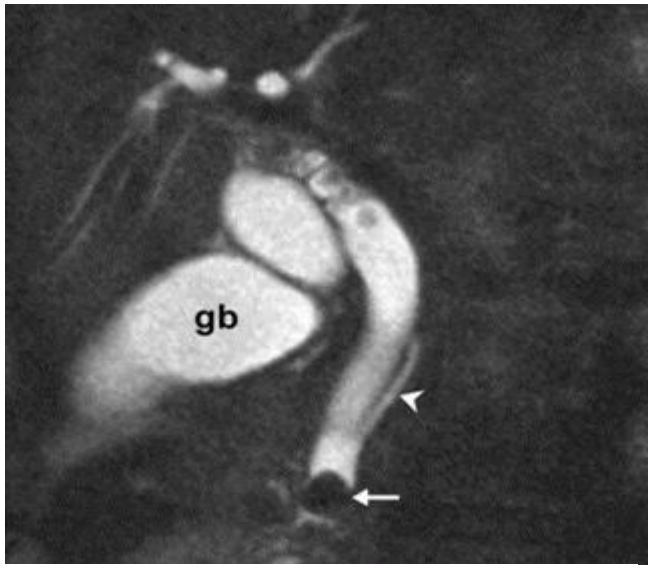
The Sunflower Study

Presenter: (ADD NAME)
Associate Principal Investigator: (ADD NAME)
Principal Investigator: (ADD NAME)

Background

- Approximately 70,000 cholecystectomies performed annually in the UK.
- Occasionally (2-5% of patients), gallbladder stones may move in to the common bile duct, where they may remain without symptoms, cause problems or move spontaneously in to the stomach.
- There is uncertainty amongst surgeons as to whether or not, in low/medium risk patients, further tests to look for common bile duct stones are necessary.
- As a result, some surgeons choose to perform the test and others don't.
- A robust study is required to establish which approach leads to the best outcomes for patients and is most cost effective.
- The results from the Sunflower Study will shape the future care of patients at low/medium risk of common bile duct stones who are undergoing gallbladder removal surgery.



