

(Organization /Hospital)

## Custom-printed consent form in Tuen Mun Hospital

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**SD(Q&S) NTWC/ Hon CON(A&IC) NTWC**

*Fairness Innovation Respect Safety Teamwork*

HA Convention 2014

08 MAY 2014





# Standard statement of HA Annual Plan

## Section 3, Standard No. 9

“Appropriate information is provided to patients on the risk and benefit of the proposed treatment or investigation and the alternatives available before consent is sought”



# What usually happens to the written consent?

乙、適應症及手術/醫療程序/治療

病人的診斷/適應症：  
 病人接受的手術/醫療程序/治療名稱或性質：  
*USG guided drainage of liver cyst*  
 預期得到的效果：

丙、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：(包括不進行手術/醫療程序/治療)  
 (如有需要，可記錄在病歷內)



病人需要先作討論才可進行的其他治療程序：

丁、醫生/醫療專業人員聲明

(由醫生或熟知有關知識的醫療專業人員填寫)  
 我已向病人/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解釋院方建議的手術/醫療程序/治療，其重點如下：

- 嚴重或常見風險：  
*Injury to adjacent structures  
 Bleeding / infection, need for further drainage*
- 病人曾表示不會接受的特定治療如下：
- 我亦有講解在療程中可能涉及的事項，其他可供選擇的治療(包括不進行治療)的好處和風險及他們所關注的事項：
- 已提供之資訊單張如下(如有)：

全3頁之第2頁

	_____ 醫生/醫療專業人員簽署 見註四	_____ 見證人簽署(如適用) 見註五
<i>OK</i> 	_____ 醫生/醫療專業人員姓名正楷及職級	_____ 見證人姓名正楷(如適用)
<b>30 OCT 2013</b>	_____ 日期	_____ 見證人(如適用) (職員職級/如家屬請註明與病人關係)

## 戊、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的責任聲明：

我是本同意書之簽署人，我聲明如下：

- 醫生/醫療專業人員如上所述，已向我解釋，並回答我所提出的問題。我同意/我同意病人接受院方建議的手術/醫療程序/治療。
- 我明白院方並不保證有關手術/醫療程序/治療由特定醫生/醫療專業人員進行。
- 我明白是項手術/醫療程序/治療可能會/不會需要局部麻醉。



# Audit on Informed Consent

## Audit results on Informed Consent in June 2011

- Signature and Name of Doctor in Block Letters and Staff Rank

Hospital	Audit Year	No. of patients	Compliance rate
TMH	2006	30	33%
	2009	101	68%
	2011	102	68.3%

- Comments from surveyor: some deficiencies were found relating to use of junior medical staff name, number stamp and anesthetic consent.



# Organization Wide Survey in TMH

Referring to the Report of the Periodic Review in SEP 2012

Surveyor commented that in most Hong Kong hospitals, the consent forms were noted to contain abbreviations for the name of the procedure and site and this is no longer recognized as acceptable practice throughout the international community.



# Surveyor's Recommendation

- Working with HA to identify the best practice for documentation of the name and site of the operation/procedure on consent forms in order to eliminate the use of abbreviation.
- Matters are being addressed prior to the next scheduled audit.



# Code of conduct from HK Medical Council

- For written consent, a reasonably clear and succinct record of the explanation given should be made in the consent form.
- The patient, the doctor and the witness (if any) should sign the consent form at the same time.
- Each signatory must specify his/her name and the date of signing next to his/her signature.
- Risk of misconduct for badly completed consent forms.



