

CUHK Center for Bioethics  
Clinical Ethics Workshop Series:  
The Duty of Disclosure and What it means to All of Us



# Informed Consent – a Practitioner’s Viewpoint

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# A real life situation...

- Nurse call: Dr XXX, your patient is ready at the operation theatre on the table. Your assistants have prepared the patient's position for you. The only thing lacking is... the consent!!!
- The Surgeon (in his mind): Where is my junior?!

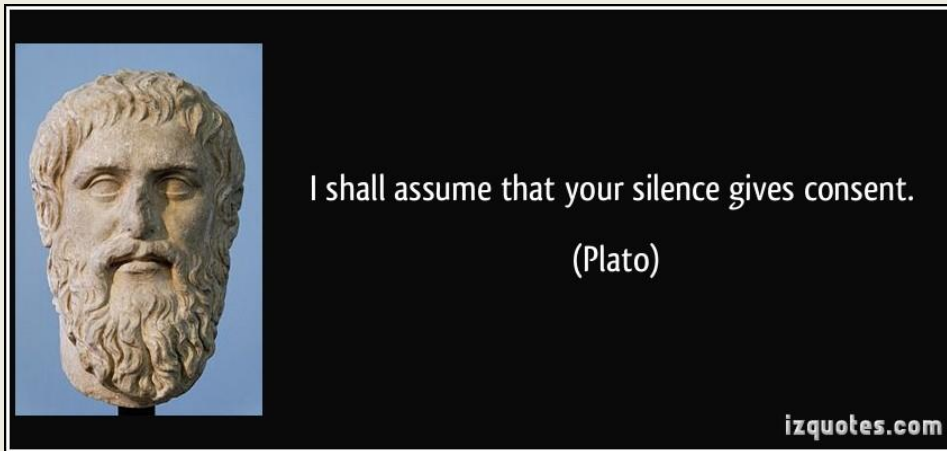


# Informed Consent

- **Informed consent (知情同意) is a process for getting permission before conducting a healthcare intervention on a person**
- **The informed consent process has become a staple both ethically and legally of surgical practice, disclosing all information:**
  - Natural course of the disease without therapy
  - Different therapies available
  - Reasoned recommendation of which to choose
  - Expected outcome citing data from the attending surgeon
  - Possible complications

# Informed consent in the Ancient time

- **In Laws by Plato**
  - Free born doctor should gather information from patient and friends about the illness
  - He informed the patient about nature of his illness
  - Did not give him any prescription until he had gained patient's consent





# Informed consent in the Ancient time

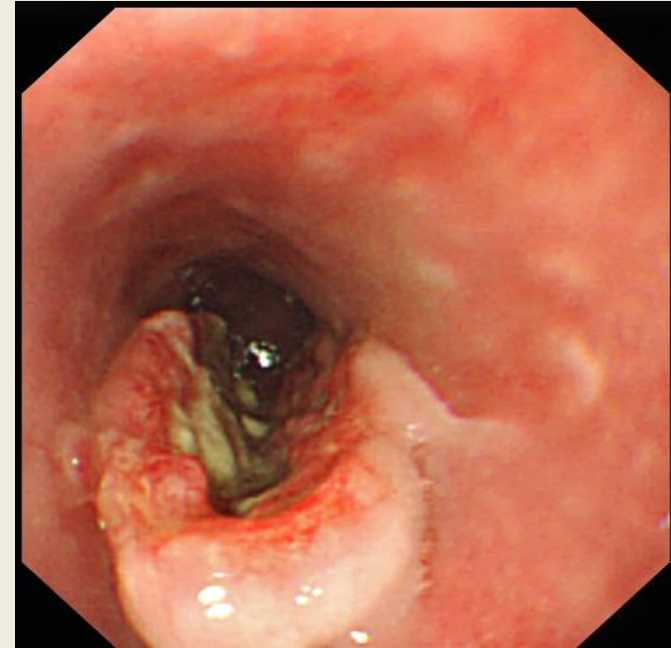
- **Alexander the great in 326 BC**
  - Seriously injured during seige of Mallians in India
  - Critobulus (skilled physician) finally operated on Alexander with much reservation & being terrified for prospect of failure
  - Alexander understood his hesitation and encouraged him



No one wishes to operate and bare the responsibility!

# M / 62 yrs with Esophageal Cancer

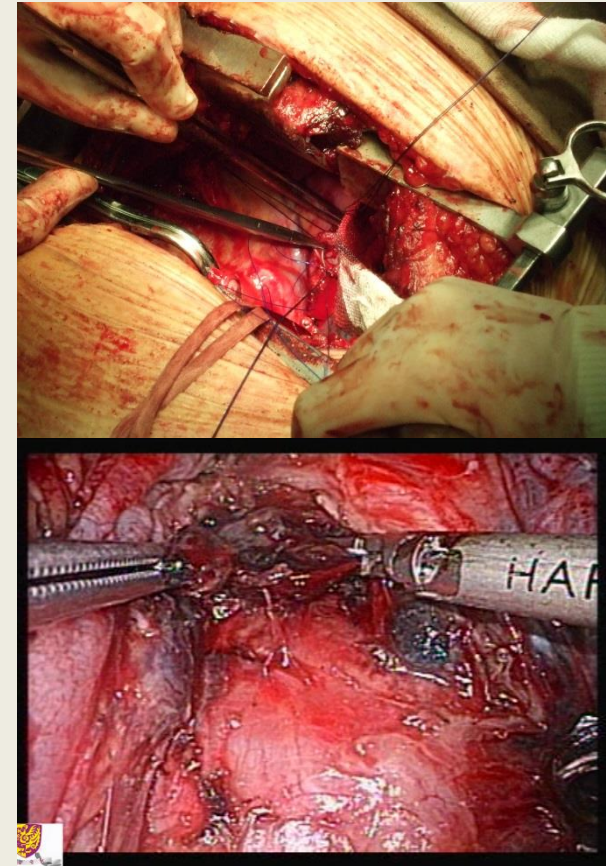
- Painless progressive dysphagia for 2 months
- OGD – Ulcerative tumor from 25-30cm
- Biopsy
  - Squamous esophageal carcinoma
- PET CT
  - No distant metastasis
  - Periesophageal lymph nodes



