



Full title of study	Study of Advice and Decision-making on prognosis using the Judge-advisor System within multi-disciplinary Teams (ADJUST)
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1 Protocol Version History

Version Number	Date	Protocol Update Finalised By (insert name of person):	Reasons for Update

2 Signatures

The Chief investigator agrees to perform the investigations and to abide by this protocol.

The investigator agrees to conduct the study in compliance with the approved protocol, the UK Data Protection Act (1998), the Trust Information Governance Policy (or other local equivalent), the current Research Governance Framework, the Sponsor's SOPs, and other regulatory requirements as amended.

Chief investigator

Professor Patrick Stone

UCL



01-September-
2020

Signature

Date

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4 List of abbreviations

AE	Adverse Event
APR	Annual Progress Report
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
EAPC	European Association for Palliative Care
GSF	Gold Standards Framework
IPR	Intellectual Property Rights
JAS	Judge-Advisor System
LCP	Liverpool Care Pathway
LACDP	Leadership Alliance for the Care of Dying People
MDT	Multidisciplinary Team
NHS R&D	National Health Service Research & Development
OACC	Outcome Assessment and Complexity Collaborative
PaP	Palliative Prognostic Score
PI	Principal Investigator
PiPS	Prognosis in Palliative care Study
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PPI	Palliative Prognostic Index
PPS	Palliative Performance Scale
REC	Research Ethics Committee
SD	Standard Deviation
SOP	Standard Operating Procedure
SMG	Study Management Group
WOA	Weight Of Advice

5 Study personnel

See protocol cover page for Chief Investigator and Sponsor contact details.

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6 Summary

Objective:	To understand in quantitative terms how multidisciplinary teams form intuitive judgements about the prognoses of palliative care patients.
Type of study:	Online psychological experiment.
Study design and methods:	<p>In this study, using the Judge-Advisor System, we will recruit clinicians working in palliative care for adults. Participants will be asked to complete a survey and review five patient summaries (“vignettes”) based on real cases derived from a previous study. Clinicians will be presented with key prognostic information and will be asked to provide an estimate of the probability that the patient will survive for two weeks (0-100%). After providing this initial estimate, participants will receive prognostic advice. While in reality all participants will receive the same advice, participants will be randomised into two groups and these groups will be informed that the advice is either: (1) provided by an algorithm; or (2) provided by a team colleague. Participants will then be given the opportunity to give a second, possibly revised estimate in the light of the advice received.</p> <p>Study data will be collected using two different recruitment methods (Arm A and Arm B). Participants in arm A will be recruited at a series of (online) seminars, and participants in arm B will be recruited through their hospice employment. All participants will be asked to complete an online questionnaire, including five vignettes. Clinicians will be asked some demographic questions including age, gender, profession and experience.</p>
Study duration per participant:	Approximately 10-15 minutes
Estimated total study duration:	36 months
Planned study sites:	For arm A, we will approach clinicians attending a series of (online) seminars on palliative care. For Arm B, we will approach clinicians working in non-NHS hospices in the UK.
Total number of participants planned:	100-300
Main inclusion/exclusion criteria:	<p>Participants must be clinicians working in palliative care for adults.</p> <p>They must be willing and able to provide informed consent</p>

Statistical methodology and analysis:

Analysis will be conducted by the study team. Participant demographics will be described.

The primary outcome will be the weighting of advice that each judge attributes to the advice that they receive. The weighting of advice reflects the importance that a judge gives to the advice provided and the level to which the judge incorporates this into their decision (ranging from '0' if completely discounting the advice to '1' if shifting completely to the advice). The weighting of advice will be analysed using regression analysis, taking into account the judge's initial and final estimates and the advice given. We will explore whether the weighting of advice is influenced by characteristics of (1) the advisor (a clinician or algorithm); (2) the judge (e.g. seniority); and (3) the advice itself (e.g. distance from judge's initial estimate).

7 Background and Rationale

7.1 Background

This study is part of the 'Improving care, assessment, communication and training at end-of-life' (I-CAN-CARE) programme of research. The overall aim of this programme is to improve end-of-life care for patients and their families by better assessment of dying patients, by improved understanding of how clinicians identify dying patients, by improving clinicians' skills in making prognostic decisions and by understanding how prognoses are communicated to relatives of dying patients.

This project uses an experimental design to study decision-making about prognoses within multidisciplinary teams.

7.2 Prognostication

Studies show that patients, carers and clinicians all value accurate prognostic information (Adams et al., 2009, Degner et al., 1997, Kirk et al., 2004, Kutner et al., 1999, Steinhauer et al., 2000, Steinhauer et al., 2001). This information can help patients and family members to make decisions and feel prepared, can help family members to prioritise commitments, and can help to access funding and services, and plan treatment and care in the hospital or community (Pontin and Jordan, 2013).