The Sunflower Study

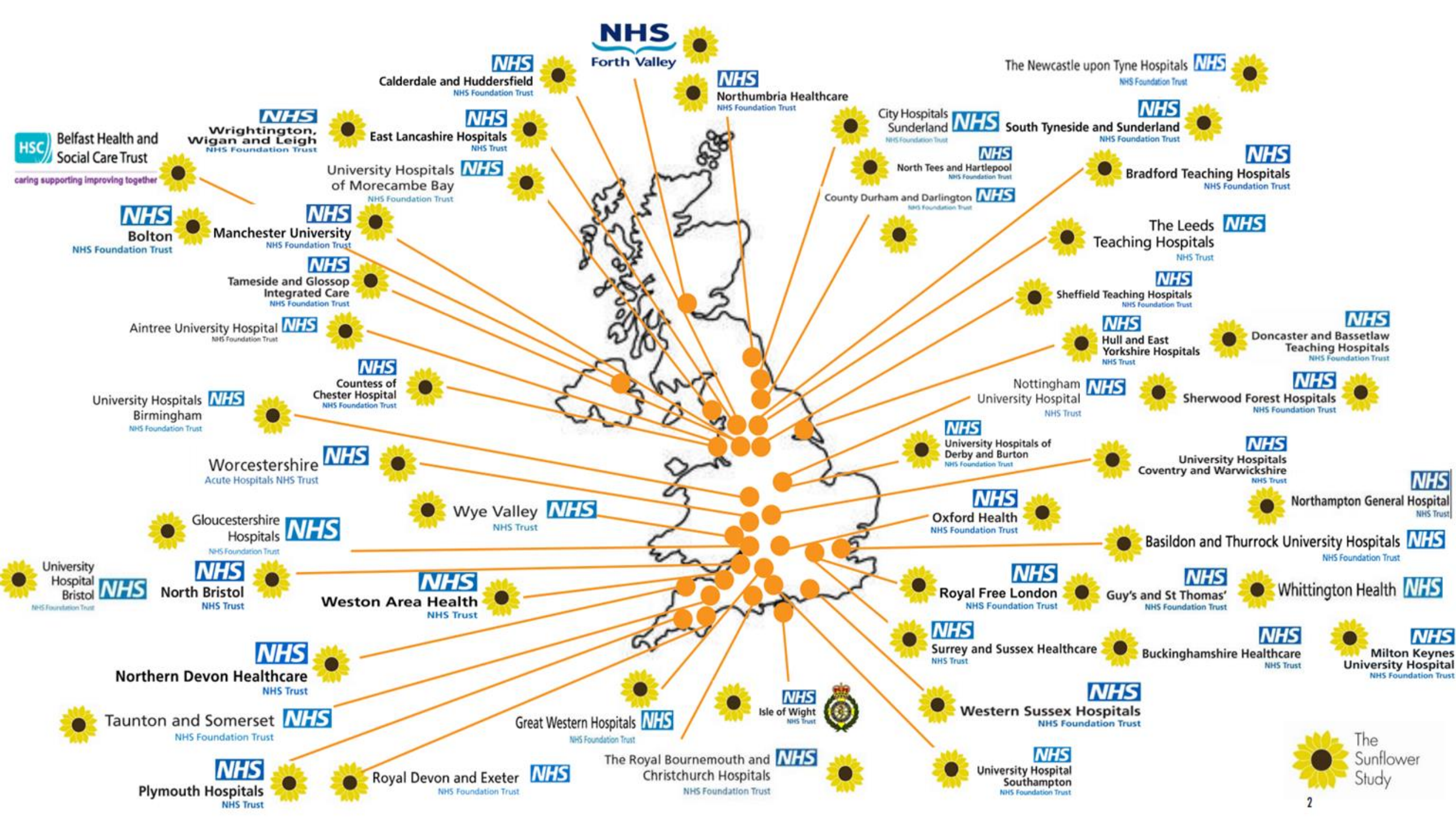
Aim of study

A randomised controlled trial to establish the clinical and cost effectiveness of expectant management versus pre-operative imaging with MRCP in patients with symptomatic gallbladder disease undergoing laparoscopic cholecystectomy at low or moderate risk of common bile duct stones

Primary outcomes to review:

- **Any hospital admission within 18 months of randomisation for treatment of complications of gallstones, whether in the CBD or gallbladder.**
- **Complications during the admission for lap cholecystectomy for the treatment of gallstones or any readmission for post-operative complications.**
- **Complications during any ERCP for the treatment of gallstones.**

The Sunflower Study


NHS Forth Valley
Belfast Health and Social Care Trust
caring supporting improving together
Calderdale and Huddersfield NHS Foundation Trust
Northumbria Healthcare NHS Foundation Trust
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Wrightington, Wigan and Leigh NHS Foundation Trust
East Lancashire Hospitals NHS Trust
City Hospitals Sunderland NHS Foundation Trust
South Tyneside and Sunderland NHS Foundation Trust
University Hospitals of Morecambe Bay NHS Foundation Trust
North Tees and Hartlepool NHS Foundation Trust
Bradford Teaching Hospitals NHS Foundation Trust
County Durham and Darlington NHS Foundation Trust
Bolton NHS Foundation Trust
Manchester University NHS Foundation Trust
The Leeds Teaching Hospitals NHS Trust
Tameside and Glossop Integrated Care NHS Foundation Trust
Sheffield Teaching Hospitals NHS Foundation Trust
Aintree University Hospital NHS Foundation Trust
Hull and East Yorkshire Hospitals NHS Trust
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Countess of Chester Hospital NHS Foundation Trust
Nottingham University Hospital NHS Trust
Sherwood Forest Hospitals NHS Foundation Trust
University Hospitals Birmingham NHS Foundation Trust
University Hospitals of Derby and Burton NHS Foundation Trust
University Hospitals Coventry and Warwickshire NHS Trust
Worcestershire Acute Hospitals NHS Trust
Northampton General Hospital NHS Trust
Wye Valley NHS Trust
Oxford Health NHS Foundation Trust
Gloucestershire Hospitals NHS Foundation Trust
Basildon and Thurrock University Hospitals NHS Foundation Trust
University Hospital Bristol NHS Foundation Trust
North Bristol NHS Trust
Weston Area Health NHS Trust
Royal Free London NHS Foundation Trust
Guy's and St Thomas' NHS Foundation Trust
Whittington Health NHS
Surrey and Sussex Healthcare NHS Trust
Buckinghamshire Healthcare NHS Trust
Milton Keynes University Hospital NHS Foundation Trust
Northern Devon Healthcare NHS Trust
Western Sussex Hospitals NHS Foundation Trust
Taunton and Somerset NHS Foundation Trust
Great Western Hospitals NHS Foundation Trust
Isle of Wight NHS Trust
Plymouth Hospitals NHS Trust
Royal Devon and Exeter NHS Foundation Trust
The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust
University Hospital Southampton NHS Foundation Trust
The Sunflower Study

