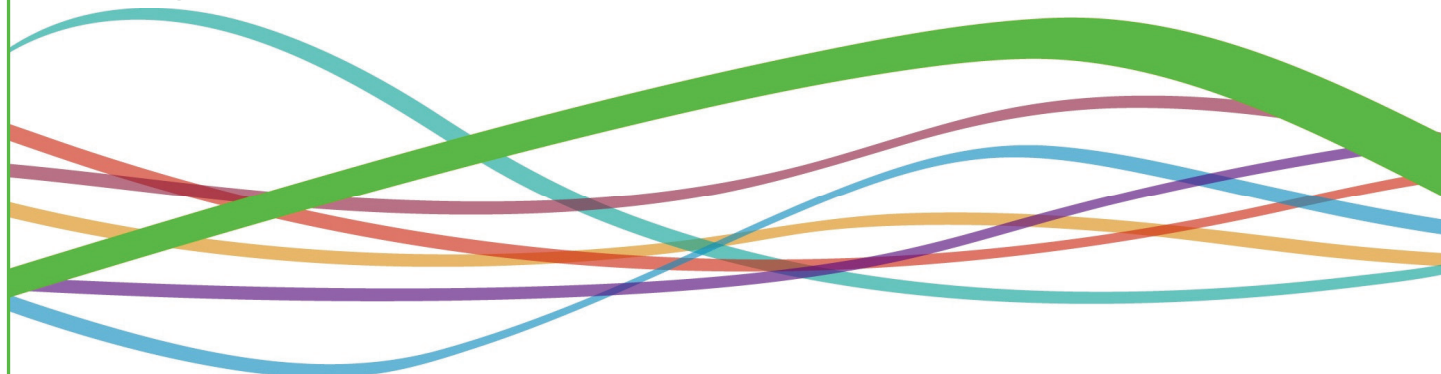


# Protocol

## **Assessment of the clinical and economic effectiveness of anti-infective urinary catheters when implemented in routine clinical practice**

CEP09014

May 2009



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## Current products

Catheter-associated urinary tract infection (CAUTI) represents an important economic burden on healthcare providers. There have been many initiatives to reduce the risk of these infections, both by healthcare product manufacturers and infection control teams. One such initiative is the production of catheters coated with anti-infective materials.

Products currently on the market include catheters impregnated with antimicrobial drugs like nitrofurazone, minocycline and rifampin or antiseptic material coatings such as silver oxide and silver-hydrogel. Although some NHS trusts have adopted these devices, others are seeking more evidence. Most studies which have tried to test the efficacy of these products have been too small in scale to be able to detect or quantify their effect, or have methodological flaws that affect the interpretation of the results [1]. There is one promising multi-centre study currently evaluating two different anti-infective catheter types but the results are not yet available [2].

## This protocol

This protocol has been developed as a means of assessing the clinical and cost effectiveness of any new anti-infective urinary catheter. It can be used as part of a controlled implementation programme in a clinical setting. It addresses methodological problems found in previous studies and, because of the stepped wedge design employed, can be used to combine assessment with the phased roll-out of the new catheter. At the end of the study, all participating wards will have adopted the new catheter, and can continue to use it where the results are favourable. The practicability of the stepped wedge design make it ideally suited to the assessment of a product which can reasonably be assumed to be at least as good as that which it is intended to replace.

Local policies, procedures and ethical considerations should be incorporated as appropriate.

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## Stepped wedge design

The stepped wedge design [3] offers a more practicable alternative to other randomised controlled methods, where the product to be assessed can reasonably be assumed to be at least as good as that which it is intended to replace. The design is intended to estimate both clinical effectiveness and cost effectiveness of a new anti-infective catheter, compared with current (conventional) catheters, when implemented in routine clinical practice. Administrative issues are minimised, and at the end of the study all eligible patients in all participating wards will be catheterised with the trial catheter.

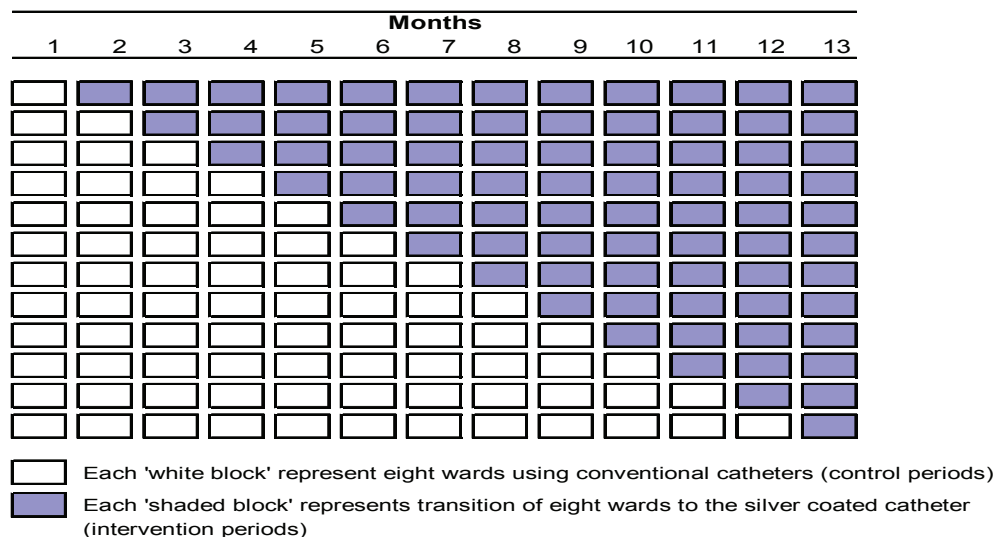
Patients requiring urinary catheterisation are allocated to receive either a conventional catheter or anti-infective catheter. The ward in which they are located is used as the unit of randomisation. For the purpose of this protocol 'conventional catheter' means whatever catheter type is normally used on the ward, and refers to catheters not coated with antibacterial material.