Clinicians' predictions about length of survival are inaccurate and over-optimistic (Glare et al., 2003, Gwilliam et al., 2013b, White et al., 2016, Christakis and Lamont, 2000) and no clear guidance exists on how clinicians can be taught to perform this task better. Nonetheless, clinical predictions of survival remain the most common method of arriving at a prognostic estimate and the European Association for Palliative Care (EAPC) recommends that the "clinical prediction of survival (in combination with other prognostic factors) is a valid tool to obtain a general prognostic evaluation of patients".

In 2013, due to substantial criticism of the Liverpool Care Pathway (LCP), a care plan that had been designed to help doctors and nurses provide quality end-of-life care, an independent committee

chaired by Baroness Neuberger was asked to review LCP use (Neuberger et al., 2013). A particular concern expressed by many relatives and professionals was that clinician predictions of survival were inaccurate and that this had the potential to adversely affect patient care. A frequent theme of the Neuberger report was that clinicians needed to be better at identifying patients who are dying. The Leadership Alliance for the Care of Dying People (LACDP) responded to the Neuberger review and identified “the recognition of dying” as one of the five key priority areas for improving end-of-life care (Leadership Alliance for the Care of Dying People, 2014, Leadership Alliance for the Care of Dying People). Systematic identification of patients approaching the “end-of-life” was also a key recommendation of the End-of-Life Care Strategy (Department of Health, 2008). The Gold Standards Framework (GSF) service improvement programme (widely used in general practice, nursing homes and increasingly in acute hospitals) uses a needs-based coding system dependent upon whether patients are expected to live for “days”, “weeks”, “months” or “years” (Thomas and Free, 2011). Similarly the Outcome Assessment and Complexity Collaborative (OACC) suite of measures includes a “phase of illness” assessment in which clinicians are asked to judge whether a patient is “stable”, “unstable”, “deteriorating” or “dying” (Witt et al., 2014). However, clinicians’ predictions about length of survival are inaccurate and over-optimistic (Christakis and Lamont, 2000, Glare et al., 2003, Gwilliam et al., 2013a, White et al., 2016) and no clear guidance exists on how clinicians can be taught to perform this task better.

Nonetheless, clinical predictions of survival remain the most common method of arriving at a prognostic estimate and the European Association for Palliative Care (EAPC) recommends that the “clinical prediction of survival (in combination with other prognostic factors) is a valid tool to obtain a general prognostic evaluation of patients (grade A)¹” and that “a second opinion by a more experienced professional could be useful (grade D)²” (Maltoni et al., 2005). This latter recommendation was based on experts’ recommendations (Christakis and Lamont, 2000, Higginson and Costantini, 2002), but more recently a few studies have investigated whether multidisciplinary team discussions can improve the accuracy of prognostic estimates (Gwilliam et al., 2011, Kee et al., 2007). One study investigated whether 6-month survival predictions for patients with newly diagnosed lung cancer made by individual clinicians and the multidisciplinary team (MDT) as a whole became more accurate following MDT discussion (Kee et al., 2007). While clinicians felt more confident following the MDT discussion, this did not lead to better accuracy of individual clinicians, and only slightly better accuracy was found at the group level. Notably, this study did not ask clinicians to explicitly share their prognostic estimates. Our own research has shown that, in patients with advanced cancer, an MDT survival estimate was slightly more accurate than either a doctor’s or a nurse’s estimate alone (Gwilliam et al., 2013a). More broadly, a systematic review has found indications that MDT discussions can lead to significant changes in assessment and management of cancer patients (Pillay et al., 2016). It is thought that a multidisciplinary approach can help to reduce variations and improve

¹ Grade A recommendations relied on research evaluated as level I (impact studies with low risk of bias or homogeneous meta-analyses) or level II (Heterogeneous meta-analyses or confirmatory studies with a low risk of bias)

² Grade D recommendations relied on research evaluated as level V (expert opinion) or inconsistent or inconclusive studies of any level.

consistency of care, provide a learning opportunity for junior staff, and improve communication between different specialties (Ruhstaller et al., 2006).

Another approach to improving accuracy of predictions is to provide advice in the form of a prognostic score. Several scores are available, including the Palliative Prognostic Score (PaP score) (Maltoni et al., 1999, Pirovano et al., 1999), Palliative Prognostic Index (PPI) (Morita et al., 1999), Palliative Performance Scale (PPS) (Anderson et al., 1996) and Prognosis in Palliative care Scales (PiPS) (Gwilliam et al., 2011). One study found indications that doctors' estimates became more accurate when they used the PPI to supplement their own intuitive judgments (Morita et al., 2001). Another recent study showed that, for a cohort of 38 patients, the PaP and the PPI more accurately predicted survival than junior doctors and palliative care experts and the most accurate estimates were obtained when palliative care experts used the PaP score (Tavares et al., 2017).