Benefits for trainee involvement

Learn about trial design

Learn how to recruit patients

GCP Certificate valid for 3yrs

Bolt-on projects

Presentations/ publications

National collaborative authorship

CCT tick boxes:
Team working/ leadership/ communication skills/GCP

If you want to be involved in the Sunflower project at **(INSERT YOUR SITE HERE)** please speak to:

- Principal Investigator: (ADD NAME)
- Associate Principal Investigator: (ADD NAME)
- Research Nurse: (ADD NAME)

Inclusion criteria

Inclusion criteria (ALL must apply)

- 18 years of age or older
- Symptomatic gallbladder disease confirmed by USS or CT scan
- Scheduled and fit for lap chole (elective or urgent)
- Low or moderate risk of CBD stones, i.e.

  a) CBD diameter ≤8mm on USS, and

If the patient does not meet the definition of low or moderate risk of CBD stones solely based on their blood results, if repeat blood tests are carried out and at least one of the subsequent test results is within range, the patient may be recruited.

N.B. If CBD cannot be seen on USS or CT scan, the patient may be recruited as long as no intrahepatic duct dilatation is reported.

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Exclusion criteria

Exclusion criteria (NONE may apply)

- Unable to undergo MRCP
- Evidence of empyema or perforated gallbladder requiring urgent intervention
- High risk of CBD stones
- Previous gastric bypass
- Previous MRCP or endoscopic ultrasound within last 3 months
- Any previous ERCP
- Haemolytic disease
- Pregnancy
- Prisoner
- Unwilling to participate in follow up
- Unable to provide informed consent

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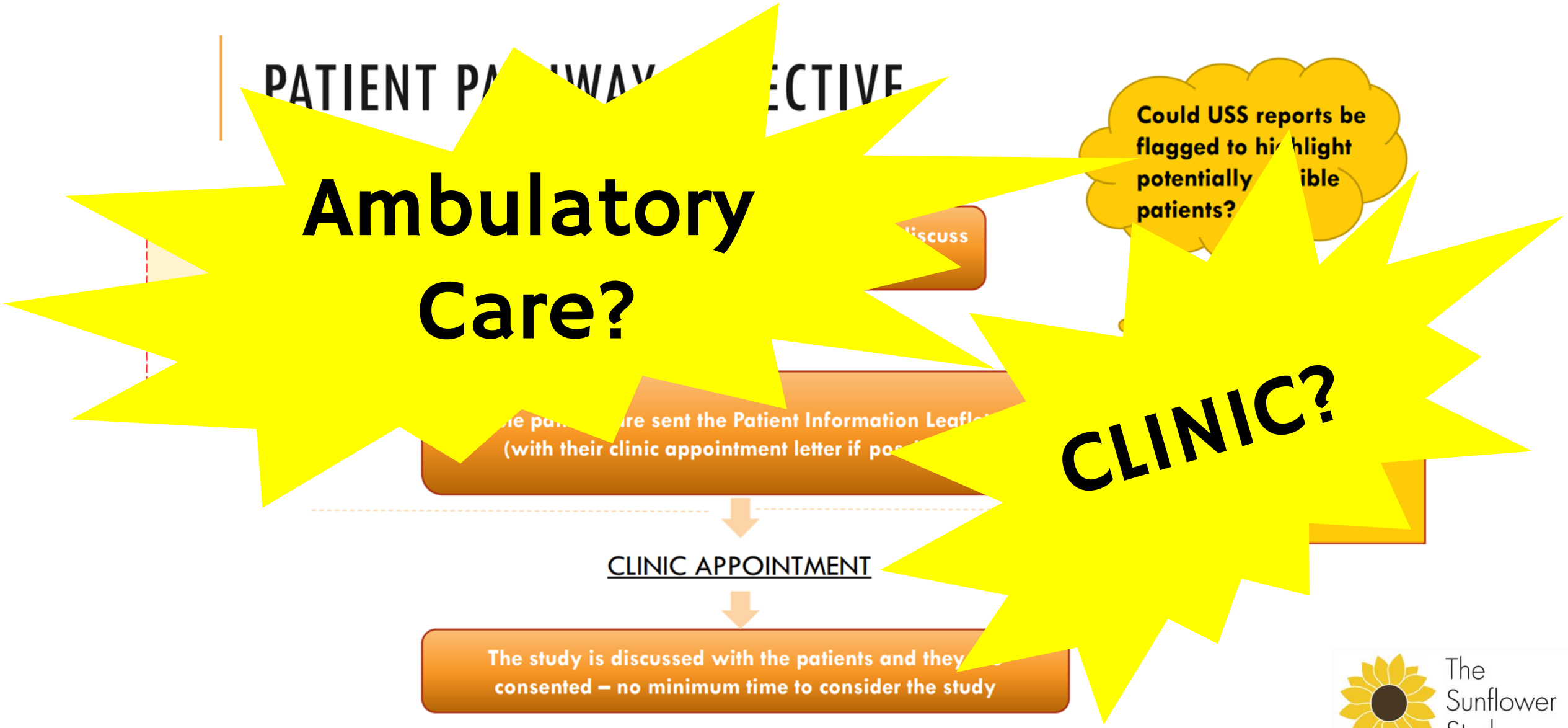
Elective patient recruitment



