Determining post-operative morbidity and mortality following gynaecological oncology surgery: protocol for a multicentre, international, prospective cohort study (Global Gynaecological Oncology Surgical Outcomes Collaborative)

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### **ABSTRACT**

### **Background**

The Global Gynaecological Oncology Surgical Outcomes Collaborative aims to develop a network of gynaecological oncology surgeons, surgical departments and other interested parties that will have the long-term ability to collaborate on outcome studies. Presented is the protocol for the first collaborative study.

### **Primary objective**

To evaluate international variation in thirty-day post-operative morbidity and mortality following gynaecological oncology surgery between very high/high and medium/low human development index country settings.

### **Hypothesis**

There is no variation in post-operative morbidity and mortality following gynaecological oncology surgery between very high/high and medium/low human development index country settings.

### Study design

International, multi-centre, prospective cohort study. Patient data will be collected over a consecutive thirty-day period through gynaecological oncology multidisciplinary teams/tumour boards and clinics across different human development index country groups. All data is collected on a customised, secure, password protected, central REDCap database.

### Major inclusion/exclusion criteria

Inclusion criteria include women aged ≥18 years undergoing elective/emergency, curative/palliative surgery for primary/recurrent tubo-ovarian/peritoneal, endometrial, cervical, vulval, vaginal, gestational trophoblastic malignancies. Surgical modality may be open, minimal access (laparoscopic/robotic), or vaginal.

# **Primary endpoint**

Thirty-day post-operative morbidity and mortality defined as per Clavien-Dindo classification system.

# Sample size

1100 (550/arm).

## Estimated dates for completing accrual and presenting results

It is estimated recruitment will be completed by 2022 and results published by 2023.

# **Trial registration**

ClinicalTrials.gov registry: NCT04579861 (https://clinicaltrials.gov/ct2/show/NCT04579861).

### **PRECIS**

GO SOAR1 is a prospective study evaluating international variations in post-operative morbidity and mortality rates following gynaecological oncology surgery.

### **HIGHLIGHTS**

- The GO SOAR Collaborative aims to improve surgical outcomes through collaborative research.
- 2. The GO SOAR international database will help standardise surgical outcome reporting.
- GO SOAR1 evaluates international variations in post-op morbidity & mortality following gynae-oncology surgery.

#### **INTRODUCTION**

In 2018 globally, the prevalence, incidence and mortality of gynaecological oncology cancers (cervix, endometrial, tubo-ovarian, vulval, vaginal) were 25.18 per 100 000 (954 439 cases), 29.35 per 100 000 (1 309 165 cases) and 13.03 per 100 000 (609 377 cases), respectively. Gynaecological cancers collectively after breast cancer account for the second greatest disease burden amongst all female cancers and by the year 2040, incidence is set to rise by 69%. Annually, 45% of all individuals diagnosed with cancer undergo surgery with curative intent. This amounts to 589 124 cases per annum of gynaecological cancer surgery worldwide. Hence due to the current and growing disease burden of gynaecological malignancies, surgical care for gynaecological malignancies is an indispensable component of a functioning health system.<sup>1-4</sup> However surgery has historically had a disproportionately low profile in global health priorities at the World Health Organization due to the erroneous perception that it is a high cost intervention benefitting a small segment of society. The recent interest in surgical outcomes has been prompted by the recognition that conditions amenable to surgery such as gynaecological malignancies are important public health conditions, and that there are disparities in access to life saving and disability preventing surgeries particularly for rural and marginalised populations in medium/low human development index countries representing unmet surgical needs. The World Health Organization and the World Bank, have highlighted surgery as an important component for global health development.<sup>3</sup> However, surgical care requires coordination of skilled human resources, specialised supplies and infrastructure including multicentre, international collaborations for the purpose of research to inform international policies.<sup>4</sup> It is estimated that less than 25% of patients with cancer have access to safe, affordable, and timely surgery. Whilst death rates from cancer are decreasing in very high/high human development index countries, the opposite is true in medium/low human development index countries and up to 1.5% gross domestic product is lost because of cancer in some medium/low settings.5,6

Despite 45% of women with gynaecological malignancies receiving surgical care with curative intent, safety and quality of care remain poorly measured and a low priority in many medium/low human development index countries. In addition, there is a lack of standardised gynaecological oncology surgical data globally and a shortage of patient level data. Gynaecological oncology surgical outcomes data, is not located or reported in any standardised way and requires information to be compiled from multiple agencies, ministries, health reports and published literature, as there is no central source for collecting or reporting. In addition, collected data does not take into account country specific epidemiological factors.