At the beginning of the study all participating wards will catheterise patients with conventional urinary catheters for a period of one month. The protocol aims to establish whether the new anti-infective catheter confers any benefit over conventional catheters (without an antibacterial coating), eg latex or latex hydrogel, but does not attempt to distinguish between the performance of different types of conventional catheters.

This will provide baseline data on the incidence of CAUTI (as defined in table 1). At the end of each subsequent month, wards will be selected at random to convert to the anti-infective catheter and subsequently all patients requiring catheterisation on that ward will receive an anti-infective catheter until the end of the study. At the end of the study period all participating wards will have converted to using the anti-infective catheter (figure 1).

The organisation responsible for co-ordinating the study will inform the hospital which wards should change to anti-infective catheters. Ideally, hospital study staff should be blinded to the type of catheter in use, though this might not be feasible if different catheter types can be identified by their appearance.

**Figure 1. Representation of the stepped-wedge study design for investigation of anti-infective urine catheters**



Baseline demographic data will be collected on all catheterised patients included in the study. They will then be monitored for CAUTI according to the case-definitions described in Table 1 and using a defined method of case finding e.g. patients with a catheter being monitored three times per week for signs/symptoms that meet the case definitions to include review of treatment/temperature charts, nursing and medical records and microbiology results. Patients will be followed up for the duration of their catheterisation and for 48 hours after removal (or until discharge), unless a new catheter is inserted within 24hrs of removal when monitoring will be continued. Collection and testing of urine specimens will follow local procedures for following up catheterised patients. Local procedures should as far as possible be based on National Standard Method BSOP41 [4].

Data on the treatment and additional length of hospital stay attributable to CAUTI, together with data on morbidity and outcome will be collected for all patients that develop CAUTI to evaluate the costs associated with infection and the cost-benefit of using the anti-infective catheter.

## Outcome measures

The effect of using the anti-infective catheter will be measured by comparing the two groups for the following outcomes:

- primary outcomes
  - percentage of catheterised patients with CAUTI
  - incidence of CAUTI per 1000 catheter days
- secondary outcomes
  - sub-group analysis of risk of CAUTI associated with patients colonised at the time of catheterisation.

**Table 1. Proposed definitions of CAUTI to be used during the study (5)**

Catheter associated urinary tract infection	<p>More than or equal to <math>10^4</math> CFU/ mL from a catheter specimen <b>PLUS</b> at least one of the following with no other recognised cause:</p> <ul style="list-style-type: none"> <li>○ Loin pain</li> <li>○ Loin or supra-pubic tenderness</li> <li>○ Fever (skin temperature of more than 38 °C)</li> <li>○ Pyuria (<math>\geq 10^4</math> white blood cells/ mL)</li> </ul> <p><b>OR</b></p> <p>Physician diagnoses UTI, initiates anti-microbial treatment and patient has at least two of the following with no other recognised cause:</p> <ul style="list-style-type: none"> <li>○ Loin pain</li> <li>○ Loin or supra-pubic tenderness</li> <li>○ Fever (<math>\geq 38^\circ\text{C}</math> skin temperature)</li> <li>○ Pyuria (<math>\geq 10^4</math> white blood cells/ mL)</li> </ul>
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## Study population

The wards recruited to the study will be general surgery, orthopaedics, gynaecology and general medicine as these wards are likely to have the greatest proportion of patients with urinary catheters. Participating trusts will recruit all wards in their area into the study that fulfil the inclusion criteria.

### Inclusion criteria

- Wards should have a catheterisation rate of at least 20% of admissions.
- Average duration of catheterisation of at least 2 days.
- Patients transferred from a ward with the control catheter to a ward with the trial catheter, if re-catheterised on the trial ward.
- Patients to be at least 18 years of age.

### Exclusion criteria

- Wards already using anti-infective catheters.
- Wards with a catheterisation rate below 20%.
- Duration of catheterisation less than 2 days.
- Multiple catheterisation episodes, eg two catheters inserted >24 hours apart.
- Patient discharged home with a trial catheter, ie lost to follow-up.
- Patient discharged with the trial catheter but returned to hospital with a CAUTI.
- Patient less than 18 years of age.

## Sample size calculations

A program was written in STATA 8.2 software (6) to provide an estimate of the statistical power for the proposed study. A 13 month study gives a power of 81% for a 20% reduction in CAUTI.

To achieve this, 96 wards need to be recruited into the study (for example 32 general surgical wards, 32 orthopaedic wards, 16 general medical wards, and 16 gynaecological wards). This is based on an assumption that each of these wards will have 30 admissions per week, ie 120 admissions in a month.

The parameters required for the simulation were obtained from Glynn *et al* [7].

**Table 2. Estimates obtained from a clinical audit of hospital acquired infections**

Ward	Percentage of patients catheterised	Average (SD) duration of catheterisation	Incidence of catheter-associated UTI (CAUTI)
General surgery	34%	3.5 (1.17) days	3.9 per 1000 catheter days
Orthopaedics	17%	6 (2.00) days	3.5 per 1000 catheter days
General medicine	12%	5 (1.67) days	2.8 per 1000 catheter days
Gynaecology	40%	2 (0.67) days	16.7 per 1000 catheter days

Combined with the number of admissions per ward the mean number of CAUTIs per month was estimated. These were used as Poisson means in a random generation of Poisson counts. A fixed denominator of the number of catheter-days per month in each ward was also calculated.

From two published papers (8, 9) it would appear that there is an estimated 20% reduction in the incidence of catheter-associated UTI. A range of reductions in CAUTI from 10% to 80% was used to simulate outcomes.

A “mixed” model was fitted to the randomly generated outcome data, using the xtreg command in STATA. The residuals from this model are assumed to have a normal distribution.

Outcome variable: randomly generated Poisson count (using mean number of CAUTI per month).

Predictor variables: intervention (silver-coated catheters) (binary) (fixed effects) specialty of ward (4 level factor).

Offset: natural logarithm of the number of catheter-days.

