

**Management and Outcomes of Perioperative Care of European Diabetic Patients**

**MOPED: Confidential Patient Identification  
Coversheet for CRF**

*This coversheet is intended to help site staff and local investigators link local patient data to the study-specific patient identification code.*

*After completing follow-up, this coversheet should be saved separately from the CRF and filed in a secure place. The information on this coversheet will NOT be collected in the CRF.*

*This coversheet is for local use ONLY.*

Patient Identifying Data	
<b>Date paper CRF created</b>	_ _  /  _ _  /  _ _ _ _  (dd/Mmm/YYYY)
<b>Date of birth</b>	_ _  /  _ _  /  _ _ _ _  (dd/Mmm/YYYY)
<b>Subject ID</b> (OpenClinica eCRF Subject ID number)	_ _ - _ _ - _ _  <i>(Use the 3 digit code for the country, 3 digit code for the hospital and 3 digit individual patient number)</i>
<b>Identification</b> <i>Complete with available data – only for local follow-up use:</i>	Patient Hospital/local Identification Number (handwritten or sticker):  First name:  Last name:

CRF number	Paper CRF	OpenClinica electronic CRF
<b>CRF1: Preoperative, Intraoperative and Postoperative Day1</b>		
Section 1: PATIENT DATA	<input type="checkbox"/>	<input type="checkbox"/>
Section 2: DIABETES MELLITUS CLINICAL DATA	<input type="checkbox"/>	<input type="checkbox"/>
Section 3: PREOPERATIVE DATA	<input type="checkbox"/>	<input type="checkbox"/>
Section 4: INTRAOPERATIVE DATA	<input type="checkbox"/>	<input type="checkbox"/>
Section 5: PACU DATA AND POSTOPERATIVE IN-HOSPITAL DAY 1	<input type="checkbox"/>	<input type="checkbox"/>
<b>CRF2: Discharge and Outcome</b>		
Section1: POSTOPERATIVE DAY OF DISCHARGE	<input type="checkbox"/>	<input type="checkbox"/>
Section2: OUTCOME DATA 30 days	<input type="checkbox"/>	<input type="checkbox"/>



**MOPED Appendix 7-Case Report Form**

**Management and Outcomes of Perioperative Care of European Diabetic Patients**

CRF number	Section Title
CRF1: Preoperative, Intraoperative and Postoperative Day1	Section 1: PATIENT DATA
	Section 2: DIABETES MELLITUS CLINICAL DATA
	Section 3: PREOPERATIVE DATA
	Section 4: INTRAOPERATIVE DATA
	Section 5: PACU DATA AND POSTOPERATIVE IN-HOSPITAL DAY 1
CRF2: Discharge and Outcome	Section1: POSTOPERATIVE DAY OF DISCHARGE
	Section2: OUTCOME DATA 30 days

CRF1: Preoperative, Intraoperative and Postoperative Day1	
Section 1: PATIENT DATA	
1. Subject ID*	_ _ _ - _ _ _ - _ _ _  (Use a 3 digit code for the Country, Hospital and individual Patient number, respectively, separated with hyphens: xxx-xxx-xxx)
2. Informed consent applicable? *	<input type="radio"/> No <input type="radio"/> Yes Is Informed consent required for your centre?
2.1 If obtained, date of informed consent*	d   d   -   m   m   m   -   2   0   2   y   Enter date in this format [dd-Mmm-YYYY] (Month in English starting with capital letter)
3. Age (yrs) *	_ _ _  (18-100)
4. Gender*	<input type="radio"/> Male <input type="radio"/> Female
5. Height (cm) *	_ _ _  (140-200)
6. Weight (kg) *	_ _ _  (40-140)
7. Ethnicity*	<input type="radio"/> Caucasian <input type="radio"/> African <input type="radio"/> Arabic <input type="radio"/> Asian <input type="radio"/> Other
Section 2 : DIABETES MELLITUS CLINICAL DATA	
8. Diabetes Mellitus type*	<input type="radio"/> Type I <input type="radio"/> Type II <input type="radio"/> Other
9. Year of first DM diagnosis*	_ _ _
10. Is this patient on Insulin? *	<input type="radio"/> No <input type="radio"/> Yes
10.1 If yes: Insulin (any type) total daily dose units per day (IU) *	_ _ _ . _ _  (9-99)
11. Oral hypoglycaemics*	<input type="checkbox"/> None <input type="checkbox"/> Metformin <input type="checkbox"/> SGLT 2 Inhibitors <input type="checkbox"/> GLP-1 analogues <input type="checkbox"/> DPP-4 Inhibitors <input type="checkbox"/> Alpha-Glucosidase Inhibitors <input type="checkbox"/> Sulphonylureas <input type="checkbox"/> Other
12. Daily Glucose monitoring*	<input type="radio"/> Blood <input type="radio"/> Urine <input type="radio"/> None
13. HbA1c: lowest in last 3 months	<input type="radio"/> Not available <input type="radio"/> mmol.mol <sup>-1</sup> (1-100) <input type="radio"/> Percentage (2-15%)  _ _ _ . _ _
14. Hypoglycaemic episodes: number in last 3 months (if any)	_ _ _
15. Ketoacidosis episodes: number in last 3 months (if any)	_ _ _
16. Glucose: Fasting in last 3 months*	<input type="radio"/> Not available <input type="radio"/> mmol/L (1-70) <input type="radio"/> mg/dL (1-199)  _ _ _ . _ _
17. Corticosteroid taken in past 6 months*	<input type="radio"/> Yes <input type="radio"/> No
17.1 If yes, was it*	<input type="radio"/> prednisolone Dose  _ _ _  (1-700) (mg) Duration  _ _ _  (1-180) (days) <input type="radio"/> hydrocortisone Dose  _ _ _  (1-1000 per day) (mg) Duration  _ _ _  (1-30 days) (days) <input type="radio"/> dexamethasone Dose  _ _ _  (1-100) (mg) Duration  _ _ _  (1-180) (days)
18. Indwelling Insulin pump*	<input type="radio"/> Yes <input type="radio"/> No 18.1 If Yes, total units per 24 hr*  _ _ _ . _ _  (5-500)
Section 3: PREOPERATIVE DATA	
19. Date of Admission*	d   d   -   m   m   m   -   2   0   2   y   Date cannot be before 25th March 2021
20. Date of Surgery*	d   d   -   m   m   m   -   2   0   2   y
21. Urgency*	<input type="radio"/> Immediate (< 1-2 hr) <input type="radio"/> Urgent (< 6 hr) <input type="radio"/> Expedited (< 1-3 days) <input type="radio"/> Elective