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Emergency patient recruitment

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Paperwork

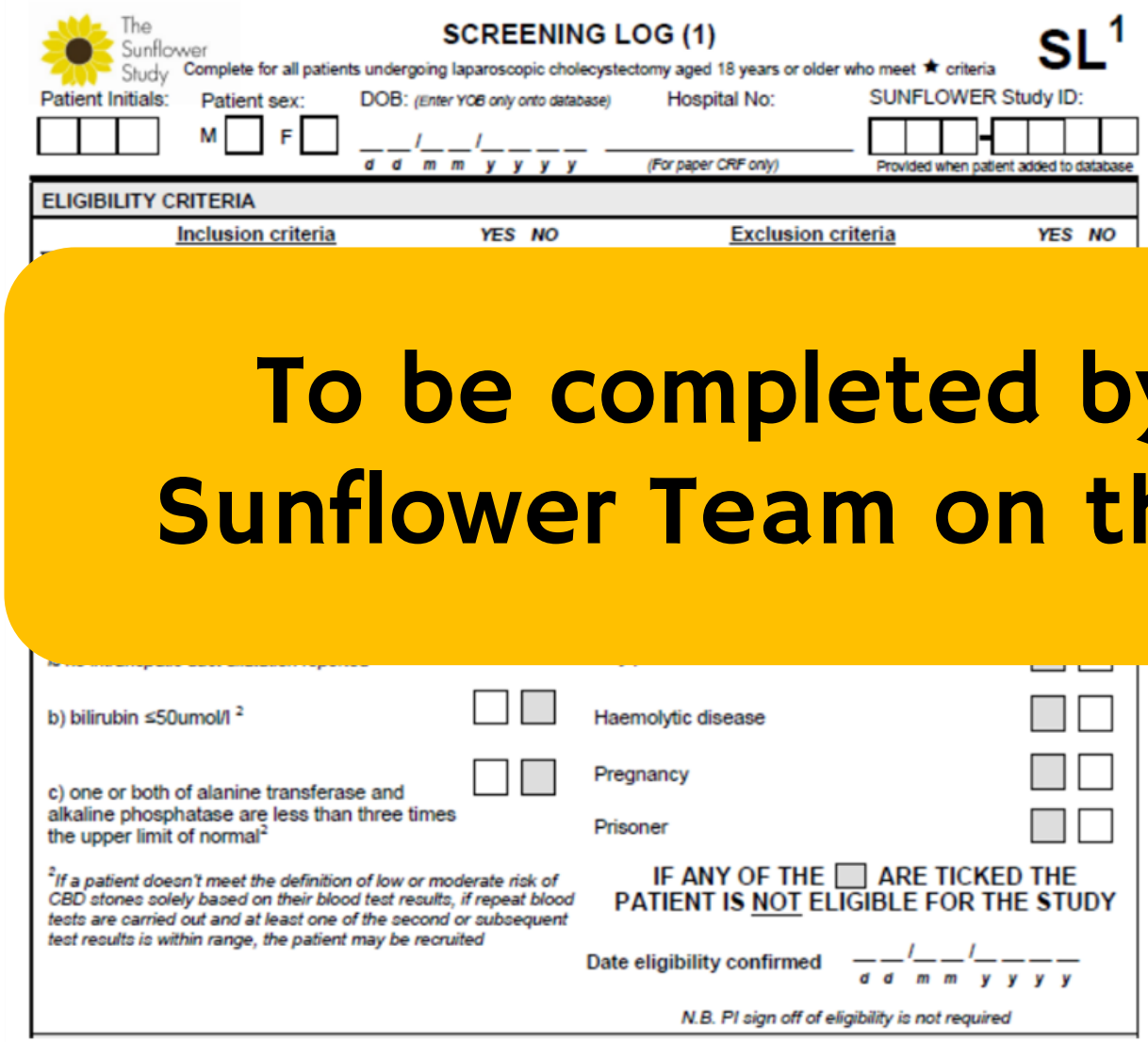
ADD INFORMATION HERE ABOUT WHERE SCREENING LOGS, PILS CAN BE FOUND AT YOUR SITE..

