why he/she was chosen, what the *ImproveCare* study is about and what taking

part involves. Please take the time to read the following information and discuss it with others if you wish.

Thank you in anticipation for considering whether your relative should take part. We very much hope you will feel able to contribute. Your participation is important and will help to shape better care for patients and families.

Contact details of the Lead Researcher:

Dr Jonathan Koffman

Senior Lecturer in Palliative Care

Cicely Saunders Institute

Department of Palliative Care, Policy and Rehabilitation

King’s College London Bessemer Road

London SE5 9PJ

Telephone: 0207 848 5516/55909

Email: jonathan.koffman@kcl.ac.uk

Website: www.csi.kcl.ac.uk/

*ImproveCare:*

*The management of clinical uncertainty in hospital settings*

INFORMATION LEAFLET (CONTROL WARD)

We are inviting your relative, companion or person you know well to take part in a research project called: *ImproveCare - The management of clinical uncertainty in hospital settings*

We are very interested in the health and wellbeing of patients cared for in hospital settings who situations are clinically uncertain . Typically these patients and their families have not been communicated with adequately about their situation and have not been involved in making important decisions about their current or future care. This is not good for them or their family members and can lead to distress and dissatisfaction. We want to understand how health care professionals can better support and care for patients and their families in this situation better. The *ImproveCare* study is undertaken by King’s College London and the University of Cambridge and is funded by the National Institute for Health Research.

We understand that your relative or person you know well may find it difficult to make decisions about participation because of memory problems. However it is really important that we find out about their needs as we believe they can make a valuable contribution to improving care.

We would be grateful for your opinion as to whether you think they would wish to take part in this research. We are not asking you to provide a personal view on the research topic or consent on behalf of the person. We are asking you to consider, to the best of your knowledge, if they would not object to taking part in this study, and that their participation would not cause any undue distress by participation.

Before you decide whether your relative or person you know well should to take part, it is important for you to understand why we are asking you to do this,

Dr Jonathan Koffman

Principle Investigator

ImproveCare

IRAS Project ID: 212178/REC reference 16/LO/2010 Consultee PIS control ward v2.0 06.12.16

Why are we asking your opinion?

The research team are very experienced in working with people who are very unwell. We also understand that some individuals may have difficulty in fully understanding what taking part in this research study would involve. In other cases a person who consented to take part in an earlier stage of the study may now be having memory problems and will be unable to fully understand the implications of continuing in the study. In all cases such as these we have a legal duty to seek advice from another individual known as a ‘*consultee*’ who will act in the person’s best interest.

Why was I chosen to take part in the research as a consultee?

A consultee may be ‘personal’ or ‘nominated’. A personal consultee is usually a spouse, partner, close relative or friend and may have been nominated by the person taking part in the research at a time when they were able to make such a decision. A nominated consultee is usually an individual who is a paid carer or healthcare professional, who has knowledge of the person but no connection with the research study. An individual would be approached to be a nominated consultee in situations where:

* There are no relatives or close friends willing and able to act as consultee
* Family or friends live a long distance away and are not in frequent contact with the person

Please understand you are under no obligation to act as a consultee and you may feel that someone else is better placed to take this role. If this is the case then let us know.

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What should I do if I do not want to take part?

If you do not want to take part in the study then please indicate this on the REPLY FORM enclosed and return it to the researchers in the FREEPOST envelope. Alternatively phone Dr Jonathan Koffman on 020 7848 5590.

Who can I contact if I have any concerns?

If you have any concerns or complaints about the ImproveCare study you can telephone the research team on 0207 848 5516/55909, jonathan.koffman@kcl.ac.uk

and ask to speak directly to the lead researcher, Dr Jonathan Koffman .

Alternatively, if you would like to write to the person in charge, please send your letter to:

Dr Jonathan Koffman, Senior Lecturer in Palliative Care Cicely Saunders Institute

Department of Palliative Care, Policy and Rehabilitation

King’s College London

Bessemer Road, London SE5 9PJ

Telephone: 0207 848 5516/55909

Email: jonathan.koffman @kcl.ac.uk

We will reply to your concerns in writing. If you prefer to be contacted by telephone please enclose your telephone number.

Lastly…

We thank you for taking the time to consider participating in the study.