Detecting variations associated with outcomes following gynaecological oncology surgeries, and modifiable practices associated with these variations, are likely to act as surrogate markers for best performance of gynaecological oncology surgical units.<sup>7,8</sup> Globally relevant risk factors for variations in outcomes relate to the training of the operating surgeon, availability of investigations, use of safety checklists, equipment and access to critical care facilities.<sup>9-11</sup>

A prospective audit of surgical outcomes following gynaecological oncology surgery in the United Kingdom (UKGOSOC: United Kingdom Gynaecological Oncology Surgical Outcomes and Complications), 12-14 a very high human development index country, may lack relevance and comparability in medium/low human development index countries or indeed other very high/high human development index countries which do not have a nationalised government funded health care system but private healthcare. Whilst the GlobalSurg collaborative has set up a consortium of general surgeons investigating surgical outcomes following general surgery, this has not included gynaecological oncology.

The Global Gynaecological Oncology Surgical Outcomes Collaborative (GO SOAR) aims to supplement the World Health Organization Global Initiative for Emergency and Essential Surgical Care by providing risk adjusted patient level outcome data to advise human development index country group specific policy formation and develop educational resources to reduce morbidity and mortality from gynaecological oncology surgery thereby addressing an urgent unmet need within gynaecological oncology. In addition, GO SOAR will develop a network of gynaecological oncology surgeons, surgical departments and other interested parties that will have the long-term ability to collaborate on future outcome studies, including randomised trials. Widespread provision of protocols and supporting educational materials will empower individual practitioners to participate and will facilitate audit and research capacity building in regions that currently lack local opportunities for development.

We present the protocol for the first GO SOAR collaborative study (GO SOAR1) which evaluates international variation of post-operative morbidity and mortality rates following gynaecological oncology surgery between country groups defined by human development index. The full protocol has also been registered at https://clinicaltrials.gov/ct2/show/NCT04579861 (ClinicalTrials.gov registry: NCT04579861).

Our hypothesis is that there is no variation in morbidity and mortality following gynaecological oncology surgery amongst human development index country groups.

### **METHODS**

Study design

Study design is that of an international, multicentre, prospective, observational, cohort study. There are one hundred sites planned (nine currently active and an additional fifty-six participating sites currently in the set up phase). Funding: The NHS Grampian Endowment Fund; Medtronic; Karl Storz.

### **Participants**

Inclusion criteria include women aged ≥18 years undergoing curative, curative attempted but then abandoned (open/close laparotomy) or palliative surgery for primary or recurrent tubo-ovarian/peritoneal, endometrial, cervical, vulval, vaginal, gestational trophoblastic malignancies. Surgical modality may be open, minimal access (laparoscopic/robotic), minimal access converted to open or vaginal. Both elective and emergency cases are included. Surgeries where pre-operative pathology was thought to be benign but malignancy was subsequently confirmed on histopathology post-operatively are also eligible.

#### **Objectives**

The primary objectives are to evaluate international variation in post-operative morbidity and mortality rates following gynaecological oncology surgery between country groups defined by the human development index. This is a composite index of life expectancy, education, and per capita income indicators, used to rank countries into four tiers of human development: very high, high, medium, low. Secondary objectives include intra-operative morbidity/mortality, histological clearance rates following cytoreductive surgery and to identify human development index group specific modifiable surgical processes associated with best care taking into account resource availability/infrastructure.

#### **Endpoints**

Primary endpoints are thirty-day post-operative morbidity/mortality defined as per the Clavien-Dindo classification system. <sup>15</sup> Secondary endpoints include intra-operative morbidity/mortality, tumour clearance and comparison of current practice against selected tumour specific audit standards derived (where available) from the European Society of Gynaecological Oncology guidelines for the diagnosis, investigation and management of gynaecological cancers (table 1).