# Squamous cancer of esophagus

## Treatment options

- **Surgery: Esophagectomy**
  - Transthoracic
  - Transhiatal
  - Minimal Invasive Esophagectomy
  - Robotic assisted Minimally Invasive Esophagectomy
- **Neoadjuvant Chemoradiotherapy**
- **Primary (Definitive) Chemoradiotherapy**







# Current practice of informed consent at Department of Surgery, The Chinese University of Hong Kong

醫院管理局  
接受手術 / 醫療程序 /  
治療同意書 (須要麻醉科醫生參與)

院內/門診號碼: \_\_\_\_\_ 姓名(英文): \_\_\_\_\_ 性別: \_\_\_\_\_ 年齡: \_\_\_\_\_ 姓名: \_\_\_\_\_ 部門: \_\_\_\_\_ 病房: \_\_\_\_\_

**簽署人資料**  
病人的名字在本表格右上方。  
簽署本同意書之人士為: (請在適當空格內加上✓號)  
 病人本人  
 病人 (未成年, 但能理解同意書的內容及有關解釋) (見註二)  
 未成年病人的父母或監護人  
 根據「精神健康條例」下為病人所委任並獲授權代其同意, 接受院方建議的治療的法定監護人

姓名(中文): \_\_\_\_\_ (英文): \_\_\_\_\_  
香港身份證/身份證明文件號碼: \_\_\_\_\_  
地址: \_\_\_\_\_  
電話號碼(日): \_\_\_\_\_ (夜): \_\_\_\_\_  
與病人關係: (請在適當空格內加上✓號)  
 未成年病人的父母或監護人  
 根據「精神健康條例」下為病人所委任並獲授權代其同意, 接受院方建議的治療的法定監護人

**二、 解釋手術 / 醫療程序 / 治療的性質、影響、效果及風險 / 併發症**  
簽署本同意書的醫生已向病人 / 病人的父母或監護人 / 根據「精神健康條例」下病人所委任的法定監護人, 就手術 / 醫療程序 / 治療的性質、影響、效果及風險 / 併發症作如下:  
**適應症及手術 / 醫療程序 / 治療的性質及影響 / 效果**  
病人就手術 / 醫療程序 / 治療的診斷 / 適應症:  
病人接受的手術 / 醫療程序 / 治療名稱及性質:  
病人就手術 / 醫療程序 / 治療得到的預期影響 / 效果:

**三、 一般與手術 / 醫療程序 / 治療有關的風險 / 併發症**  
一般與手術 / 醫療程序 / 治療有關的風險 / 併發症, 包括:  
1. 分發物聚集於肺部造成肺栓塞。  
2. 傷處出血或感染為常見的術後併發症;  
3. 肺部深處靜脈可能出現栓塞, 如栓塞血塊脫落流到肺部, 可能危及生命, 但併發症非常罕見  
4. 心臟或肺部循環可能出現問題, 而引致心臟病或中風;  
5. 若發生嚴重併發症, 病人可能在手術中或手術後死亡。

**四、 重要風險 / 併發症及其他治療方法**  
手術 / 醫療程序 / 治療的重要風險及併發症 (包括罕見而有嚴重後果的風險 / 併發症):  
其他治療 (包括選擇不進行治療) 的風險及併發症為:  
其他治療選擇:  
風險 / 併發症:  
日期: \_\_\_\_\_

病人簽署 見註一、二、三及五  
醫生的簽署 見註五  
日期: \_\_\_\_\_

病人的父母或監護人 (精神健康條例) 下為病人 見註一、二  
醫生的簽署 見註五  
日期: \_\_\_\_\_

日期: \_\_\_\_\_

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**五、 在手術 / 醫療程序 / 治療進行中可能需要的其他治療**  
 輸血  
 其他治療程序 (請說明) \_\_\_\_\_  
其他治療方法: (包括額外醫療程序) \_\_\_\_\_

病人需要先作討論才可進行的其他治療程序: \_\_\_\_\_

**六、 同意提問**  
負責解釋的醫生已回答病人、病人的父母或監護人, 或根據「精神健康條例」下為病人所委任並獲授權代其同意接受治療的法定監護人所提出的問題:  
\_\_\_\_\_

**七、 以下清單置讀 (手術 / 醫療程序) 已提供予病人 / 病人的父母或監護人**  
\_\_\_\_\_

**八、 同意接受手術 / 醫療程序 / 治療**  
作為病人、病人的父母或監護人, 或根據「精神健康條例」下為病人所委任並獲授權代其同意接受治療的法定監護人及本同意書之簽署人, 我 / 我們  
1. 同意 / 同意病人接受列於本同意書二部的手術 / 醫療程序 / 治療及併發症。我 / 我們完全明白有關的解釋。  
2. 同意 / 同意病人在醫生認為必須或有需要的情况下, 接受其醫療程序 / 治療。  
3. 同意 / 同意病人接受醫生認為必須或有需要的檢驗及檢查。  
4. 同意院方可用其認為適當的方式, 處理由手術 / 醫療程序 / 治療或組織, 此不適用於保留組織 / 器官作研究之用。  
5. 明白院方並無保證有關手術 / 醫療程序 / 治療, 以及進一步治療將由特定的醫生進行, 但此項手術 / 醫療程序 / 治療將由特定的醫生進行。  
6. 同意如上述手術 / 醫療程序 / 治療, 本同意書仍然有效。  
7. 明白如果我們 / 我們有其他問題, 可以向院方詢問; 我 / 我們在簽署這份文件後有權改變主意。

