Project Title

Evaluating and Improving Communication with the Public During a Pandemic, Using Rapid Turn-Around Telephone Surveys (NIHR Reference: 10/45/21)

How the Project has Changed since the Expression of Interest was Submitted:

The project has changed to take account of suggested revisions made by the funders and the peer reviewers during the course of the application process. Substantive changes include the translation of our survey into Welsh, increased public and patient involvement and the inclusion of questions relating to children.

Planned Investigation

Research objectives

1. To select outcome measures for a new telephone survey that will allow the Department of Health to track the uptake of key behavioural recommendations among the general public during a future influenza pandemic.

2. To select predictor variables for these outcomes that are well-grounded in psychological theory and are amenable to change using a multimedia communications campaign.

3. To test and refine the clarity and reliability of the outcome and predictor variables during a normal influenza season.

4. To test the feasibility of using a sampling strategy for the telephone survey that incorporates a prospective design.

5. To assist the Department of Health in launching our new survey design when a pandemic occurs, to analyse the results in real-time and to provide regular feedback to the Department of Health on the implications of the results for their communications strategy.

6. To adapt the survey as required during the pandemic, so as to meet the developing needs of the Department of Health and other key stakeholders, and to incorporate the results of any new research.

Existing research

The low uptake of recommended protective behaviours during a pandemic

During the 2009 to 2010 influenza H1N1/A ('swine flu') pandemic, the Department of Health used an extensive multimedia campaign to inform the public about the nature of swine flu and to encourage people to adopt various behaviours. Several types of behaviour were singled out as particularly important. First, people were asked to wash their hands regularly using soap and water or sanitising gel, and to use and dispose of tissues when coughing or sneezing. Second, people were given a series of recommendations about the most appropriate ways of accessing

information and healthcare services, such as using a nominated 'flu friend' to collect antiviral medication or telephoning a helpline if ill rather than presenting in person at a healthcare facility. Third, in the latter stages of the pandemic people in defined 'at-risk' groups were advised to have the new vaccination against swine flu. These behaviours would have reduced the overall impact of the pandemic by delaying or reducing the spread of illness (1;2) and by preventing frontline medical staff from being overwhelmed by patients who were experiencing mild symptoms (3;4). Unfortunately, the uptake for these behaviours was low (see Table 1 for rates).

Table 1: Uptake of behaviours recommended by the Government among the British population during the 2009/10 swine flu pandemic.

Reference	Recommended behaviour	Percentage of the population performing that behaviour	Method and date of data collection
Rubin et al 2009 (5)	Washing hands with soap and water more often than usual	28.1%	Cross-sectional telephone survey, 8 to 12 May 2009
Rubin et al 2009 (5)	Increasing the amount you clean or disinfect hard surfaces	17.3%	Cross-sectional telephone survey, 8 to 12 May 2009
Rubin et al 2009 (5)	Making a mutual support plan with a 'flu friend.'	15.2%	Cross-sectional telephone survey, 8 to 12 May 2009
Rubin et al 2010 (6)	Carrying tissues with you	33.1%	Cross-sectional telephone survey, 1 to 17 May 2009
Rubin et al 2010 (6)	Buying sanitising hand gel	9.5%	Cross-sectional telephone survey, 1 to 17 May 2009
Sethi & Pebody 2010 (7)	Having the swine flu vaccine	37.6% of at-risk patients	Primary care reporting system, cumulative data for period up to 31 March 2010

It is likely that the uptake of recommended behaviours will also be low during the next pandemic, particularly as the official response to the swine flu outbreak is now seen by some as having been an over-reaction (6). Persuading members of the public to view a new influenza outbreak as a personally relevant health threat and encouraging them to adopt those

behaviours that are being recommended by the Government will therefore pose a substantial challenge. The main burden of meeting this challenge will fall on the Department of Health's communications team (8).

Although encouraging people to change their behaviour over a short period of time and in the face of scientific uncertainty about the nature of the new influenza outbreak will not be easy, several strategies can help with this task. One of the most important strategies is to obtain regular feedback from the general population, ensuring that communication during the pandemic becomes a two-way process between the Government and the public. Among other things, this feedback can be used to identify current levels of uptake or likely uptake of recommended behaviours; to identify demographic or psychological variables that show strong correlations with uptake and which therefore suggest targets for future communication campaigns; and to assess whether new communication strategies, policy announcements or major events are associated with changes in the uptake of particular behaviours.