# Measures to eliminate the use of abbreviation

1. Designated stamps for common procedures in respective departments
  - Useful for abbreviation of high volume identical procedures

乙、適應症及手術／醫療程序／治療

病人的診斷／適應症：  
\_\_\_\_\_ **Epigastric Pain / Coffee Ground Vomiting / Anaemia x Ix** \_\_\_\_\_

病人接受的手術／醫療程序／治療名稱或性質：  
\_\_\_\_\_ **Oesophago-Gastro-Duodenoscopy (OGD) +/- Biopsy** \_\_\_\_\_

預期得到的效果：  
\_\_\_\_\_ **Diagnostic** \_\_\_\_\_

丙、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：(包括不進行手術／醫療程序／治療)  
(如有需要，可記錄在病歷內)

\_\_\_\_\_

病人需要先行討論才可進行的其他治療程序：  
\_\_\_\_\_

\_\_\_\_\_

丁、醫生／醫療專業人員聲明

(由醫生或熟知有關知識的醫療專業人員填寫)

我已向病人／病人父母或監護人／根據「精神健康條例」下為病人所委任的法定監護人解釋院方建議的手術／醫療程序／治療，其重點如下：

\_\_\_\_\_

\_\_\_\_\_

• 嚴重或常見風險：  
\_\_\_\_\_ **Bleeding, Infection, Aspiration +/- Pneumonia** \_\_\_\_\_  
\_\_\_\_\_ **Perforation of Oesophagus / Aspiration +/- Pneumonia** \_\_\_\_\_





## 2. Pre-printed consent form (C/F) to facilitate staff compliance

- Similar for high volume identical procedures
- Many pre-printed forms, very difficult to retrieve
- Take up a lot of storage space

### 肝癌 (Hepatocellular Carcinoma)

病人接受的手術／醫療程序／治療名稱或性質：

射頻消融術治療肝內腫瘤±經皮無水乙醇治療肝癌±肝活組織檢查±腹腔電腦掃描造影。

預期得到的效果：

肝癌得到治療或緩解

丙、 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：(包括不進行手術／醫療程序／治療)  
(如有需要，可記錄在病歷內)

病人需要先作討論才可進行的其他治療程序：

丁、 醫生／醫療專業人員聲明

(由醫生或熟知有關知識的醫療專業人員填寫)

我已向病人／病人父母或監護人／根據「精神健康條例」下為病人所委任的法定監護人解釋院方建議的手術／醫療程序／治療，其重點如下：

#### 射頻消融術治療肝內腫瘤

• 嚴重或常見風險：

- 因病人在患有肝癌手術後可能引起肝功能不全●出血到腹腔、胸腔、胸腔等●無症狀的右胸肋骨液會於大部份病人形成。中或重胸痛的積液可出現於有大腫瘤的病人●雙側腋下皮膚的灼傷(罕見)●癌症於穿刺針道復發(罕見)
- 因手術而引致死亡(罕見)●因熱能而引起鄰近器官的損傷●形成氣腫(偶然)●接受動脈或靜脈注射造影劑產生的副作用

• 病人曾表示不會接受的特定治療如下：



### 3. Laterality issue not addressed

– Lt and Rt abbreviation

乙、適應症及手術／醫療程序／治療

病人的診斷／適應症：

R RTx

病人接受的手術／醫療程序／治療名稱或性質：

CA mastectomy

預期得到的效果：

丙、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：(包括不進行手術／醫療程序／治療)  
(如有需要，可記錄在病歷內)

病人需要先作討論才可進行的其他治療程序：

丁、醫生／醫療專業人員聲明

(由醫生或熟知有關知識的醫療專業人員填寫)