病人簽署 見註一、二、三及五  
醫生的簽署 見註五  
日期: \_\_\_\_\_

病人的父母或監護人 (精神健康條例) 下為病人 見註一、二  
醫生的簽署 見註五  
日期: \_\_\_\_\_

日期: \_\_\_\_\_

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**九、 解釋麻醉及麻醉風險 / 併發症**  
簽署本同意書的麻醉科醫生已向病人、病人的父母或監護人, 或根據「精神健康條例」下為病人所委任並獲授權代其同意接受治療的法定監護人解釋麻醉及麻醉風險 / 併發症:  
病人將採用一項或多項一類藥物, 如全身麻醉、區域性 (脊椎) 和 / 或局部麻醉。現今的麻醉一般安全, 不過, 麻醉風險會因病人為吸煙者、體重過高或患有其他疾病如感冒、糖尿病、心臟病、腎科嚴重病等; 其他內科疾病而增加, 而年長者的麻醉風險亦較高。因麻醉而引起的嚴重併發症不常見; 例如  
1. 呼吸困難;  
2. 中風或腦部受損, 可能導致永久性的傷殘;  
3. 心臟損害, 可能導致心臟病發作;  
4. 全身麻痺期間仍具有知覺;  
5. 對藥物藥物有過敏反應;  
6. 區域性麻醉後之神經痛等;  
部份嚴重併發症可能會引致死亡。  
輕微的麻痺問題較常見, 包括噁心、嘔吐、全身疼痛、頭痛、手術及注射部位疼痛和麻痺等, 有時也可能及牙齒和唇部。  
手術的麻醉或手術後鎮痛可能引起的重要風險併發症 (包括罕見而有嚴重後果的風險 / 併發症) 如下:  
\_\_\_\_\_

**十、 同意提問**  
負責解釋的麻醉科醫生已回答病人、病人的父母或監護人, 或根據「精神健康條例」下為病人所委任並獲授權代其同意接受治療的法定監護人所提出的問題, 有關的問題概括如下:  
\_\_\_\_\_

**十一、 以下清單置讀 (麻醉) 已提供予病人 / 病人的父母或監護人 / 根據「精神健康條例」下為病人所委任的法定監護人**  
\_\_\_\_\_

**十二、 同意接受麻醉程序**  
作為病人、病人的父母或監護人, 或根據「精神健康條例」下為病人所委任並獲授權代其同意接受治療的法定監護人, 及本同意書之簽署人, 我 / 我們  
1. 同意 / 同意病人接受列於本同意書二部的手術 / 醫療程序 / 治療而需要的麻醉程序。負責解釋的麻醉科醫生已向我們 / 我們詳細解釋此項麻醉程序的影響、風險及併發症。我 / 我們完全明白有關的解釋。  
2. 同意 / 同意病人在麻醉科醫生認為必須或有需要的情况下, 接受局部 / 全身或其他麻醉程序。  
3. 同意 / 同意病人接受麻醉科醫生認為必須或有需要的檢驗及檢查。  
4. 明白院方並無保證有關麻醉程序以及進一步的麻醉程序將由特定的麻醉科醫生進行, 但此項麻醉程序將會由合資格的麻醉科醫生執行。  
5. 同意如上述手術 / 醫療程序 / 治療, 本同意書仍然有效。  
6. 明白如果我們 / 我們有其他問題, 可以向麻醉科醫生詢問; 我 / 我們在簽署這份文件後有權改變主意。

