cent (80) were found to have strains of the Zika virus and thus the disease exist in Tanzania. The news about Zika traces in Tanzania was taken up by both the mainstream and social media and spread rapidly. The central question was: Does the disease exist in Tanzania or not? Crucial in this discussion is the fact that the National Institute of Medical Research (NIMR) is a government research agency responsible for conducting all kinds of health related studies in the country and accordingly advise different actors including policy makers and clinicians. Thus a report by the Director General, who is appointed by the President of Tanzania, carries significant weight of trust given the responsibilities of the institute.

The same day, the Director General shared the findings publicly, the minister responsible for health, via the media debriefed the public on the news about the Zika virus and refuted the claim on the presence of the disease in the country and that the public should not be worried. The minister invited the Director General to meet her and discuss the same. After indoor meetings, a press conference was called and it was addressed by the Minister of Health and Social Welfare, Deputy Minister, Chief Medical Officer and NIMR Director General to refute the statement on the presence of the Zika virus in the country.[121] The same night, the President of the United Republic of Tanzania dismissed the Director General and by the following morning, a new director had been named.

In the press conference convened by the minister, it was pointed out that Tanzania does not have any person affected by the virus. It was not mentioned whether the country has any trapping stations to check the spread of the disease, and whether travellers are screened for or not. The findings, which were presented by the then NIMR Director General, were described as diagnostic trials and thus the outcome of an 'early stage study' and were not conclusive.[122] The minister further noted that the release of the early report had not followed the laid down procedure of reporting an outbreak in keeping with established mechanisms.[123] Furthermore, it was

[121] See Minister of Health Live Press Conference, clip available on line http://millardayo.com/nim20/ Accessed 22 December 2016.

[122] Diagnostic trials are studies aimed at evaluating the method of detecting disease and hence cannot be used to generalize an outbreak of a disease in an area. In the 2016 Budget speech by the Ministry of Health, Zika was not even indicated as an area of study. The following diseases were listed for deep studies: Schistosomiasis, stomach worms, HIV, and Ebola. See budget speech, Ministry of Health 2016/17 pages 81/82.

[123] February 1, 2016, the government issued a statement arguing residents to rush to the hospital if they see any symptoms of Zika, which is in the same classification as Dengue, West Nile and Chikungunya fevers and all are found in Tanzania. Doctors were asked to keep a sharp eye on the disease as well and report any outbreak. A sharp deconstruction of this call by the government reveals that the government kept its right to declare an outbreak intact.

pointed out that Zika fever is one of the diseases which fall under the family of internationally 'reportable diseases'. The Director General was given a chance to give her remarks and she noted that a section of media had misquoted her presentation. The family of medics, general population and politicians would have many questions on this issue but that is not of interest in this essay. The chief interest here is the reporting angle of study findings.

Magufuli Sacks NIMRI Boss

… However, in a quick response, Health Minister Ummy Mwalimu on Friday allayed fears over the reported Zika virus detection, saying the World Health Organisation (WHO) was yet to confirm the reports.

She said any outbreak of a disease with serious international concern had to be verified and announced by the global health agency.

WHO Representative in Tanzania Dr Grace Saguti yesterday confirmed that there were no reports about the Zika virus in Tanzania, adding that there was not a single child born with signs of the virus.

"WHO is working closely with the Ministry of Health to monitor outbreak of the disease. We have never received any reports indicating that there are people affected by the Zika virus," Dr Saguti told a news conference in Dar es Salaam.

Ministry of Health Chief Medical Officer Dr Mohamed Kambi, for his part, said the ministry had laid down procedures for getting information on the outbreak of diseases, but hastened to add that there was no information showing outbreak of the Zika virus.

"There is no Zika patient in Tanzania. Let me repeat – there is no Zika patient in Tanzania," stressed Dr Kambi.

...

Source: *The Guardian* 18December 2016.

https://www.ippmedia.com/en/news/magufuli-sacks-nimr-boss Accessed o n October 20th 2018

No detected virus in Tanzania – Minister

Health minister clarifies that the authoritative body on such a sensitive issue, the WHO, was

yet to issue a statement to that effect.

The government yesterday allayed fears over the reported detection of the Zika virus in the country, explaining that the occurrence or absence of the virus was yet to be confirmed by the authorized international health body – the World Health Organization (WHO).

The Zika virus, which was isolated from monkeys in Uganda about 70 years ago, has prompted worldwide concern after it began spreading very fast in the Americas early this year.