The potential for telephone surveys to provide feedback

In normal circumstances, several options are available for obtaining feedback from the general public about their behaviours and perceptions. During a pandemic, however, these options are heavily constrained by the need to obtain information quickly and by the speed with which the outbreak can develop. In practice, telephone surveys commissioned though market research companies remain the most pragmatic and robust way of obtaining the quantitative data about public reactions that is required to inform policy decisions in real time (9;10). Within Britain, such surveys typically use random digit dial (to ensure that every landline telephone number in the country has an equal chance of being called) and proportional quota sampling (to ensure that the eventual sample is demographically representative of the population, using Census data as the gold standard). Using these techniques, data from over 1000 participants can be collected within a period of three days, with a top-line summary of the results being available almost immediately and a spreadsheet of individual-level data being available for full analysis within a week. This speed reduces the risk that major events or news stories will disrupt the ongoing data collection. It also allows the findings to be used to inform policy quickly. The trade-off for this speed is a low response rate, with around 10% being typical. Importantly, however, these response rates are rarely associated with high levels of non-response bias for most outcomes of interest. Several studies have demonstrated that improving telephone survey response rates by 5, 25 or even 50 percentage points has little impact on their results (11-15), while one recent comparison of the results of a rapid turnaround telephone survey (response rate 9%) against a more traditional postal survey (response rate 51%) found that the telephone survey produced a more accurate estimate of the known level of healthcare use among the target population than the postal survey (16). As a result, the use of telephone surveys to obtain feedback from a population during a crisis has becoming an accepted part of any fully-formed public health response (10;17).

The telephone surveys used in Britain during the swine flu pandemic

During the swine flu outbreak, a series of 39 cross-sectional telephone surveys was commissioned by the Department of Health to obtain information on public perceptions of, and behavioural responses to, the pandemic. Questions for these surveys were designed by the Department of Health in collaboration with Ipsos MORI, the market research company that conducted the data collection. Each survey collected data from a new sample of approximately 1050 participants, with data collection taking three days to complete for each. As part of a previous NIHR grant, our team was given access to the resulting dataset, with a remit to add value by using psychological theories to understand the associations within the data. The four reports we provided to the Department of Health during the pandemic have since been published (6;18). These identified several important findings. Most notably, we were able to demonstrate that the Department's communications campaign was having a beneficial effect on people's behaviours and that this was mediated by the impact their advertising had on people's perceptions about the efficacy of the behaviours. We were also able to identify concern about the efficacy and side effects of the swine flu vaccine and low levels of worry about the illness itself as important reasons resulting in low intended uptake of the vaccine among the general public. Finally, we observed strong associations between the level of media reporting about the pandemic and the level of worry in the community in the first few months of the outbreak, although it appeared that people were not worried by media reporting until the first swine flu cases started to appear in Britain and that they had habituated to the high level of reporting by the time the second peak of swine flu occurred during the winter of 2009/10. Our work with this dataset later won an award for Best Scientific Work at the 2010 UK Society for Behavioural Medicine Conference.

One of the key learning points from our work, however, was that substantial room for improvement existed in the design of the surveys themselves. Four key problems hampered our ability to draw useful conclusions from the data. First, several important outcome variables were not measured at all. For example, although the importance of good hand hygiene was a central recommendation in most of the Department of Health's communications material, the early surveys did not include any questions relating to this behaviour. Second, the surveys lacked an underlying theoretical basis, meaning that many key variables specified by theories in health psychology that might have provided useful insight into the reasons why people were not taking up recommended behaviours were not assessed. Third, those questions which were included were sometimes poorly worded, making interpretation difficult. For example, the sole question used to assess worry about the outbreak asked participants "how worried, if at all, would you say you are now about the possibility of personally catching swine flu." This conflated feelings of worry about the illness with perceptions about the likelihood of catching it. Fourth, because a new sample was recruited for each survey, the data were cross-sectional, making it difficult to determine causality from the associations we observed.

Pre-pandemic research to improve the survey methodology

The speed with which the surveys needed to be designed, written and put into the field accounted for many of these shortcomings. So too did the limited contact that occurred at the start of the pandemic between the Department of Health's communications team and their behavioural science expert panel, the Behaviour and Communication sub-group of the Scientific Pandemic Influenza Advisory Committee (SPI-B&C). Expert review panels have since considered these difficulties and produced two relevant recommendations. First, in her official review of the UK's response to the pandemic, Dame Deirdre Hine recommended that "the Department of Health should build relationships between [SPI-B&C] and the Department of Health's policy and communications teams so that SPI-B&C's expertise can be used… in planning for vaccine uptake and other relevant policy areas" (Recommendation 13 (19)). Second, in their document on "Lessons to be learned from the A/H1N1 pandemic," the Council of the European Union observed that "polls and surveys are considered to be essential tools for understanding the perceptions and behaviours of our citizens in a health crisis. These methods make it possible to monitor changes in behaviour and, consequently, to assess whether we are passing on the right messages. A plan for conducting polls / surveys must be established *before* a crisis" (emphasis added (20)). In this application, we propose fulfilling both recommendations by having a team of behavioural scientists and survey specialists (including the Chair of SPI-B&C) work in partnership with the Department of Health to develop a new survey template and to complete the main preparatory work for this survey before the next pandemic occurs. Our preparatory work will result in a new survey template that offers four advantages over the existing approach:

1. We will ensure that the most relevant outcomes are included in the survey.
2. We will ensure that psychological predictor variables are selected for inclusion that are well-grounded in psychological theory and that are amenable to change through a communications campaign.
3. We will test all questions for clarity and reliability, revising them as necessary.
4. We will assess whether, in this instance, the benefits of using a prospective design for data collection outweigh the costs.