我已向病人／病人父母或監護人／根據「精神健康條例」下為病人所委任的法定監護人解釋院方建議的手術／醫療程序／治療，其重點如下：

• 嚴重或常見風險：

post, injury left breast organ/  
hemorrhage blood clot



# Objectives in development of custom-printed Consent Form

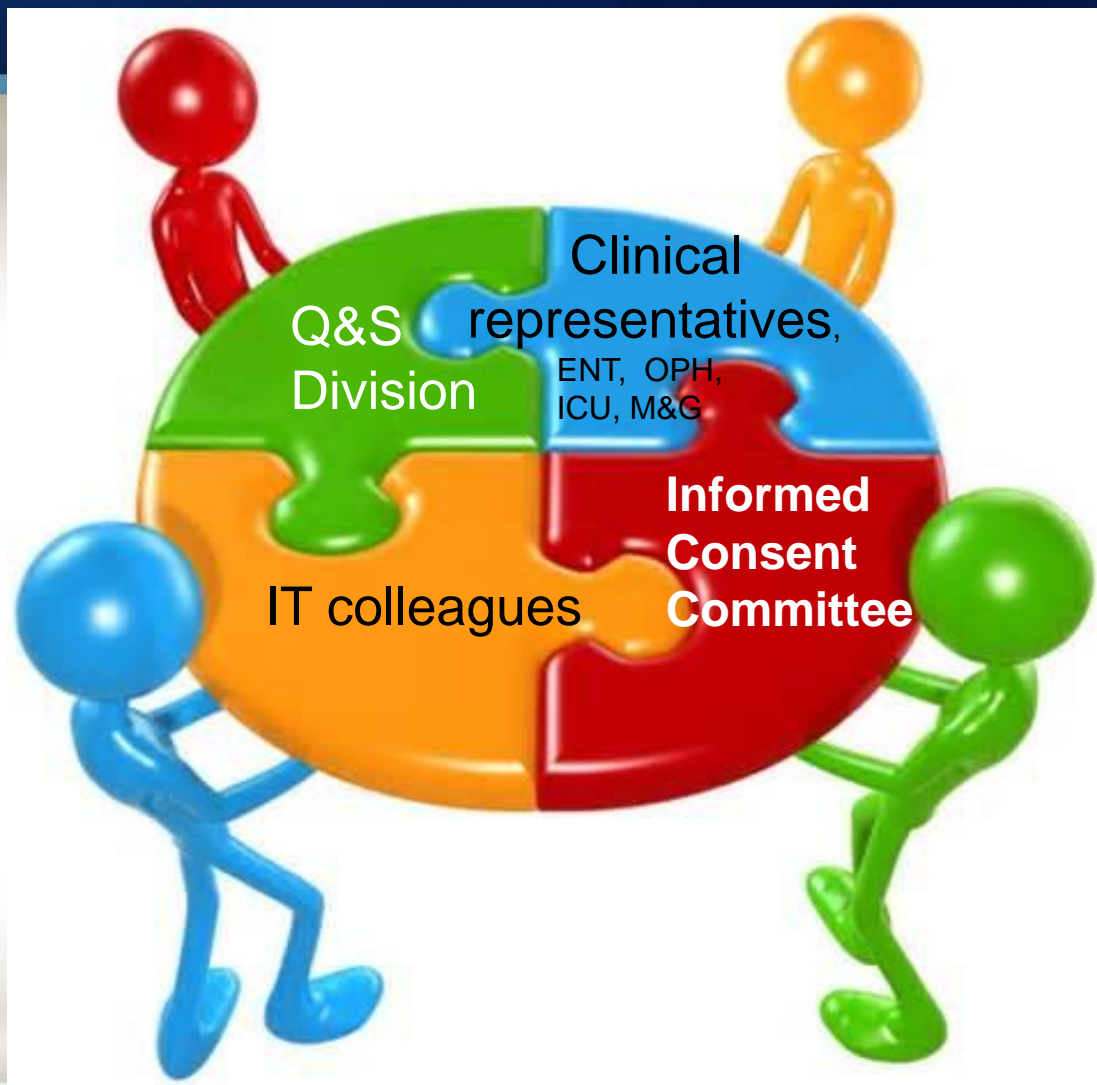
1. Explore ways for documentation of the name and site/ side of the operation/procedure on consent forms in order to eliminate the use of abbreviation.
2. Explore ways to ensure a reasonably clear and succinct documentation in the consent form of the explanation given by Doctors.
3. Explore ways to ensure consistent documentation of doctor's name and the date of signing next to his/her signature.