Qualitative studies have explored how palliative care doctors and nurses formulate a prognostic estimate and how they view this process (Clarkson et al., 2013, Pontin and Jordan, 2013). Clinicians mentioned using objective patient data such as Karnofsky Performance Status as well as less tangible factors such as intuition. One interviewee commented how prioritizing different patient data to formulate a prognosis could lead to disagreements between professionals from different disciplines (Pontin and Jordan, 2013). Furthermore, it was suggested that registered nurses and healthcare assistants working on wards might be best placed to formulate a prognosis, because they spend most time with patients and are closely involved in care delivery (Pontin and Jordan, 2013). While, in practice, many prognostic decisions are taken by a senior doctor, a quantitative study in a multidisciplinary team providing supportive care and palliative radiotherapy for cancer patients has shown that prognoses from doctors were equally (in)accurate as those from other professionals, including nurses, radiation therapists and allied health professionals (Fairchild et al., 2014). It was suggested that nurses, because they spent more time with patients, were therefore better placed to assess certain symptoms and signs. In sum, involving professionals from various disciplines may help to combine knowledge on various symptoms and signs and reduce error. However, the manner in which different estimates are combined to arrive at an MDT estimate is not well understood.

The research team has recently completed a study investigating the accuracy of doctors, nurses and MDT predictions of 14 day survival compared to the accuracy of an algorithm (PiPS2) (Kalpakidou et al., 2018). As part of this study we collected observational data about the clinical condition of 1800+ palliative care patients. Furthermore, the research team has completed another study investigating how individual clinicians decide when a patient is imminently dying by using judgement analysis (Cooksey, 1996, White et al., 2018)

The current study will build on this work by using the Judge-Advisor System (JAS) research methodology to investigate the factors which affect MDT decision-making. The ultimate purpose of this research will be to make recommendations about measures that clinicians can take to improve the accuracy of prognostic judgements. It is recognised that real-world MDT decision-making is inevitably more complicated than our simple experimental set-up will allow. This is one of the reasons why the overall project will also investigate the interactions occurring during MDT meetings using qualitative methods (not described in this protocol). By combining the results from these two different approaches, the project will give a nuanced insight into MDT prognostication.

7.3 The Judge-Advisor System (JAS)

A key component of the dynamics in a JAS is the differentiation between the roles of the judge and the advisor(s). The judge is the decision maker who assesses the information concerning a specific decision and makes the final decision. An advisor is the person who offers advice, information, or suggestions to the judge (Snizek and Buckley, 1995). While actual decision-making power resides solely with the judge, the advisor may have some stake in the judge's decision (Snizek and Buckley, 1995).

Using advice is an essential practice in making decisions in real life, whether it is as simple as seeking directions in an unfamiliar environment or more complex situations such as those involving legal or medical issues (Yaniv, 2004b). Advice is usually sought from someone with more expertise or providing a different perspective, because of a need to improve the accuracy of a judgement and the expectation that advice will help (Snizek and Van Swol, 2001, Yaniv, 2004b). In the context of prognostication, a doctor may also seek advice for social reasons, including self-affirmation and sharing of responsibility, knowing the difficulties of prognostication and having concerns about the consequences of making an inaccurate prediction (Kennedy et al., 1997, Yaniv and Milyavsky, 2007). The JAS offers a robust basis from which hypotheses on advice-giving in dyads or groups can be tested (Van Swol and Snizek, 2005).

7.4 JAS Research

In traditional JAS research, judges are asked to complete an experimental task that usually requires a quantitative answer. Judges provide an initial estimate and they may also be asked to express a level of confidence regarding the accuracy of this initial decision (Bonaccio and Dalal, 2006). Next, the judge will receive advice, which could come from a real advisor or could be fictional, depending on the aims of the study. The judge is then invited to reconsider the initial estimate and provide a final, possibly revised estimate. Research has focussed on the importance (weighting) that a judge gives to the advice provided and the level to which the judge incorporates this into their decision or not (discounting). When revising estimates, people tend to use two strategies: choosing between two estimates or averaging them. A surprising result of previous research has been that averaging was the more effective strategy across a wide range of commonly encountered environments. Authors have observed that despite this finding, choosing was the preferred strategy although greater accuracy would have been achieved had they always averaged (Soll and Larrick, 2009).

One of the main findings reported in the literature is that people tend to discount advice (Yaniv, 2004b, Yaniv and Kleinberger, 2000b, Bonaccio and Dalal, 2006). Although the appropriate use of advice leads to better judgements (because of the reduction of random error), respondents prefer their own estimates; this is referred to as egocentric discounting (Yaniv and Kleinberger, 2000a). Additionally, the distance of the advice from one's own opinion can affect the weight it receives. High-knowledge respondents discounted the advice given while the low knowledge group averaged less and chose to remain with their own initial judgment more (Yaniv, 2004b).

7.5 JAS research in the context of this study

While research is available on advice and information seeking among clinicians (Rappolt, 2002, Weber et al., 2007, Weinberg et al., 1981) to the best of our knowledge no experimental studies have used the JAS to explore the dynamics of receiving and using advice in the context of medical prognostic decision-making.

