

## **Original article**

**Title:** Applying a public health ethics framework to consider scaled-up verbal autopsy and verbal autopsy with immediate disclosure of cause of death in rural Nepal

**Running title:** Ethical issues of Verbal Autopsy in Nepal

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## **Summary**

Verbal Autopsy (VA) presents the opportunity to understand the disease burden in many low-income countries where vital registration systems are underdeveloped and most deaths occur in the community. Advances in technology have led to the development of software that can provide probable cause of death information in real time and research considering the ethical implications of these advances is necessary to inform policy. Our research explores these ethical issues in rural Nepal using a public health ethics framework. We considered the burdens and benefits of VA and giving cause of death information to families of the deceased through qualitative research with VA interviewers, community members, national policy stakeholders, and international academics. Burdens can be experienced differently, and it is important to balance the emotional burden of VA with utilization of the data to inform planning, and increased access to health services. The training, support and supervision of VA interviewers should be prioritized if VA is taken to scale. Initial and ongoing community engagement is recommended in addition to engaging ethical, legal, health and policy personnel in developing protocols and systems. Integrating rigorous research while cautiously moving forward is recommended to ensure systems and responses to concerns are relevant to contexts.

**Key words:** bioethics; epidemiology; qualitative; surveillance; vital registration;

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## **Conflict of Interest**

We declare no conflict of interests

## **Introduction**

The World Health Organisation estimates that around 50% of 56 million deaths worldwide in 2015 were not registered with information on cause (World Health Organisation, 2017). Most of these uncounted deaths occur in low- and middle-income countries, particularly in Africa and Asia, that lack adequate vital registration systems to record deaths and their causes (Mikkelsen et al., 2015). Documenting and analysing the reasons why people die is key to designing responsive public health systems, and measuring progress towards targets such as the Sustainable Development Goals and Universal Health Coverage (AbouZahr et al., 2011, World Health Organisation, 2017). Routine mortality surveillance using verbal autopsy (VA) is becoming an increasingly feasible strategy to collect data on cause of death in communities in low-income countries.

VA is a survey method that gathers information on the signs, symptoms and circumstances of death from interviews with a person or persons familiar with the deceased (usually a family member). These data are then analysed to ascertain cause of death. Until recently, VA data have typically been gathered using pen and paper, and later been reviewed by one or more physicians to identify the most likely cause of death. Advances in technology and analytical methods have offered alternatives to paper based VA with physician review such as electronic data capture, often on a mobile phone, and automated, computer coded cause of death analysis. These advances have been shown to produce results comparable to physician review whilst being more reliable and better suited to routine application in emerging Civil Registration and Vital Statistics (CRVS) systems (de Savigny et al., 2017). Recent integration of digital, mobile direct data capture tools further creates opportunities

to integrate VA into routine health surveillance systems (Bird et al., 2013, de Savigny et al., 2017). In this paper we consider a system which is based on the WHO standard VA questionnaire and uses one of the most widely applied automated interpretation methods: InterVA ([www.interva.net](http://www.interva.net)). The system, known as MIVA (Mobile InterVA), applies the Bayesian InterVA analysis method to gathered VA data to determine the probabilities of a range of possible causes of death on a case-by-case basis. The VA interview data and assigned cause(s) of death can then be transferred from the phone to a remote, user-specified location and the derived probable cause(s) of death can, in principle, also be directly reported back to the VA respondent.

Such developments of the VA process have mainly been considered within a technical and scientific discourse (Brolan et al., 2017). Researchers and programme implementers are excited about the possibilities that mHealth tools, such as MIVA, offers in terms of efficiency and real-time data processing. Yet technology is often only as good as the systems that it is implemented within, and the feasibility and acceptability of its utilisation is often dependent on the engagement of diverse and local perspectives. It is therefore important to consider the ethical, legal and social issues of VA and MIVA when considering its integration into health systems (Gouda et al., 2017). Locally appropriate ethically informed protocols are important before considering scale-up (Gouda et al., 2016, Carrel and Rennie, 2008). In this paper, we consider the utility of a public health ethics framework to explore the implications of using VA at scale in rural Nepal, and the acceptability and utility of giving probable cause of death information to families of the deceased immediately after VA in rural Nepal. This data collection and processing using a

mobile phone, giving probable cause of death information and counselling, is herein referred to as MIVA. While we refer to this specific method in our research, our findings are of relevance to all mobile-based methods of VA data processing and the scale-up of such methods.

### **Public health ethics and VA**

Conventional medical and research ethics guidance gives high priority to individual autonomy, specifying the need for respect for individuals, beneficence (maximising the benefits and minimising risks to participants), and ensuring a fair and equal distribution of risks and benefits (National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979). Public health policy making is challenged in trying to balance need for interventions that produce the most gain for populations, while considering equity and the rights of individuals within populations (Roberts and Reich, 2002). Given this need for balance, public health interventions require adapted ethical frameworks (Gostin and Lazzarini, 1997).

Several ethical frameworks have been developed for public health which aim to articulate the value base and moral aims of public health, and the synergies and tensions between these values, in order to assist policy makers in decision making. There is no consensus on the normative framework for public health ethics, and so performing an ethical analysis of a particular public health intervention, such as MIVA, requires making contestable decisions about which framework to use.

We elected to use Kass's popular and influential framework (Kass, 2001). Kass proposes a public health ethics framework which intends to help public health professionals to recognise moral issues that arise from an intervention and think about ways to deal with them. She suggests that public health practitioners should work through the answers to six questions in order to analyse the ethical implications of proposed interventions or activities:

1. What are the public health goals of the proposed intervention?
2. How effective is the intervention in achieving its stated goals?
3. What are the known or potential burdens of the intervention?
4. Can burdens be minimised, and alternative approaches be used?
5. Is the intervention fairly implemented?
6. How can the benefits and burdens of an intervention be fairly balanced?

Kass proposes that in responding to these questions, practitioners are more likely to implement evidence-based interventions with an explicit awareness of the relationship between the intervention and an ultimate reduction in morbidity and mortality, and also have adequate consideration of burdens, harms and risks, and knowledge of who is likely to experience these. It is important to ensure that reasonable steps have been taken to reduce risks, and ensure that benefits outweigh burdens. Kass' framework also recommends early and on-going engagement of affected communities to help practitioners answer these questions and investigate locally appropriate standards of burdens, harms, benefits, and fairness. We chose this framework because of its methodological clarity, its general public health focus, and because of its practical applicability as demonstrated in other studies (Omar, 2013, Pedersen et al., 2012, Kass, 2005). We use this framework to consider the ethical questions of using VA and MIVA at scale, in a population which has experience of VA. We also consider the utility of the

framework and make recommendations for future research into the ethics of VA at scale and MIVA.

