格里菲斯大学

全球一百万置留针

国际外周静脉置留针现况课题研究

Participant Information Sheet

参与者信息书

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

项目名称： 全球一百万：国际外周静脉置留针现况课题研究（OMG 课题）

Principal Chief Investigator: Mr Evan Alexandrou, Lecturer, School of Nursing and Midwifery, University of Western Sydney, Australia 先生， 澳洲 西悉尼大学 助产和护理学院 讲师

Principal Investigator 首席研究员 Name 名称 _____ Hospital 医院 _____

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

如需更多本课题相关信息资料，请联系本课题项目负责人：

Email 电子邮箱: omgstudy-group@griffith.edu.au

Please read the following information about the study. If you would like to participate in the study, please click on the website link to register your intent to participate.

请仔细阅读以下关于本课题的信息资料。如果您希望成为本课题的参与者，请点击网页连接登记成为参与者

Why is the research being conducted?

为何要实施本课题研究

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.

全球一百万（OMG）外周静脉留置针（PIVC）课题是一项在全球超过 50 个国家进行的专门针对关于外周静脉留置针评价与管理 的国际性现况调查研究。本课题将会成为同类型课题中规模最大范围最广的研究课题，并且会提供以前不曾采集的关于外周静脉留置针管理和现状的数据，其中包括外周静脉留置针的平均驻留时间和识别外周静脉留置针失败的危险因素。这将为临床提供非常有价值的信息资料，可以避免数百万例潜在的不必要的外周静脉留置针的反复穿刺，同时很大程度的减少医疗费用，尤其是在

发展中国家。本课题还将会提供关于各机构是否使用最佳的外周静脉留置针护理和管理的指导方针的有价值信息资料。总体而言，本课题研究所得将对临床外周静脉留置针的实践操作, 护理政策制定以及病人预期结果提供非常有意义的依据.

What you will be asked to do
您需要做些什么

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

每个参与的机构将会被要求完成一份 OMG 课题信息表格。此表格将会询问以下问题：

- Who is responsible for inserting IVs at your organisation?
  贵机构由谁负责外周静脉留置针穿刺
- Which, if any, guidelines/policy does your organisation follow for PIVC insertion and care?
  贵机构是否有外周静脉置留针穿刺或护理的政策/指导原则
- PIVC make/brands in use at your organisation
  贵机构所使用的外周静脉置留针的生产商/品牌
- PIVC dressings in use at your organisation
  贵机构所使用的外周静脉置留针的敷料
- Cleaning solutions in use for PIVC insertion and dressing changes at your organisation
  贵机构所使用在外周静脉置留针穿刺和更换敷料的清洁溶液

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:

在 2014 年指定的日期里，所有参与本课题的机构将会被要求为该机构的所有患者（包括成人和儿童）实施一份有关外周静脉留置针的评估。您将会被要求为每个带有外周静脉留置针的患者完成一份 OMG 课题数据采集表格。为此，您将需要对患者的外周静脉留置针部位进行评估。采集相关的课题数据包括：

- Age and gender of patient
  患者的性别与年龄
- Type of health condition 患病的种类:
  Medical/surgical/oncology/critical care
  内科/外科/肿瘤科/病危护理科
- Date and time of PIVC insertion.
  外周静脉置留针穿刺的日期与时间
- Cannula type/brand (if known)
  置留针的种类/品牌（如果知晓）
- Who inserted the PIVC (if known)
  外周静脉留置针穿刺人员（如果知晓）
- Where was the PIVC inserted (if known)
  外周静脉留置针穿刺地点（如果知晓）
- Site/position of PIVC insertion
  外周静脉留置针穿刺的部位/位置
- Cannula gauge/size
  留置针的型号
- IV connectors in use
  所使用的留置针连接器
- PIVC site assessment
  外周静脉留置针穿刺部位评价
- IV securement method
  所使用的留置针固定方法
- IV dressing type
  留置针敷料种类
- IV dressing assessment
  留置针敷料评价
- IV orders today
  当日静脉用药医嘱
- IV fluids today
  当日静脉输液种类
- IV medications today
  当日静脉用药种类

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.