病人簽署 見註一、二、三及五  
醫生的簽署 見註五  
日期: \_\_\_\_\_

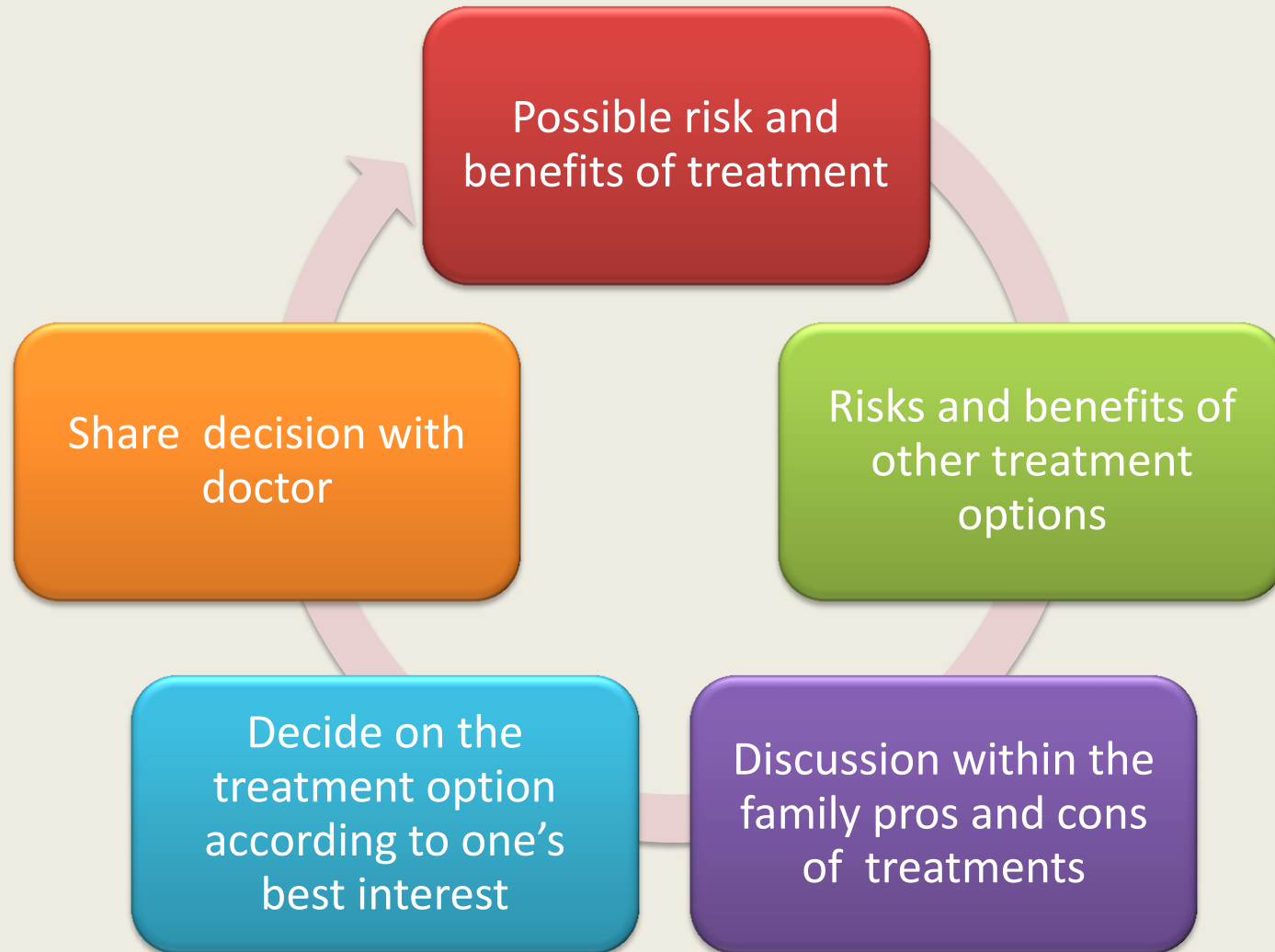
病人的父母或監護人 (精神健康條例) 下為病人 見註一、二  
醫生的簽署 見註五  
日期: \_\_\_\_\_

日期: \_\_\_\_\_

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# Process of getting informed consent



# Risks of the procedure

- **Procedure related risk / complications**
  - Bleeding
  - Anastomotic leakage
  - Conduit ischemia
  - Chylous leakage
  - Recurrent laryngeal nerve injury
  - Damage to surrounding organs
- **General surgical risks**
- **Perioperative mortality**
  - 2% Hong Kong wide
  - 2-4% International standard
  - < 1% at PWH
  - BUT...

**Life and Death is either 0 or 100% in a single patient**

# Multi-media may help in explanation of the esophagectomy



# Informed consent: Who?

- **Surgeon: Who should be responsible?**
  - In a Team based service
    - Anyone in the team?
    - One of the few surgeons listed for operation?
    - The surgeon who is operating as chief surgeon?
    - The “most junior” guy (who should serve as the slave??)
    - The Consultant
  - In private sector



# Informed consent: Who

- **The Patient**

- Must be competent to take the decision
- Received sufficient information
- Not acting under stress

- **The Relatives**

- Best to have a close relative / group of relatives
  - Support
  - Ensure patient really understand

# Informed consent: When and Where

- **A comfortable consultation room or ward**
  - Easy and quite communication
  - No disturbance or interruption
  - Patient should not feel threatened
- **Allow time for**
  - Patient and relatives to decide for treatment options
  - Process of obtaining the consent

# How do we know patient understand fully?

- **Ask if the patient / relatives have any question**
- **Skillful explanation with consideration of**
  - Patient's background
    - Social background
    - Ethnic group
    - Educational background
  - Language barrier

# Rapport

- **Rapport is a process and can be defined as recognition of and willingness to communicate and share values with each other**
  - Relation of trust between people
  - A feeling of sympathetic understanding
  - Having a mutual understanding



## Before induction of anaesthesia

(with at least nurse and anaesthetist)

**Has the patient confirmed his/her identity, site, procedure, and consent?**

- Yes

**Is the site marked?**

- Yes  
 Not applicable

**Is the anaesthesia machine and medication check complete?**

- Yes

**Is the pulse oximeter on the patient and functioning?**

- Yes

**Does the patient have a:**

Known allergy?

- No  
 Yes

Difficult airway or aspiration risk?

- No  
 Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?

- No  
 Yes, and two IVs/central access and fluids planned

## Before skin incision

(with nurse, anaesthetist and surgeon)

**Confirm all team members have introduced themselves by name and role.**

**Confirm the patient's name, procedure, and where the incision will be made.**

**Has antibiotic prophylaxis been given within the last 60 minutes?**

- Yes  
 Not applicable

**Anticipated Critical Events**

To Surgeon:

- What are the critical or non-routine steps?  
 How long will the case take?  
 What is the anticipated blood loss?