### **VA in Nepal**

Like many low-income countries, vital registration data (data about births and deaths) in Nepal is of very poor quality, and population surveys like the Nepal Demographic and Health Surveys are used to calculate the numbers of births and deaths. Paper forms and physician review have been used to ascertain cause of death in these studies and in research and programme evaluation contexts (USAID 2014). There is interest in improving vital registration systems, and the WHO is working with the Government of Nepal on a pilot of improved vital registration in 15 districts using VA. Progress has been slow, however, not least because of an earthquake in 2015 and political change over recent years. Surveys have used community key informants to locate deaths, and interviewers were either incentivised health workers, or trained field researchers. In 2017, Nepal held its first election in over 10 years, when a new constitution enabled the population to vote for representatives to seven provincial assemblies. The constitution has given some legislative, executive and judiciary roles to these bodies, and while there are fears about lack of local capacity and accountability, there is cautious optimism about the possibilities for increased local engagement in governance. The increased potential to provide health services on the basis of local level data may also motivate and provide the opportunity for local bodies to implement and improve vital registration systems.

MIRA, a Nepalese non-governmental research organisation and the University College London (UCL) Institute for Global Health have conducted collaborative research in Makwanpur over a 15 year period researching the effect of community based interventions on maternal and newborn health (Manandhar et al., 2004, Morrison et al., 2011). VA was integral to this research, and data has been collected on neonatal deaths, infant deaths, child deaths, and deaths of married women between the age of 15 to 49 - including maternal and non-maternal deaths through large-scale surveillance systems (Osrin et al., 2003). At the time of this study, paper forms for data collection had only ever been used with standardised WHO VA tools. We collaborated with the UCL Department of Philosophy to explore the ethical implications of using VA at scale in rural Nepal, and the acceptability and utility of MIVA.

## **Methods**

### **Setting**

Nepal lies between India and Tibet, and is a poor country with the lowest Human Development Index score in the region, apart from Afghanistan. Caste, ethnic and rural/urban inequalities are pervasive. Advantaged, high caste Brahmins have a relative poverty rate of 10.3% compared to a poverty rate of 43.6% in disadvantaged hill *dalit* untouchable castes, and 32.8% for disadvantaged plains *dalit* untouchable castes (UNDP and Government of Nepal, 2014).

Our study was conducted in rural areas of Makwanpur District in the central hills of Nepal, south of Kathmandu. Makwanpur has a population of around 420,500, who are mainly engaged in subsistence farming. Makwanpur has a mid-range Human Development Index

of 0.479 (UNDP and Government of Nepal, 2014, Government of Nepal, 2012). Literacy is improving but there is still a gap between male (75.41%) and female literacy (60.59%) (Central Bureau of Statistics, 2012). Mobile phone coverage is good in Nepal, and the 2011 census shows that 67% (57,427) of households in Makwanpur have a mobile phone (Central Bureau of Statistics, 2012). The dominant ethnic group is the Tibeto-Burman Buddhist Tamangs, followed by the Hindu Brahmin/Chhettri ethnicity. Tamangs and Brahmin/Chhetris traditionally cremate bodies on the day of death, and hold memorial feasts in the dry season when other obligations are less pressing. For Tamangs, at the feast, a lama performs ceremonies to separate the soul from the body, cleanse it of demerit or pollution, and ensure fortunate rebirth (Holmberg, 1989). For Brahmin/Chhetris there is usually a period following the death when close family members of the deceased must maintain ritual purity (characterised by following strict bathing rituals, wearing specific clothing, refraining from eating certain foods and touching other people) to enable fortunate rebirth of the deceased (Holmberg, 1984).

### **Rationale for the qualitative approach**

A systematic review by Davies et al. found that empirical ethics methodologies tend to fall on a continuum between the dialogical and consultative (Davies et al., 2015). Consultative approaches consult with participants to obtain their views and experiences, but participants do not take part in the process of forming a normative conclusion. Dialogical approaches are based on a dialogue between stakeholders and they attempt to reach a shared understanding with researcher and participants together. Our research has elements of both approaches.



## Consultative qualitative research

Kass and others (MacDonald, 2015) see consultative research as being an important part of the decision-making process about public health interventions, and qualitative methodologies allow this approach to be completed in a rigorous way. Qualitative research is committed to seeing the topic of investigation from the point of view of the actor, in their context (Bryman, 1984). It allows for an exploration of the meaning that people attribute to practices and events, a revealing of processes, and an exploration of what matters to whom (Green and Thorogood, 2005, Pope and Mays, 1995). We used this approach in developing an understanding about the burdens and benefits of MIVA and cause of death disclosure, the equity of these burdens and benefits, and to consider the level of acceptability of the burdens among different groups. The qualitative methodology allowed us to purposively sample a diverse range of participants and use open questioning to explore their perspectives (Patton, 2002). We describe the sampling, data collection, and analysis of data from VA interviewers, community members, and Nepali policy stakeholders, before describing our dialogical approach with internationally experienced researchers and academics.

### **Qualitative sampling**

#### *Sampling and data collection with VA interviewers*

First, we conducted one focus group discussion (FGD) with a team of male VA interviewers who have been conducting VAs of neonatal, infant, and women of reproductive age deaths over the past ten years as part of ongoing research in the district. There were only two female interviewers in the team and they were unavailable at the time of the FGD. We explored interviewers experience of conducting VA and issues they might

face in giving cause of death information. We distributed a list of all potential causes of death, and reviewed which causes might be difficult to discuss in communities.