TOP TIP:

1. PLACE A 'SUNFLOWER FOLDER' CONTAINING ALL THE RELEVANT PAPERWORK IN A&E / AMBULATORY CARE / CLINICS / WARDS, SO THEY ARE EASILY ACCESSIBLE

2. ADD POSTERS IN CLINIC ROOMS / A&E / AMBULATORY CARE / WARDS TO REMIND TEAMS ABOUT THE STUDY AND RECRUITMENT

Screening log



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SCREENING LOG (1) SL 1

Complete for all patients undergoing laparoscopic cholecystectomy aged 18 years or older who meet ★ criteria

Patient Initials: | Patient sex: M F | DOB: (Enter YOB only onto database) d d m m y y y y | Hospital No: (For paper CRF only) | SUNFLOWER Study ID: Provided when patient added to database

ELIGIBILITY CRITERIA

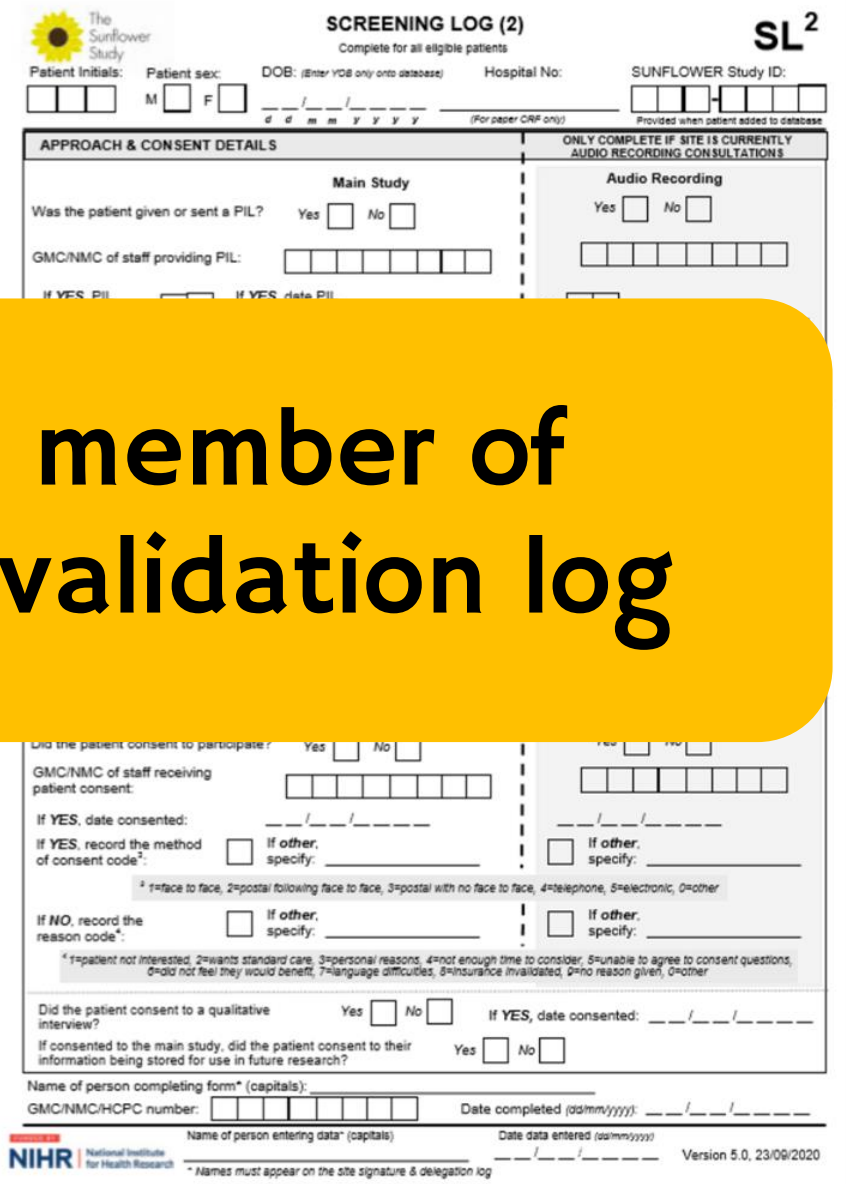
Inclusion criteria	YES	NO	Exclusion criteria	YES	NO
b) bilirubin ≤50umol/l [2]			Haemolytic disease		
c) one or both of alanine transferase and alkaline phosphatase are less than three times the upper limit of normal [2]			Pregnancy		
			Prisoner		