Random effect: ward (assumed to be normally distributed  $N(0, \sigma)$ ).

One thousand simulations were performed for each combination of intervention effect from 10% to 80% reduction in CAUTI, in steps of 10% (table 3). The simulations included number of participating hospitals, being either 4 or 8, with each hospital having 12 wards in the study (4 each of general surgery and orthopaedics, and 2 each of general medicine and gynaecology). This will lead to a study with either 48 or 96 wards in total. No hospital effect has been included in this study, with all wards being considered as independent in the simulations. The estimated power is defined as the proportion of simulations for which the intervention effect is significant at the 5% level.

**Table 3. Estimated statistical power for a range of intervention effects and numbers of recruited trusts**

Assumed reduction of intervention	Number of hospitals (wards) recruited to study:		
	9 months study duration		13 months
	4 (48 wards)	8 (96 wards)	8 (96 wards)
CAUTI outcome			
5%	NC	NC	7.7%
10%	12%	20%	29.5%
15%	NC	NC	54.1%
20%	36%	57%	<b>81.0%</b>
25%	NC	NC	<b>94.6%</b>
30%	67%	<b>92%</b>	<b>98.3%</b>
40%	<b>88%</b>	<b>100%</b>	NC
50%	<b>98%</b>	<b>100%</b>	NC
60%	<b>100%</b>	<b>100%</b>	NC
70%	<b>100%</b>	<b>100%</b>	NC
80%	<b>100%</b>	<b>100%</b>	NC
<b>Notes:</b>	Emboldened cells indicate those with sufficient statistical power. NC = not calculated.		

On the assumption that eight hospitals would be used, each having 12 study wards, around 74,880 patients would be expected to be admitted to each arm of the study resulting in around 19200 catheters in the anti-infective catheter study arm and 19200 catheters in the conventional catheter study arm (38400 urinary catheters in total) using the catheterisation rates observed by Glynn *et al.* This should result in 393 and 314 CAUTIs in the conventional and anti-infective catheter groups respectively, assuming a 20% reduction. It might be possible to use six hospitals in the study each having 16 study wards, provided that the correct type of wards are recruited and that the data collector assigned to each hospital can realistically cover 16 wards.

## Background

This section describes the requirements for capture, validation and storage of data for an anti-infective catheter study. A technical specification for a suitable database is available on request from CEP.

This document does not cover procedures to be followed by data collection staff and study nurses. These must be designed and implemented by the study manager/coordinator.

The software and hardware used to develop the database will depend on local expertise and available technology. Current software such as SQL Server (structured query language), SQL Express, SQL Server Client and Microsoft Visual Studio.Net may be appropriate together with relevant database servers. The machines used by study nurses must be configured to use systems such as Internet Information Services (IIS) and the .net framework.

## System activity

In the example given in this protocol the system will be used by six study nurses (or clinical data coders) located in separate hospitals. Between them they will cover ninety-six wards across these hospitals and approximately 38,500 patient records will be collected during the life of the project.

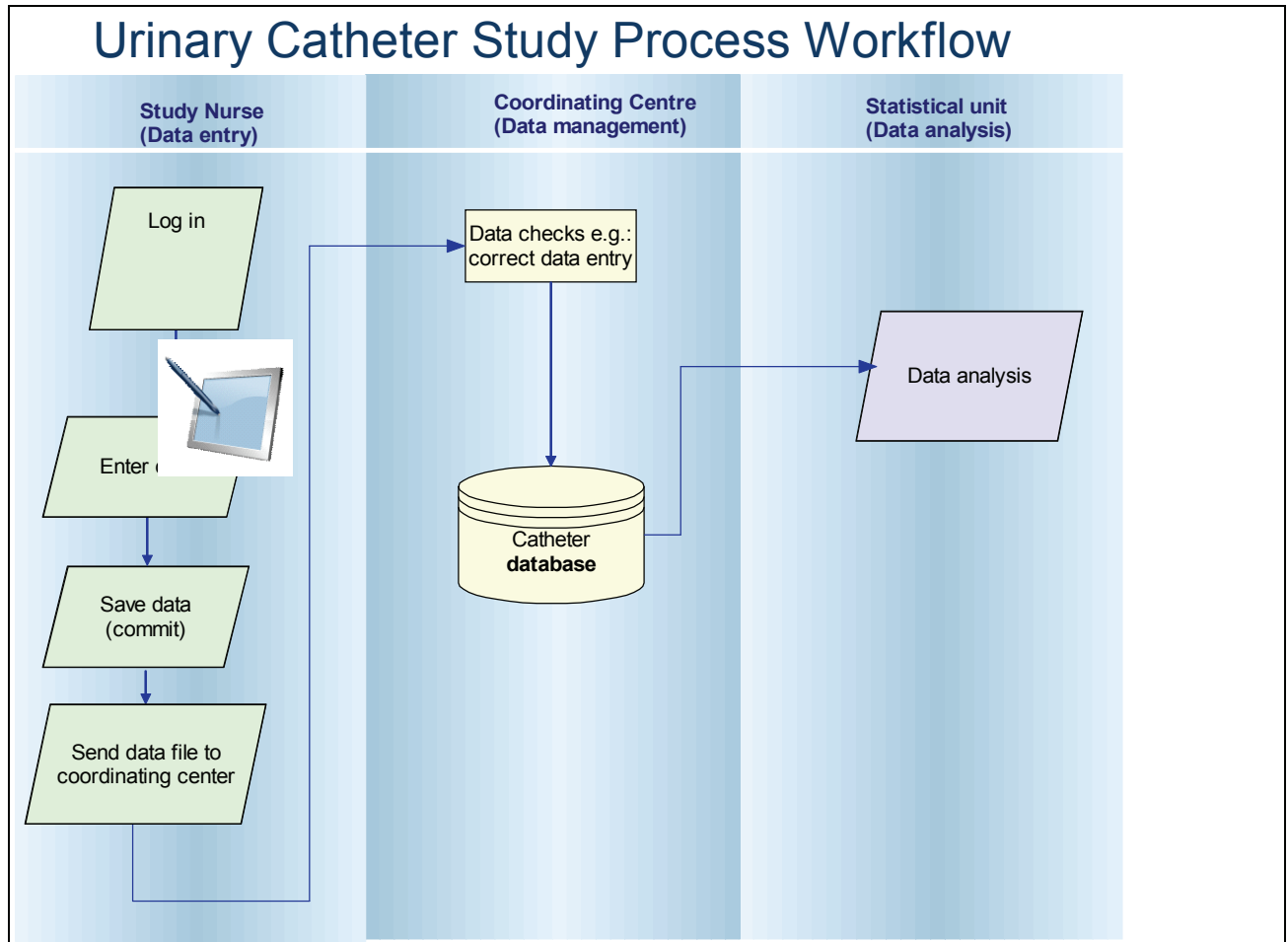
The maximum daily volume of data which could be generated will not impact on database performance to any significant degree, though the pilot study will provide a more accurate view of daily activity levels.