#### *Sampling and data collection methods with community members*

We purposively sampled community members who had experienced the death of a family member between one and five years prior to the interview or discussion. We chose this time period to enable them to recall their feelings immediately after the death. We sampled participants according to the age of their deceased family member because we wanted to explore how this affected their feelings about VA interviews. Age groups were: 50 years old and above; 15-49 years old; 5-14 years old; 1-4 years old; 2-11 months old, 0-28 days old. We sampled equally from remote and less remote areas to compare the views of populations with differential access to services and education. VA interviewers located community members and invited them to participate. Those interested were approached by researchers who discussed the study and took verbal informed consent due to high levels of illiteracy. We had planned to conduct 24 FGDs and four semi-structured interviews (SSI) but it was difficult to find participants that met our inclusion criteria who could conveniently attend an FGD. Therefore, we conducted nine group interviews (GI) (Basch, 1987), 15 SSIs and five FGDs (Table 1). GIs enabled researchers to be more sensitive to grieving participants. Only a few participants had previously participated in a VA.

#### *Data collection and tools*

Data were collected by two trained female qualitative researchers who had been working in Makwanpur for ten years (MM and RS). JM has been living in Nepal for over 10 years

working in Makwanpur with MIRA and speaks Nepalese. MM, RS and JM discussed how to interview bereaved family members in a sensitive way. Topic guides were informed by the Kass framework (Kass, 2001), and were developed iteratively over the process of data collection. JM and JW observed three FGDs and one interview. We asked participants their general feelings about VA, the timing of VA, issues of confidentiality and consent during a VA, and data collection on a mobile phone. We then discussed MIVA, using hypothetical vignettes to explore ethical issues.

### *Vignettes in data collection*

Vignettes are short stories about a hypothetical person or event used to explore sensitive topics (Gourlay et al., 2014, Hughes and Huby, 2004) and have been used in this context before (Heys et al., 2017). These vignettes were specific for each age of death experienced by participants. The first vignette discussed a situation whereby cause of death information might help the family to prevent further illness. The second vignette described a situation whereby MIVA gave a cause of death that was different from the cause given by a health professional. The third vignette presented a suspicious or potentially shameful death, which had been identified as such by VA interviewers. These vignettes were developed in consultation with two physicians and senior researchers at the UCL Institute for Global Health.

Data were collected in a private place convenient to participants, usually their home, with some interruptions from family members and friends. When these interruptions occurred, we paused data collection and resumed when privacy was achieved again. Researchers

conducted data collection together, with one making field notes, and the other conducting the discussion. Group discussions were usually with persons from several different ethnic groups, although 16 of the interactions contained at least one person of Tamang ethnicity and nine contained persons of Brahmin/Chhetri ethnicity.

### *Sampling and data collection with policy stakeholders in Nepal*

We purposively sampled participants who had been involved in discussions about verbal autopsy at a policy level in Nepal, or had experience considering ethical issues in health (herein referred to as policy stakeholders). Participants were suggested by study advisors and invited to participate by a trained qualitative Nepali researcher who was working for MIRA (MB). She conducted semi-structured interviews with four participants using a topic guide to explore the policy and systems implications of doing VA and MIVA at scale. We interviewed one Ministry of Health employee, one consultant who has worked extensively with the Ministry of Health, an employee of an International Non-Governmental Organisation, and an ethical review board member. We obtained written informed consent from these stakeholders.

### **Data management and analysis**

Data were collected in Nepali, digitally recorded and transcribed directly into English by MB. Samples of transcripts were checked for accuracy by a bilingual researcher. We used descriptive content analysis (Green and Thorogood, 2005) to describe participants' key issues of concern. JM read and memo-ed the English data and JW read a sample of the transcripts. JM developed and presented a description of the data and an inductive coding

scheme (Hsieh and Shannon, 2005) to MB, EF and JW. They commented on the coding scheme and discussed the preliminary findings, and then JM coded all the transcripts in Nvivo, version 10. JM explored relationships and patterns in the data (Pope et al., 2000), comparing responses from different types of respondents to explore the effect of gender, remoteness and age of the deceased. She then wrote a descriptive report, including quotes and comparative analysis.

#### Dialogical qualitative research

Dialogical approaches use dialogue between stakeholders to reach a shared understanding about the ethical considerations of interventions. The analysis, and reaching of a conclusion, is undertaken by the researcher and participants together (Davies et al., 2015). We describe our dialogical approach with a group of academics, researchers, and public health professionals with international experience to reach a shared understanding about the ethical issues of VA at scale, and MIVA.

JW, EF and JM compiled a list of academics, researchers, and public health professionals with international experience that were known to them, and invited them to participate in a roundtable discussion of findings. Eight informants from different disciplines of epidemiology, metrics, ethics and philosophy agreed to participate. They were provided with the descriptive report prior to a meeting in London. JW facilitated discussions about our findings and their implications. We then used the notes from this discussion, and the report to distil the key ethical considerations.

The study received ethical approval from the UCL Ethics Committee (4199/001) and the Nepal Health Research Council (114/2013).

## **Results**

We use our data to answer the questions in Kass' framework, presenting emergent burdens, risks and benefits related to VA at scale and the potential to immediately disclose probable cause of death to VA respondents in rural Nepal.

### **Question 1: What are the public health goals of the proposed intervention?**

The purpose and importance of VA at scale in reducing mortality and morbidity was clear to policy stakeholders, and they used examples from maternal and newborn health to illustrate this: "Without targeting specific causes of death, specific medical facilities, and particular community situations, maternal mortality cannot be reduced. We must have cause of death data for this. Other data can't give us that information." (policy SSI)

Community members understood the purpose of VA in a more proximal sense referring to the usefulness of the information in preventing others from dying of the same causes, and raising awareness of prevention and care-seeking strategies. We found that most community participants expected to receive information and advice after a VA, and VA interviewers usually gave general advice to the family, even without knowing the cause of death. Most participants felt that their family and community would benefit from VA at scale and receiving cause of death information, and they were keen for VA information to be used: "Through people like you we can learn about our child's death so that the same thing isn't repeated for the next child" (neonatal death FGD female). Most participants

discussed this benefit spontaneously and not as a result of the vignette which presented some of the benefits of knowing the cause of death. Community respondents also referred to the sense of peace that comes with knowing cause of death, particularly if the death was sudden or unclear: “We will feel relieved. We will feel good because we didn’t know anything about it.” (Adult 50+ years old death GI female).

## **2. How effective is the intervention in achieving its stated goals?**

This question forces implementers and planners to consider the assumptions underlying proposed interventions, and the evidence that leads policy makers to believe that an intervention will achieve stated goals.

