Participant Information Sheet

Project title: One Million Global catheters: PIVC worldwide prevalence study (OMG study)

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Principal Investigator for *(insert name of hospital)* *: (Insert name of hospital chief investigator)*

For further information about the study, please contact the Principal Investigator or

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Please read the following information about the study. If you would like to participate in the study, please go to the website www.omgpivc.org to register your intent to participate.

Why is the research being conducted?

The One Million Global (OMG) peripheral intravenous catheters (PIVC) study is an international prevalence investigation specifically targeting assessment and management of PIVCs across more than 50 countries. This study will be the largest of its kind ever attempted and will provide previously unavailable data on the prevalence and management of PIVCs including the average dwell of a PIVC and identifying risk factors contributing to PIVC failure. Such valuable information can potentially save millions of unnecessary PIVC re-insertions and reduce health care costs substantially, particularly in developing nations. The study will also provide valuable information on whether organisations utilise best practice guidelines for care and management of such devices. Overall, the evidence gained from this research will be easily translatable for informing clinical practice and health care policy and to improve patient outcomes related to PIVC care and management.

What you will be asked to do

Every participating organisation will be asked to complete an OMG Study Site Information Form. This form asks questions about the following:

- Who is responsible for inserting IVs at your organisation?
- Which, if any, guidelines/policy does your organisation follow for PIVC insertion and care?
- PIVC make/brands in use at your organisation
- PIVC dressings in use at your organisation
- Cleaning solutions in use for PIVC insertion and dressing changes at your organisation

On a given day in 2014, all participating organisations will be asked to conduct one assessment of all patients (both adults and paediatrics) with a PIVC. You will be asked to complete an OMG study Data Collection Form for each patient with a PIVC. To do this, you will assess the patient's IV site. Information to be collected will include:

- Age and gender of patient
- Type of health condition: Medical/surgical/oncology/critical care
- Date and time of PIVC insertion.
- Cannula type/brand (if known)
- Who inserted the PIVC (if known)

- Where was the PIVC inserted (if known)
- Site/position of PIVC insertion
- Cannula gauge/size
- IV connectors in use
- PIVC site assessment
- IV securement method
- IV dressing type
- IV dressing assessment
- IV orders today
- IV fluids today
- IV medications today

All data will be de-identified and no physical interventions are planned within the study, however, patients who show signs of intravascular phlebitis or infection will have the treating team notified regarding the patient's condition.

Aims of the study

This study has several aims:

1. To identify and compare the prevalence of PIVCs in hospital populations worldwide
2. To evaluate the prevalence of PIVC complications (extravasation, phlebitis, occlusion, thrombosis) in patients with PIVCs worldwide
3. To benchmark international use of PIVCs, including cannula characteristics such as type and size, anatomical placement along with types of intravenous fluids and medications infused.
4. To identify risk factors associated with PIVC failure
5. To identify the prevalence of redundant (unused or unneeded) catheters in situ
6. To identify the current practice in PIVC dressing use and management
7. To identify the current practices in PIVC securement
8. To compare local hospital policies on PIVC insertion and management with international guidelines
9. To encourage future international collaborative research among vascular access nurses and physicians

Selection of participants

It is expected that all patients with a PIVC in situ in every participating organisation on the day of the prevalence study will their PIVC site assessed. The person assessing the PIVC site will explain to the patient that they are assessing the patient's PIVC site for a research study and collecting data about the PIVC site. The assessor should assure the patient that no personal or medical information about the patient will be collected. The patient will be asked for their verbal consent before the PIVC site is assessed and data is collected. Participation is completely voluntary. If patients do not give verbal consent to have their PIVC site assessed, no data will be collected.

Expected benefits of the research

This study is expected to provide extensive information about the standards of PIVC management in many different countries. This study will have international significance in documenting the prevalence of PIVC use and its complications, such as phlebitis, worldwide. The information gained from this study will be invaluable in directing future policy and budget initiatives in the healthcare sector and provide clinicians, administrators and manufacturers with vital evidence that can be translated into practice. The collaborative nature of the study will also assist in building networking opportunities and research capacity among healthcare workers in diverse environments, which will facilitate the beneficial development of further research opportunities in the future.

As this assessment of the PIVC site will be in addition to routine IV assessment and will be conducted by someone with extensive experience in IV assessment and management, it is possible that the assessor might identify early signs of PIVC concerns, such as phlebitis or infiltration. In this case, the assessor will notify the treating team. Therefore, there may be a possible benefit to the patient with a PIVC in situ.

Risks of the research

There are no foreseeable risks of the research. The PIVC site will be assessed as per usual standard IV practice. No interventions are planned as part of this research.

Confidentiality

Each organisation will be given a unique identification code. No patient personal, demographic or medical condition details will be collected as part of this research. No data will be able to be tracked back to any patient.

Storage of data

Stringent processes will be used to ensure that the data of organisations participating in the study are kept confidential. Details about PIVC sites will either be entered in LimeSurvey, a secure survey database housed at Griffith University. Participating sites that do not have access to the website will be able to record data on paper and email/fax/post the data collection forms to the researchers at Griffith University. Paper data forms will be recorded on a paper file and stored in a locked filing cabinet whose key will only be accessible by the principal researchers. Computer data will be stored on a secure computer located in the Research Room at the Griffith University School of Nursing and Midwifery, Brisbane, Australia, accessible only by the principal researchers. Information will be stored for a mandatory period of seven years in accordance with the Griffith University research policy.

Reporting of results

The results of this prevalence study will be published in peer-reviewed journals and presented at national and international conferences. No data identifying any participating organisations will be disclosed.

Ethical approval for the study

Human research ethics approval has been gained from the Griffith University Health Research Ethics Committee. A copy of this approval will be sent to all participating organisations.

If you have concerns about the ethical conduct of this study, please contact the Manager, Research Ethics, Office for Research, Bray Centre, Nathan Campus, Griffith University, Brisbane, Australia (ph +61 7 3755 5585 or research-ethics@griffith.edu.au).

If you have any other questions about this study, please contact the Principal Investigator Evan Alexandrou for further information. Email: omgstudy-group@griffith.edu.au