### Site selection strategy

To ensure surgical outcome data collected are representative of care received in each country, attempts will be made where possible to recruit large/medium/small centres performing gynaecological oncology surgery in a 1:1:1 ratio. Centres will be defined according to surgical caseload as follows: large >150, medium 75-149, small <74 new surgical gynaecological cancer cases per annum. Large centre threshold of >150 was set as per European Society of Gynaecological Oncology training centre accreditation criteria

Patient data will be collected over a consecutive thirty-day period through gynaecological oncology multidisciplinary teams/tumour boards and clinics across different human development index country groups. This collaborative model for a snapshot clinical audit is well established. It is vital that all patients operated on during the consecutive thirty day period are entered onto the database. Data will not be presented at the level of individual surgeon/site. Additional data entry (beyond thirty-days) is encouraged and may take place at the discretion of the participating site. All patients are followed up as per local protocols for thirty-days post-operatively to identify post-surgical morbidity/mortality. In the absence of established local follow-up protocols, at the very minimum, a telephone call to the patient within the thirty-day follow up period from surgery is required to capture morbidity data.

### Data quality and validation

To ensure high data quality, a detailed protocol has been produced and published online (https://clinicaltrials.gov/ct2/show/NCT04579861). Collaborators are encouraged to perform data input in real time using the REDCap system. Data quality rules built into the REDCap database, will also ensure data quality and highlight disparities in data fields to the local collaborator for review. Training is available to collaborators prior to the commencement of data collection and entry.

Data validation is completed in three stages across a representative sample of centres. First, centres self report key processes used to identify and follow-up patients. Second, independent validators locally not part of the recruiting teams quantitatively report case ascertainment and sampled data accuracy. Third, local teams are interviewed by the central coordinating team to qualitatively assess collaborator engagement and data collection processes.

#### Sample size

Whilst there is a paucity of data on morbidity and mortality following gynaecological oncology surgery in medium/low human development index country settings, data for very high/high human development index country settings suggest morbidity is 26% and mortality 2%. Using this as a baseline, a sample size of 1100 (550/arm) inflated by 20% to account for missing data and loss to follow-up, at 90% power,  $\alpha$ =0.05, will be able to determine a 10% point difference in thirty-day post-operative morbidity and mortality following gynaecological oncology surgery between very high/high human development index countries and medium/low human development index country settings.

#### Statistical methods

Baseline characteristics will be calculated using descriptive statistics. Appropriate statistical tests will be used for analyses. Chi-square tests will compare categorical variables and t-Test (parametric) and Mann Whitney (non-parametric) tests will compare continuous outcome variables between groups. Random effects models adjusted for covariates/confounders will be used to compare outcomes between human development index groups over time. Progress on data collection and summary statistics will be reported to the international steering committee at their regular meetings. Analysis of the full data set will be undertaken at the end of the study.

#### **DISCUSSION**

The GO SOAR Collaborative plans to implement a series of internationally collaborative studies. This protocol describes the first GO SOAR collaborative study which is a multicentre, prospective cohort study evaluating international variation in post-operative morbidity and mortality following gynaecological oncology surgery between human development index country groups.

The World Health Organization's analysis of excess surgical mortality established three significant findings. First, surgical interventions take place on a massive and previously unrecognised scale in all countries and resource settings. Second, the inequity in service provision amongst countries and settings is dramatic. Third, little is known about the indications for, quality, safety, and outcomes of surgical care. Whilst the GlobalSurg Collaborative has made headway investigating these issues within the context of general surgery, for gynaecological oncology there is a paucity of comparable international data across different human development index country groups on surgical outcomes. The first GO SOAR study aims to generate data to help fill this knowledge gap. Despite the likely increased risk of morbidity and mortality for patients undergoing gynaecological oncology surgery in

medium/low human development income country settings, robust, empirical data are currently unavailable. Additionally, in countries with limited resources, applicability of gynaecological oncology surgical guidelines are yet to be tested. By using a collaborative model and a thirty-day snapshot data collection period, our study will recruit sufficient patients to measure this, whilst avoiding over burdening low resource centres that may otherwise be unable to participate.