## Database design

The database system is designed to facilitate the accurate collection of data from a number of separate locations and to amalgamate the data in a single secure database ready to be converted into a suitable format for analysis at a later stage.

It is proposed that input of data to the catheter study database should be done on the wards using a portable or hand held computer device. The data will then be entered by the study nurses into local databases at the point of collection, where they will be validated prior to being uploaded to the central database on a daily basis. Figure 2 illustrates a broad overview of the flow of data through the life cycle of the study.

Figure 2. Database system overview



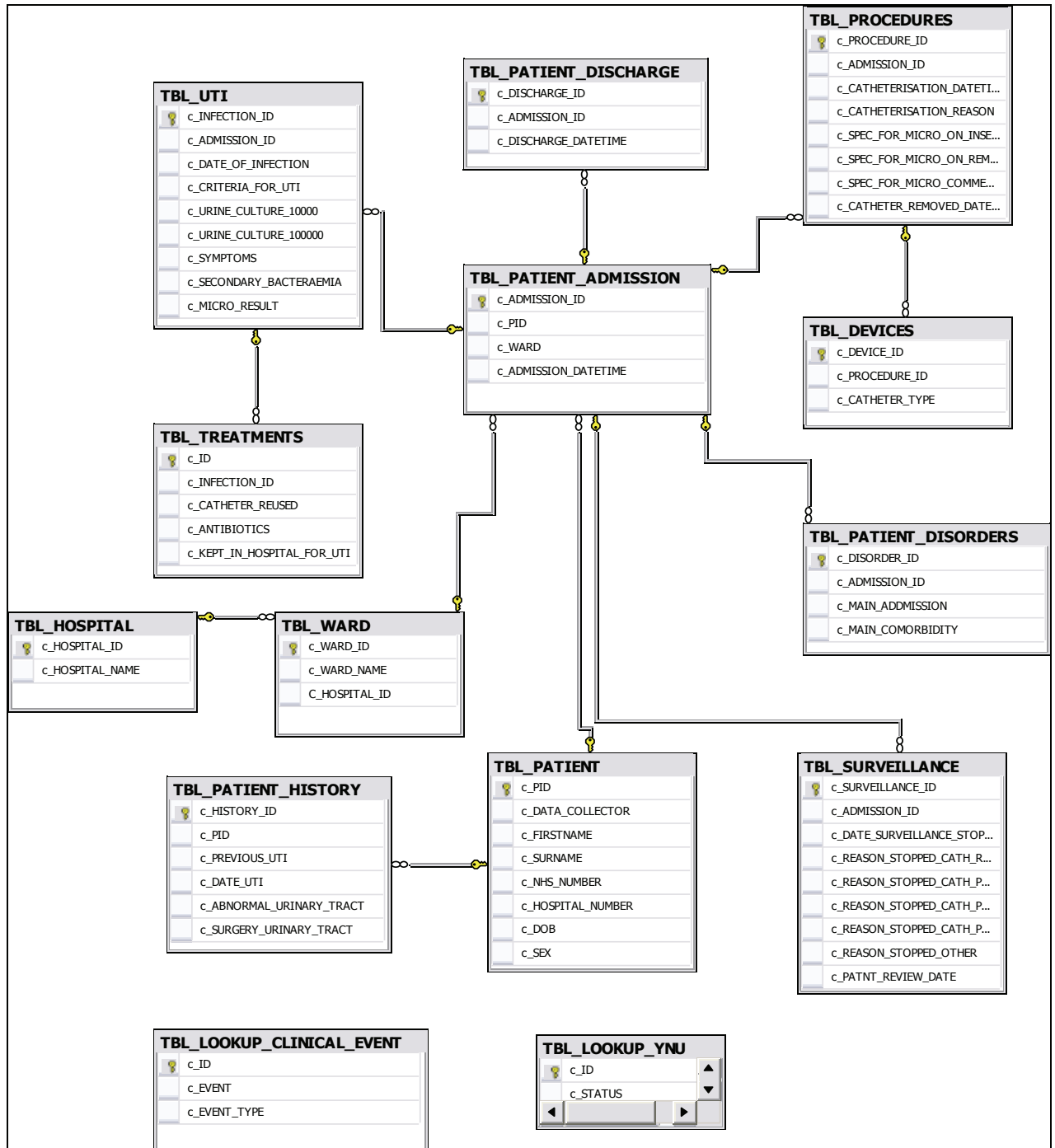
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## Data capture & validation

Figure 3 summarises the categories of data to be collected for the study. In order to reduce the risk of erroneous entry and to minimise the data entry burden on the study nurses, data entry, wherever possible, should be achieved using drop-down lists of appropriate values. It should not be possible to enter free text into this type of field. The list below summarises some of the constraints on the system.