# Idea: Custom printed consent forms

- Current consent form: 4 A4 pages in the form of a A3 paper
- Change to 4 A4 pages with exactly the same format and content
- Limited Customization of printing of important data fields
  - Procedure
  - Risks of procedure
  - Side
  - Name of doctor
  - Date of signing
  - Associated fact sheets

# Workgroup on custom printed C/F was established





# Common Concerns

- Any legal implication of 'loosely printed A4 consent forms' from HAHO
  - LSD consulted
  - HAHO Q&S consulted
- Additional cost and manpower on printed-out forms
  - Finance
- Endorsement sought from
  - CCE
  - Cluster Management Committee
  - COS meeting

# Design on Custom-printed Consent



鼻中隔偏曲 deviated nasal septum

病人接受的手術／醫療程序／治療名稱或性質：

Septoplasty

預期得到的效果：

減輕鼻塞 reduce nasal obstruction

## 丙、一般與手術有關的風險

任何手術都可以有風險，包括：

1. 分泌物集留於肺部造成胸腔感染；
2. 傷區出血或感染為常見的術後併發症；
3. 腿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，但此併發症
4. 心臟或腦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。

## 丁、重要風險及其他治療方法

醫生已解釋病人所須治療的情況 (包括診斷、預後、結果和併發症)，亦解釋接受手術／醫療程序／治療和有關管理計劃 (包括觀察)，其利益、用途和這項手術的主要風險，和這些風險 (包括可能引致的併發症) 對病人的影響。

醫生亦解釋病人將接受的手術／醫療程序／治療，有可能出現以下的風險和併發症：(由醫生記錄)

出血 鼻塞 鼻腔黏連 血腫 鼻中隔穿孔 鼻樑塌陷 詳列於附件 PILIC0127 nasal bleeding, nasal obstruction.

1. The complete procedure indication/name/side/expectancy/potential complications could be printed in the custom printed consent form for each procedure from the website.



## 2. Date of signature, doctor's name and code could be printed by request.

些人士，或當時情況危急，良好的做法，是諮詢病人的親近人士（例如配偶／伴侶、根據「精神健康條例」委任但未獲授權代病人同意醫治的法定監護人、家庭成員和朋友、照顧者等）。「最佳利益」的定義是比「最佳醫療利益」更闊，並包括病人若能瞭解及同時清醒時的意願和信仰、其現時的意願、一般的福利和精神和宗教信仰。

### 丁、 以上為病人主診醫生的意見

\_\_\_\_\_  
醫生簽署 見註二

\_\_\_\_\_  
07/04/2014

日期

\_\_\_\_\_  
Dr TANG Kam-shing (Hon Consultant), A0275

醫生姓名正楷和職級





# 3. Fact sheets

- could be printed following by the consent form.

**診斷和治療程序施行的鎮靜麻醉概覽**

**什麼是鎮靜麻醉?**  
鎮靜麻醉是指在一些帶來相當不適的手術或檢查中，透過則舒適。在你關係、平靜和靜止時，醫生就可順暢和安全地施麻醉後，你可能不察覺手術或檢查期間所發生的事情，而記不起相關手術程序。

**鎮靜麻醉前的評估**  
在施行鎮靜麻醉前，你會先接受評估。評估項目包括：  

- 相關病歷、身體檢查和檢驗 (如需要)
- 詳細解釋手術或檢查程序和風險
- 鎮靜麻醉下施行手術或檢查的知情同意書

**如何作準備?**  

- > 醫生會建議你在手術或檢查前至少六小時不准進食或檢查前兩小時，這稱為「禁食」。
- > 對於兒童患者，在手術或檢查前六小時不應該被餵食 (如幼兒奶粉)。在手術或檢查前四小時亦不應該被餵食。
- > 醫護人員或院方會給你清晰的禁食指引，你必須遵守。
- > 在緊急情況下禁食指引未必能依時遵守，請與醫生溝通。
- > 你必需告訴醫生有關你的病歷、最近是否患上任何疾病或服用任何藥物。

**鎮靜麻醉期間會怎樣?**  

- > 在鎮靜麻醉前，手臂靜脈 (或其他可施行的靜脈) 會插入針管，以便注射鎮靜麻醉藥物，或在適當需要時，醫生可能給你止痛藥。
- > 為確保安全，合資格的醫護人員會在鎮靜麻醉期間陪伴你。