Investigating the morbidity and mortality caused by gynaecological oncology surgery globally, this study will provide a platform to build future quality improvement programmes and interventional trials. A detailed study protocol, training, data quality control and validation will ensure standardisation to deliver a reliable and accurate data set. This study will be delivered using an international multidisciplinary collaborative network of healthcare researchers and clinicians.

The four key mandates of the GO SOAR Collaborative are to 1) set the research agenda through research prioritisation in gynaecological oncology, 2) gather high quality data via a centralised database accessible to all sites that perform gynaecological oncology surgery, 3) build sustainable international research by producing protocols/guidelines, and 4) train the researchers and leaders of tomorrow by providing open access to all GO SOAR training materials. In combination, this in turn will help provide safe and effective surgical care in gynaecological oncology globally.

The GO SOAR international database will help standardise surgical outcome reporting. Standardised reporting renders comparable data across different healthcare systems for more extensive research and analysis. The international database will also allow all participating centres/units performing gynaecological oncology surgery to audit their local practice and implement local changes whilst at the same time contribute patient level data reported using standardised electronic forms for use in global GO SOAR studies which will help inform and drive policy change internationally.

Often research in gynaecological oncology takes place within very high/high human development

index country settings with outcomes difficult to reproduce and recommendations difficult to

implement in medium/low human development index countries with limited resources. Inclusion of

medium/low human development index country partners are vital to be able to identify context

specific solutions and to ensure high quality surgical care in a low resource setting.

In conclusion, the GO SOAR Collaborative aims to improve surgical outcomes through collaborative

research. It will provide risk adjusted patient level outcome data collected via a centralised database

to advise human development index country group specific policy formation.

#### **Contribution to authorship**

Collaborative conception and design: FG.

Study conception and design: FG.

Protocol development: FG, DC, NB, PR, PK, AS, SP, OB.

Database development: FG, NB, PK, AS, SP, OB, DC.

Steering committee: FG, DC, PR, NB, PK, AS, SP, OB.

Study management: FG, NB, PK, AS, SP, OB.

Preparation of tables and figures: FG.

Initial draft of manuscript: FG.

Statistical aspects: FG, OB.

Manuscript writing and approval: All authors.

### **Disclaimers/Conflict of interest statement**

FG declares funding from The NHS Grampian Endowment Fund, Medtronic, Karl Storz for the GO SOAR1 study and is Chief Investigator. All other authors declare no conflict of interest.

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#### **Ethical approval**

The study has been approved and registered with the Quality Improvement & Assurance Team (QIAT) at NHS Grampian (project ID 5009), UK.