Minister for Health, Community Development, Gender, Children and the Elderly Ummy Mwalimu made the clarification during an interview with BBC, saying that any outbreak of international concern had to be verified and announced by the appointed global focal person after serious coordination and consultation with the respective local authorities.

> "No Zika virus has been verified in the country so far. The Zika virus is an international reportable disease of which any discerned condition must be verified by the WHO in collaboration with the office of the Chief Government Medical Officer in the respective country," she said.
> ...

Source: *The Guardian* 17 December 2016.
https://www.ippmedia.com/en/news/no-detected-zika-virus-tanzania-minister Accessed October 20th 2018

Dissemination of findings is a methodological aspect of research and it depends on how the research was done; it may have implications on the outcome of the whole research project. It has to be noted here that the dispute over the findings of the Zika study was not about the technical procedures of the study but rather the reporting of the findings and the uptake of results obtained. While the reporting of the findings has nothing to do with the technical work of research, reporting could damage the good work done by the research team.

Fundamental Question

The critical and fundamental methodological question at this juncture is: Why would the government choose to reject the findings? Asked differently: What are the methodological issues which warrant the government to insist that the findings were not conclusive and hence Zika was not a problem in Tanzania? Looking at this problem from this angle, it suggests that there was a methodological procedure which was not followed, that if it was followed, the findings would have been approved and hence avoid the state-researcher clash. It further suggests that the implied procedure has all what it needs to verify what is claimed in the controversial findings. It is possible to logically make this claim by looking at the responses of the government carefully as they were issues by the ministry responsible for health in Tanzania:[124]

- There is an established methodology of reporting such an outbreak which was not followed;
- The research is a very early stage research and the findings are not conclusive.

There is no mention of the 80 people who were pointed to as carrying the virus; all speakers at the press conference focused on the procedure.[125] Therefore the question that needs analysis is: What is the methodology referred to? In this reflection essay, the attempt is to answer this question.

Doing research in certain disciplines or fields requires one to be familiar with their respective terrains to avoid pitfalls that may be disappointing to all stakeholders. It presupposes that the researcher if fully aware of all expectations held by the public on the work. It is also expected that the researcher would

[124] See footnote number five above.
[125] Ibid.

publish and disseminate the results since not doing so is considered misconduct (Song et al. 2014) which may lead to a clash of parties.

Reportable Diseases Reporting Protocols

It is important to know what the reportable diseases and the protocol that come with reporting such diseases. A reportable disease is a sickness which has a great public health concern and needs very close monitoring by government agencies (Davies 2012; Youde 2015).

Globally, there is a system of reporting outbreaks of diseases whether such a disease reaches an epidemic level or not (Youde 2011; Davies 2012; McInnes and Lee, 2006). This is designed to protect the health of the people globally by controlling its spread in other regions. In the minister's press conference, it was noted that Zika is a reportable disease and thus it has a specific reporting protocol.

The reporting requirements of reportable disease in Tanzania demand that once the disease is diagnosed, the physician should report the findings to the authorities responsible at local and or national level immediately (URT 2009). The reason behind this demand is to monitor the trend of such a disease, to see if it is spreading or disappearing, trace its origin, frequency of outbreak and design ways to combat its spread. Such reporting allows for the tracking and monitor of its geographical spread and number of affected people as well. According to the regulations, the responsibility to report is not with the patient but the service provider and in some situations, anyone who has information about the patient.[126] Furthermore, according to the Public Health Act of Tanzania (2009), it is an offense for one not to fail to report and or obstruct the process of reporting.

Different reportable diseases have different reporting formats which include: what must be reported, criteria of reporting and where specimens have to be submitted and how they should be submitted (Laxminarayan et al. 2008). While there are diseases that have maximum hours within which to be reported after diagnosis; some diseases demand immediate telephone reporting to begin planning the suitable process through which to tackle the disease. Some other diseases require full written reports which may take a few days (Malani and Laxminarayan 2006). The point of reporting is to cause some action to happen and there are variations in pace of different actions. Reported information may be used to control the spread of the disease by taking steps such as water purification, vector control, animal tracking and food poison control. In some instances it may necessitate controlling the movement of people

[126] The law in Tanzania, Public Health Act No. 1 of 2009, Section 9, demands that anyone establishing an outbreak of a notifiable/reportable disease reports findings to the responsible authorities. The minister in consultation with the authorized officer will announce the outbreak.

by putting quarantines and for STDs, reporting helps to track the circle of infected partners.