IF ANY OF THE ☐ ARE TICKED THE PATIENT IS NOT ELIGIBLE FOR THE STUDY

[2] If a patient doesn't meet the definition of low or moderate risk of CBD stones solely based on their blood test results, if repeat blood tests are carried out and at least one of the second or subsequent test results is within range, the patient may be recruited

Date eligibility confirmed d d m m y y y y

N.B. PI sign off of eligibility is not required



The Sunflower Study

SCREENING LOG (2) SL 2

Complete for all eligible patients

Patient Initials: | Patient sex: M F | DOB: (Enter YOB only onto database) d d m m y y y y | Hospital No: (For paper CRF only) | SUNFLOWER Study ID: Provided when patient added to database

APPROACH & CONSENT DETAILS	ONLY COMPLETE IF SITE IS CURRENTLY AUDIO RECORDING CONSULTATIONS
Main Study	**Audio Recording**
Was the patient given or sent a PIL? Yes ☐ No ☐	Yes ☐ No ☐
GMC/NMC of staff providing PIL:	
Did the patient consent to participate? Yes ☐ No ☐	
GMC/NMC of staff receiving patient consent:	
If YES, date consented: d d m m y y y y	d d m m y y y y
If YES, record the method of consent code[3]: ☐ If other, specify:	☐ If other, specify:
[3] 1=face to face, 2=postal following face to face, 3=postal with no face to face, 4=telephone, 5=electronic, 0=other	
If NO, record the reason code[4]: ☐ If other, specify:	☐ If other, specify:
[4] 1=patient not interested, 2=wants standard care, 3=personal reasons, 4=not enough time to consider, 5=unable to agree to consent questions, 6=did not feel they would benefit, 7=language difficulties, 8=insurance invalidated, 9=no reason given, 0=other	
Did the patient consent to a qualitative interview? Yes ☐ No ☐	If YES, date consented: d d m m y y y y
If consented to the main study, did the patient consent to their information being stored for use in future research? Yes ☐ No ☐	

Name of person completing form* (capitals):

GMC/NMC/HCPC number: Date completed (dd/mm/yyyy): d d m m y y y y

Name of person entering data* (capitals) Date data entered (dd/mm/yyyy): d d m m y y y y

NIHR National Institute for Health Research

** Names must appear on the site signature & delegation log*

Version 5.0, 23/09/2020

To be completed by a member of Sunflower Team on the validation log

Recruiting patients

YOU CANNOT CONSENT A PATIENT FOR THE STUDY UNLESS YOU HAVE COMPLETED THE ONLINE TRAINING AND ARE LISTED ON THE VALIDATION LOG....

- All eligible patients should be given a patient information leaflet (PIL) to read over.
- All patients should be consented by a member of team on the validation log and given an opportunity to ask any questions they may have.
- If you don't have time/experience to consent an eligible patient you can:

  Give the patient a PIL
  Take their contact details and forward them onto to your Sunflower team (with patient permission)
  The Sunflower team can contact them and take consent via post or in-person at a clinic

- A copy of the consent should be filed in the patient's notes.

....BUT YOU CAN MAKE YOUR SUNFLOWER TEAM AWARE OF AN ELIGIBLE PATIENT THAT YOU HAVE SEEN ON-CALL OR ON WARDS!

(ADD your site name) Progress

From site initiation (ADD DATE SITE RECRUITMENT STARTED) to date (ADD YOUR SITE NAME) have screened:

- Patients screened: (ADD NO.)
- Patients randomised: (ADD NO.)

How can we improve recruitment at our site?

Social Media

Follow The Sunflower Study's progress and any updates at:

@SunflowerStudy

Could your site be this months Top Recruiters?

Monthly certificates for:

Top Recruitment Site
Most Improved Recruitment Site

SUPPORTED BY

NIHR | National Institute for Health Research

The Sunflower Study is funded by the NIHR HTA Programme (project number 16/142/04).

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.


Thank you for listening,
any questions?