Our four preparatory aims are justified further below.

1. Choice of outcomes for the survey

The choice of which outcome variables to assess will be determined as part of the project, in collaboration with the Department of Health, the Health Protection Agency and other stakeholders. However, existing literature suggests five types of outcome will be particularly important to assess:

- Hand hygiene using soap and water or sanitising gel, which is known to reduce the spread of respiratory infections and is likely to be recommended in any future pandemic (1).

- Carrying and using tissues, which is also known to reduce the spread of respiratory infections and is likely to be recommended in any future pandemic (1).

- Intended and actual vaccine uptake. Vaccination represents our best weapon against an influenza pandemic. During the early phases of a pandemic, however, a vaccine will not be available and decisions as to who should receive it may not have been made. Initially, it will therefore be important to assess intended uptake across the entire population, followed by actual uptake amongst those who are eligible to receive it.

- The presence of influenza-like symptoms and the propensity to use healthcare services if ill. Measuring changes in the prevalence of influenza-like illness among the general population is a pressing concern for infectious disease modellers who wish to predict the likely future course of an outbreak. Basing models on the known consultation rates for influenza-like illness is problematic, however, as a person's propensity to seek medical attention for flu-like symptoms is influenced by fluctuating levels of worry and media reporting (21;22). Telephone surveys provide a quick and cost-effective way to assess the prevalence of influenza-like symptoms in the community (23) and were used for this purpose by some countries during the swine flu pandemic (24;25). They may also help in the analysis of more traditional consultation-based data by providing information on the likelihood of someone seeking care if symptomatic.

- Appropriate use of healthcare facilities. Assessing where an individual will go to seek help if ill is also likely to be relevant data for communicators, who may wish to divert patients with mild illness away from front line services and ensure that people with information needs and health care needs access the most appropriate type of care (3;4).

2. Use of theory to select predictor variables

Two recent systematic reviews by members of our team have assessed psychological predictors of behaviour during pandemics and analogous infectious disease outbreaks (26;27). These have suggested that variables associated with a psychological model called Protection Motivation Theory (28) are well suited to explaining whether a person will perform behaviours such as washing hands or being vaccinated. This theory states that an individual's motivation to protect themselves from a threat is influenced by their appraisal of the threat and by their appraisal of the techniques that are available to protect themselves. Threat appraisal encompasses perceptions about the severity of the threat and the likelihood of being affected by it, factors which may in turn trigger anxiety or worry. Coping appraisal is composed of perceptions about the efficacy of specific protective behaviours, the costs associated with them, and the person's

own ability to perform the behaviours (their 'self efficacy'). In line with the theory, the two systematic reviews observed repeated associations in the literature between behaviour and each of these components (26;27). In the case of vaccination, for example, low perceived threat, low worry, fears about the safety of the vaccine and a perceived lack of benefit to the vaccine were particularly associated with lower likelihood of uptake (27). Remarkably few of the studies included in the reviews measured all aspects of the model, however, limiting the usefulness of any single study in informing policy.

In addition to measuring the psychological factors that are likely to predict behaviour during a pandemic, identifying where people are receiving pandemic information from and how much they trust that information source is another key requirement for any survey if it is to be of practical use to a communications team. Assessing whether people who have received information via a particular source such as Government advertising, their primary care physician or Twitter are more or less likely to engage in particular behaviours, and whether that association is mediated by any of the variables specified by Protection Motivation Theory, would make it possible for communications teams to specifically target those sources with better information.

3. Testing questions for clarity and reliability

At present, no psychometrically tested set of items exist which can be used to measure most of the outcome or predictor variables that we would wish to assess. While a small number of items have been developed for use in a pandemic within Australia (29), their usefulness in a British sample has not been tested. Similarly, although some existing generic scales might be used to measure concepts such as anxiety or worry during a pandemic, their length often makes it difficult to incorporate them within a telephone survey which should be, at most, about 15 minutes long. As a result, many previous studies in this field have relied on questionnaires that were developed quickly after the outbreak of an infectious disease was detected. This has resulted in questions that are ambiguous to participants (e.g. (18)), conflate different theoretical concepts (e.g.(30)) or have unknown test-retest reliability, making it difficult to assess changes over time. Spending time prior to a pandemic developing, testing and refining a questionnaire is essential if these problems are to be avoided.

4. Use of a prospective design

Another weakness noted in the literature to date is the heavy reliance on cross-sectional surveys (26;27). This creates problems in interpreting the direction of causality within the data. Prospective designs are often seen as preferable, but these too come at a cost. In particular, the

accumulating attrition of participants over time may result in accumulating bias. As such, prospective designs can be inappropriate when the main aim of a study is to track aggregate trends over time (17). Ways exist of minimizing attrition, however. For example, following Hurricane Katrina, prospective surveys of mental health needs within the New Orleans area achieved 90% follow-up rates by asking participants to commit to a future follow-up at the initial recruitment stage and by increasing their 'ownership' of the survey by designating participants as Members of the New Orleans Consumer Advisory Group. Assessing whether such strategies can reduce attrition to reasonable levels within a British study relating to influenza remains to be seen.