*Is human resource capacity adequate and systems support sufficient?*

Although policy stakeholders felt it would be preferential to have health workers conduct VA at scale, problems with retaining skilled health workers in rural areas weakened the feasibility of this strategy. Policy stakeholders were confident that lay workers could conduct VA at scale on the basis of previous studies, but they were concerned that non-medical VA interviewers would not have adequate training or experience to explain the cause of death, deal with follow-up questions from families and give advice after MIVA. The successful implementation of VA at scale depends on the extent that families trust interviewers, and anything that could call this into question would jeopardise the system. Both VA interviewers and policy stakeholders felt that MIVA would increase the possibility for an erosion of trust.

Policy stakeholders also felt it was not appropriate for cause of death to be given by a lay person: “the interviewer is not entitled to declare the exact cause of death to the informant...(in the case of tuberculosis, they should) inform (the family) indirectly that it may be due to tuberculosis and it may be infectious to them, and it’s better for them to go and get a check-up.” (policy SSI).

*Are the systems and budget adequate to act on data generated?*

Policy stakeholders and VA interviewers noted that government systems were not ready to manage and respond to data generated by VA at scale. “If we only receive information, without having a response mechanism, we won’t be successful. We should prepare a team who knows how to respond.” (policy SSI). Although maternal and neonatal death audits were cited as evidence of successful use and response to VA in an institution, they felt there was little evidence of using VA to target interventions at the community level. They also cited the importance of national political commitment and cross-sectoral co-ordination for successful utilisation of VA data: “Inter sectoral co-ordination is the most important thing, because the civil registration domain is in the Local Development Ministry, the Ministry of Health is the technical agency which looks after cause of death, and the Central Bureau of Statistics collects data on behalf of the Nepal Government” (policy SSI). Non-governmental organisations supplement social service delivery in Nepal, and they would also need to be part of the response mechanism. Policy stakeholders also mentioned budgetary issues in responding to VA data at scale, using this as one justification of keeping data analysis at a national aggregate level: “Every individual death in the community affects the whole community but at the country level, community level and district level it



is difficult to know where to prioritize. As a country with limited resources we cannot address all levels.... for that reason, national aggregate information is most important” (policy SSI).

*Are families able and willing to act on the basis of information from MIVA?*

Using MIVA at scale could encourage families to seek care earlier, or seek screening services, but we found that this was dependent on availability of services, trust in those services, and the financial resources to access services, as well as the extent of trust in the person who delivers the information about the need to seek care.

Many community participants told us about the financial barriers to care-seeking in rural areas. One woman told us: “(I had) enough for one day’s treatment, but the next day more medicine was needed. So I told my son he needed to go and find money, and that evening, my daughter-in-law died” (Adult death SSI female). Many felt that a lack of quality health services that were within affordable reach of their homes prevented families from timely care-seeking.

Some participants felt that when information given after disclosure was not well understood, this could prevent care-seeking. Participants felt that this was more likely to happen in less educated, poorer families. Participants felt that these families were also more likely to be fatalistic or believe the death was caused by a curse: “Most poor and uneducated people believe in sorcerers” (Adult death, GI, female 80). Older persons would be less likely to trust a MIVA diagnosis which would affect care-seeking: “Those people who are

over 50 years old do not believe in any scientific methods. They believe in their old system.” (Adult FGD male 802).

### **3. What are the known or potential burdens of the intervention?**

#### *Emotional burden of VA at scale*

Talking about the cause of death was upsetting to family members, but was commonplace: “When someone in our family dies, everyone from the village gathers at our house to discuss their death” (Adult death, SSI, female 806). Generally, participants felt obliged to participate in a VA interview: “I would have to console myself. We have to tell them what they asked despite feeling sad” (5-14 year old child death, GI female 700). This compulsion could be the result of prolonged surveillance activities and awareness of community consent to participate in surveillance, or a sense of duty to the deceased. Compulsion to give a VA interview is important to consider, particularly against propositions that consent procedures may protect against emotional burden.

Some participants felt that they would be more coherent after the period of mourning, when the immediate pain of the death had lessened: “after 13 days will be a good time (to do a VA) because before then we can’t talk properly and can’t give proper information” (Adult death, FGD, female 801). Mourning customs varied by ethnicity and religion and for some it was forbidden to talk to those outside the family until after the mourning period. If VA was implemented at scale, it would be important to establish local standards for the timing of VA.

Data suggest that the emotional burden of VA might be relatively low in cases where an older person or a baby died. Participants who had experience of those ages of deaths suggested completing a VA a few days after the death and VA interviewers corroborated saying that it was easier to conduct a VA after the death of a neonate or young infant, as opposed to a child or young person who the family had become attached to: “If a child is 2-3 months old then they tend to forget about them easily... when a child of 3-4 years old dies then the family will feel very sad. At that time, they will remember about the child and when we ask one thing after another, they get emotional. They can’t give all the information and they will start to cry.” (VA interviewers FGD). They also found it difficult to interview people who had experienced multiple deaths. A VA interviewer told us: “Once I had a scenario that a woman had experienced three babies dying. I went once and she gave me information, then after one year I went again and she gave information, and then again I went to her and she told me that she was unhappy giving information again and again. It’s very difficult to interview people who have suffered many times” (VA interviewers, FGD).

### *Guilt and regret*

Many participants felt responsible for the death of their relative. They felt guilty that they had not known what to do, or they had not done everything they could, or they had not been able to find them appropriate care. VA interviewers told us that this resulted in either an insistence that the interviewer record and confirm that they had done everything they could, or a reluctance to be interviewed: “If (the death occurred because) of their mistake and carelessness then a person will hide, feel ashamed and hesitate to give us information. But if their child dies of other things then they won’t hesitate, they will give every piece of

information” (VA interviewers, FGD). For example: “In one place there was a baby whose umbilical cord was not tied after birth, and so it was bleeding. I had to work hard to find out the reasons why the baby died. I think they thought it was their mistake, so they were trying to hide as much information as possible.” (VA interviewers, FGD).

When we discussed the implications of MIVA, all types of community participants were upset that it was not possible to complete an interview before the death, and be given information that might prevent the death: “We would feel anxious (during a VA) because if the interviewer had given us that information before he died, then we could have saved him” (1-4 year old child death GI Male). While many participants felt that information after a VA would help prevent future deaths, many also felt that being given information about cause of death was not useful because it was “too late” and they were unable to do anything with the information. One woman told us: “the cause of death given by the interviewer is useless because the person is already dead” (5-14 year old child death GI female).

