Appendix 4. Guideline Questions and PICO’s

# Bile Duct Injury Prevention & Anatomic Identification

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| 1. Should the CVS (critical view of safety) versus **other techniques of anatomical identification** (infundibular, top down, IOC) be used for limiting the risk or severity of bile duct injury in patients undergoing laparoscopic cholecystectomy?
 |
| Main outcome(s) | Bile duct injury (incidence and severity) |
| Potential Proxy outcomes | Conversion, complications (major/minor), mortality |

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| 1. Should **subtotal cholecystectomy** versus **the** fundus-first (**top down) technique of total cholecystectomy** be used for limiting the risk or severity of bile duct injury when the critical view of safety cannot be achieved during laparoscopic cholecystectomy?
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| Main outcome(s) | Bile duct injury (incidence and severity), vascular injury, 30 day mortality, Readmission |
| Potential Proxy outcomes | Conversion, complications (major/minor), mortality |

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| 1. **Should video documentation of the CVS (alone or in addition to operative notes) vs photo documentation (alone or in addition to operative notes) be used for limiting the risk or severity of BDI during laparoscopic cholecystectomy?**
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| Main outcome(s) | Bile duct injury (incidence and severity) |
| Potential Proxy outcomes | Quality of the critical view of safety documentation, cost, ease of performing the documentation, conversion, complications (major/minor), mortality |

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| 1. Should **intraoperative biliary imaging** (e.g. intraoperative cholangiography, ultrasound) versus **no intraoperative biliary** **imaging** be used for limiting the risk or severity of bile duct injuryduring laparoscopic cholecystectomy?
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| Main outcome(s) | Bile duct injury (incidence and severity), Recognition of bile duct in injury in laparoscopic cholecystectomy patients with suspicion of BDI or unclear anatomy |
| Potential Proxy outcomes | Quality of the critical view of safety, conversion, complications (major/minor), mortality |

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| 5a. Should **near-infrared (NIR) intraoperative biliary imaging** versus **intraoperative cholangiography** be used for limiting  the risk or severity of bile duct injuryduring laparoscopic cholecystectomy? |
| Main outcome(s) | Bile duct injury (incidence and severity) |
| Potential Proxy outcomes | Quality of the critical view of safety, conversion, complications (major/minor), mortality, visualization of CBD, cystic, and common hepatic ducts  |

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| 5b. Should **near-infrared (NIR) intraoperative biliary imaging with white light** versus **white light biliary imaging alone** be used for  limiting the risk or severity of bile duct injuryduring laparoscopic cholecystectomy? |
| Main outcome(s) | Bile duct injury (incidence and severity) |
| Potential Proxy outcomes | Quality of the critical view of safety, conversion, complications (major/minor), mortality, visualization of CBD, cystic, and common hepatic ducts  |

# Bile Duct Injury & Disease Factors

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| 1. Should **surgical (complexity) risk stratification (risk factors or risk prediction models)** **guided surgery** versus **alternative risk stratification or** **no risk stratification guided surgery** be used for limiting the risk or severity of bile duct injuryin candidates for laparoscopic cholecystectomy?
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| Main outcome(s) | Bile duct injury (incidence and severity) |

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| 1. Should **risk stratification that accounts for cholecystolithiasis** versus **no risk stratification or alternative risk stratification** be used for limiting the risk or severity of bile duct injuryin candidates for laparoscopic cholecystectomy?
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| Main outcome(s) | Bile duct injury (incidence and severity) |

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| 1. Should **immediate** **cholecystectomy (WITHIN 72 HOURS From SYMPTOM ONSET)** versus **cholecystectomy delayed beyond 72 hours (**between 72hrs and 10 days after symptom onset; b) 6-12 weeks after symptom onset; c) greater than 12 weeks after symptom onset) be used in patients with acute cholecystitis?
 |
| Main outcome(s) | Bile duct injury (incidence and mortality), Mortality, Conversion, Complications, Duration of Surgery, Length of total hospitalization, Failure to complete chole (cholecystostomy, subtotal chole, abandonment), Readmission, Wound infection  |
| Potential Proxy outcomes | Quality of the critical view of safety |