**鎮靜麻醉後會怎樣?**  

- > 在鎮靜麻醉/手術或檢查後，你需要接受評估。
- > 如到門診進行此程序，在鎮靜麻醉藥力消失後，由成人陪同出院。

Page 1

Procedural Sedation Safety Committee Version 1.0 (Nov 2013)

醫院管理局·新界西醫院聯網  
急症部  
病人手術資料單張  
膿瘡切開及引流  
Version No. 2014\_01

Name of Patient: \_\_\_\_\_  
HKID No. \_\_\_\_\_  
Sex: \_\_\_\_\_  
Date of Birth: \_\_\_\_\_  
HN: \_\_\_\_\_

**概要**  
皮膚膿瘡是由膿液於皮膚間積聚而成。一般膿瘡為藏於皮膚深處的膿瘡是由細菌感染所引起。最有效治療膿瘡的治療是手術切開及引流。

**步驟**  
醫護人員首先為病人進行局部麻醉，接着在患處切開皮膚，取出膿液樣本或會被收集作細菌培植之用。膿腔將會被妥善清理，一般的引流傷口將會自然癒合。

- 可能出現的風險及併發症(包括常見及重要的風險，未必全部列出)**
- 傷口疼痛，痺麻，傷口流血
  - 結疤
  - 神經線、血管及附近組織受傷
  - 傷口癒合困難
  - 膿瘡復發
  - 對局部麻醉藥物過敏，嚴重可引致死亡

**內視鏡逆行胰膽管造影術**  
病人資料單張 No EDU/ERCP/02

8/2012

**簡介**  
逆行性胰膽管造影術是用作診斷胰臟、膽管、肝臟及膽囊等器官病變的檢查。醫生利用內視鏡技術，能從十二指腸膽管開口處，逆方向地將導管放進胰管或膽管進行X光造影顯影。在進行檢查的同時，也可進行一些小型的治療手術，例如括約肌切開術及放置支架作膽汁引流術。

**適應症**  
病人懷疑患有胰膽管閉塞(如因結石或腫瘤)、急性膽管炎、急性或慢性胰腺炎、手術後胰膽管滲漏等。

**手術步驟**

1. 局部麻醉(咽喉部噴射局部麻醉藥)
2. 進行靜脈注射止痛鎮靜藥
3. 內視鏡將經由口腔插入胃及十二指腸
4. 將顯影劑注入膽管及胰管
5. 將膽管及胰管造影拍成X光片
6. 在需要情況下會進行附加的程序：如括約肌切開術並將膽管內的結石清除，插入膽管固定管或鼻膽引流管

**可能發生之危險及併發症**

1. 與手術有關
  - a. 麻醉併發症：例如血壓降低或肺部吸入消化道物質
  - b. 損傷附近器官包括小腸穿孔(0.6%)、括約肌切開術後流血(1.2%)、胰臟發炎(2%) 及膽管發炎(0.6%)
  - c. 這些併發症如情況嚴重時，可能需要進行緊急手術(2%)，而因此有生命危險(1%)

# 4. A unique serial number of form is enclosed to ensure a correct set of consent form pages are signed and filed.



己、**確認同意** (若病人/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在六個月前已預先簽署此同意書，當病人入院接受手術/醫療程序/治療時，此欄須由醫生/醫療專業人員填寫)

我確認這名病人/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沒有任何其他疑問，並同意這項手術/醫療程序/治療如期進行。

\_\_\_\_\_  
醫生/醫療專業人員簽署

\_\_\_\_\_  
醫生/醫療專業人員姓名正楷/日期

**重要事項：**(請在適當空格內加上✓號)

- 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撤銷此手術/醫療程序/治療同意書 (請病人/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簽署並填寫日期)

\_\_\_\_\_  
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簽署

\_\_\_\_\_  
日期

SN: C0000004986

全3頁之第3頁

SN: C0000004986

全3頁之第2頁

SN: C0000004986

全3頁之第1頁



# Characteristics of custom printed consent

- The HA standard consent forms will be strictly followed in words and format to avoid legal issues.
- A intranet based webpage designed for consent form printing.
- Hyperlink would be uploaded at cluster website and/or committee/ department website for easy reach by users.