### *Risk to family honour*

Families were unwilling to give information if they felt they were to blame, the death was suspicious, or it was culturally shameful. Death from leprosy, suicide, abortion or HIV/AIDS were considered shameful in this context. Over half of our participants from all sampled groups, VA interviewers and policy stakeholders felt that people would hide information to avoid punishment, or to protect the reputation and social standing of their family. Women from a group interview in a less remote area told us: “(a family) will feel that their social prestige has been lost, they will be embarrassed. Prestige is more important

than money” (5-14 year old child death, GI female 700). Also, if the respondent feared the reaction of other family members, they would be unlikely to give information. Women may suffer this risk more than men in this context because of patriarchal norms and their caring role. A woman from a remote area told us: “I don’t think (a wife) would reveal the truth (if the death was suspicious)...her husband might throw her out of the house.” (Neonatal death SSI female 904). Community respondents were concerned that an appropriate, trusted person be interviewed about the death, or receive cause of death information, in order to control the flow of information and maintain family honour.

This reluctance to give information to protect family honour indicates a perceived lack of confidentiality in the VA process. In practice, confidentiality can be difficult to maintain, as often, many people participate or gather around when a VA interview happens. Although interviewers had been trained to maintain confidentiality and were only meant to interview a main caregiver at the time of death, they told us that it was sometimes useful to talk to several people in building a coherent narrative of the death, or to protect a distraught relative: “(if a key informant) refuses to give information we have no other option than to take information from another person” (policy SSI). Interviewers, and all but one policy stakeholder agreed that it was acceptable to interview several people about the death, but cause of death information should only be given within a confidential context. As participants were not always confident that the information they gave or received would be confidential, the trustworthiness of the interviewer was very important in enabling the VA to take place. We found a broad acceptance of a lack of confidentiality if families were convinced that their information would be handled honestly and with good intention. An

important part of this was locating interviewers from within the community, and establishing trustworthiness through informal reciprocal community networks.

### *Risk of confusion*

We discussed two particular instances where giving cause of death information could introduce confusion: MIVA could reveal multiple probable causes of death; and it could reveal a different diagnosis than a health worker had given. Generally, participants appreciated the sense of peace and clarity in learning about the cause of death through MIVA, but felt that if it introduced confusion this would be upsetting.

Community participants found it difficult to understand that MIVA could present more than one probable cause of death. Confusion with more than one cause of death was particularly an issue for those who had experienced adult deaths and deaths of older persons. They would either presume that multiple illnesses caused the death, or they would not trust MIVA: “if it tells us three reasons then we will think that this technology is fraudulent. People will stop believing in it” (Adult death FGD male 802). Although some VA interviewers felt that families would understand the concept of ‘probable cause’ of death this if it was clearly explained before the interview, others felt that lack of clarity would erode community trust: “if we cannot provide them with the true cause, then it would be better not to give them cause of death... if other reasons come then people will start to argue about that” (VA interviewers FGD).

Community participants said they would be confused if MIVA did not corroborate a doctor's diagnosis: "If the hospital and the technology say different things then people will be in confusion, they will feel stressed" (Adult GI male 802). In the event of a discrepancy between a doctor and MIVA diagnosis, more participants were ready to believe the MIVA diagnosis. This was either because the diagnosis was based on the information that they gave, or because generally, technology was considered more reliable: "in the generation of computers I think the doctor might have made the mistake." (Adult death FGD female 801). If a doctor had disappointed a family in the past, or if they were perceived as not being well trained, then families were more likely to believe information from MIVA: "Doctors here are not as well trained as in city areas, so they may not know the real disease and give the medicine of another disease. Sometimes people can lose their life if a mistake like this happens." (5-14 year old child SSI female 702). Except for cases of neonatal deaths, some male and female participants predicted that they would feel angry with discrepancies between the doctor and MIVA diagnosis: "I would be angry with that doctor. If they had treated her well then they would have found the disease" (1-4 year old child death SSI female 602).

Policy stakeholders were also uncomfortable with giving cause of death information that was based on probable cause, as opposed to diagnostic tests or physician review. One said: "It is a big question about how to give cause of death in the community. We need a system to trace the medical reports and only then we can tell the cause of death, but it still it might not be appropriate 100% of the time." (policy SSI).

### *Risks to the interviewer*

Policy stakeholders were concerned about the mental health risks to VA interviewers when considering VA at scale and MIVA: “There might be negative impact on the interviewer’s mind because he has to handle numerous cases of death...I have heard many interviewers have gone into depression because they handled some sensitive cases.” (policy SSI), but VA interviewers were more concerned with the risks of eroded trust. Interviewers were fearful that a lack of clarity around cause of death – for example by giving more than one potential cause of death during MIVA– could reduce community trust, making them vulnerable to criticism, humiliation, and unable to work. Building and maintaining trust was fundamental to protecting interviewers from harm.

Interviewers said they would feel most at risk when delivering cause of death information during MIVA in the case of a suspicious or culturally shameful cause of death. Interviewers would be upset, and families would not believe them, which would ruin their relationship. There was also a fear that families “might misunderstand that (interviewers) were trying to prove that family members acted carelessly” (policy SSI). VA interviewers also worried for their own safety in controversial deaths: “Immediately after we tell them the information then an explosion would happen...if someone dies of AIDS then we would not have the courage to tell the family that they died because of AIDS” (VA interviewers, FGD). A few participants confirmed that if MIVA revealed a suspicious or culturally shameful cause of death, they would find this difficult to believe: “I would not believe that because (death by poisoning) can’t happen to a child.” (1-11 month old child death SSI male 501). The unpredictability of the cause of death and the family response was enough



to convince policy stakeholders that information should only be given at an aggregate level, and not at an individual level.

#### **4. Can burdens be minimised, and alternative approaches be used?**

##### *Appropriate recruitment and support of interviewers*

Policy stakeholders suggested minimising harm to interviewers through appropriate training and support, and all respondents felt that having sensitive, trustworthy interviewers, who were from the local area and a part of the community would lessen the risks to community members and interviewers: “A local interviewer would know the local language, the tricks to deal with locals, and have the capability to develop intimacy. Although some problems of bias may arise, we should control this, and I think comparatively, a local person is better for the job.” (policy SSI). Although it was acknowledged that disclosure of shameful information could be more difficult between locals, most participants felt that this could be overcome through building rapport, establishing social integrity through community rootedness and demonstrating trustworthy behaviour. Policy stakeholders suggested utilising a local person to conduct the VA interview and a medically trained person to give information and counsel families, preventing the resultant risks of inaccurate information being provided. Systematised emphasis in training and strict protocols for VA interviewers may help to enforce and clarify the importance of confidentiality, therefore minimising risks to family honour if VA were taken to scale.