In the context of our study, it is often the responsibility of a (senior) doctor to formulate a prognosis to consider hospice enrolment, assess eligibility for a clinical study, plan care and treatment, and prepare patients and families. As described above, doctors could obtain advice in a formal MDT setting or ask a more experienced colleague, a colleague from a different background that brings a different perspective, or a colleague who has spent more time with the patient. JAS studies have used different types of questions, including estimations of the dates of historical events and multiple-choice questions (Bonaccio and Dalal, 2006). The current study will ask participants to estimate the probability of patients surviving two weeks (0-100%).

A recent series of experiments using a variety of judgement tasks has shown that, contrary to prior work, people placed a higher weight on advice from an algorithm as compared to advice from another person (Logg et al., 2019). The researchers provided judges in the study with equivalent advice that was labelled as coming from an algorithmic versus human source. In the first experiment, judges were asked to estimate the weight of a person in a photograph. The actual weight of this person was 164 pounds. All judges then received the same advice (163 pounds), which was the estimate provided by 415 participants in another experiment (Moore and Klein, 2008). Half of the judges were told that: 'An algorithm ran calculations based on estimates of participants from a past study. The output that the algorithm computed as an estimate was: 163 pounds'. The remaining judges were told that 'The average estimate of participants from a past experiment was: 163 pounds'. In this study, we will do an experiment similar to this, by randomising clinicians to receive equivalent advice, described as coming from a prognostic tool or another professional.

This research will provide greater understanding of the factors affecting the quality of MDT prognostic estimates and will provide an evidence-base to improve clinician training.

8 Assessment and Management of Risk

The table below summarises the risks and mitigations of all study procedures:

Intervention	Potential risk	Risk Management
Completion of an online experimental task to provide five prognostic estimates and receive prognostic advice from an 'advisor'	There are no obvious risks associated with the completion of this task. However, predicting survival is a difficult task, therefore participants may experience some feelings of frustration.	Participants will be advised that they can withdraw from the study at any time and without giving a reason.
Collection of data, using a secure online platform.	There is a small risk that data could be lost or accessed by unauthorised personnel.	Data will be encrypted, backed up and stored securely on UCL computers.

9 Objectives

To understand how clinicians form intuitive judgements about the prognoses of palliative care patients after receiving advice perceived as coming from either a team member or an algorithm.

9.1 Primary objective:

To assess the level to which clinicians incorporate advice received from other clinicians or an algorithm into their estimates of the prognosis of palliative care patients.

9.2 Secondary objective:

To investigate the extent to which clinicians' integration of advice is influenced by the characteristics of the judge, the advisor or the advice itself.

10 Study design

Study data will be collected using two different recruitment methods (arm A and arm B). Both study arms involve participants being asked to provide a prognostic estimate of the probability of survival for palliative care patients. Participants are asked to provide information about their gender, age, role, grade and experience. They will be presented with five case summaries ("vignettes") (see Appendix 2 – Sample vignette) based on real cases derived from a previous study (PiPS2) (Kalpakidou et al., 2018). In the PiPS2 study, data were collected on palliative care patients in order to calculate a prognostic score (the PiPS score). Doctors and nurses were asked to make a prediction about how long they expected the patient to survive, and the subsequent length of survival of the patients was recorded. We will create vignettes using the anonymised data already collected as part of the PiPS2 study (see Appendix 2 – Sample vignette). Participants will be presented with key prognostic information and will be asked to estimate the probability that the patient will survive the next two weeks (0% 'certain to die' to 100% 'certain survival').

Participants will be randomised into one of the following two groups: The clinicians' advice group or the algorithm advice group. In the clinicians' advice group, participants will receive advice labelled as coming from another clinician. Doctors will receive advice labelled as coming from nurses and *vice versa*. Seminar attendees with other clinical backgrounds in this group will be further randomised into receiving advice labelled as either coming from a doctor or a nurse. In the algorithm group, participants will receive advice labelled as coming from the PiPS-B algorithm. In fact, participants in both groups will receive the same advice. After receiving the advice, participants will be given the opportunity to give a revised estimate, in the light of the advice received.

A schedule of study assessments and procedures is set-out in Appendix 1 - Schedule of assessments.

11 Data collection and study procedures

We expect that data collection for this study will take approximately ten months starting in August 2020 and end by April 2021. See the Gantt chart in the appendix.

Clinicians will be invited to participate in the study as part of a (online) seminar on palliative care by the CI or through an invitation email sent to their hospice medical director (see section 12.3). Seminar participants will receive information about the study before the seminar and will be invited to complete the online questionnaire in preparation for the seminar. The CI will make it clear that delegates at the seminar are under no obligation to complete the questionnaire.