Reporting may cause public anxiety thus care should be taken in publicising such information. WHO (2005) highlights the importance of getting the right information communicated within the health care system and to the general public in a timely manner. While communicating to the general public is good, it should be done professionally to prevent any harm that might be caused on the social, political and economic fronts. Governments need to have a standard communication plan to fall whether there is an outbreak or not. A communication plan helps to ensure that only the right information is communicated to achieve the intended goals.

Tanzania has its own list of reportable diseases and they are regulated by the Public Health Act No. 1 of 2009. According to this Act, the main person responsible for reporting outbreaks of diseases is the Government Chief Medical Officer (CMO). Prior to this Act, there were several Acts which catered for some of the aspects now covered by the 2009 Act. These were the Internationally Notifiable Diseases (Prevention) Act of 1964, Infections Disease Act and Mosquito Control Act which have been repealed and replaced by the Public Health Act No. 1 of 2009. The relevant guides are found under sections 25-29 of the Act, which defines the diseases – epidemic, endemic or pandemic; which are reportable in Tanzania. Section 25 reads as follows:

> The provision of this part shall apply to plague, cholera, celebralspinal meningitis, malaria, schistosomiasis, tuberculosis, dysentery, typhoid, viral hemorrhagic-fevers and any other disease which the minister may, by notice in the Gazette, declare that disease to be an epidemic, endemic or pandemic disease for the purposes of this Act.

The Act points out who should report the diseases, where to report, who should receive the reports and actions to be taken by the receiver of the reports – the Chief Medical Officer. Individuals conducting research in any area which is covered by the above mentioned Act have to be aware of the official protocol of declaring a disease in any part of the country including submitting the relevant information to the right authority.

Reporting can be made from cases diagnosed in a health facility or can be done from active population screening. The former, which is also called passive reporting, depends very much on the number of people who visit a health facility for treatment and may be a slow way of identifying the existence of a disease. The latter is preferable but expensive as it involves screening a large number of people who are healthy only to find a few who need to be treated. In all such cases, the reporting requirements/protocol remain and have to be observed.

Monitoring of Diseases

Every country has its own institutions, procedures of monitoring and reporting outbreaks of diseases. Even before setting out to do a study on a particular disease, a researcher ought to know all the details of the disease, its family, treatment and known sanctions and protocols. It is good to monitor diseases which are epidemic in nature so that controls can be put in place and reduce mortality. Monitoring is good for early identification of outbreaks of both known and new diseases in a country (Youde 2015). It is good to recognize trends in drug performance and drug resistant cases. Monitoring does promote not only awareness on what is currently happening but it is also helps to advance research in areas where such problems are reported.

In this period where globalization has opened up many things and transportation made easy, the spread of diseases from one part of the world to another is easy. Monitoring is thus useful in managing outbreaks and spread of disease to different regions. The reasons for monitoring have implications on reporting because once an outbreak is reported, it invokes action hence, false reporting may lead to a waste of resources. Research methodologists should be careful with the design of their studies to avoid raising false alarms.

There are other reportable diseases under WHO's monitoring globally. However, the list differs from country to country depending on the kind of threats that exist in a given region and what diseases have been eradicated there. These include: yellow fever, plague, cholera, meningococcal disease, dengue fever and dengue haemorrhagic fever, influenza, African trypanosomiasis, HIV/AIDS, leishmaniasis and leishmania/HIV co-infection. In some countries such as the United States, the list is much longer with different reporting requirements. Countries which have eradicated certain diseases, usually would add those to their lists of reportable disease. This is done strategically as a way of monitoring resurfacing of eradicated diseases. Thus there is reporting to monitor outbreaks and reporting to monitor resurfacing of certain diseases.

Politics of Reporting Reportable Diseases

Politics tend to shape government responses in almost everything and the health sector is not immune to this reality (Parker and Allen 2014). There is politics around the reporting of reportable diseases and it is not always to the best interest of the government to report outbreaks of such diseases (Hooker and Harris 2009; Youde 2011). Governments may use different delaying tactics to reveal an outbreak of an epidemic to the public. In Asia, the outbreak of avian flu was called avian cholera, because reporting directly the disease comes with sanctions particularly focused on the poultry industry. Such reporting could lead to not only

import bans of all poultry products, eggs, live and processed chicken, but also the movement of people to and from such countries.