Aims during the pandemic

Our four pre-pandemic aims are essential in ensuring that a useful, robust survey template is available for immediate use in the next pandemic. However, it is also important that the data from these surveys are analysed appropriately during the pandemic, that their implications are discussed with policy makers in a timely manner, and that unexpected changes in the pandemic or developments in research are reflected by timely changes to the survey questions. Our fifth and sixth aims for this research relate to work which will be conducted during the pandemic period and which will meet these challenges.

5. We will analyse the survey data in real-time during the next pandemic, liaising closely with the Department of Health communications team and other stakeholders to ensure that our analyses produce policy-relevant results.

6. We will adjust the survey template to meet unexpected developments in policy, the outbreak, or other research findings.

Research methods

Our study will include four stages. The first three concern the selection of variables, preliminary testing and refinement of survey questions, and the piloting of the full survey during a normal influenza season. The study will then be put on hold until a pandemic occurs. At this point, the survey will be deployed as required by the Department of Health. The fourth stage of our research will consist of our team analysing the data during the pandemic, reporting on it for the Department of Health and adapting the survey as required.

Stage One: Selection of Outcome and Predictor Variables, and Item Generation

A kick-off meeting will be held at the start of Month One for our study. This will include representatives from our key stakeholders: namely, the Department of Health communications team, the Health Protection Agency's Modelling and Economics Unit, the Health Protection Agency's Emergency Response Department and the SPI B&C sub-committee. A prioritised list of outcome variables that are of importance to these groups will be developed, though initial contact suggests that behaviours linked to respiratory and hand hygiene, healthcare use, information seeking and vaccine uptake are likely to predominate.

Based on these priorities, we will re-review the literature that has already been compiled in our earlier systematic reviews (26;27). This re-review will be used to highlight those psychological and demographic variables that have previously been shown to predict selected outcome variables. We will use Protection Motivation Theory as an overarching guide to ensure that we develop items relevant to the perceived likelihood and severity of catching pandemic flu, the perceived efficacy and costs of the behaviour, self-efficacy and emotional response to the pandemic (including items relating to worry). In addition to asking items about the participant, we will also include items concerning their children (e.g. intended vaccination of the child). Item generation for outcome and predictor variables will be based on existing items identified in the literature (26;27) or in our own previous work in this area (5;6;31). As part of this work, we will also produce items to assess where a member of the public has received information from relating to influenza, and how much they trust that source, based on previous work by our group (5;6;21). The resulting 'long-list' of draft items will then be reviewed for clarity and usefulness by the project team and at a second stakeholder meeting to occur in Month Two.

Stage Two: Cognitive Testing of Items

Up to three rounds of cognitive interviews will be used to test the newly developed items for their comprehensibility, face validity and usability in the context of a telephone interview. Participants for these cognitive interviews will be recruited using an existing database of potential research volunteers maintained by King's College London (Mindsearch: http://mindsearch.iop.kcl.ac.uk/). Participants for each round of interviews will be purposively selected to ensure that sufficient numbers of people within predefined quotas for age, gender, ethnicity and educational level are included.

Participants will be asked to take part in a telephone interview in order to replicate the conditions under which our items will be used during a pandemic. Participants will be read each item in turn, asked to provide their answer and asked to explain the reasoning behind their response. Where required, they will also be asked to explain what they believe the question is asking and / or to suggest an alternative wording for the question. This process, which is a

standard way of piloting questionnaire items (32), will allow us to assess the comprehensibility and usability of the questions. By assessing whether participant perceptions of the meaning of items matches our own interpretation of them, we will also be able to assess the face validity of the items.

Items which are identified by two or more participants in any given round of interviews as being difficult to understand or answer will be reworded. These revisions will then be tested in the next round of interviews.

To enhance the patient and public involvement in this research, participants in Stage Two will be also asked their views on: whether questions are overlapping, whether questions seem to be missing entirely, the appropriateness of our proposed sampling strategy for Stage Three and the appropriateness of our informed consent procedure for Stage Three. Two participants from Stage Two will also be asked to join our stakeholder group.

Stage Three: Pilot Surveys

After we have produced a list of useable predictor and outcome variable items, we will pilot these further in a telephone survey of a representative sample of the general population of Britain (n=1,067), with a follow-up survey of the same sample occurring seven days later. We will use the first survey to assess the factor structure and internal consistency of any scales that are produced as a result of Stages One and Two, and to produce baseline data for eventual comparison against the pandemic data obtained in Stage Four. We will use the follow-up survey to assess the test-retest reliability of our items and scales, and to assess the possible non-response bias associated with a follow-up survey in this context.

The first survey will be conducted during a normal flu season and will use an identical sampling strategy to that which is conventionally used for rapid turn-around psychosocial surveillance surveys with Britain (6;10). This will use random digit dialling and proportional quota sampling, with quotas based on the most recent Census data for age, gender, geographical region and social grade (33). To be eligible for the survey, respondents will be aged 16 or over and speak English or Welsh (we will produce a Welsh language translation of the survey items). Data collection will be limited to a three or four day time-period, allowing us to obtain a stable snap-shot of perceptions and behaviours at a single period in time. Data collection for the survey will be subcontracted to a specialist market research company.