Participants will be provided with a link to the study website and will complete all assessments online. The website will provide information regarding the study and a link to a PIS. Participants will be asked to tick check boxes to indicate that they are giving informed consent. After filling in the demographics section, eligible participants will be considered to be enrolled and a participant ID will be assigned. Next, participants will be randomly allocated to one of the two study groups. This will be performed through the web-based system, using a pre-generated blocked randomisation list.

Participants will be given tailored instructions, shown a practice vignette and will then be able to start the decision tasks and to provide estimates of the probability of patients surviving two weeks. Participants will be presented with five vignettes. Vignettes will be presented in random order to prevent order effects.

There will be no time limit for completion, so that each participant will be able to consider their responses. Participants will be given the opportunity to log out and return to the same place at a more convenient time. Participants will not be able to move on to the next page if required information is missing or is in an incorrect format (e.g. incorrect email format). The online environment will be piloted by the study team in close collaboration with the study statistician who will review the data being collected before, during, and at the start of the recruitment phase to ensure data integrity.

After completing the series of vignettes, participants will be shown a debrief page to remind the participant what the results will be used for and they will be able to download a certificate of participation. Participants will be asked if they wish to receive a summary of the results at the end of the study and whether they would be willing to be approached for subsequent studies.

Responses collected through the website up until the scheduled seminar will be added to a spreadsheet to provide the attendees with preliminary study findings during the presentation.

12 Selection of Participants

12.1 Inclusion criteria

- 1 Clinicians working in an adult palliative care service.
- 2 Willing and able to provide written informed consent.

12.2 Exclusion criteria

Participants who do not meet the inclusion criteria will be excluded

12.3 Recruitment

In both study arms, before participants complete the vignettes, they will be asked to complete a brief demographic section. Questions in this section will be used to assess the participant's eligibility for the study (i.e. are they a clinician working in palliative care for adults) as well as to describe the study population and conduct analyses of associations between judges' characteristics and their integration of advice.

12.3.1 Arm A (recruited at (online) seminars)

Clinicians will be recruited at (online) seminars where the CI is scheduled to give presentations on prognostication. The study will be presented before the seminar and attendees will be invited to fill

in the online questionnaire in preparation for the seminar. The CI will stress that participation in the study is voluntary. The study can be completed by international clinicians attending the (online) seminars.

12.3.2 Arm B (recruited online)

We will recruit clinicians to complete the online survey in the time period from August 2020 to April 2021, and we will identify eligible clinicians in several ways. The Hospice UK website includes a database listing adult and children's hospice care providers in the UK (<https://www.hospiceuk.org/about-hospice-care/find-a-hospice>). The database includes 310 hospices, of which 47 hospices have the word 'children' in their name. We will start by approaching a small number of the remaining 263 hospices on the list to explore the ease of recruitment for this study. We will not recruit from NHS services. In a first wave of recruitment, we will approach the nine Marie Curie hospices in the UK (Belfast, Bradford, Cardiff and the Vale, Edinburgh, Glasgow, Hampstead, Liverpool, Newcastle, and West Midlands), as these hospices may be more inclined to participate because of their link with Marie Curie. We will approach additional hospices as needed until we reach our lower limit for our sample size (see more in section 16.1 Sample size calculation). We will make individual contact with each hospice to inform them about the study, which could include approaching the medical director, head of nursing or matron, and/or the education and research lead. We will initially approach hospices via email and then follow up with a phone call, we will offer that the research team should come and present the study at their unit. If the hospice agrees to participate in the study, we will forward the template for the invitation email to be circulated to all doctors and nurses working in the hospice.

If necessary, we will use additional recruitment strategies, including Marie Curie Palliative Care Research Department's social media platform or newsletters, where interested clinicians will be able to contact the research team to participate in the study.

12.4 Informed consent

Participants will consent to complete the decision tasks, to have their data collected, stored and processed, to receive a results summary, and to be contacted by the research team to be prompted to complete the study.

Participants will receive information about the aims, methods, anticipated benefits and potential hazards of the study in the invitation email, on the study website and in the PIS. The PIS will be available to download from the study website. This information includes an explanation that participants are under no obligation to enter the study and that they can withdraw at any time during the study, without having to give a reason. It also includes a transparency message to inform participants how we will use their information.

On completion, a debrief page will be provided to remind the participant what the results will be used for. Contact details will be provided on the introduction and debrief pages should participants have any questions or issues they wish to follow up.

Informed consent will be obtained via checkboxes before starting the study assessments. The checkboxes will be to confirm that the participant is willing:

- 1 To participate.
- 2 To acknowledge the results will be used in future publications and research.
- 3 To provide an email address in order to enable participants to log out and return, and for the research team to send reminder emails, send feedback and approach them about future research, if desired.

12.5 Participant withdrawal

A participant may be withdrawn from the study whenever continued participation is no longer in the participant's best interests, but the reasons for doing so must be recorded. Reasons for discontinuing the study may include:

- 1 Participants withdrawing consent
- 2 Persistent non-compliance to protocol requirements

The decision to withdraw a participant from the study will be recorded in the study database. If a participant explicitly states they do not wish to contribute further data to the study their decision will be respected and recorded in the study database.