- Data entry should be via drop-down lists wherever possible , limiting free text entry.
- All data should be validated according to set rules (including format checking, range validation and mandatory/optional checks).
- Each record written to the database should be automatically assigned an integrity key which will be used to ensure that no changes have been made to the data outside the study system.
- A record should be kept of the user (including hospital identifier) who entered the data and the time and date they were stored in the database. Any subsequent changes to the data should be user and date-time stamped.
- No data should be deleted when changes are made; old data should be assigned a status flag which identifying them as 'archived' data. This will ensure that a full audit trail can be maintained on all data.
- The study nurses should transfer data daily to a system resident on a central server for automated processing. The system should flag each record sent to the central server as "transferred" on the local database.
- Access to the system should be controlled via a user ID/password combination which should define the rights of the user.
- The system should be designed and built in a way which ensures that ordinary users require no expertise in the underlying technology. An expert system/database administrator is, however, required.
- A standard data extraction routine should be provided within the system to allow data to be output for subsequent processing in statistical applications.
- This processing will consist of checking each record's integrity key – i.e. ensuring that the data have not changed since entry. Any data failing this check should be written to an area for manual checking/resolution. All successfully validated data should be written to the catheter study database.

Figure 3. Example representation of the relationships between data groups

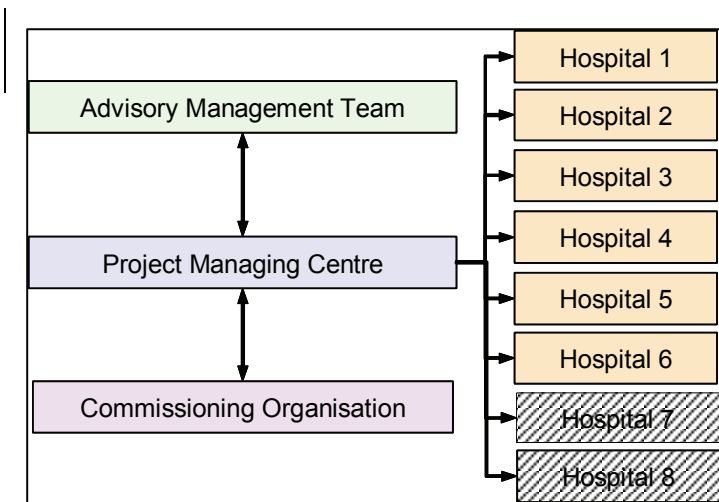


## Interactions

At an organisation level the study depends on interaction between the commissioning organisation, an advisory management team, hospital trusts and a managing centre (figure 4).

The advisory team should provide advice on the design and operational aspects of the study and should comprise experts involved in healthcare associated infection, urology, nursing, statistics and health economics.