The first survey will be presented to potential respondents as a Healthcare Advisory Panel, which we would like them to join as members. The exact name for the panel will be confirmed with our stakeholders and piloted with the participants of our Stage Two cognitive interviews. Survey participants will be informed that if they would like to take part, we would require them to complete two surveys, one week apart. They will also be asked to make a firm date for the second survey with the interviewer and to provide at any additional telephone numbers that they can be contacted on. After verbal consent has been obtained, participants will be asked to complete our new survey template. This will be limited to 15 minutes in length. Participants will then be re-contacted seven days later and asked to complete the survey again. Up to seven attempts will be made to re-contact each participant.

On-Hold Period

At the end of Stage Three, the project will be placed on-hold until the commencement of a pandemic or other significant event that requires rapid psychosocial surveillance. To enable us to begin promptly when a pandemic occurs, we will produce an interim report at the end of Stage Three. This will include the full wording for all items in our survey template and details about the results of testing with these items. The report will serve as an easy-to-use instruction manual for the survey, for use when the pandemic occurs. At the end of Stage Three, we will also seek to produce a memorandum of understanding with our stakeholders. This will specify the expectations and responsibilities for the various parties for the final stage of our work, allowing us to begin work swiftly once a pandemic has been declared. At the end of Stage Three, an ethics application for our Stage Four pandemic work will also be submitted, requesting pre-emptive approval for the work. We will renew this application annually.

Stage Four: Analysis of Surveys Conducted During the Pandemic

When a pandemic or significant epidemic occurs, Stage Four of our research can be activated immediately. A first survey using our new template can be put into the field within a matter of days. The decision on when to launch the survey while be made in conjunction with the Department of Health. Data collection will be subcontracted to a market research company and will follow an identical sampling strategy to that used for the baseline survey in Stage Three. Repeated surveys incorporating a new sample of participants can then be run weekly, allowing us to track aggregate level changes in behaviour and perceptions over time. Depending on the results of Stage Three with respect to the extent of non-response bias, it will also be possible to commission additional follow-up studies for specific samples of participants, allowing us to assess changes in perceptions and behaviour over time using individual-level data.

Following the same successful working model that our team established with the Department of Health during the 2009/10 pandemic (6), we propose that data collection for the Stage Four surveys will be commissioned and managed by the Department of Health. The role of our research team will be to analyse the data, provide feedback to the Department of Health and other stakeholders as to the practical implications of our results, and to adapt the surveys as required should unexpected developments occur.

Two primary analyses are planned for Stage Four. First, weekly cross-sectional data will be pooled across surveys as required to increase statistical power. They will then be analysed multivariately to investigate associations between the use of specific information sources and behaviour. We will also assess the possible psychological mediators of these associations, using Protection Motivation Theory as our guiding model. Trust in information sources and variations across region, socioeconomic status and other demographic variables will be assessed as potential moderator variables. Analyses will be based on structural equation modelling, with separate models being constructed for each outcome variable.

Second, a longitudinal assessment of changes in aggregate perceptions or behaviour over time will be conducted to identify if specific events or major policy announcements are associated with shifts in perceptions or behaviour. It is unlikely that enough surveys will be conducted to allow us to perform a statistical analysis of these trends. However, plotting survey data over time will provide a useful indication of any large effects. The longitudinal data will also allow us to explore the association between perceptions and behaviour with other metrics relating to information dissemination, including the volume of reporting in the mass media (as measured using the Nexis database which catalogues all national and regional newspaper reports www.lexisnexis.com/nexis) and a range of Internet-based metrics including the volume of Twitter posts and blog comments. These analyses will require us to use data from as many surveys as possible, to increase statistical power. By necessity they will therefore occur at the end of Stage Four and will assist academics and policy makers to learn the lessons of the pandemic.

Throughout Stage Four, we will hold meetings with our stakeholders on at least a monthly basis. This will provide an opportunity to discuss the practical implications of our results for the on-going communications strategy and other work. It will also provide an opportunity to discuss any recent developments with the pandemic, public health policy or research from other teams which necessitate changes being made to the survey.

Planned inclusion / exclusion criteria

Participants for Stages 2 to 4 will be eligible for inclusion if they are aged 16 or over and speak English or Welsh.

Ethical arrangements

Ethics applications for Stages Two, Three and Four will be submitted to the King's College London Research Ethics Committee. Participants for Stage Two will be drawn from an existing database of people who wish to be considered for inclusion in research of this type. Members of this database will be sent our information sheet and invited to contact us if they wish to take part. We foresee no particular ethical issues for this Stage. Participants for Stages Three and Four will consist of members of the public whose telephone number has been selected at random by the market research company. This is a standard procedure for telephone surveys of this nature and has been approved by our Ethics Committee for several similar studies (5;34-36). All participants for these stages will be informed that the survey relates to their thoughts, behaviours and opinions about pandemic flu within the first minute or so of their interview.