Throughout the study, the research team will monitor and review the responses given by the participants, and the time taken by each participant to complete the online decision tasks; in order to assess for compliance with the protocol. Participants may be excluded from the analysis if their response record strongly suggests that they did not comply with the study protocol (e.g. all vignettes answered too speedily or with the same response).

13 Recording and reporting of adverse events

This is a very low risk study. Clinicians will be asked to review ~~either one or~~ five vignettes and will receive advice from an advisor. Clinicians will be familiar with the type of information provided. Clear instructions and appropriate debrief will be provided. For these reasons, there are no expected adverse events of our study.

13.1 Notification of reportable protocol violations

A reportable protocol violation is a breach which is likely to effect to a significant degree:

- (a) the safety or physical or mental integrity of the participants of the study; or
- (b) the scientific value of the study.

The sponsor will be notified immediately of any case where the above definition applies during the study conduct phase.

14 Data management

14.1 Confidentiality

All data will be handled in accordance with the General Data Protection Regulation. Participants will be asked for their email address as well as being assigned a participant ID. The purpose of this is to:

- Enable the participant to log out and back in to the study website to continue the series of vignettes
- Contact participants with a reminder email if the participant should not complete the series of vignettes. One reminder email will be sent, one week after starting the study/the last website visit (Arm B only)
- Populate the certificate of participation at the end of the study
- Send feedback at the end of the study
- Contact participants regarding future studies

The participants will not be asked for any other personal identifiable information.

15 Data handling

In the study, demographic data and estimates of probabilities obtained through decision tasks will be collected from professionals in accordance with the PIS and participants' informed consent.

Data obtained from the study will be kept on a web-based database on UCL servers, which is encrypted and password protected. The database will be accessible only to approved members of the research team by limiting access to the intranet to their IP addresses. Once online data collection is completed, the research team at Marie Curie Palliative Care Research Department will download the data from the website for statistical analysis at UCL. UCL will act as the data controller.

This database will be pseudonymised as only the participant ID will be referenced, but a separate database linking email addresses with participant ID numbers (but not with other study data) will be kept in a separate location on UCL servers. Email addresses will be encrypted in the database with the decryption key stored in a separate location. The only member of the study team who will have access to this database is Dr Christopher Tomlinson. These data will only be used if requested by relevant authorities, such as to demonstrate the authenticity of the data. The copy of the final databases including email addresses will be retained until three years after publication of the last paper arising from the study, or no longer than five years from the end of data collection.

A separate database of email addresses will be kept for those participants who have indicated that they are willing to be approached for future research.

A UCL email account will be set up for members of the study team to contact participants. Emails held in this account will include participants' email addresses but not their participant ID. These data will be retained until three years after publication of the last paper arising from the study, or no longer than five years from the end of data collection.

Procedures for data handling will be explained clearly in the PIS and informed consent will be sought.

The research team at Marie Curie Palliative Care Research Department will process, store and dispose of all data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 1998, the GDPR, and any amendments thereto. Data will be stored on password protected, access-restricted, shared drives (S:Drive) on UCL servers. The S:Drives are maintained by UCL and routinely backed up.

Data (suitably anonymised) may be shared with other research groups if a reasonable request is submitted to and agreed by the CI.

16 Statistical Considerations

16.1 Sample size calculation

We aim at recruiting between 100-200 clinicians within the 10 month time period of recruitment (August 2020-April 2021). This will be sufficient to address the objectives of the study. We will stop recruiting and close down the website when we have accrued 300 respondents with complete data within the recruitment period (before April 2021).

We want to compare the means of the weighting of advice (WOA) of the two groups, (the group receiving advice labelled as coming from an algorithm and the group receiving advice labelled as coming from a clinician), with a confidence interval (CI) of 95%. Based on calculations from a similar study by Logg et al. (2019) we expect the standard deviation (SD) to be between 0.3 and 0.4. This will give a width of the CI between 0.17 and 0.31, depending on the sample size and the SD (see the table below). These numbers are based on and calculated from the guidelines by Machin et al. (2018). This means that a sample size between 100-200 respondents should be sufficient to detect a significant difference between the mean WOAs of the two groups if the mean difference is greater than 0.085 to 0.22.

Table 1: The width of the confidence interval varying by sample size and SDs

Sample Size	Expected SD for mean diff in WOA	
	$\sigma = 0.3$	$\sigma = 0.4$
50	0.33	0.44
100	0.24	0.31
150	0.19	0.26
200	0.17	0.22
250	0.15	0.20
300	0.14	0.18

The calculations above are sufficient to address the primary objective of the study which is to assess the level to which clinicians incorporate advice received from other clinicians or an algorithm into their estimates of the prognosis of palliative care patients.