**Figure 4. Organisation interactions**



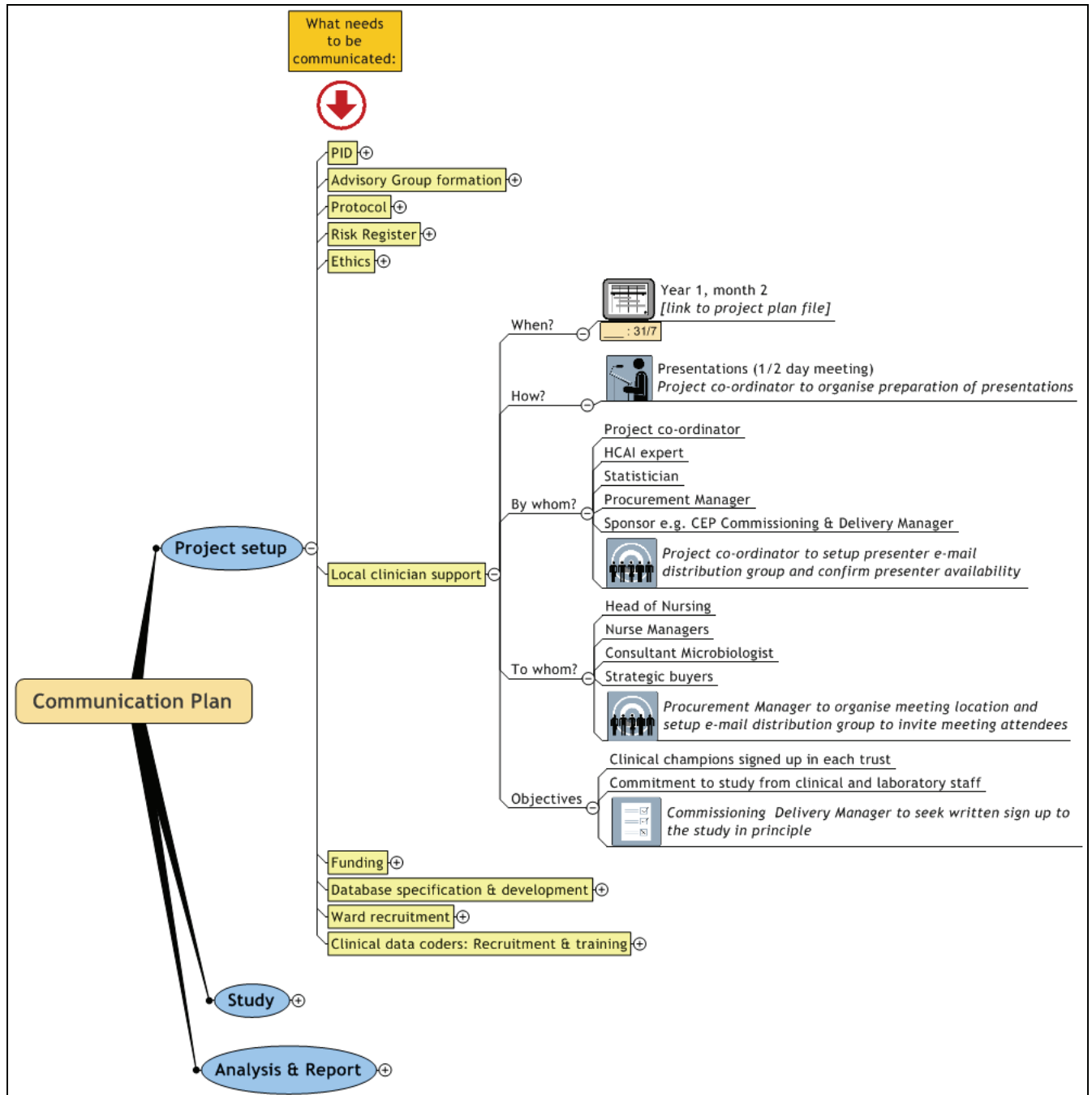
## Communication plan

The study requires an effective communication plan to manage interactions between participants and associated information transfer. The project co-ordinator needs to identify what aspects of the project need to be communicated, when, how, by whom, to whom, and associated objectives and measures of success. Figure 5 shows how a communications plan might be developed using mind mapping software. In this map one aspect of the project (local clinical support) has been used as an example; other aspects would need to be developed in the same way.

A RACI matrix (figure 6) can provide a basis for the communication plan by identifying those **R**esponsible for information transfer, the people to whom they are **A**ccountable, the people with whom they must **C**ommunicate, and the people they must simply **I**nform.

For a project spread across different sites, a project website (via login) can be a valuable way of sharing documents and information.

Figure 5. Communication plan (mind mapping software format)



**Figure 6. RACI matrix for project delivery**

Task	Responsible	Accountable	Communication	Information
<b>Project delivery</b>				
Protocol	MC	CM	S HCAI	
Risk Register	MC	CM	PM NM	
Ethics	MC	CM		CC
Salaries for study nurses	NM	HR	MC	
Dataset	MC	CM	HCAI HE CC	
Database	SC	MC		CC
Clinical Data Coder job description, person spec	NM	DN	MC HCAI PM NM CC	
Clinical Data Coder recruitment	NM	DN	HCAI	
Ward recruitment	PM	MC	DN NM S CC	
Training (pre-study)	NM	DN		
Training of Clinical Data Coders	MC	NM	PM NM HCAI CC	
Data collection	SN	MC	CM HCAI SS	
Data analysis (technical)	S	MC	HCAI	
Data analysis (economic)	HE	MC		
Report	MC	CM	HE HCAI S	

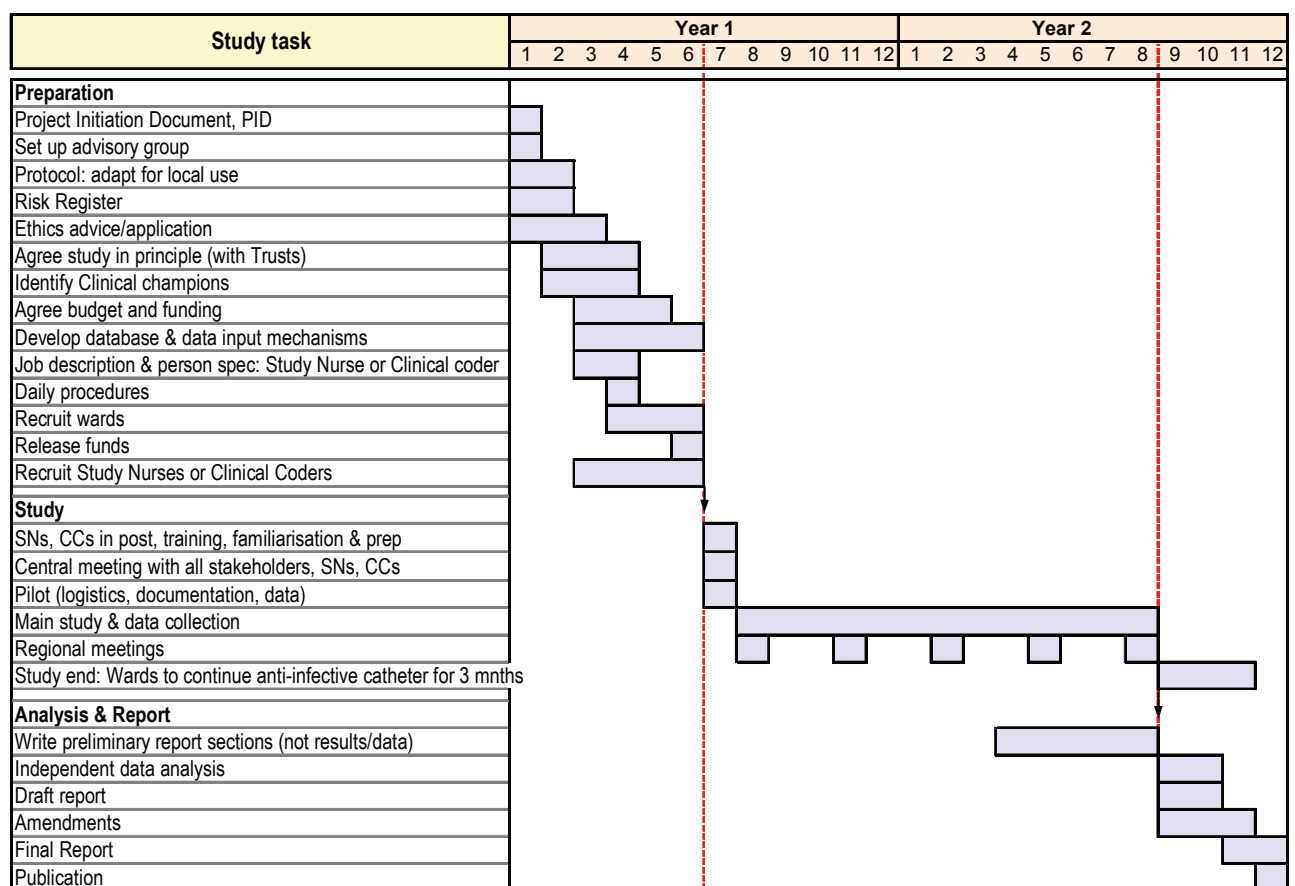
Abbreviation    Role

MC	Managing centre
S	Statistician
HE	Healthcare economist
HCAI	Hospital & community acquired infection expert
NM	Nursing manager
DN	Director of nursing
SN	Study nurses or clinical data coders
CC	Clinical champion
SC	Software consultant
SS	Software support
PM	Procurement manager (or strategic buyer)
CM	Commissioning manager
HR	Local human resources / personnel department

## Project plan

The outline project plan in figure 7 indicates that the study requires a lead in time of 6 months with the main constraints being Trust agreement, database development, and staff and ward recruitment. The pilot phase is for one month and then the actual study lasts 13 months. The data analysis and report writing is anticipated to take about 3 months, to bring the overall length of the project to 2 years.