所有的数据将会被去除个人信息，本研究将不涉及身体干预措施，然而，如果患者出现静脉炎或感染的症状和体征，请联系患者的医疗团队讨论相关的情况。

Aims of the study
本课题研究目的

This study has several aims 本课题有以下数个研究目的:

1. To identify and compare the prevalence of PIVCs in hospital populations worldwide
   为识别和对比国际性住院人口的外周静脉置留针的现况
2. To evaluate the prevalence of PIVC complications (extravasation, phlebitis, occlusion, thrombosis) in patients with PIVCs worldwide
   为评估国际性带有留置针患者的外周静脉留置针并发症的发病率（外溢，静脉炎，导管堵塞，血栓）
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.
   为设置国际公共的外周静脉置留针的使用标准，包括留置针的特征，例如种类和尺寸，穿刺的人体部位，和静脉输液与用药的种类。
4. To identify risk factors associated with PIVC failure
   为识别外周静脉置留针失败的危险因素
5. To identify the prevalence of redundant (unused or unneeded) catheters in situ
   为识别冗余留置针的发生率（未使用的与不必要的）
6. To identify the current practice in PIVC dressing use and management
   为识别目前临床使用的外周静脉留置针敷料的使用与管理
7. To identify the current practices in PIVC securement
   为识别目前临床使用的外周静脉留置针的固定装置
8. To compare local hospital policies on PIVC insertion and management with international guidelines
   为了对比当地医院与国际上相关于外周静脉留置针穿刺和管理的指导原则与政策
9. To encourage future international collaborative research among vascular access nurses and physicians
   为了鼓励医生和护士未来关于血管通路课题研究的国际性合作

Selection of participants
参与者的入选标准

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.

在所指定的课题实施日期里，每所参与研究的机构里的所有带有外周静脉留置针的患者的穿刺部位将会被检查评估。评估员将会向患者解释正在进行一项关于评估留置针的课题研究. 该评估员必须向患者保证将不会采集任何和该患者个人隐私和医学资料有关的资料。在外周静脉留置针穿刺部位评估和采集数据前，必须得到患者的口头同意。参与者是完全自愿的。如果任何病人不愿给与穿刺部位评估的口头协议，此患者的数据将不会被采纳使用。

Expected benefits of the research
本课题的预期成果贡献

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.

本课题预期将提供全面而丰富的，多个国家的，有关外周静脉留置针管理标准的信息。本课题预计将在关于记录全球性的外周静脉留置针使用和其并发症(例如静脉炎) 的现况（患病率）方面，取得国际性的重要意义。从本课题中获取的宝贵的信息资料将会对对未来有无法估计的帮助，包括制订指导方针，提出医疗预算，和给临床医生，管理人员，生产厂商提供重要的论证并易于用在实践操作方面。本课题以合作为中心思想，致力于为不同环境的医疗工作者提供交流和科研机会，同时促进未来的课题研究良性有益发展。

由于本次课题为常规静脉评估外的额外检查评估，并且由一些拥有留置针评估和管理丰富经验的人员来实施，所以，评估员有可能识别出患者出现早期留置针并发症症状和体征，比如静脉炎和渗漏。在这种情况下，评估员需要联系患者的医疗团队。因此，可能有利于该携带留置针的患者。

Risks of the research
本课题的风险

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.

本课题不存在任何可预计的风险。参考常规静脉临床实践，外周静脉留置针穿刺部位将会被同等检查评估。本课题不包括计划任何医疗干预措施。

Confidentiality
隐私问题

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.

每个机构将会被给以一个独有的标识代码。本课题将不会采集任何关于患者的个人信息，人口统计信息，或患病信息。将不会有任何途径存在可以通过数据查回患者的个人隐私。

Storage of data
数据存储

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.

本课题将采取严格的流程为确保参与机构数据的隐私和保密性。所有和外周静脉留置针相关的详情都将被输入进 LimeSurvey，一个安置在格里斯菲大学的安全调查数据库。参与者的网站无法获得相关网站的访问权，以便记录文本数据和通过电邮/传真/邮递数据采集表格给格里斯菲大学的研究人员。

所有的文本数据表格都记录成档案并且保存在一个保密上锁的保险箱内，其钥匙只有负责课题研究员可以获取。电脑数据将会被存档在一部保密电脑内，该电脑将被保密上锁在澳大利亚，布里斯本，格里斯菲大学护理和助产学院的研究室内，并只有负责课题研究员可以访问使用。根据格里菲斯大学研究政策，所有的信息资料将被义务保存七年。

Reporting of results
结果报告

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.

本患病率课题研究的结果将会在同行评审的文献上发布，并会在国家级和国际性的会议上展示。不会有任何关于参与机构信息的数据被公开。

Ethical approval for the study
本课题的伦理审批

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

本课题的人类研究伦理审批经过了格里菲斯大学人类研究伦理委员会的同意。人类研究伦理审批书的复印件将会邮寄给所有的参与机构。

如果您对本课题的伦理实施有任何的疑问，请联系澳洲，布里斯本，格里斯菲大学，Nathan 校区，Bray 中心，研究中心，研究伦理部经理 (ph +61 7 3755 5585 or research-ethics@griffith.edu.au).

如果您对本课题有任何其他的疑问，请联系本课题项目负责人 Evan Alexandrou 先生索取更进一步的资料。电子邮箱 Email: omgstudy-group@griffith.edu.au