The online survey consists of five vignettes. Increasing the number of vignettes would increase generalisability of the study but would add to the study burden for the participants and increase the risk that the study would not be completed by respondents. It was considered that five vignettes was a suitable balance between generalisability and study burden.

16.2 Statistical analysis

A fully detailed statistical analysis plan will be drawn up in a separate document prior to data analysis. Participants who do not complete the required number of vignettes or violate the protocol (e.g. providing the same estimate for every vignette) will be removed from the analysis.

16.2.1 Summary of baseline data and flow of participants

Baseline demographic characteristics (gender, age, work environment, role, seniority, expertise) will be summarised by group and overall. As a result of the randomisation process, we expect them to be balanced across groups. Categorical data will be described using numbers and percentages. Continuous data will either be described with mean and standard deviation, or median and interquartile range, pending the distribution. We will produce a CONSORT flow diagram of all participants (<http://www.consort-statement.org/>).

16.2.2 Primary outcome analysis

The primary outcome will be clinicians' estimates of the probability of a patient surviving for two weeks. In order to assess the level to which participants incorporate the advice into their final estimates of the probability of survival, the WOA is calculated for each participant for each vignette(s). This is done by comparing their final estimate against the initial estimate and the advice provided. The final estimate of probability of surviving two weeks can be represented as a weighted combination of the participant's initial estimate and the advice received, with the weights being proportional to the extent of the shift towards (away from) the advice. WOA will be defined as $= |f - i|/|a - i|$, where 'i', 'f', and 'a' stand for initial, final, and advice, respectively (Yaniv, 2004a).

If a participant decides to adhere completely to his or her initial estimate (100% discounting of the advice), the weight of the advice will be 0. If the participant decides to shift completely to the advice then the weight of advice will be 1.0 (0% discounting). Intermediate weights indicate that positive weights were assigned to the initial estimate and the advice (partial discounting) (Yaniv and Kleinberger, 2000a).

We will then use regression analyses to compare the means of the WOA scores for the two arms, the algorithm arm and the clinicians' arm.

16.2.3 Secondary outcome analysis

The secondary outcome will be clinicians' estimates of the probability of a patient surviving for two weeks. We will perform regression analyses to explore any associations between participants' weighting policies and characteristics of the participants (gender, age, work environment, role, seniority, expertise, confidence).

We want to explore any associations between participants' weighting policies and the advice itself (e.g. the strength of the advice) as well. Participants will receive five pieces of advice from the PiPS data. They will receive advice given with high confidence from 85% and upwards (i.e. the patient has 90% probability of surviving the next 14 days), with lower confidence (i.e. 75% probability of survival) and one where the advice is equivocal (i.e. 50% probability of survival). Multilevel regression analyses will be used to take into account multiple vignettes are completed by each participant.

17 Record keeping and archiving

At the end of the study, all essential documentation will be archived securely by the CI for a minimum of 20 years from the declaration of end of study.

Essential documents are those which enable both the conduct of the study and the quality of the data produced to be evaluated and show whether the site complied with all applicable regulatory requirements.

The sponsor will notify the research team when study documentation can be archived. All archived documents must continue to be available for inspection by appropriate authorities upon request.

18 Study Management Group (SMG)

The SMG will be formed of the CI (Patrick Stone) and all of the personnel listed in section 1. The group will meet regularly and will review recruitment figures and substantial amendments to the protocol prior to submission to the REC.

19 Ethics

The sponsor will ensure that the study protocol, PIS, consent form and submitted supporting documents have been approved by the appropriate Research Ethics Committee, prior to any participant recruitment. The protocol, all other supporting documents including and agreed amendments, will be documented and submitted for ethical and regulatory approval as required. Amendments will not be implemented prior to receipt of the required approval(s).

An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. The CI or delegate will prepare the APR.

Within 90 days after the end of the study, the CI/Sponsor will ensure that the main REC is notified that the study has finished. If the study is terminated prematurely, those reports will be made within 15 days after the end of the study.

The CI or delegate will supply the Sponsor with a summary report of the study, which will then be submitted to the REC within 1 year after the end of the study.

20 Patient and public involvement (PPI)

This study does not involve patients or members of the public directly. The participants are all clinicians working in palliative care. The CI (Patrick Stone) is a Palliative Care Consultant and a member of the Study Management Group. As such, he has been involved in the design of the research and will be involved in management of the research, undertaking the research, analysis of results and dissemination of findings. In addition, we will ask a small number of other palliative care clinicians to review the recruitment materials and pilot the study website.

21 Monitoring

The sponsor will determine the appropriate level and nature of monitoring required for the study. Risk will be assessed on an ongoing basis and adjustments made accordingly.

The degree of monitoring will be proportionate to the risks associated with the study.

22 Finance

This study is funded by the Marie Curie Chair's grant and the Marie Curie I-CAN-CARE Programme grant (MCCC-FPO-16-U). There are no financial interests by the CI, PI, or study management members.