**Figure 7. Project plan**



## **Ethical considerations**

Ethical approval is not generally required for this type of service evaluation study. However, studies should always be conducted in accordance with good ethical practice, and local trust advice should be sought in this regard. Care should be taken to ensure compliance with the provisions of the Data Protection Act (2000), and issues of patient confidentiality should be reviewed locally within participating hospitals.

### **National Research Ethics Service**

The National Research Ethics Service (NRES) considers studies of this type service evaluation, which does not require ethical approval, either from NRES or from local research ethics committees. However, all studies on human subjects should be conducted in accordance with good ethical practice.

With regard to use of patient data, only the patient's health care professional will have access to identifiable data. The managing centre will only see anonymised data. Given this, and the insensitive nature of the data, NRES were of the opinion that consent for use of the data is not required.

### **Multi-research Ethics Committee**

The London MREC considers that ethical approval and an SL24 letter are not needed for a study of this type. The MREC felt that the wording of the response provided by NRES (which oversees RECs) mirrored that of the SL24 letter and it would be a duplication of work to ask a REC to issue the same wording, albeit in a letter format.

### **Patient Information Advisory Group**

Under section 60 of the Health and Social Care Act 2001, the Patient Information Advisory Group (PIAG) must be informed if patient identifiable information is used when patient consent has not been obtained.

The database used for an anti-infective catheter study must be developed to ensure that all such data are coded at the hospital site. External sites such as the managing centre must not have access to patient identifiable information. Where these conditions are met, it is not necessary to inform PIAG.

## Direct NHS costs

The aim of the economic analysis is to establish whether implementation of the new anti-infective catheters is cost-effective. The objective is to measure the resource use of inpatient care during catheterisation and treatment of CAUTI, in order to determine the potential cost benefits associated with any measured reduction in the incidence of CAUTI.

The data collection will be used to measure total resource use required during a hospital episode of catheterisation (including treatment of CAUTI where necessary) and to measure the difference in resource use associated with implementation of the new anti-infective catheters. Local and national unit costs are applied to each resource to determine the cost difference between catheters. The outcome is presented as the cost per catheterised patient.

**Table 4. Resource use data collection**

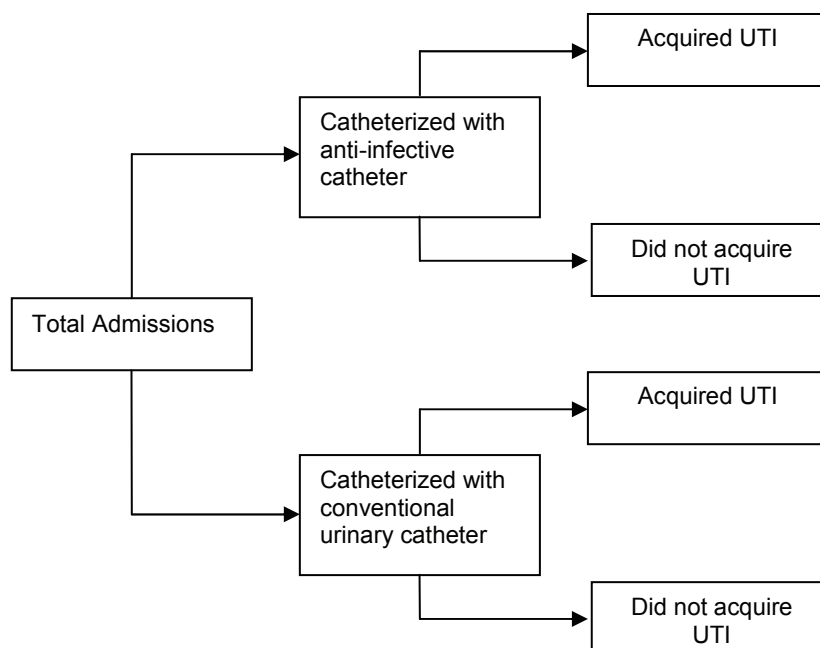
Resource use data	Source/comment
Length of stay (bed days)	Patient demographic data
– Attributable to CAUTI	
Length of catheterisation	
Nursing time	
– Overall	
– Attributable to CAUTI	
Medical time	
– Overall	
– Attributable to CAUTI	
Consumables	Type and quantity
- Overall	
- Attributable to CAUTI	
Medication	Type and quantity
- Overall	
- Attributable to CAUTI	
Laboratory tests	Type and frequency.
– Overall	
– Attributable to CAUTI	

The data collection is designed to populate an economic model based on Plowman et al, 2001 (10). Plowman et al calculated the number of catheterized patients affected by UTIs, the costs incurred in secondary care and identified the potential benefits of reducing the incidence of CAUTI through the use of silver alloy coated catheters. This analysis will compare the total cost of care of catheterised patients with anti-infective or conventional catheters, based on incidence and costs of CAUTI. The model is intended to evaluate a number of alternative scenarios. The structure of

the model is presented in figure 8. An interactive Excel version of the model (CEP09014-I) may be downloaded from the CEP website.