新界西醫院聯網 - Windows Internet Explorer  
 http://ntwc.home/

# Informed Consent

**Custom-printed Informed Consent** NEW ←

**Policy on Informed Consent** NEW

**Special Points to note**

- Recommend to provide relevant Fact Sheet(s) to patients / relatives to view before signing of informed consent.
- Direct the request for photocopy of a signed form by patients / relatives to HIRO (Fee charging service).
- Sets of DVDs on Informed Consent Forums / Seminars are available in Hospital Medical Library.

**Guiding Principles of Obtaining Informed Consent for Inter-department Referral Procedures (endorsed on 2012 01 31)** NEW

M&G Department

## Department of Medicine & Geriatrics

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- Contingencies
- Department Announcement
- Duties ▼
- Interns' Corner ▼
- Subspecialty Training Programs
- Department Academic Meeting ▼
- Q&S Subcommittee
- Treatment Protocols and Guideline of Subspecialties
- Fact Sheets
- Handbook
- Link to UpToDate Website
- Kaizen
- Photo Galleries
- Nurse's Corner
- Leave Planning System
- Custom-printed consent**
- Training on Macro & VBA (OLD) Updated Call List (POH)
- (OLD) Treatment Protocols and Guideline

←

TMH Intranet x http://ntwc.home/qualityj...

## tmh.home

- Commonly Used Forms
- CCE's Letter
- NTWC Controlled Document
- Organization Chart
- Guidelines & Procedures
- Hospital Committee
- Departmental Information
- VNC
- Master Index of Store Items(CDC)

NTWC Oasis 新西聯靜心園

電腦應用貼士

10 Feb 11 13:00 密碼重置

Patients' Choice 病人選擇

- HA Drug Formulary
- Infectious Disease Outbreaks (including SARS & AI)
- NTWC ERP Information
- TMH Canteen 屯門醫院餐廳
- TMH Shops 屯門醫院商店資訊
- Event Catering Planning Handbook

Applications

- Advanced Incident Reporting System
- Leave Enquiry and e-Payslip System (LEAPS)
- Computer -Based Maintenance Management System (CMMS)
- Conference Room Booking System
- CPH/SLH Call Management System (CaMS)
- Change LANS Account Password 更改網域帳號密碼
- Custom-printed Informed Consent ICU M&G Paed & AM** ←



# Timeframe of Custom-printed Consent Form Implementation

- Chairman have invited other departments to join during Informed Consent Committee meeting in SEP 2013
- The program have been piloted in late OCT 2013
- Feedback have been collected in DEC 2013
- Second phase of implementation in 1Q 2014



# Feedback from department coordinators

- Comments from users were submitted time to time and fine tuning would be supported by IT colleagues.

Dear Chi Ho,

Thanks for your reply. Point 2 is solved if copy no. is chosen at the screen specified in your email. i.e. We should NOT choose no. of copy at the last print prop up screen after pressing "printer picture icon" on left upper corner of the bottom page. You may need to remind users of this tip or disable the copy no. option of the last printer prop up page.

For point 3, I'll try on other computers and let you know if there's still problem.

Thank you.

Regards,

Hilary

寄件者: C H LAW, NTWC SA(IT)

寄件日期: Wednesday, 23 October, 2013 9:35

收件者: K TSANG Dr, TMH Asso Cons(OPH)

副本: [REDACTED] K S TANG Dr, NTWC SD(Q&S) / NTWC Hon CON(A&IC); P F TANG, NTWC M(Q&S)

主旨: RE: serial no & print sequence: Follow up on uploading custom-printed consent at CMS

Dear Dr. Tsang,

Thanks for your comment.

For point 2, I am not sure if I understand the problem correctly or not. Let me try to explain. If you want multiple copies of the same set consent form with different serial number, you should choose Print Copies option to specify how many copies you required (screen attached). Then, the system will try to generate the file in the lower part of the screen with the number of copies specified and different serial number.