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#### **REFERENCES**

- 1. Farmer PE, Kim JY. Surgery and global health: a view from beyond the OR. World journal of surgery. 2008 Apr;32(4):533-6.
- 2. Luboga S, Macfarlane SB, von Schreeb J, Kruk ME, Cherian MN, Bergström S, et al. Increasing access to surgical services in sub-saharan Africa: priorities for national and international agencies recommended by the Bellagio Essential Surgery Group. PLoS medicine. 2009 Dec;6(12):e1000200.
- 3. Meara JG, Leather AJ, Hagander L, Alkire BC, Alonso N, Ameh EA, et al. Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development. Lancet (London, England). 2015 Aug 8;386(9993):569-624.
- 4. Weiser TG, Haynes AB, Molina G, Lipsitz SR, Esquivel MM, Uribe-Leitz T, et al. Size and distribution of the global volume of surgery in 2012. Bulletin of the World Health Organization. 2016 Mar 1;94(3):201-9f.
- 5. Fitzmaurice C, Allen C, Barber RM, Barregard L, Bhutta ZA, Brenner H, et al. Global, Regional, and National Cancer Incidence, Mortality, Years of Life Lost, Years Lived With Disability, and Disability-Adjusted Life-years for 32 Cancer Groups, 1990 to 2015: A Systematic Analysis for the Global Burden of Disease Study. JAMA oncology. 2017 Apr 1;3(4):524-48.
- 6. Alkire BC, Raykar NP, Shrime MG, Weiser TG, Bickler SW, Rose JA, et al. Global access to surgical care: a modelling study. The Lancet Global health. 2015 Jun;3(6):e316-23.
- 7. Symons NR, Moorthy K, Almoudaris AM, Bottle A, Aylin P, Vincent CA, et al. Mortality in high-risk emergency general surgical admissions. The British journal of surgery. 2013 Sep;100(10):1318-25.
- 8. Pearse RM, Moreno RP, Bauer P, Pelosi P, Metnitz P, Spies C, et al. Mortality after surgery in Europe: a 7 day cohort study. Lancet (London, England). 2012 Sep 22;380(9847):1059-65.
- 9. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. The New England journal of medicine. 2009 Jan 29;360(5):491-9.
- 10. Funk LM, Weiser TG, Berry WR, Lipsitz SR, Merry AF, Enright AC, et al. Global operating theatre distribution and pulse oximetry supply: an estimation from reported data. Lancet (London, England). 2010 Sep 25;376(9746):1055-61.
- 11. Kwok AC, Funk LM, Baltaga R, Lipsitz SR, Merry AF, Dziekan G, et al. Implementation of the World Health Organization surgical safety checklist, including introduction of pulse oximetry, in a resource-limited setting. Annals of surgery. 2013 Apr;257(4):633-9.
- 12. Burnell M, Iyer R, Gentry-Maharaj A, Nordin A, Liston R, Manchanda R, et al. Benchmarking of surgical complications in gynaecological oncology: prospective multicentre study. BJOG: an international journal of obstetrics and gynaecology. 2016 Dec;123(13):2171-80.
- 13. Iyer R, Gentry-Maharaj A, Nordin A, Burnell M, Liston R, Manchanda R, et al. Predictors of complications in gynaecological oncological surgery: a prospective multicentre study (UKGOSOC-UK gynaecological oncology surgical outcomes and complications). British journal of cancer. 2015 Feb 3;112(3):475-84.
- 14. Iyer R, Gentry-Maharaj A, Nordin A, Liston R, Burnell M, Das N, et al. Patient-reporting improves estimates of postoperative complication rates: a prospective cohort study in gynaecological oncology. British journal of cancer. 2013 Aug 6;109(3):623-32.
- 15. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Annals of surgery. 2004 Aug;240(2):205-13.

# Figure 1: Study flowchart

GO SOAR - Global Gynaecological Oncology Surgical Outcomes Collaborative; FIGO – International Federation of Gynecology and Obstetrics.

Table 1: Tumour specific measurable audit standards

#### **Ovarian**

Surgery performed by a gynaecologic oncologist or a trained surgeon specifically dedicated to gynaecological cancer management.

Treatment planned and reviewed at a Multidisciplinary Team Meeting.

#### **Endometrial**

Complete macroscopic cytoreduction and comprehensive staging is recommended in advanced endometrial cancer.

Multimodality management should be considered for the treatment of advanced endometrial cancer when surgery may significantly impair vaginal function.

#### Cervical

Surgery performed or supervised by a certified gynaecologic oncologist or a trained surgeon dedicated to gynaecological cancer.

Treatment discussed at a multi-disciplinary team meeting.

#### Vulva

Surgery performed or supervised by a certified gynaecologic oncologist or a trained surgeon dedicated to gynaecological cancer.

Treatment discussed at a multi-disciplinary team meeting.

Vaginal – in the absence of international guidelines on surgical management, the following is proposed.

Surgery performed or supervised by a certified gynaecologic oncologist or a trained surgeon dedicated to gynaecological cancer.

Treatment discussed at a multi-disciplinary team meeting.

Gestational trophoblastic malignancies - in the absence of international guidelines on surgical management, the following is proposed.

Surgery performed or supervised by a certified gynaecologic oncologist or a trained surgeon dedicated to gynaecological cancer.

Treatment discussed at a multi-disciplinary team meeting.