To Anaesthetist:

- Are there any patient-specific concerns?

To Nursing Team:

- Has sterility (including indicator results) been confirmed?  
 Are there equipment issues or any concerns?

**Is essential imaging displayed?**

- Yes  
 Not applicable

## Before patient leaves operating room

(with nurse, anaesthetist and surgeon)

**Nurse Verbally Confirms:**

- The name of the procedure  
 Completion of instrument, sponge and needle counts  
 Specimen labelling (read specimen labels aloud, including patient name)  
 Whether there are any equipment problems to be addressed

**To Surgeon, Anaesthetist and Nurse:**

- What are the key concerns for recovery and management of this patient?

# WHO Surgical Safety: Patients for patient safety (PFPS)



## Patient's Communication Tool for Surgical Safety

***If you or your child will shortly undergo a surgical procedure, communicate the following to your health-care provider:***  
*(you may wish to involve a family member or friend)*

### **BEFORE SURGERY**

1. Tell them about your previous surgeries, anaesthesia and medications, including herbal remedies
2. Tell them if you are pregnant or breast-feeding
3. Tell them about your health conditions (allergies, diabetes, breathing problems, high blood pressure, anxiety, etc.)
4. Ask about the expected length of your hospital stay
5. Ask for personal hygiene instructions
6. Ask them how your pain will be treated
7. Ask about fluid or food restrictions
8. Ask what you should avoid doing before surgery
9. Make sure that the correct site of your surgery is clearly marked on your body



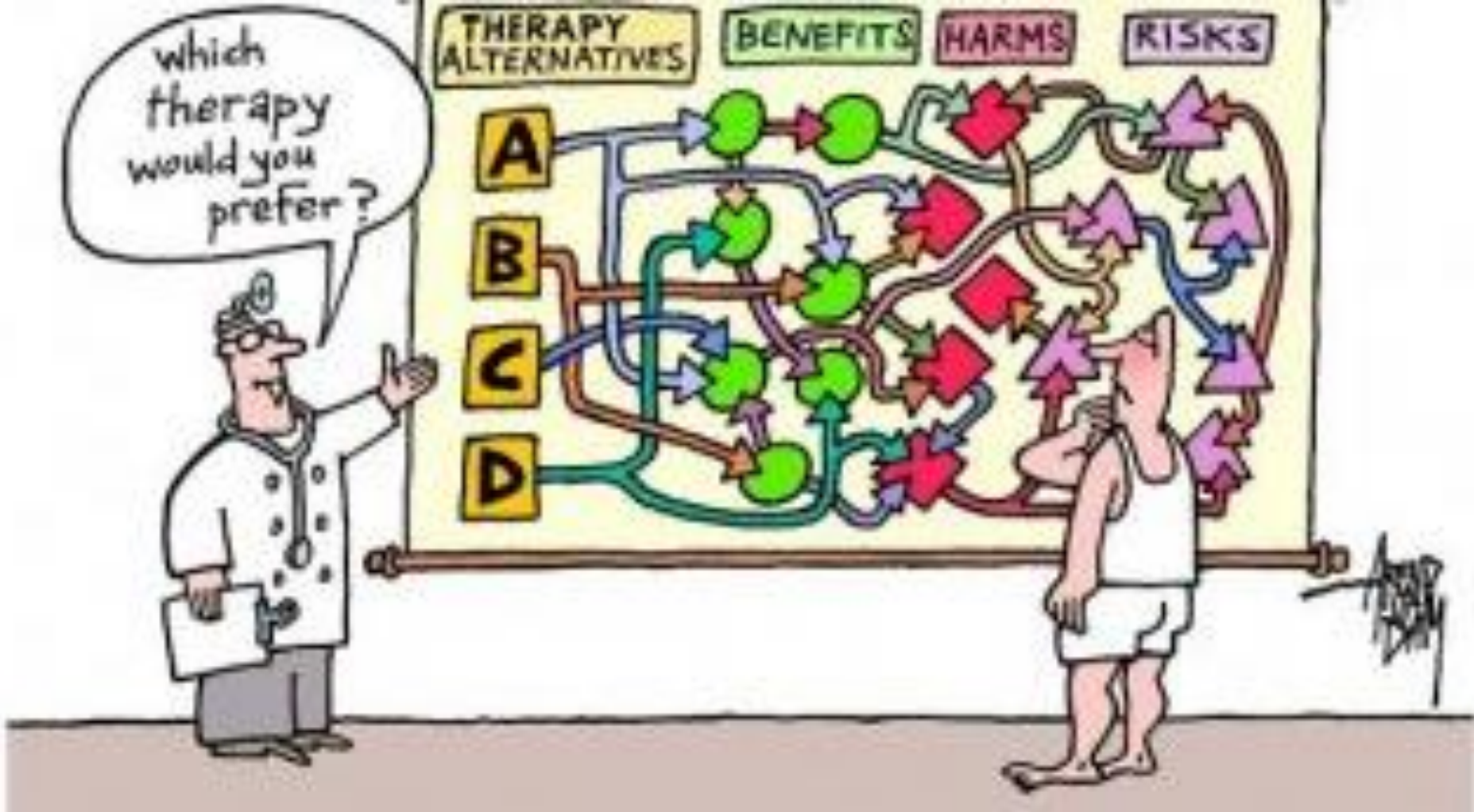
Emergency and Essential  
Surgical Care Programme  
&  
Patients for Patient Safety  
Programme

Service Delivery and Safety  
Department  
World Health Organization  
Geneva, Switzerland  
[www.who.int/surgery](http://www.who.int/surgery)  
[surgery@who.int](mailto:surgery@who.int)