The move to hide outbreaks is motivated by economic interests where a country considers the value of business interests that are at stake if an outbreak reported. Loss of export business, tourism, sporting events, and restricted travels abroad for fear of spreading such diseases to other countries push countries to hide. Additionally, countries are not prepared to deal with outbreaks of diseases it costs them a lot to step up and put in place all the measures needed to fight the disease as required by the international community. Ideally reporting is internationally good as it helps to confront the problem and save lives by maintaining a global health order. Countries, all over the world, have the duty to report information which is over and above their own national interest (Davies 2012, Fidler 2015). Diseases know no borders and within a short period, an outbreak of an epidemic in populous country such as China or Nigeria, for example, if not controlled, can lead to a global health crisis. Below are some of the global outbreaks that have caused concerns. This list is small and it is meant to be indicative as there are many outbreaks that have caused global threats and panic due to scale and speed of the virus spread.

Global Outbreaks of Pandemics

H1N1 flu (1918)
Deaths between 50-100 millions

Marburg (1967, 1998-2000, 2004-2005)
Deaths 7; 168; 227

Nipah (1999)
Deaths: 100

Sars (2003)
Deaths: 774

Middle East Respiratory Syndrome – Coronavirus (MERS-Cov) (2012)

Ebola (2014)
Deaths: 11,000+

Zika (2015-2016)
Deaths: 20

Source: Aisha Majid, 2018. USAID 2016; De Groot, R.J. et al. 2013

A disease may exist in a country but its presence may not constitute an outbreak since for that to be declared, the number of cases reported must reach the critical minimum threshold set by a given government.[127] For an outbreak to be declared, there must be a threat to the general public emanating from its spread – more cases happening than would be expected in a defined period (AGDH

[127] A case is defined as an affected individual person from the general population and when cases are above the normal expected pattern they constitute an outbreak.

2010). In a situation where it is difficult to declare an outbreak, more information must be collected and organized in time, area, and number of cases to help determine if there is an outbreak or not (trend analysis). At times, governments may change the minimum threshold, by lowering or raising it, depending on circumstances. An outbreak is declared to not only increase effort to control but also alert the general public to be aware and take appropriate measures.[128] Outbreaks may come with additional measures such as travel bans, isolations and quarantines, which may not necessarily be of interest to the government and some other quarters which at times panic with such news (Gulland 2018).

Thus, reporting of an outbreak has a publicity which may drastically and promptly affect trade, tourism, public confidence in agricultural and animal products from the country (Malani and Laxminarayan 2006; Rich 2004; Youde 2011). An outbreak of Rift Valley Fever (RVF), for example, which affects both animal and human beings (Muchim 2018) may lead to not only drastic decline of meat and milk products business, but also it erodes the volume of visitors, discourage public gatherings and social events due to the fact that the disease is spread by mosques and contacts with infected livestock products. The same is the case with foot and mouth disease (FMD) which affects animals (cows), lowering milk yield and growth rate of pigs (FAO 2001). Seen from this perspective, misreporting or unverified information can harm businesses in a country.

Prompt reporting, within the civil service, has been found to be delayed and or even concealed because officials have interest to defend their positions. Reports may reveal that responsible officers did not take measures to prevent an outbreak in a timely manner and hence face sanctions. Controlling information may also be used as a technique of minimizing public fear and panic, as well as, image management and keeping trust of the people in the government (Dew 999; Youde 2011). As it is known, diseases and in particular infectious diseases are security issues with many dimensions to the state and global community (Hooker and Harris 2009; Curley and Herington 2011) and hence there are hidden and unhidden interests to not declare outbreaks without taking precautions.

The reluctance to reporting comes with the fact that by reporting promptly, it may lead to an economic crisis and decline of trust in the public health sector and even isolation of the country (Laxminarayan et al. 2008). An outbreak of disease may call for stringent measures to be taken with regard to the movement of people, produce and businesses and all these might cause a crisis in an economy (McNeil and O'Connor 2009). Once declared, an outbreak implies

[128] An outbreak is declared so as to increase public health response. This includes mobilization of human resources, and the required supplies to contain the situation. Every disease has its worn key indicators of an outbreak.

that emergency measures must be taken to control the disease such as isolation of a regions or the country as whole; and screening of people. A good example of this situation is the 2018 reporting of Ebola disease in the Democratic Republic of Congo (DRC) and its consequences in Tanzania. Tanzania and Congo has close interaction, especial people living around Lake Tanganyika. As a result of the Ebola outbreak in DRC, Tanzania took all the measures to monitor movements of people across the border, strengthened health services in Kigoma by sending more supplies, adequate health sector staff and consolidated border patrols. Concealing may be a tactic to avoid some of these consequences.