The overall length of stay, nursing and medical time, consumables, medication, laboratory tests and data on additional care attributable to CAUTI will measure the total cost of care per patient per hospital episode. This will be the basis for the cost comparison between anti-infective and conventional catheters for the study population. The breakdown of resource use in to what is attributable to catheterisation and what is attributable to CAUTI will allow more detailed analysis of the data if required. This can be useful for distinguishing the key cost differences between the use of the different catheters compared in the study, as well as highlighting additional resource usage of catheterisation attributable to CAUTI.

**Figure 8. The structure of the economic model**



The mean value from the whole study population for each resource needs to be calculated and then the appropriate unit costs applied to determine a mean cost per resource. As well as presenting the total mean cost per patient, results are disaggregated into the main resource headings of length of stay, nursing time, medical time, medication, consumables (it may be useful to include the total cost of catheters separately), laboratory tests and the additional care for CAUTI.

## Indirect costs

Costs other than the direct resource cost to the NHS demonstrated in the model above should be considered when determining the cost effectiveness of anti-infective urinary catheters. Effectiveness measures like patient quality of life and the indirect costs associated with the sequelae of secondary infections are more difficult to quantify, but should nevertheless be taken into account in the final decision-making process, particularly, for example, where the new anti-infective catheter appears to be cost neutral or to incur greater costs than the conventional catheter on the basis of direct costs alone.

Quality adjusted life years (QALYs) are one method of assessing the effectiveness of the different types of catheters, measuring the difference in quantity and quality of life associated with catheterisation and acquiring a CAUTI. This involves using baseline questionnaires at the time of first catheterisation and a questionnaire prior to hospital discharge. These questionnaires assess the patient's relative health state. More information on QALY usage in assessing the efficacy of anti-infective catheters is provided in the HTA (2006) protocol [2].

We should like to thank the following for their contribution to this protocol.

Adele Long (Director) and Dr Nicola Morris (Research Manager), BioMed Centre,  
Bristol Urological Institute, Southmead Hospital, Bristol, BS10 5NB

Graeme Hall, Almac (BPS) Ltd

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## Appendix 1: Data collection fields for a study of anti-infective catheters

Section	Title	Field Type	Details	Comments/sample data
[A]	Study number			Study number convention to be decided
[B]	Patient Identifiers			
	Surname	Free text (25 characters)		Managing centre must not view this information
	Forename	Free text (25 characters)		Managing centre must not view this information
	NHS number	Free text (50 characters)		Managing centre must not view this information
	Hospital number	Text (30 characters)		Managing centre must not view this information
	DOB	Dropdown	Enter as DD/MM/YYYY format	Eg: 29/03/1960 Managing centre must not view this information
	Age	Numerical	3 digits	To be calculated from DoB. HPA to be able to view 'Age field, but not 'DoB' field
	Hospital	Dropdown		Fixed field according to each hospital?
	Ward	Dropdown		Dropdown to relate to hospital field To be decided on pilot
	PID	Auto number	Number randomly generated to identify a patient for this particular study	Number to start with prefix to identify the hospital
[C]	Patient demographic data			
	Sex	Dropdown	Male, Female, Unknown	
	Main reason for this admissions	Dropdown	To include Other, Please specify	
	Main co morbidities	Dropdown	To include Other, Please specify	Ability to select more than one option is required (space for 10 choices)
	a. Date admitted to hospital b. Time admitted	a. Calendar selection b. Clock selection	a. Calendar is compulsory field b. Time is optional	
	a. Date of discharge b. Time of discharge	a. Calendar selection b. Clock selection	a. Calendar is compulsory field b. Time is optional	

Section	Title	Field Type	Details	Comments/sample data
<b>[D] Patient risk factor data</b>	Previous history of UTI (in last 4 weeks)	Dropdown	Yes / No / Unknown	
	(if yes) Date of last episode	Dropdown	Select date from calendar	
	Abnormality of urinary tract	Dropdown	<ul style="list-style-type: none"> <li>o Enlarged prostate</li> <li>o Carcinoma</li> <li>o Kidney stones</li> <li>o Other –please specify</li> </ul>	
	Surgery on urinary tract	Dropdown	<ul style="list-style-type: none"> <li>o TURP</li> <li>o Kidney</li> <li>o Prostrate</li> <li>o Ureter</li> <li>o Bladder</li> <li>o Other –please specify</li> </ul>	Ability to choose more than one
<b>[E] Type of catheter</b>	a. Date catheterised b. Time catheterised	a. Calendar selection b. Clock selection	a. Calendar is compulsory field b. Time is optional	
	Catheter material	Dropdown	<ul style="list-style-type: none"> <li>o Hydrogel</li> <li>o Hydrogel and silver coated</li> <li>o Other, please specify</li> </ul>	
	Catheter size	Dropdown	<ul style="list-style-type: none"> <li>o 12 CH</li> <li>o 14 CH</li> <li>o 16 CH</li> <li>o Other, please specify</li> <li>o Hydrogel and silver coated</li> <li>Other, please</li> </ul>	
	Reason catheterised	Dropdown	<ul style="list-style-type: none"> <li>o Urine measurement</li> <li>o Surgery</li> <li>o Incontinence</li> <li>o Retention</li> <li>o Other, please specify</li> </ul>	
	Specimen taken for micro: a. ON insertion: b. On removal:	a. Dropdown b. Dropdown	a. Yes/ No/ Unknown b. Yes/ No/ Unknown	
a. Date catheter removed b. Time catheter removed	a. Calendar selection b. Clock selection	a. Calendar is compulsory field b. Time is optional		
Date surveillance discontinued	Calendar selection	Calendar is compulsory field		
Reason surveillance discontinued:	Dropdown	<ul style="list-style-type: none"> <li>o Catheter removed</li> <li>o Patient discharged</li> <li>o Patient died</li> <li>o Patient discharged from study ward</li> <li>o Other-please specify</li> </ul>		
<b>[F] Surveillance data</b>	Date patient reviewed	Calendar selection		

## **Protocol: Assessment of the clinical and economic effectiveness of anti-infective urinary catheters when implemented in routine clinical practice**

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