### **AFTER SURGERY**

1. Tell them about any bleeding, difficulty breathing, pain, fever, dizziness, vomiting or unexpected reactions
2. Ask them how you can minimize infections
3. Ask them when you can eat food and drink fluids
4. Ask when you can resume normal activity (e.g. walking, bathing, lifting heavy objects, driving, sexual activity, etc.)
5. Ask what, if anything, you should avoid doing after surgery
6. Ask about the removal of stitches and plasters
7. Ask about any potential side effects of prescribed medications
8. Ask when you should come back for a check-up

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**Difficult and controversial situations!**



# Extreme situations: A new procedure / tool used up in the air

## In-flight 'surgery' improvised

LONDON (AP) — Aircraft medical kits are great for delivering babies, but two doctors on a flight from Hong Kong to London found they aren't much help in dealing with a collapsed lung.

So Dr. Angus Wallace and Dr. Tom Wong improvised with a coat hanger, some brandy as disinfectant and a rubber tube from the medical kit to treat a passenger who was struggling for breath.

The passenger, Paula Dixon, 39, from Aberdeen, Scotland, was reported in stable condition Tuesday at Ashford Hospital in west London.

Dixon had been involved in a motorcycle accident on the way to the airport in Hong Kong, the London newspaper Today reported.

She complained of pains in her arm as the plane departed Saturday, British Airways said.

The doctors put a splint on the arm, but when the pain continued they realized she had at least two broken ribs, Wallace told BBC radio Tuesday.

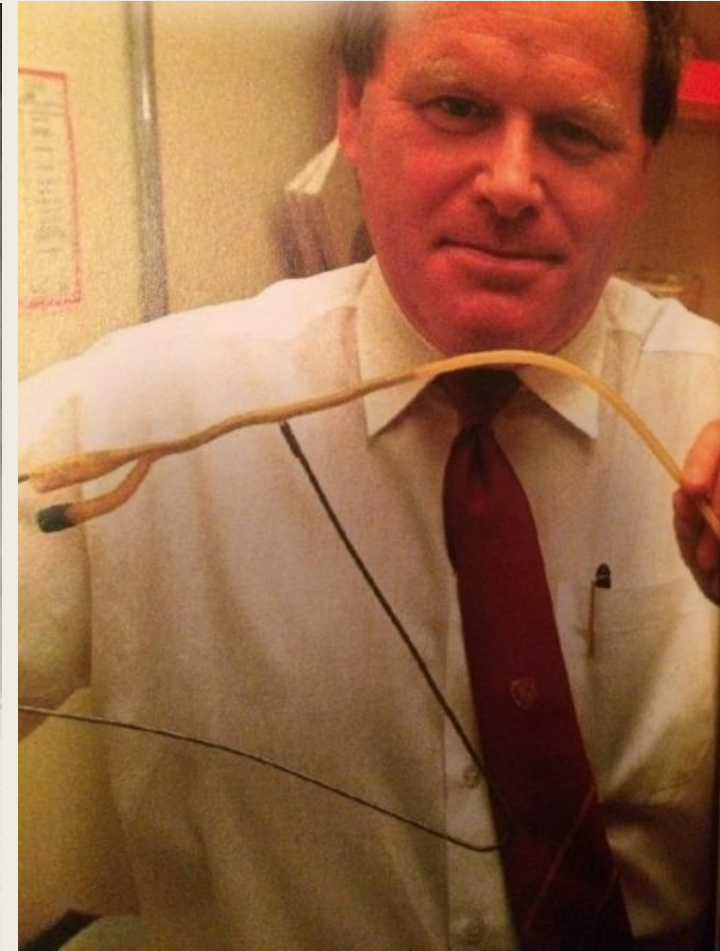
As her condition worsened, the doctors decided on surgery to drain her collapsed left lung.

The aircraft's medical kit is "quite well-equipped for having babies and for people who develop urinary blockages, but there's absolutely nothing in the set that helps you if you need to put a chest drain in," said Wallace, an orthopedic specialist from Nottingham, England. Wong is a senior doctor at a Scottish hospital.

Wallace and Wong slipped the coat hanger inside the tube — known as a catheter — to help them push it through an incision in her chest.

"We gave her a little bit of local anesthetic in the skin on her chest. She was conscious during the whole procedure," Wallace said. "It was a little unpleasant when we went through the chest wall."

Wallace said he consulted with the flight captain, and the Boeing 747 continued on its 14-hour flight to London, arriving Sunday.

