Prevention of Bile Duct Injury during Cholecystectomy Consensus Conference Guidelines:

Question 1: Should the critical view of safety (CVS) versus other techniques (e.g. infundibular, top down, or intraoperative cholangiography) be used to mitigate the risk of bile duct injury during laparoscopic cholecystectomy?

Recommendation: In patients undergoing laparoscopic cholecystectomy, we suggest that surgeons use the critical view of safety (CVS) for anatomic identification of the cystic duct and artery (expert opinion).

Question 2: Should the fundus-first (top down) technique versus subtotal cholecystectomy be used to mitigate the risk of bile duct injury when the CVS cannot be achieved during laparoscopic cholecystectomy?

Recommendation: When the critical view of safety cannot be achieved and the biliary anatomy cannot be clearly defined by other methods (e.g. imaging) during laparoscopic cholecystectomy, we suggest that surgeons consider subtotal cholecystectomy over total cholecystectomy by the fundus-first (top down) approach. (expert opinion)

Question 3: Should video documentation of the CVS (alone or in addition to operative notes) versus photo documentation (alone or in addition to operative notes) be used for limiting the risk or severity of BDI during laparoscopic cholecystectomy?

No recommendation could be provided for this question due to a lack of agreement of the expert panel and concerns regarding feasibility, acceptability, and medico-legal considerations.

Question 4: Should intraoperative biliary imaging (e.g. intraoperative cholangiography, ultrasound) versus no intraoperative biliary imaging be used for mitigating the risk of bile duct injury during laparoscopic cholecystectomy?

Recommendation: In patients with acute cholecystitis or a history of acute cholecystitis, we suggest the liberal use of intraoperative cholangiography during laparoscopic cholecystectomy to mitigate the risk of bile duct injury (conditional recommendation, very low certainty of evidence). Surgeons with

appropriate experience and training may use laparoscopic ultrasound imaging as an alternative to IOC during laparoscopic cholecystectomy.

In patients with uncertainty of biliary anatomy or suspicion of bile duct injury during laparoscopic cholecystectomy, we recommend that surgeons use intraoperative biliary imaging (in particular intraoperative cholangiography) to mitigate the risk of bile duct injury. (strong recommendation, very low certainty of evidence).

Given that the evidence for the benefit of IOC in elective non-acute cholecystectomy is inconclusive, no recommendation addressing this scenario could be made.

Question 5A: Should intraoperative near-infrared (NIR) biliary imaging versus intraoperative cholangiogram (IOC) be used for limiting the risk or severity of bile duct injury during laparoscopic cholecystectomy?

No recommendation was made as current evidence comparing near infrared cholangiography for identification of biliary anatomy during cholecystectomy to intraoperative cholangiography is insufficient.

Question 5B: Should intraoperative near-infrared biliary imaging with white light versus white light biliary imaging alone be used for limiting the risk or severity of bile duct injury during laparoscopic cholecystectomy?

Recommendation: We suggest that the use of near-infrared imaging may be considered as an adjunct to white light alone for identification of biliary anatomy during cholecystectomy (conditional recommendation, very low certainty of evidence). The GDG noted that relying on near-infrared imaging must not be a substitute for good dissection and identification technique (expert opinion).

Question 6: Should surgical (complexity) risk stratification versus alternative or no risk stratification be used for mitigating the risk of BDI associated with laparoscopic cholecystectomy?

Recommendations:

A1: For patients with acute cholecystitis, we suggest that surgeons may use the Tokyo Guidelines 18 (TG18), AAST classification, or another effective risk stratification model for grading for severity of cholecystitis and for patient management (expert opinion)

A2: During operative planning of laparoscopic cholecystectomy and intraoperative decision-making, we suggest that surgeons consider factors that potentially increase the difficulty of laparoscopic cholecystectomy such as male gender, increased age, chronic cholecystitis, obesity, liver cirrhosis, adhesions from previous abdominal surgery, emergency cholecystectomy, cystic duct stones, enlarged liver, cancer of gallbladder and/or biliary tract, anatomic variation, bilio-digestive fistula, and limited surgical experience. (expert opinion)

Question 7: Should risk stratification that accounts for cholecystolithiasis versus no/alternate risk stratification be used for mitigating the risk of BDI associated with laparoscopic cholecystectomy?

No recommendation was made as no risk prediction models exist that incorporate the presence or absence of gallstones as a factor that increases bile duct injury or difficulty of laparoscopic cholecystectomy.

Question 8: Should immediate cholecystectomy defined as performed within 72 hrs of symptom onset be used in acute cholecystitis (AC) versus delayed cholecystectomy? Delayed cholecystectomy is defined either as: a) between 72hrs and 10 days after symptom onset; b) 6-12 weeks after symptom onset; c) greater than 12 weeks after symptom onset.