### *Aggregate level data dissemination*

There was consensus among policy stakeholders that the easiest way to minimise some of the risks of MIVA, was to give information at an aggregate, not an individual level. Although they felt it was important to refer family members in the case of communicable diseases, there was concern at making one protocol for all situations, “It depends how the community people take it. It’s a difficult situation and it is very unpredictable in each situation. Different situations arise in different conditions and in different communities and between different community members so it’s totally unpredictable.” (policy SSI). There was acknowledgement among policy stakeholders that the risks were too great to leave it to the discretion of the interviewer as to whether to reveal cause of death or not. Therefore, they preferred feedback of information at an aggregate level, targeting health promotion activities as a way of ensuring benefits to communities. “We can give feedback in the form of leaflets or posters with simple language which can be understood by everyone in the community...In this way we can provide them benefits or advantages in return for the information provided by them.” (policy SSI).

### **5. Is the intervention fairly implemented?**

Fair implementation refers to the principles of distributive and social justice and this question forces examination of whether inequalities are maintained or created through the activity. As a result of budgetary constraints, policy stakeholders felt that it was unrealistic to think that VA could be carried out at scale for all community-based deaths, and referred to this as a reason for targeting maternal and neonatal deaths in previous work. Fair

implementation could also mean targeting VA in areas with known high mortality, but this would require vital registration systems to be functional. They did not mention random sampling for VA, which may help ensure fair implementation. Scaled-up training and supervision of VA interviewers was also cited as important in ensuring fair implementation of VA and MIVA. It is important to ensure that interviewer bias would not prevent less-educated or poorer families receiving less information and counselling, based on perceptions that they would be less likely to act on this information.

## **6. How can the benefits and burdens of an intervention be fairly balanced?**

If we consider VA at scale without giving cause of death information, some burdens and benefits would remain. Remaining risks of the emotional burden of VA, and a slightly lessened risk to family honour, and remaining benefits of feeling unburdened, receiving advice (if we presume that all VA interviewers provide some information like the ones in our study), and better informed public health planning and implementation. The addition of MIVA appears to introduce an imbalance of burdens compared with benefits. Individually, policy stakeholders felt uneasy taking a ‘risky’ decision of giving cause of death information at scale, and suggested that a national advisory committee should lead on determining the modality of VA. The roundtable discussion participants also felt that although public deliberation was of importance on deciding VA modality, there was a need to ensure that the most marginalised were protected when decisions were made.

## **Discussion**

Digital data capture and automated computer coding of VA data, such as that offered by MIVA, are likely to play a key role in meeting WHO and World Bank targets that 50% of

deaths in the community will have probable cause of death determined by 2030 (World Bank and WHO, 2014). It is important that research and development of technologies to support better planning are accompanied by research to consider the ethical implications of implementing them. Kass' public health ethics framework allowed us to consider the burdens, risks and benefits of VA and MIVA in rural Nepal as discussed by community, policy and ethics stakeholders (Kass, 2001). The framework enables consideration of the ethics of public health interventions, which do not fit within traditional medical ethics guidance. We discuss how our findings fit within the existing literature, and make recommendations for future research to further develop knowledge about the acceptability of the balance of burdens and benefits of VA at scale and MIVA.

#### The Kass framework

There are many frameworks available to consider the public health ethics of interventions, but they can lack in justification, and it can be unclear how they should be used (Grill and Dawson, 2017). One of the reasons that we privileged the Kass framework over others (for example (Tannahill, 2008, Baylis et al., 2008)) was because of its methodological clarity. We found that the stepped approach and question driven method was easy to apply and allowed consideration of key issues.

The Kass framework acknowledges that ethical principles of health care are insufficient for public health, which requires a different framework of ethics that does not prioritise individual autonomy. Kass's framework suggests that tensions between public health interests and individual autonomy should be addressed through a system of fair process -

procedural justice and engagement in the democratic process (MacDonald, 2015). Our study found that socio-cultural and contextual elements affected potential burdens and benefits of this intervention, and Kass's method allowed for consideration of context, and outlined the importance of public engagement in decision-making about an intervention. A strength of Kass's approach, is that it enables local norms to be given a central place in decision-making, but ensures protection for minority or disadvantaged groups.

Kass states that an examination of the effectiveness of an intervention should be based on sound data rather than informed speculation (question two of the framework). Given the fact that MIVA and VA at scale have not been implemented, we were unable to examine the evidence for their effectiveness. Despite this, we used our data to consider the assumptions and pre-conditions necessary to implement VA at scale and MIVA which was useful. Participants referred to their experience and knowledge of VA to inform their consideration of scaled up VA and MIVA.

We feel that in the absence of 'sound data', decisions about public health interventions can be made on the basis of rigorous pilots (Turcotte-Tremblay and Ridde, 2016). Strict monitoring and evaluation of interventions coupled with ongoing dialogue with stakeholders could develop evidence to inform decisions. For example, while large-scale surveillance sites should not be considered scaled-up VA, research questions about the ethical issues of VA could be explored in these contexts. A rigorous monitoring and evaluation process with timely modification or stopping of an intervention could avoid unintended harm while building evidence about an intervention.

Efficiency has been prioritised in other frameworks, and the lack of explicit reference to the cost-effectiveness ratio in Kass's framework may mean that this is not considered adequately. However we did not consider this to be a significant limitation of the framework for our purposes, as the main ethical questions we were exploring arose from the information-sharing possibilities of MIVA rather than the costs of scale-up. An estimation of cost-effectiveness would also require pre-existing data to be evaluated which would not have been possible in regards to MIVA.