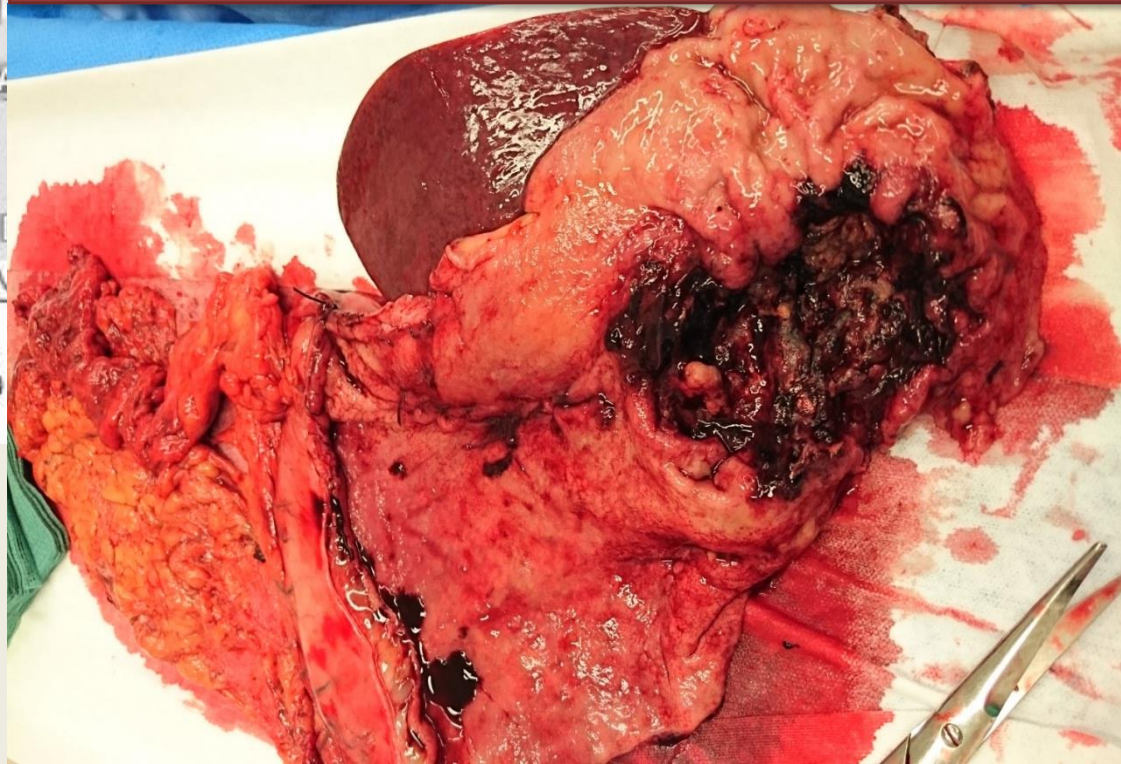




# Extreme situations: Change of plan



- ICU case intubated and ventilated
- Present with GI bleeding
- Attempted OGD - increasing abdominal distension
- X-ray: Free gas under diaphragm
- Laparotomy



# Residents / Trainees participating in your surgery

- **Tertiary level US Army Hospital**
  - All patients scheduled for elective surgical procedure & arrived at general surgical clinic for preoperative evaluation
- **Questionnaire survey (2 pages)**
  - What extent patients expect to be informed regarding involvement of trainees
  - who should be held responsible for surgical complications
  - whether they believe that societal and/or personal benefit accrues from allowing residents to take part in their care

**Table 1. Demographics of 316 Respondents<sup>a</sup>**

Characteristic	Value
Age, mean (SD), y	46 (16)
Sex	
Male	120 (38.0)
Female	196 (62.0)
Status	
Active duty military	56 (17.7)
Retired military	82 (25.9)
Dependent family member	178 (56.3)
Highest educational level	
High school diploma or lower	88 (27.8)
Any college or higher	228 (72.2)
Any prior surgical procedure	259 (82.0)
Prior surgical procedure at MAHS	145 (45.9)
Degree of difficulty of the planned procedure	
Simple	136 (43.0)
Intermediate	123 (38.9)
Complex	57 (18.0)

Abbreviation: MAHS, Madigan Army Health System.

<sup>a</sup>Data are given as number (percentage) unless otherwise indicated. Percentages may not total 100 because of rounding.

## From: Training Surgeons and the Informed Consent Process: Routine Disclosure of Trainee Participation and Its Effect on Patient Willingness and Consent Rates