# Bile Duct Injury Prevention & Alternative Surgical Techniques

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| 1. Should **subtotal cholecystectomy** versus **total laparoscopic or open cholecystectomy** be used for limiting the risk or severity of bile duct injury in patients who at the time of operation have MARKED acute LOCAL INFLAMMATION or CHRONIC cholecystitis with biliary inflammatory fusion (BIF) of tissues and tissue contraction?
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| Main outcome(s) | Bile duct injury (incidence and severity) |
| Potential Proxy outcomes | Quality of the critical view of safety, conversion, complications (major/minor), mortality |

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| 1. Should **standard 4-port lap cholecystectomy** versus **reduced port laparoscopic cholecystectomy (single incision)** versus **robotic cholecystectomy** versus **open cholecystectomy** versus **other technique** be used for limiting the risk or severity of bile duct injuryin candidates for cholecystectomy?
 |
| Main outcome(s) | Bile duct injury (incidence and severity), Total severe grade III or more Clavien-Dindo complications, Port site hernia, Readmission, Total analgesic consumption, Duration of surgery, Treatment cost, conversion to open, cosmesis (patient self-reported), quality of life |
| Potential Proxy outcomes | Quality of the critical view of safety, conversion, mortality, intraoperative blood loss |

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| 1. Should **interval/delayed laparoscopic cholecystectomy** versus **no additional treatment** be used for patients previously treated by cholecystostomy?
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| Main outcome(s) | Bile duct injury (incidence and severity), 30-day mortality, Duration of surgery, Readmissions, Complications (minor/ major), conversion  |

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| 1. Should **conversion of laparoscopic cholecystectomy to open cholecystectomy** versus **no conversion** be used for limiting the risk or severity of bile duct injury during difficult laparoscopic cholecystectomy?
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| Main outcome(s) | Bile duct injury (incidence and severity) |
| Potential Proxy outcomes | 30 day mortality, complications (major/minor) |

# Bile Duct Injury Prevention & Surgeon/Education Factors

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| 1. Should **surgeons taking a time out to verify the critical view of safety** versus **no time out** be used for limiting the risk or severity of bile duct injury during laparoscopic cholecystectomy?
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| Main outcome(s) | Bile duct injury (incidence and severity) |
| Potential Proxy outcomes | Quality of the critical view of safety, 30 day mortality, conversion, omplications (minor/ major) |

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| 1. Should **two surgeons** versus **one surgeon** be used for limiting the risk or severity of bile duct injury during laparoscopic cholecystectomy?
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| Main outcome(s) | Bile duct injury (incidence and severity) |
| Potential Proxy outcomes | Quality of the critical view of safety, 30 day mortality, conversion, complications of surgery (minor/ major) |

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| 1. Should **critical view of safety coaching of surgeon** versus **no specific critical view of safety coaching** be used for limiting the risk or severity of bile duct injury during laparoscopic cholecystectomy?
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| Main outcome(s) | Bile duct injury (incidence and severity) |
| Potential Proxy outcomes | Quality of the critical view of safety, 30 day mortality, conversion, complications (minor/ major) |

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| 1. Should **training of surgeons by simulation method or video-based education** versus **alternative surgeon training** be used for limiting the risk or severity of bile duct injury during laparoscopic cholecystectomy?
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| Main outcome(s) | Bile duct injury (incidence and severity) |
| Potential Proxy outcomes | Quality of the critical view of safety, 30 day mortality, conversion,cComplications (minor/ major) |

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| 1. Should **more surgeon experience** versus **less surgeon experience** be used for limiting the risk or severity of bile duct injury during laparoscopic cholecystectomy?
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| Main outcome(s) | Bile duct injury (incidence and severity) |
| Potential Proxy outcomes | Quality of the critical view of safety, 30 day mortality, conversion, complications (minor/ major) |

# Management of Bile Duct Injury

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| 1. For patients with bile duct injury during laparoscopic cholecystectomy (in the OR or early postoperative period), should the patient be referred to a **specialist with experience in biliary reconstruction** or should the reconstruction be performed by **the operating surgeon**?
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| Main outcome(s) | Total serious or major adverse events, 30 day mortality, repeat surgery, intraoperative blood loss, length of hospital stay, Readmission |

*Note: When it was suspected there may be insufficient evidence for the main outcome, potential proxy outcomes were prespecified.*