The Kass framework has been criticised for not stating a defined ethical foundation (Marckmann et al., 2015), which makes it too open to interpretation. This can be harmful if decision-making is framed in an inappropriate set of values (Dawson, 2009). A new framework of interest addresses these concerns by proposing a value-based, pluralist framework which uses 'common-sense' discursive decision-making through a five-step process. This process identifies alternatives to the intervention, ranks the alternatives, before evaluating their merit and submitting the process and results to an oversight organisation (Grill and Dawson, 2017). Instead of prioritizing a set of values, Grill and Dawson propose that all values are eligible for consideration in public health decision making. Ethics is a reflective task that requires participants to be explicit about what they believe, why, what they value and on what grounds (Upshur, 2002). Grill and Dawson propose that through the stepwise process, values can be made explicit through judging alternatives against all values. This is an interesting alternative to value-based and value-free approaches which merits empirical study.

### **Differentials in burdens and benefits**

We have demonstrated how benefits and burdens may differ for different types of people. Women may be particularly susceptible to blame due to the patriarchal context of Nepal, affecting information disclosure and creating inequalities in the burdens experienced. Those experiencing infant or neonatal deaths may be less upset by VA as they may form less emotional attachment in this context (Winch et al., 2005), whereas adult deaths may be more distressing. Poorer families may experience more distress during a VA, because they are more likely to be constrained by lack of resources and poor access to services which could leave them feeling more guilt than those who feel like they did everything they could. Our study also shows that when a VA is perceived to be less useful for participants, for example in accidental deaths, the burdens for participants may outweigh the benefits. Yet from an epidemiological perspective, understanding the prevalence of accidental deaths is important. Community engagement and consultation with key informants from marginalised groups is recommended in considering where differentials in burdens might lie before commencing VA at scale. Where VA is already integrated into surveillance systems, there may be scope for studies to measure mental stress in those exposed to VA, as compared to those not exposed to VA, which could complement community engagement processes.

### **Trust**

A cross cutting theme which affected participants views on VA at scale and MIVA was trust. A decision to trust is based on a combination of 'good reason' (previous experience

or existing relationships) or a ‘leap of faith’, and the larger the ‘leap of faith’, the higher risk involved in trusting (Giddens, 1991). Sociologists have noted that when mistrust in a system occurs, it often starts with the interactions between people who represent the system. Therefore, trust is often built on and predetermined by interpersonal relationships (Meyer et al., 2008).

The interpersonal relationships between VA interviewers and community members were central to the success of VA, VA at scale, and MIVA in our research. Our analysis showed VA interviewers need to be able to develop, maintain and potentially rebuild trust in communities, and this was evident to interviewers and national policy makers. Other research also notes the important role of VA interviewers in enabling VA to take place (Gouda et al., 2016), but is inconclusive about what cadre of worker is an optimal VA interviewer (Gouda et al., 2017). Our results align with Aborigo et al (Aborigo et al., 2013) who found that local interviewers were more likely to know and understand the cultural traditions around death and mourning. They could be sensitive when considering appropriate timing and approach, and they were perceived as being more trustworthy.

Participants broadly accepted that some information would not remain confidential, but were comfortable with this if they trusted the VA interviewer. An interviewer was more likely to be trusted with sensitive information if they were known, from the local area, and their family had honour and a good reputation. In addition, interviewer linkages to the community may be protective to the interviewer if they were in a conflict situation.



The role of interviewers in maintaining confidentiality and protecting family honour during a VA was very important, with or without MIVA. In Nepal, households that retain their honour are invited to participate in informal networks of essential financial and social support (Rankin, 2003), while lost honour causes intense shame, damaged marriage prospects for one's children (Davis, 2003) and possibly excommunication from the wider family and community (Minturn and Kapoor, 1993). In this context, maintaining confidentiality was particularly important where there were perceived instances of carelessness or death that carried social stigma. It was difficult to maintain privacy at the time of a VA (Mony and M, 2011), and although discussions with nonfamily members or multiple interviews could enable a more accurate, detailed and nuanced VA (Iyer et al., 2013), this may distort information exchange between the interviewer and family of the deceased.

VA interviewers and policy stakeholders were wary that MIVA would risk breaking community trust with detrimental effects on the utilization of health services (Thiede, 2005), the vulnerability of VA interviewers, and the effectiveness of VA itself. This breakdown in trust could occur either through a discrepancy between MIVA and physician diagnosis of cause of death; through proving multiple causes of death; or through the disclosure of a potentially shameful cause of death by VA interviewers. Our study also shows that there was a lack of trust among policy stakeholders in the ability of MIVA to assign cause of death accurately enough to disseminate this information at the individual level. The consultative process necessary for an ethical analysis of VA at scale and MIVA (which allowed these issues of trust to be revealed) also requires a level of trust between

participants and researchers. There is a need to explore the centrality of trustworthiness if considering implementing MIVA in other contexts (Ward, 2017), and an evaluation of trust, could help to understand the potential for success of an intervention (Dawson, 2015).

### Health system readiness

In order to minimise risks of interviewers and community members losing honour, careful recruitment, training and supervision of interviewers is necessary. This is particularly pertinent because our study suggests that interviewers were often already providing a counselling role, and giving advice to families of the deceased. Implementing VA at scale would require interviewer supervision to be integrated within health systems and could simultaneously provide support to interviewers and help to maintain data quality. In Nepal, current health systems were not ready to implement VA (and MIVA) at scale, requiring institutionalised supervision systems, and large numbers of interviewers to be deployed who have the skills and knowledge to fulfil the advice and information expectations of families. Ethics research integrated within the scale-up of VA for particular cases such as newborn or maternal death offer opportunities to develop systems and further develop knowledge about the balance of burdens and benefits.

### **Maximising benefits through developing sensitive systems**

We found that policy stakeholders were not supportive of the use of VA and MIVA at scale, partly due to the lack of readiness of health services to respond to the data generated. The usefulness of MIVA would also depend on the accessibility of health care and referral

centres. Without responsive services and systems, the distress of VA, with or without MIVA, may not be fairly balanced by benefits of better public service planning.

Health system integration of VA and/or MIVA requires policy support. This may be difficult to galvanise if there is doubt about the validity of cause of death derived through VA methods. Validity of cause of death from VA have been widely discussed. There has been more comparison between methods in terms of concordance and methodological pragmatism rather than absolute validity (Byass, 2011). In this sense, InterVA (and thus MIVA) has been shown to have strong concordance with physician coding over large and diverse datasets (Byass et al., 2015, Byass et al., 2013). Nevertheless, more engagement is necessary to address the concerns of stakeholders, including clinicians, if considering using VA and/or MIVA at scale.