Arch Surg. 2012;147(1):57-62. doi:10.1001/archsurg.2011.235

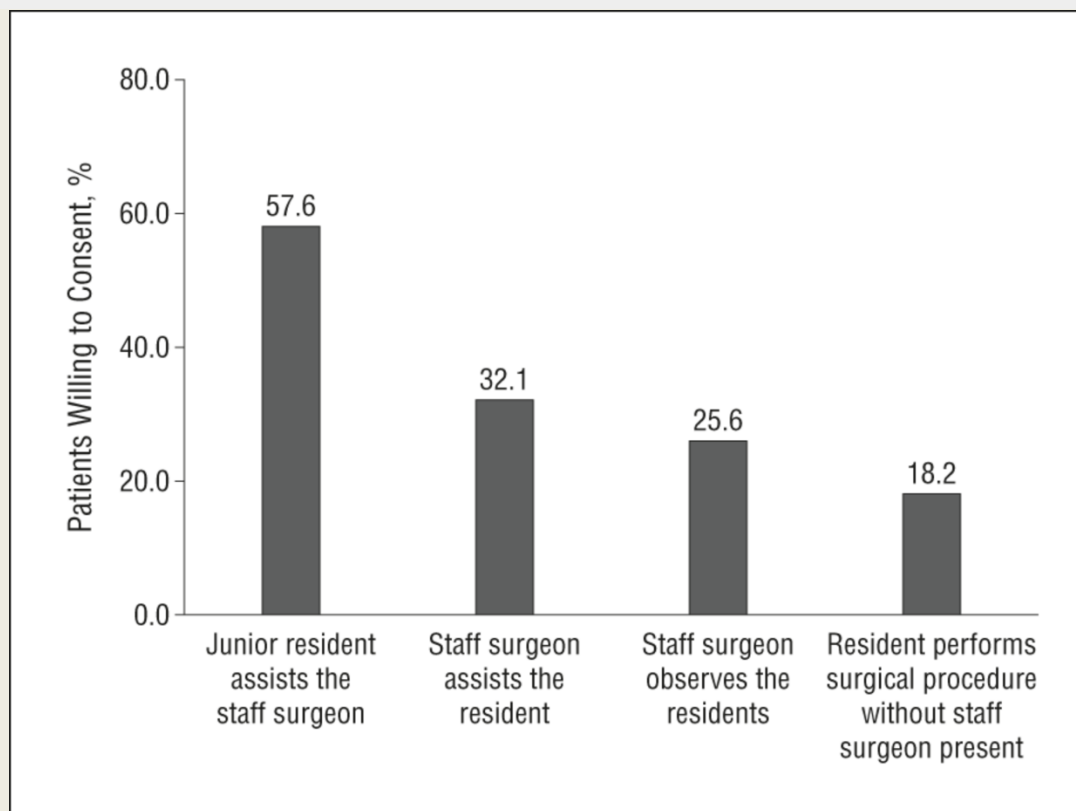


Figure Legend:

Figure. Percentage of respondents willing to consent to scenarios involving increasing levels of trainee participation, from assisting only (far left) to fully performing the procedure without the responsible staff surgeon present in the operating room (far right).

## From: Training Surgeons and the Informed Consent Process: Routine Disclosure of Trainee Participation and Its Effect on Patient Willingness and Consent Rates

Arch Surg. 2012;147(1):57-62. doi:10.1001/archsurg.2011.235

**Table 2. Demographics of Respondents Categorized as Highly Unwilling to Consent to Trainee Involvement Compared With the Rest of the Cohort<sup>a</sup>**

Variable	Highly Unwilling Group (n=82)	Remainder of the Respondents (n=218)	P Value
Age, mean (SD), y	41 (14)	47 (17)	<.001
Sex			.02
Male	22 (26.8)	92 (42.2)	
Female	60 (73.2)	126 (57.8)	
Active duty military	18 (22.0)	35 (16.1)	.30
Retired or family member	64 (78.0)	183 (83.9)	
Highest educational level			.09
High school diploma or lower	29 (35.4)	54 (24.8)	
Any college or higher	53 (64.6)	164 (75.2)	
Any prior surgical procedure	64 (78.0)	181 (83.0)	.44
Prior surgical procedure at MAHS	29 (35.4)	110 (50.5)	.03
Degree of difficulty of the planned procedure			.48
Simple	32 (39.0)	98 (45.0)	
Intermediate to complex	50 (61.0)	120 (55.0)	
Whether patient knew that MAHS is a teaching hospital			.004
Yes	55 (67.1)	192 (83.1)	
No	27 (32.9)	39 (16.9)	
Whether patient believes a personal benefit will accrue from participating			<.001
Yes	36 (46.8)	154 (76.6)	
No	41 (53.2)	47 (23.4)	
Whether patient believes a societal benefit will accrue from participating			.001
Yes	56 (75.7)	187 (91.7)	
No	18 (24.3)	17 (8.3)	

Abbreviation: MAHS, Madigan Army Health System.

<sup>a</sup>Data are given as number (percentage) unless otherwise indicated; excluded 16 patients who did not answer all 9 of the scenario-based questions.

- Younger age
- Female
- Not knowing Teaching Hospital
- Not belief a societal benefit will accrue



# Your first time in doing this procedure, doctor?

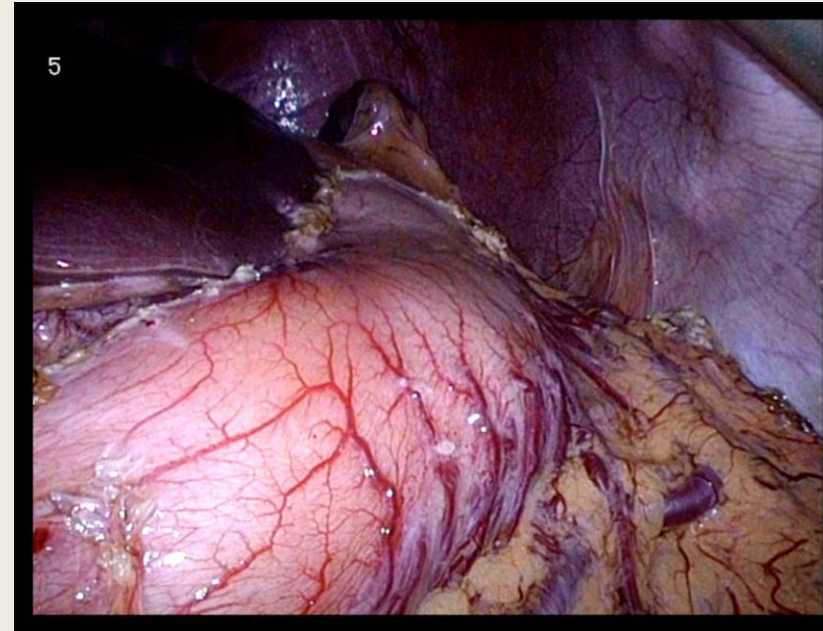
1<sup>st</sup> Case of  
Laparoscopic  
implantation  
of Enterra for  
Gastroparesis



Joint NTEC-CUHK  
Clinical Research  
Ethics Committee



Hospital  
Authority Central  
Technology  
Office



- First well established surgical procedure in Hong Kong
- First experimental surgical procedure worldwide / region wide

# Summary

- **Informed consent is absolutely essential for performance of any surgical procedures**
- **The process of getting informed consent shall include informative explanation of risk & benefits of the surgery, alternative treatments and patients / relative consenting to the most appropriate treatment**