Risks and benefits for participants and society

There is a small risk that some people who are contacted by the market research company in Stages Three and Four will find this contact intrusive. The impact of this intrusion on any given member of the public will be low. There is a small risk that some of those who take part in a Stage Four survey will find the interview topic upsetting, particularly if friends of family members are seriously ill or have died during the pandemic. Interviewers will be briefed to tactfully terminate an interview if a participant becomes overtly distressed and will be able to provide information on sources of support should this be necessary.

We do not expect participants to experience any direct benefits from the research. The benefits to society will accrue from the improvements that can be made to the Department of Health's communications strategy, which will improve uptake of protective behaviours and reduce the incidence and impact of the illness.

Informing potential participants of possible benefits and known risks

In order to reduce the risk of self-selection bias, potential survey participants will initially be informed that the survey relates to "important issues facing Britain." However, once consent to proceed with the interview has been given, participants will be informed of the true topic of the

interview. Those who feel they would find the topic distressing will then have the opportunity to withdraw at this stage.

Obtaining informed consent

Participants in Stage Two will receive an information sheet and will have the opportunity to discuss the study in detail with the Principal Investigator prior to participating. Participants in Stages Three and Four will receive a verbal briefing from the interviewer and will have the opportunity to ask the interviewer to call back at a later date if they wish to have more time to consider whether or not to participate. In accordance with normal industry practice for telephone interviews, all participants in this research will be asked to provide verbal, rather than written, consent for our study. This is also in line with best practice as specified by the King's College London Research Ethics Committee.

Retention of study documentation

All documents and datasets relating to the study will be retained for seven years and then reviewed.

Proposed sample size

A total sample size of 30 participants for each round of interviews in Stage Two will allow sufficient opportunity for any obvious difficulties with question wording to emerge.

Sample sizes of 1,067 participants for the surveys in Stages Three and Four will provide us with a sample error of plus or minus three percentage points for our prevalence rates. These sample sizes will also be sufficient for the structural equation modelling planned for Stage Four, particularly where data from two or more surveys are pooled together.

Statistical analyses

In Stage Three, we will use exploratory factor analysis to assess the clustering of those items that we intend to use as scales using data derived from the first survey. We will use principal axis factoring, examine scree plots to determine how many factors to extract and perform oblique rotation using direct oblimin. Internal reliability of scales will be tested using Cronbach's alphas, item-total correlations and inter-item correlations. Test-retest reliability will be calculated using data from both surveys, using intra-class coefficients (ICC (2,1)) for scales and

weighted Kappa coefficients for individual items. Non-response bias as a result of participant attrition in Stage Three will be assessed using *t*-tests and chi-squared tests to compare respondents and non-respondents in the second survey with respect to their baseline data from the first survey.

The Protection Motivation Theory and specific associations between variables will be tested in Stages Three and Four through the use of structural equation modelling, which will allow us to simultaneously test the relationships of predictor, outcome and moderator variables (the precise variables involved having been determined at Stages One and Two). In Stage Four, we will test whether the strength of relationships seen in Stage Three has changed in any significant manner using Wald tests, allowing us to update recommendations for the communication strategy

Along similar lines to our prior work (6), we will use ARIMA time series modelling, where possible, to analyse the cross-sectional data collected in the weekly surveys in Stage Four with respect to data collected on media reporting, online activity or measures of the pandemic's spread (e.g. hospitalisations).

Proposed outcome measures

The definition of relevant outcomes will be conducted as part of Stage One. Primary outcomes are likely to include respiratory and hand hygiene, vaccine uptake (intended and actual) and use of healthcare resources (actual and intended). Secondary outcomes will include the presence of self-reported influenza-like illness.

Research governance

The sponsor for this research will be King's College London.

Project timetable and milestones

Our timetable is based around the need to trial our Stage Three surveys during a normal influenza season. Given that we will not have sufficient lead-in time to do this in 2011, we have based the timetable around a start date in late 2012.

Study Stage	**Date**	**Activity**	**Milestone**
Stage One	1 Aug 2012	Kick off meeting of Stakeholder Group Definition of target outcome variables	
	Aug 2012	Submission of ethics application for Stage Two work	
	Aug 2012	Selection of predictor variables	
	Sept 2012	First draft of items presented to Stakeholder Group	
	1 Oct 2012	Agreed long list of items ready for cognitive testing	Production of long list of survey items
Stage Two	1 Oct 2012	First round of interviews	
	Oct 2012	Submission of ethics application for Stage Three work	
	Nov 2012	Second round of interviews	
	Nov 2012	Third round of interviews	
	20 Nov 2012	Final revisions made to survey items	Production of revised list of survey items
Stage Three	6 Dec 2013	Agree survey wording with market research company, who will then translate it into Welsh	
	16 Jan 2013	First survey launched	
	23 Jan 2013	Follow-up survey launched	
	Feb 2013	Data analysis and preparation of interim report	
	1 March 2013	Delivery of interim report	Production of interim report
PROJECT ON HOLD UNTIL PANDEMIC			
Stage Four	Pandemic month 1	Launch of first pandemic survey	
	Pandemic months 1 to 6	Monthly Stakeholder Group meetings to be held	
	Pandemic months 1 to 6	Analyse cross-sectional data, depending on needs of Stakeholder Group	