### **Defining the balance of harms and benefits**

We considered the potential harms of VA and MIVA in controversial causes of death, in cases of disagreement between health professionals and MIVA, and in MIVA delivering more than one cause of death. Recent research suggests that many families know the cause of death of their family member, (Hussain-Alkhateeb et al., 2015) and therefore it could be argued that using MIVA would be uncontroversial in most cases. We found that for controversial cases or those carrying stigma, the researcher or the health worker may be most at risk with some community members becoming distressed, angry or distrustful. We support recommendations for wide ranging stakeholder input to design guidance for the different situations that may arise during a VA (Gouda et al., 2017).

Ethical guidance for research with human subjects states that an injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly (National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979). Initial and ongoing engagement of community members, health workers, and interviewers is important to define an acceptable balance of burdens and benefits of VA and/or MIVA at scale. Engagement could ensure clarity around the concept of ‘probable cause’ and discussion of the trade-off between confusion and distress versus the benefits of more information on cause of death.

### **Limitations**

The district where we collected data has been the site of several cluster randomised controlled trials and large scale surveillance activities over the past 10 years. This may have made the study population more likely to respond favourably to our suggestions, and they may have answered assuming that existing interviewers or MIRA staff would be tasked with conducting MIVA. These prior relationships and activities, coupled with the good reputation of MIRA in the study area may bias our results.

We only conducted one FGD with male VA interviewers with experience of communicating about female, maternal, child and neonatal deaths. We recommend more data collection with interviewers to fully explore the gendered aspects of doing VA.

Although we discussed the ethical issues around giving cause of death at an individual level with community members, we did not discuss the ethical issues in feeding back information at a collective or population level with community members. Further research is required to understand how VA can be integrated into policy and planning systems in a timely way so that participants can experience the benefits of VA.

We recognise that qualitative data alone is insufficient to consider the answers to question one and two of Kass's framework, which refer to whether an intervention improves public health, and the extent to which it is effective in improving public health in the manner stated. Given the lack of data about MIVA, we explored these questions with participants qualitatively as to elucidate their opinions based on their experience and related data. A qualitative approach can also be useful when there is effectiveness data available about an intervention, as there may not be consensus about that data. It is important to understand where different perspectives lie and what these are, particularly when considering scale-up of interventions.

We discussed our findings with a group of academics, researchers, and public health professionals with international experience as a part of our analysis, but regrettably we were unable to complete this process with Nepalese public health ethics experts.

## **Conclusions**

VA presents the opportunity to understand the disease burden in many low-income countries where vital registration systems are underdeveloped and most deaths occur in the community. Advances in technology have led to the development of software that can

provide probable cause of death information in real time, and research on the ethical implications are necessary before considering VA and MIVA at scale. We recommend the use of ethical frameworks, such as the one used in our study (Kass, 2001), to analyse the ethical implications of proposed interventions or activities, and have summarised our findings in Table 2. Burdens can be experienced differently by different groups, and the emotional burden of VA is unlikely to be addressed fully by any intervention. Our findings suggest that in order for the benefits of MIVA to be optimised, it will be important to train and support VA interviewers within a system which also has the capacity to utilise the information provided by VA to inform planning. Initial and ongoing community engagement is recommended as well as engagement of ethical, legal, health and policy personnel in developing protocols and systems. Integrating rigorous research while cautiously moving forward is recommended to ensure systems and responses to concerns are relevant to contexts.

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**Table 1 Data collected**

Age of death	Gender	N participants	Type of data collection	Remoteness
0-1 month	F	8	FGD	Not remote
	F	1	SSI	Not remote*
	F	1	SSI	Remote
	M	1	SSI	Remote
	M	1	SSI	Not remote
	M	2	GI	Remote
1-11 months	F	2	GI	Not remote
	F	2	GI	Remote
	M	1	SSI	Not remote
	M	1	SSI	Remote
1-4 years	F	1	SSI	Not remote
	F	1	SSI	Remote
	M	1	SSI	Not remote
	M	3	GI	Remote
5-14 years	F	2	GI	Not remote
	F	1	SSI	Remote
	M	1	SSI	Not remote
	M	1	SSI	Remote
15-49	F	7	FGD	Not remote
	F	2	GI	Remote
	F	1	SSI	Remote
	F	1	SSI	Not remote
	M	6	FGD	Not remote
	M	3	GI	Remote
	M	1	SSI	Remote
50+	F	2	GI	Remote
	F	9	FGD	Not remote
	M	6	FGD	Not remote
	M	4	GI	Remote
Verbal Autopsy Interviewers	M	6	FGD	District Health Quarters
Policy stakeholders	3 M; 1F	4	SSI	Kathmandu
<b>Total</b>		<b>83</b>		

M: male, F: female, FGD: focus group discussion, SSI: semi-structured interview

\*data missing due to bad recording

## Table 2 Conclusions

<p>It is important to consider the benefits and burdens of Verbal Autopsy (VA) and immediate disclosure of cause of death and counseling (MIVA), and understand whether they would be experienced disproportionately by particular groups. We found that:</p> <ul style="list-style-type: none"><li>• Burdens could be disproportionate to the benefits for women as they take on more of the caring role in this context, and therefore were more likely to be blamed for a death by family members with potentially severe consequences.</li><li>• Burdens could be disproportionate to benefits in poorer households where family members may experience higher levels of guilt as they were poorly resourced to take action to prevent the death.</li><li>• Burdens could be disproportionate to the benefits when the cause of death was accidental (a road traffic accident for example). Those interviewed would not benefit from receiving information on the cause of death, as they would already know.</li></ul>
<p>Policy support and health system readiness are necessary to ensure that benefits of VA and MIVA at scale are realised, data is utilized and of high quality, and VA interviewers receive the support and supervision that is required.</p>
<p>Rigorous and systematized recruitment, training and support of VA interviewers should be central to the implementation of VA, with or without MIVA, particularly as they already give advice where VA is used.</p>
<p>Stakeholder consultation at policy and community level is important to enable considered contextual understanding of burdens, benefits, and the feasibility and acceptability interventions such as scaled-up VA and MIVA. This increased understanding should lead to transparent guidance for the conduct of VA and MIVA.</p>
<p>Where there is policy support and health systems readiness, and utilization of VA data in local level planning and implementation of services, there could be cautious piloting of MIVA with ongoing community engagement and rigorous evaluation that enables timely adaptation or stoppage when required.</p>