Concealing outbreaks is not science but rather politics of national interest. While it is in the interest of governments and some businesses to monitor and report certain disease outbreaks, from the science point of view, concealing an outbreak is not a good idea and does not benefit anybody in the long run. Diseases are reported in order to develop a strategy to control, if not to fight them, reduce the costs of treating a large number of patients in future, save human and other resources which would be wasted if such diseases were allowed to spread. Researchers and scientists must strive to do all that they can to make sure that an outbreak that has reporting protocols is reported in a timely manner to honour the purpose of conducting researches.

As a member of the international community, Tanzania has the duty to report and contribute to the global healthy security because infectious diseases have no boundaries (McInnes and Lee 2006). What was required in the case of Zika, was to confirm if the virus was in the country or not by conducting tracer studies and further studies in the areas of the primary study. Although the country had not confirmed the controversial findings, the international community was in suspense as to whether the virus was in the country or not since there were no clinically approved results that had followed the established protocols.

Conducting Health Studies

Conducting public health, clinical and pharmacological studies is different from conducting humanities, social science and or business studies as each area has its own established rules. Researchers conducting studies in their areas of specialisation need to be conversant with the applicable research protocols, traditions and procedures of disseminating findings. Issues are examined in a number of studies at times using different study approach or designs and later the results are reviewed to establish a consensus in supporting or rejecting a particular position (Rudnicka et al. 2012). Failure to observe the established protocols may lead to methodological problems and rejection of findings.

Two of the cornerstone tools of issuing research findings are meta-analyses and systematic reviews. The two techniques of reaching a decision have their origin on the thesis that it

is not one or two cases that can be a basis of a decision but there must be a number of cases to help map out a trend and make a decision (Zhang et al. 2015). They are used by clinicians, decision makers and patients. Systematic reviews provide information on benefits or dangers of an intervention and if such should continue or not. Currently systematic review forms the basic pillar of decision-making in clinical and heath studies in general (Mullen et al. 2006).

Meta-analyses and Systematic Reviews

All scientific studies are not created equal; this implies that there are some inconsistencies even in studies on a common area such as medical and public health studies in general. To reach a common conclusion, there is a need to manage multiple studies together. Methodologists have developed meta-analysis, a statistical procedure of analysing findings of several studies in order to reach a decision (Rubin and Babbie 2001). Decisions in the medical field need to be well informed by high quality evidence which is not readily available. Meta-analysis present weighted and pooled average results which can be used to inform decisions (Goodwin and Geddes 2004). This is applied when there are many studies on a particular problem with findings providing a wide range of inconsistencies.

Different case studies yield different results due to sample size, study design, case selection, case management and thus inconsistencies in findings; meta-analysis is used to scrutinize all cases to reach a common conclusion. This kind of analysis requires adequate study cases which will form the basis for analysis. Meta-analysis is thus applied to come up with a definitive conclusion from a large number of cases with various inconsistencies. In other words, a single study cannot adequately give a definitive answer.

Several benefits of meta-analysis include: showing relationships of different studies and examining the effects of intervention programs due to comparisons and analyses of outcomes (Brannon et al. 2014). Meta-analysis involves several studies and hence the aggregate sample size of the unit of study is fairly big. Studies are conducted in different parts of a country and differing times of the year and as such the findings used in reaching a final decision are varied. These considerations are fundamental in determining a definitive position. The contested study under discussion would thus have benefited a lot if it were part of a series of similar studies and the conclusion reached through a meta-analysis.

There are a number of criticisms that are advanced on meta-analysis as well, such as putting together studies that are weak and have methodological limitations together with strong ones which may not be a good approach. Further, some studies are limited by or have advantages emanating from

their design, quality of the team of researchers, sample size, and even study area. Despite these limitations, meta-analyses remain an important technique of decision-making with a large number of case studies.