23 Insurance

University College London holds insurance against claims from participants for injury caused by their participation in the study. Participants may be able to claim compensation if they can prove that UCL has been negligent.

Participants may also be able to claim compensation for injury caused by participation in this study without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

24 Publication policy

Study results will be published in peer-reviewed, indexed, journals using an open access format, and the results will be presented at academic conferences. Furthermore, we will also publish a PhD thesis. Authorship eligibility will be in accordance with The International Committee of Medical Journal Editors. All proposed publications will adhere to UCL publication policy. We will also publicise our findings on the Marie Curie website.

25 Intellectual property

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party's rights.

All intellectual property rights and know-how in the protocol and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used by each participating site, shall belong to UCLH. Each participating site agrees that by giving approval to conduct the study at its respective site, it is also agreeing to effectively assign all such intellectual property rights ("IPR") to UCL and to disclose all such know-how to UCL.

Each participating site agrees to, at the request and expense of UCL execute all such documents and do all acts necessary to fully vest the IPR in UCL.

Nothing in this section shall be construed so as to prevent or hinder the participating site from using know-how gained during the performance of the study in the furtherance of its normal activities of providing or commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of UCL. This does not permit the disclosure of any of the results of the study, all of which remain confidential.

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27 Appendix 1 - Schedule of assessments

28 Appendix 2 – Sample vignette

Please note that this is an example vignette and that the actual vignettes used may vary somewhat from this example in style and content.

Example Vignette 1

Mr Smith has recently been admitted to the inpatient unit at St Swithin's hospice. He has two primary cancers - colorectal (lower GI primary) and oropharyngeal (head and neck primary). He has metastases to his lungs and bones and is currently undergoing palliative radiotherapy.

He is 63 years old and has full capacity. On assessment, there is no evidence of ascites or peripheral oedema. He reports that his eating and drinking are significantly reduced and that he has lost weight, but there is no dysphagia. He feels fatigued and is unable to do jobs around the house that he used to be able to do. For the most part, he is still independent in self-care tasks. As he talks about his symptoms, it is clear that he is experiencing shortness of breath. His pulse rate is 88 (beats/min).

His blood tests show the following:

WBC:	11x10 ⁹ /L	(normal range 4.0 to 11.0)
Lymphocyte:	0x10 ⁹ /L	(normal range 1.0 to 4.0)
Neutrophil:	10x10 ⁹ /L	(normal range 1.7 to 8.0)
Platelet:	273x10 ⁹ /L	(normal range 150 to 450)
Urea:	7mmol/L	(normal range 2.5 to 7.8)
Albumin:	26g/L	(normal range 35 to 50)
Alkaline Phosphatase:	105U/L	(normal range 30 to 130)
Alanine Transaminase:	12U/L	(normal range 0 to 52)
CRP:	288mg/L	(normal range 0.0 to 10.0)
LDH:	1183U/L	(normal range 140 to 280)

PPS Level	Ambulation	Activity & Evidence of Disease	Self-Care	Intake	Conscious Level
100%	Full	Normal activity & work No evidence of disease	Full	Normal	Full
90%	Full	Normal activity & work Some evidence of disease	Full	Normal	Full
80%	Full	Normal activity <i>with</i> Effort Some evidence of disease	Full	Normal or reduced	Full
70%	Reduced	Unable Normal Job/Work Significant disease	Full	Normal or reduced	Full
60%	Reduced	Unable hobby/house work Significant disease	Occasional assistance necessary	Normal or reduced	Full or Confusion
50%	Mainly Sit/Lie	Unable to do any work Extensive disease	Considerable assistance required	Normal or reduced	Full or Confusion
40%	Mainly in Bed	Unable to do most activity Extensive disease	Mainly assistance	Normal or reduced	Full or Drowsy +/- Confusion
30%	Totally Bed Bound	Unable to do any activity Extensive disease	Total Care	Normal or reduced	Full or Drowsy +/- Confusion
20%	Totally Bed Bound	Unable to do any activity Extensive disease	Total Care	Minimal to sips	Full or Drowsy +/- Confusion
10%	Totally Bed Bound	Unable to do any activity Extensive disease	Total Care	Mouth care only	Drowsy or Coma +/- Confusion
0%	Death	-	-	-	-

What do you think the probability is that this patient will survive the next two weeks?

.....%

Please write your answer as a percentage in the box to the right

(Scale: 0-100. Where 0% means certain to die and 100% means certain to survive)

FOR THE CLINICIAN ADVICE:

A palliative care [nurse/doctor] estimated (based on the provided patient information) that the probability this patient will survive the next two weeks was:

.....%

FOR THE ALGORITHM ADVICE:

The PiPS-B14 estimated (based on the provided patient information) that the probability this patient will survive the next two weeks was:

.....%

What is your final estimate of the probability this patient will survive the next two weeks?

.....%