	Pandemic month 5	Analyse longitudinal data	
	Pandemic month 6	Final report	Production of final report

Expertise

Richard Amlôt leads the Behavioural Science Research Team within the Health Protection Agency's Emergency Response Department. His team runs a programme of research assessing psychological and behavioural responses to emergencies; risk and crisis communication; the evaluation of emergency preparedness exercises and operational research for mass causality decontamination. This has included several international studies assessing the best way to communicate with the public during a major public health crisis. Richard chairs the newly formed Psychosocial and Behavioural Issues sub-committee of the Health Protection Agency's Emergency Response Development Group. Richard will assist with selection and design of the survey items, and interpretation of the survey data.

Nicola Fear is a Reader in Epidemiology within the Department of Psychological Medicine, King's College London. Nicola's main areas of expertise are military and occupational epidemiology, statistics and the design and analysis of complex surveys. Nicola is currently a co-PI on an ESRC funded study to examine public attitudes to the military, this is part of the 2011 British Social Attitudes Survey. Nicola has led the development of the questions and will over-see the statistical analyses of the data collected. Nicola is fully funded by a grant from the UK Ministry of Defence. Nicola will assist with design of the survey sampling strategy and analysis of the data.

Susan Michie is a Professor of Health Psychology, leading the Health Psychology Unit in UCL's Division of Psychology and Language Sciences. She is known internationally for her work on understanding health related behaviours and applying psychological theory to designing interventions to change behaviour. She has worked for many years at the interface of science and policy, acting as part-time consultant to the Department of Health's Health Improvement Directorate to advise on several communication and behavioural intervention programmes. She is a member of the Government's Scientific Pandemic Influenza Advisory Committee and is Chair of its Behaviour and Communications subgroup. Susan was involved in several studies during the 2009/10 H1N1 outbreak and was Principal Investigator for our previous NIHR-funded work assessing the Department of Health's survey data. Susan will assist with the selection of items for the surveys, and interpretation of the survey data.

Henry Potts is a Senior Lecturer within the Centre for Health Informatics and Multiprofessional Education in UCL's Division of Population Health. He brings to the team expertise in statistical analysis for a health psychology context. He is also a recognised expert on new information and communication technologies and their role in health care, including non-traditional media and social networking. Henry has direct experience in the analysis of telephone survey data, and led on the statistical analysis of the Department of Health's swine flu survey data. Henry will assist with the statistical analysis of the survey data.

James Rubin is a Senior Research Fellow in the Department of Psychological Medicine, King's College London. He has a particular expertise in using telephone surveys to assess population reactions to public health crises and has previously used this technique to produce rapid reaction research during the swine flu outbreak, the 2007 flooding in the North of England, the polonium 210 incident and the 7 July London bombings. James was first author for our previous work with the Department of Health's swine flu survey data. James will supervise the literature reviewing and interviewing in Stages One and Two. He will also take main responsibility for the design and data analysis in Stages Three and Four. James will be responsible for the overall co-ordination of the project.

A suitably qualified *post-doctoral researcher* will also be appointed to work on Stages One, Two and Three. He or she will be based at King's College London, under the direct supervision of James Rubin. He or she will meet with Dr Rubin for supervision on at least a weekly basis and will be expected to meet with the core team and stakeholder group on a monthly basis. The researcher will receive training from the core team, if required, on literature reviewing, questionnaire design and survey methodology.

Stakeholder involvement and links to other studies

In order to maximise the relevance and impact of our work, we will form a stakeholder group for this study. This will help to guide the selection of variables for our survey, will provide a way of ensuring that our findings are disseminated and translated into policy, and will provide a means for us to learn about any new developments during the pandemic. By working closely with our stakeholders during the pre-pandemic period, we will strengthen our ability to work quickly and efficiently during the pandemic period.

The group will be chaired by the PI. Membership of the group will include:

- Representatives from the Department of Health communications team (to be confirmed on award of the grant by Dr Bruce Taylor, Deputy Director of the Department of Health's Pandemic Flu Team);

- Professor Susan Michie, Chair of SPI B&C subgroup;

- Dr Richard Amlôt, Chair of Health Protection Agency Psychosocial & Behavioural Issues sub-committee;

- Dr Peter White, Head of Modelling and Economics Unit, Health Protection Agency;

- Dr Ken Eames, Lecturer, Centre for Mathematical Modelling of Infectious Diseases, London School of Hygiene and Tropical Medicine.

- Two lay members, appointed from the participants recruited during Stage Two of the work.

Lay stakeholders will be asked to attend all meetings and to provide feedback and advice on all aspects of the study.