Like meta-analysis, systematic reviews are conducted over a large number of studies to be able to reach a definitive conclusion. Systematic reviews are rigorous, conducted on both quantitative and qualitative studies (Davies and Crombie 2009; Mullen and Ramirez 2006). The review begins by analysing the foundation of each individual study, how it was developed, conducted and evidence documented before it is considered for inclusion in the review. It is a rigorous structured process designed to evaluate compare and synthesize evidence (Brannon et al. 2014). For a case to be included, it must be developed properly and one that followed established procedures. Mullen and Ramirez (2006) argue that when it is well done, systematic review has the potential of transforming primary studies and hence research in general.

Systematic reviews are required for clinical and cost effectiveness of interventions to address a specific policy question (Sargeant and O'Connor 2014). In the cases of drug performance, for instance, when the majority of studies indicate that the drug is failing, it is withdrawn following evidence from systematic reviews. Even when there are areas where the drug is still perceived to be good, if it is systematically noted to be failing, it will be withdrawn. To reach a conclusion, a careful transparent systematic review has to indicate a general pattern which can be used to guide decision-making (Sullivan et al. 2014). Goodwin and Geddes (2004) point out that systematic reviews are good because they encourage formulation of good primary studies hence contribute to the making of good decisions.

Systematic reviews require adequate case studies that can be used to observe a trend. It is not a single study that would determine whether a drug is no longer good and should be taken out of the circulation or not. There must be "enough studies" to lead to a decision to withdraw a drug. Thus, the established procedure of withdrawing a drug must be followed methodically in making such a decision. Similarly, the procedure for the introduction of a new drug must be followed too in accordance with established procedures. Similarly, to declare that there is a new disease in a country or some region of the country, a procedure of declaring so must be followed. Authorities must satisfy themselves that verifications have been made after careful analysis through systematic reviews and meta-analysis.

Although systematic reviews are considered to be powerful and a useful way of reaching valid conclusions, it does not mean all is good. Davies and Crombie (2009) note that some of the reviews are badly done, case selection may be problematic and hence the outcome is bad. Recommendations

that are made might not be reflective of the actual situation due to weakness in cases section and a weak review process. However, as Helfer et al. (2015) point out, both systematic review and meta-analysis represent a high level of evidence and are of great importance in health sciences. It is near impossible to make a major decision if these two approaches have not been adhered to.

Discovery and Spread of Zika Viruses

According to WHO (2016), the Zika virus was found in Tanzania way back in 1948, while it was first reported in monkeys found in Uganda's Zika Forest in 1947 and hence the name Zika. However, the first human cases in the two countries were detected in 1952. From 1963-1983, the virus spread to other parts of the world transmitted by the Andes mosquitoes. During this period, Zika cases were reported as sporadic/irregular single cases rather than an epidemic outbreak. Between 2007-2017 major outbreaks were reported in pacific islands – Yap Island, French Polynesia, Easter Islands, Cook Island and New Caledonia (CDC 2017; WHO 2016)). In 2015, Brazil reported presence of a disease characterized with a skin rash that had affected 7,000 people. The disease was later confirmed to be Zika in 2016, after scientific reviews, which associated the disease with a neurological disorder and was hence declared a global public health concern.

The US based Centres for Disease Control – CDC pointed out in its travel advisory to Tanzania that the Zika virus is a risk in Tanzania and travellers should take appropriate measures to protect themselves from mosquito bites and sex with new partners. It further advised pregnant women not to travel to Tanzania (CDC 2017). This put the Tanzania under the category of countries with the virus.

Worth noting here is that the disease is present in Africa but in a sporadic fashion – few cases.

It has never reached outbreak levels. The news that Tanzania has traces of Zika, is not very new and what was required was to know if it had reached outbreak levels or remained sporadic or irregular as pointed out by WHO (2016). This thus is the question that needed to be addressed by different parties in Tanzania.

The Raison d'etre for the Clash on the Zika Virus Report in Tanzania

The report on the presence of the Zika virus in Tanzania could not be accepted by the government because from the state's perspective, procedures of publicly reporting such findings were not followed. Public health, medicine and pharmacology studies are areas which involve human subjects and thus precautions are in place to buffer uncalled existential threats. Systematic reviews should have been carried out as expected and an assessment of the quality of evidence assembled, assessed, before definite conclusions could be made.

From this perspective, it was not the right time to share such findings publicly since there were more stages and procedures to be followed before announcing the results to the public.