Little research has been done on how best to support patients who in hospital settings whose situations are clinically uncertain and who may not recover from their illness. This study’s findings will contribute to developing better hospital services to improve the way care is delivered, and how to better support their families at this important moment in their lives

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Who is organising and funding this study?

The ImproveCare study is a joint project between King’s College London and the University of Cambridge. The study is funded by the National Institute for Heath Technology Assessment (Department of Health, England). The study has been reviewed by an independent group of international scientists and received ethical approval from London Camden & King’s Cross Research Ethics Committee.

To guide and monitor the study the researchers work with two groups:

* A Steering Group comprising representatives from health and social care and academics
* A Lay Project Advisory group comprising older people, carers and voluntary sector representatives

How can I give approval for my relative to take part?

If you would like to give approval for your relative, companion or person you know well to take part, or if you would like to receive more information, we ask you to phone Dr Jonathan Koffman on 020 7848 5590. .

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| What can I do if I’m unsure about giving approval for my relative to take part? |

More details about the ImproveCare study are given in the remainder of this information leaflet. If this does not answer all of your questions then please contact the research team on 0207 848 5516/55909, jonathan.koffman@kcl.ac.uk for more information and to answer any questions you may have.

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What is the purpose of the ImproveCare study?

We are interested in patients who are being cared for in hospital settings, who are experiencing situations of clinical uncertainty. We want to understand how to better support patient like this and their families during this important time and how best to plan future care. We are trying to understand if patients who are experiencing situations of clinical uncertainty could benefit being involved in important decisions about their current and future care. Health care professionals on this ward have been trained to identify patients in this position how to better care for them and how to involve them and their families realise their wishes for future care.

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| What will happen if I give approval to take part in the study? |

Agreeing for your relative or person you know well to continue to take part in the ImproveCare study would mean:

* We would ask to continue to use and store any data or information already collected from your relative or person you know well by the ImproveCare.
* Our researchers may ask to arrange to visit and interview a family member or carer who knows the person well to ask about how the challenges and difficulties they have experienced and change over time. We would do this by completing a series of short questionnaires with the family member or carer.

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What about my relative’s usual medical care?

Taking part in this study will not affect usual medical care in any way. If treatment is currently received this will continue unchanged. This study does not involve taking any extra treatments (tablets/medication). We would like to keep people’s own doctor informed about their involvement in this study. The nurse will ask your permission to inform their GP about their continued participation in this study.

What are the possible benefits of taking part?

While there are no immediate personal benefits to individuals taking part in this study, we believe the information gained will improve our understanding of the health needs of other patients like them and their families.

What are the possible disadvantages of taking part?

It is very unlikely that people will experience any harm by taking part in this study. If you do find that taking part causes distress or concern, you are free to withdraw your approval at any time.

What if I change my mind and want to withdraw

If you feel that the person who you have given approval to participate in the study should now be withdrawn due to distress, any change in circumstance, or where you feel it is no longer appropriate to continue with the research then you are free to withdraw your approval and them from the whole or any part of the study at anytime without having to give a reason. You are also free to request that ALL information is destroyed by the study team. Such a withdrawal would prevent information about people from contributing to further analyses, but it would not be possible to remove data from analyses that have already been done.

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How will my relative’s information be kept confidential?

The ImproveCare study has put a number of procedures in place to protect the confidentiality of participants in full accordance with the Data Protection Act. These include:

1. Keeping information that might identify a participant (such as name and address) separate from other information about the person.
2. Keeping personal information in locked cabinets in the research team’s locked office and only storing personal information on secure King’s College London computers. NO personal data is stored on King’s College London computers.
3. Access to personal information is restricted within the research team, and all staff sign confidentiality agreements as part of their employment contracts.

Who will be able to use my relative’s information?

Personal information about participants is only accessible to researchers who have relevant scientific and ethical approval to view the data for purposes of the research study.

Data collected during the study which is anonymous, may be looked at by individuals from King’s College London and the University of Cambridge .

The study’s findings will published in scientific journals and reports to widen patient benefit. NO personal identifying details are included in any publications or reports.

The findings are made available to the Department of Health to improve future care. The findings will be available to participants and publicised through the project website at http://www.csi.kcl.ac.uk/ImproveCare

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