Justification of support required

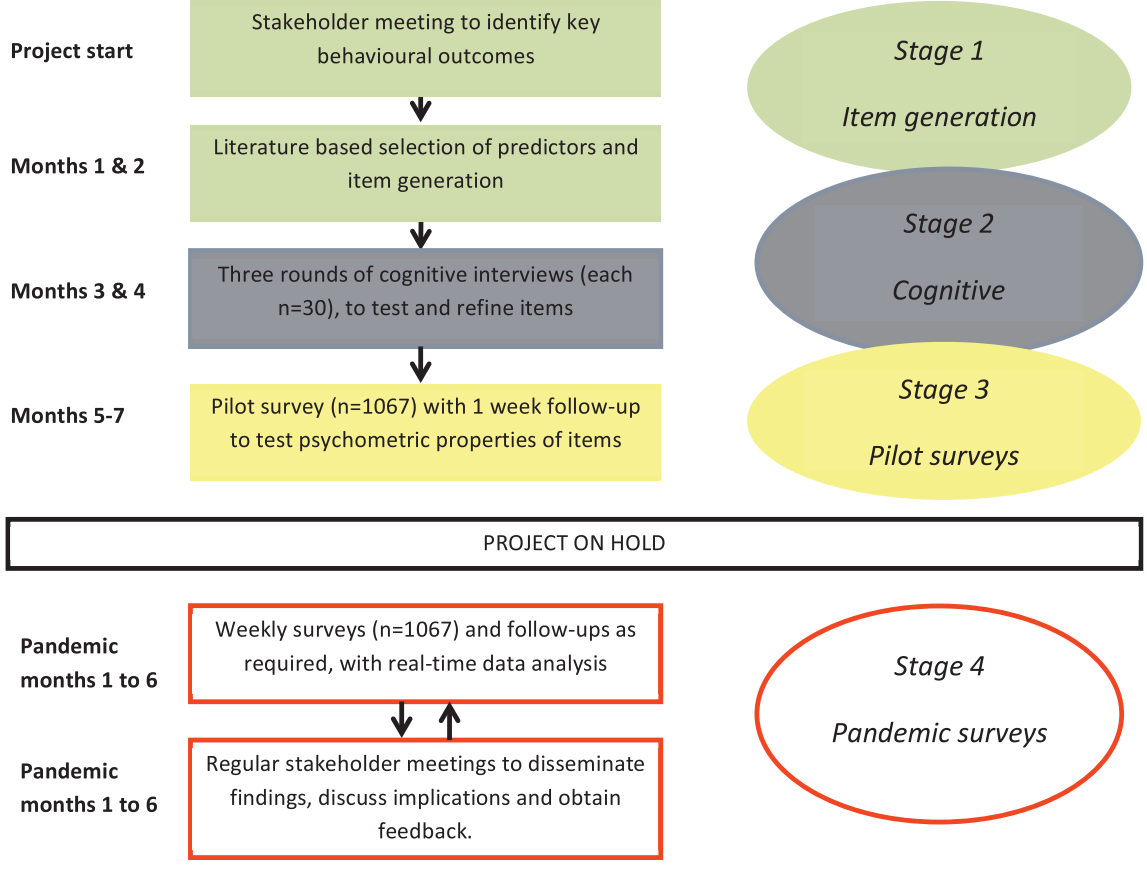
Dr Amlôt, Dr Potts and Professor Michie will each require 5% of their time throughout the study to cover time spent overseeing the design, analysis and reporting of the project. Dr Fear will devote the same amount of time to the project, but because she is currently employed on a Ministry of Defence grant, she will contribute this time for free. During the seven months of Stages One to Three, the bulk of the work will be conducted by a post-doctoral researcher (100% FTE), under the immediate supervision of the PI (Dr Rubin, at 10% FTE). To ensure that the project begins swiftly in the next pandemic, without delays caused by recruitment and training of staff, Dr Rubin will act as the main researcher during Stage Four (at 75% FTE). Please note that our salary costs have been calculated separately for the two periods of the pre-pandemic phase and the active phase, and then added together. Our pre-pandemic phase will start on 1 August 2012. For our active phase we have used the arbitrary start date recommended by NIHR of 1 November 2012. Salary costs for the active phase are estimates and may require revising depending on the actual start date of the pandemic.

For the cognitive interviews in Stage Two, we will require £1,800 to reimburse participants at a

rate of £20 each for 90 participants. An additional £5 per participant in Stage 2 (£450 total) is required to cover additional costs associated with participant recruitment and testing, including telephone charges. We will also require a one-off fee of £250 to access the volunteer database. We request £750 in travel and subsistence costs to cover intersite travel for the applicants, and £1,200 to cover publication fees. A £100 per diem will be provided for the two lay members of the stakeholder group to cover Stages Two to Three (total cost in pre-pandemic period: £1,600, total cost in pandemic period: £1,400).

Survey costs for Stage Three are based on a quotation from Ipsos MORI for £62,400. This cost includes the survey and VAT at 20%. We are not able to reclaim this VAT and must therefore charge it to the grant. The survey cost will be incurred in full at the end of the first six month period of our work. Because Ipsos are the same company that conducted the Department of Health swine flu surveys, using them will allow us to directly compare our results with the swine flu data.

Flow diagram



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