Research protocols in this public health sub-area demand that studies conducted should be verified or tested and re-tested several times before they are reported publicly. Primary studies can be shared with other scientists, a process which allows for systematic reviews and meta- analyses which are typically used in such cases. For public reporting, responsible authorities must satisfy themselves that all tests have been made and the conclusions remain the same. The CMO is answerable not only to the government, the employer, but also to the researcher community in the area of clinical and public health as well as international bodies and thus great care and precautions must be taken before making any decision and announcements.

For epidemics, the number of cases must reach an adequate number for such to be declared. Few cases remain to be defined as sporadic and cannot be relied on to declare an outbreak. This point raises question on what was the debate between the opposing sides. Was the minister refuting the presence of Zika virus in Tanzania or the purported outbreak of the diseases? Same question deserves an answer from the NIMR Director. Further questions that deserve answers at some point are whether the Zika findings presented, met the criteria established to declare that there was an outbreak of the disease in the country. Were the findings verified by follow-up studies in the traditions of meta-analysis or systematic review? Were the conclusions a shared product of systematic reviews or meta-analysis? If the findings were channelled through the established protocols, would results change? These are questions, whose answers, the general public is waiting to hear from scientists and state officials.

A Methodological Note

Methodologists need to ponder the above questions deeply in order to takeaway key lessons in doing research and releasing their findings. The purpose of any research is to inform and if this is not achieved, then it is an underachievement on multiple fronts, namely: study objectives, time, resources, and effort to mention some. One of the takeaways in this review is that reporting of findings can be controversial and thus reporting methodology has to be right. Even when study methodologies are right, the reporting should be carefully done according to established procedures. While researchers can communicate with fellow researchers, communicating with the general public has to be done carefully and methodically.

From a methodological perspective, the collision of the state and the NIMR Director provide a rare opportunity to learn about centrality of reporting results. It

challenges researchers to think through their projects from drafting stage all the way to dissemination of the final report.129 The debate between the state and the NIMR Director was not about the "science of the disease" but the "reporting of study findings". Studies that involve reportable diseases have their own protocols of reporting findings which must be adhered to. For results to be admissible, researchers need to involve key stakeholders in different processes and stages of research so as to validate the process, guide them on reporting requirements and hence increase the validity of the findings. This approach must be built-in from the design stage of the study and then be implemented. It is not something that comes last or a mere by the way.

Similarly, health and human behavioural science studies have a centrally established research protocol that must be followed in reporting findings publicly. Key in the protocol is to know who the actors are and their roles and duties when it comes to validation of such findings. They may not be part of the team but they have the authority and mandate to validate information, release and disseminate findings.

From this review and analysis, there are several other takeaway research methodology points, which researchers and students of research methods may gather. First, it is clear that a researcher doing studies in the fields of health and development, clinical, drug development or such similar studies should follow established procedures of conducting health studies, documenting, reporting and dissemination of findings. Second, studies should be done in accordance with established protocols in the area. Third, findings should be submitted to the responsible officer to validate and determine admissibility due to the sensitivity of the study before public reporting. Methodologically, the act of not following established protocols is a weakness which reduces chances of admissibility and acceptability of findings as seen in this case. According to the medical research protocol in Tanzania, the person who is responsible for declaring an outbreak of a disease in the country, is the government Chief Medical Officer (CMO) who does so after re-verifying all the details. It is not the researcher but the CMO, for this to happen, research must be of high quality and its methodology valid.

Researchers need to know the various laws and regulations which guide the sector so as not to contravene them. For example, they must know who has the mandate of declaring an outbreak of a disease or not. A disease could be endemic in a country but has not reached outbreak level.

[129] Thinking through involves logically conceptualizing every step of the project and its potential outcome, evaluating that outcome and done differently where it is necessary to achieve or avoid a particular outcome. Would you doctor the information to get what you want?

Being a researcher does not warrant an individual to break or ignore a law or a procedure. The inability to follow established protocols may lead to unnecessary stress and panic to the people and loss of trust in the state and its machinery.

Research developed as a diagnostic trial, which is aimed at evaluating a method of detecting disease, cannot be used to announce an outbreak of a disease. The design itself does not meet the criteria. If it is established that there are threats, proper methods and studies have to be applied. As earlier pointed out, improper reporting can have social, economic, and international relation consequences which a country is keen to avoid. Such improprieties may push the government to flex its muscles and prohibit such a study from being completed regardless of the investment behind it and the actual findings. The researcher may even be blacklisted and banned from working in the area or doing any further research.

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