For example, if I specified to print 3 copies of forms of Right/Left Cataract extraction +/-..... the print out will be as in the attached file, with SN: C0000000213 to SN: C0000000215

If you want to print another 3 copies, you should press print form again and other 3 copies will different serial number should be generated.

For point 3, may I ask our support staff to have a look? It seems that it's the default setting of the printer.



# Outcomes

1. Department coordinators received positive feedback from users and are enthusiastic to promote the usage of custom-printed forms.
2. Some subspecialties are advised to explore need to add more consent templates.

寄件者: K TSANG Dr, TMH Asso Cons(OPH)

寄件日期: 08/01/2014 (週三) 1

收件者: P F TANG, NTWC M(Q&S)

副本:

主旨: Re: serial no & print sequence: Follow up on uploading custom-printed consent at CMS

Dear Pui Fan,

The custom-printed system and operation method was demonstrated to our colleagues at our team meeting and received positive feedback. Subspecialty teams are advised to explore need to add other consent templates. There is not yet any new request. We are also doing pilot run to use the pre-printed consents in some clinical sessions. Meanwhile, I will keep colleagues informed of the system and encourage usage. I will also contact IT if we need to add extra forms or amendment.

Regards,

Hilary



3. The number of copies of custom-printed consent forms viewed and/or printed by pilot departments as at 31 MAR are shown:

Department of	No. of view and/or print
ENT	60
ICU	387
M&G / Gastroenterology and Hepatology	3097
M&G / Hematology	1041
OPH	240
Paed & AM (Second phase)	171
(Blank form by department selected)	504





# Way Forward

1. More departments would like to implement custom printed consent form i.e. Paed. & Adolescent Medicine, Surgery and Accident & Emergency in 1Q 2014.
2. Audit will be conducted in 2Q 2014 to check the effectiveness.
3. Customer survey would be analyzed in next phase.
4. Purchase of hard disc memory for back-up storage would be planned in 15/16.
5. Possibility to replace A3 hard copies by custom printed would be discussed.
6. ? Additional manpower for system monitoring would be planned.



# Demo on custom-printed consent

## NTWC Custom-printed Informed Consent

Department	AED
Consent Form Language	English
Print Copies	1
Consent Form	<p><input type="radio"/> Consent for Operation / Procedure / Treatment, Requiring Anaesthetist(s)</p> <p><input checked="" type="radio"/> Consent for Operation / Procedure / Treatment, NOT Requiring Anaesthetist(s)</p> <p><input type="radio"/> Form for Patient who are Unable to Consent for Operation / Procedure / Treatment</p> <p><a href="#">Print Preview (blank form only)</a></p>
Procedure	<p>Suture of Laceration</p> <p>Procedure's Indication Items</p> <p><input type="checkbox"/> Abdominal laceration   <input type="checkbox"/> Back laceration   <input type="checkbox"/> Buttock laceration   <input type="checkbox"/> Chest laceration   <input type="checkbox"/> Facial laceration</p> <p><input type="checkbox"/> Left arm laceration   <input type="checkbox"/> Left finger laceration   <input type="checkbox"/> Left foot laceration   <input type="checkbox"/> Left hand laceration   <input type="checkbox"/> Left leg laceration</p> <p><input type="checkbox"/> Left toe laceration   <input type="checkbox"/> Multiple lacerations   <input type="checkbox"/> Neck laceration   <input type="checkbox"/> Right arm laceration   <input type="checkbox"/> Right finger laceration</p> <p><input type="checkbox"/> Right foot laceration   <input type="checkbox"/> Right hand laceration   <input type="checkbox"/> Right leg laceration   <input type="checkbox"/> Right toe laceration   <input type="checkbox"/> Scalp laceration</p>
Doctor List	===Select===
(Input Doctor Name if not in list)	<input type="text"/>
Procedural Sedation	<input type="checkbox"/>
Anaesthetist	
Print Today Date	<input checked="" type="checkbox"/> Print Date



# Questions & Comments