<u>Recommendation</u>: In patients presenting with mild acute cholecystitis (according to Tokyo Guidelines), we suggest surgeons perform laparoscopic cholecystectomy within 72 hours of symptom onset (conditional recommendation, very low certainty of evidence). For patients with moderate and severe cholecystitis there is insufficient evidence to make a recommendation, particularly as it relates to the outcome of bile duct injury.

Question 9: Should subtotal cholecystectomy versus total laparoscopic or open cholecystectomy be used for mitigating the risk of BDI in marked acute inflammation or chronic biliary inflammatory fusion (BIF)?

Recommendation: When marked acute local inflammation or chronic cholecystitis with biliary inflammatory fusion (BIF) of tissues/tissue contraction is encountered during laparoscopic cholecystectomy that prevent the safe identification of the cystic duct and artery, we suggest that surgeons perform subtotal cholecystectomy either laparoscopically or open depending on their skill set and comfort with the procedure (expert opinion).

Question 10: Should standard 4-port lap cholecystectomy versus reduced port laparoscopic cholecystectomy (single incision laparoscopic cholecystectomy, SILC) versus robotic cholecystectomy versus open cholecystectomy versus other techniques be used for limiting the risk or severity of bile duct injury in candidates for cholecystectomy?

Recommendation: For patients requiring cholecystectomy, we suggest using a multi-port laparoscopic technique instead of single port/single incision technique (conditional recommendation, moderate certainty of evidence).

Question 11: Should interval laparoscopic cholecystectomy versus no additional treatment be used for patients previously treated by cholecystostomy drainage?

Recommendation: In patients with acute calculous cholecystitis previously treated by cholecystostomy who are good surgical candidates, we suggest that interval cholecystectomy is preferred after the inflammation has subsided. For poor or borderline operative candidates, we suggest a non-surgical approach that may include percutaneous stone clearance through the tube tract or tube removal and observation if the cystic duct is patent (expert opinion).

Question 12: 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?

No recommendation was made as the current evidence comparing conversion versus no conversion to open cholecystectomy to limit/avoid bile duct injury in the difficult cholecystectomy is insufficient.

Question 13: Should surgeons take 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?

Recommendation: Current evidence is insufficient to make a recommendation. However, as a best practice, we suggest that during laparoscopic cholecystectomy, surgeons conduct a momentary pause for the surgeon to confirm in his/her own mind that the criteria for the critical view of safety have been attained before clipping or transecting ductal or arterial structures (expert opinion).

Question 14: Should two surgeons versus one surgeon be used for limiting the risk or severity of bile duct injury during laparoscopic cholecystectomy?

No recommendation was made as the current evidence comparing two versus one surgeons for limiting/avoiding bile duct injury in cholecystectomy is insufficient.

Question 15: Should critical view of safety coaching of surgeons versus no specific critical view of safety coaching be used for limiting the risk or severity of bile duct injury during laparoscopic cholecystectomy?

Recommendation: We suggest as a best practice continued education of surgeons regarding the critical view of safety during laparoscopic cholecystectomy that may include coaching (conditional recommendation, very low certainty of evidence).

Question 16: Should training of surgeons by simulation methods or video-based education versus alternative surgeon training be used for limiting the risk or severity of bile duct injury during laparoscopic cholecystectomy?

No recommendation was made as the current evidence comparing simulation or video-based training versus alternative surgeon training modalities on limiting/avoiding bile duct injury during laparoscopic cholecystectomy is insufficient.

Question 17: Should more surgeon experience versus less surgeon experience be used for mitigating the risk bile duct injury associated with laparoscopic cholecystectomy?

RECOMMENDATION: We suggest that surgeons have a low threshold for calling for help from another surgeon when practical in difficult cases or when there is uncertain of anatomy (conditional recommendation, very low certainty of evidence).

Question 18: 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?

Recommendation: When a bile duct injury (BDI) has occurred or is highly suspected at the time of cholecystectomy or in the post-operative period, we recommend that surgeons refer the patient promptly to a surgeon with experience in the management of BDI in an institution with a hepato-biliary disease multispecialty team. When not feasible to do so in a timely manner, prompt consultation with a surgeon experienced in the management of BDI should be considered. (Strong recommendation, low certainty of evidence)

Additional Panel Recommendation: We suggest the development of national quality improvement initiatives for the prevention of bile duct injuries following cholecystectomy. The initiative(s) should be capable of identifying and characterizing bile duct injuries in the population under study.