22. ASA Physical Status*	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6	<input type="radio"/> E
23. SORT Score*	_ _ _  (0-100%)	To calculate SORT score use <a href="http://www.sortsurgery.com">http://www.sortsurgery.com</a> (see appendix 12)					
24. Creatinine [Preoperative]*	<input type="radio"/> Not available	<input type="radio"/> µmol/L (20-999)	<input type="radio"/> mg/dL (0.1-15)	_ _ _ . _			
25. Glucose: Fasting on day of surgery*	<input type="radio"/> Not available	<input type="radio"/> mmol/L (1-70)	<input type="radio"/> mg/dL (1-999)	_ _ _ . _			
26. Did you ask patient to stop all oral hypoglycaemic drugs on day of surgery? *	<input type="radio"/> Yes <input type="radio"/> No						
26.1 If no, what oral hypoglycaemic drug was continued*	<input type="checkbox"/> Metformin <input type="checkbox"/> SGLT 2 Inhibitors <input type="checkbox"/> GLP-1 analogues <input type="checkbox"/> DPP Inhibitors <input type="checkbox"/> Alpha-Glucosidase inhibitors <input type="checkbox"/> Sulphonylureas <input type="checkbox"/> Other						
27. Were there any single (s.c.) injections of insulin given or taken on the evening prior to surgery? *	<input type="radio"/> Yes <input type="radio"/> No						
27.1. If yes, what type of insulin? *	<input type="radio"/> Short-acting insulin	Total dose	_ _ . _	(1-20)			
	<input type="radio"/> Intermediate acting insulin	Total dose	_ _ _ . _	(1-100)			
	<input type="radio"/> Mixed insulin	Total dose	_ _ _ . _	(1-100)			
28. Were there any single (s.c.) injections of insulin given on the day of surgery before anaesthesia commenced? *	<input type="radio"/> Yes <input type="radio"/> No						
28.1. If yes, what type of insulin? *	<input type="radio"/> Short-acting insulin	Total dose	_ _ . _	(1-20)			
	<input type="radio"/> Intermediate acting insulin	Total dose	_ _ _ . _	(1-100)			
	<input type="radio"/> Mixed insulin	Total dose	_ _ _ . _	(1-100)			
29. Were any insulin infusions started preoperatively (s.c. or i.v.)? *	<input type="radio"/> Yes <input type="radio"/> No						
29.1 If yes, how was it given preoperatively? *	<input type="checkbox"/> SC pump in situ <input type="checkbox"/> Variable rate IV insulin <input type="checkbox"/> Fixed rate IV insulin (inc. GKI infusion)						
29.2 Please state the rate of infusion (IU/hour) *	_ _ _  (1-500)						
<b>Section 4: INTRAOPERATIVE DATA</b>							
30. Surgical complexity*	<input type="radio"/> Minor	<input type="radio"/> Intermediate	<input type="radio"/> Major	<input type="radio"/> Complex			
31. Surgical technique*	<input type="radio"/> Open	<input type="radio"/> Laparoscopic	<input type="radio"/> Laparoscopic-assisted				
32. Operating Surgeon: Most senior doctor present*	<input type="radio"/> Consultant	<input type="radio"/> Staff	<input type="radio"/> Trainee	<input type="radio"/> Other			
33. Intraop anaesthesia technique*	<input type="radio"/> GA volatile <input type="radio"/> GA TIVA propofol only <input type="radio"/> GA TIVA propofol remifentanyl <input type="radio"/> Regional spinal or epidural only <input type="radio"/> Regional peripheral nerve block only <input type="radio"/> Regional combined with GA <input type="radio"/> Regional + Sedation						
34. Duration of anaesthesia in minutes*	_ _ _  (5-600)						
35. Anaesthetist: Most senior doctor present*	<input type="radio"/> Consultant	<input type="radio"/> Staff	<input type="radio"/> Trainee	<input type="radio"/> Other			
36. Corticosteroids IV*	<input type="radio"/> Yes <input type="radio"/> No						
36.1 If yes, please state type*	<input type="radio"/> Dexamethasone	_ _ _  (1-100)	Dose (mg)				
	<input type="radio"/> Hydrocortisone	_ _ _  (1-1000)	Dose (per day)				
	<input type="radio"/> Methyl prednisolone	_ _ _  (1-2000)	Dose (mg)				
37. Glucose: Highest value*	<input type="radio"/> Not available	<input type="radio"/> mmol/L (1-70)	<input type="radio"/> mg/dL (1-999)	_ _ _ . _			
38. Glucose: Lowest value*	<input type="radio"/> Not available	<input type="radio"/> mmol/L (1-70)	<input type="radio"/> mg/dL (1-999)	_ _ _ . _			
39. Did patient receive any insulin intra-op and/or in PACU?*	<input type="radio"/> Yes <input type="radio"/> No						
39.1 If yes, Insulin (IU) Total dose administered intraop plus in PACU combined*	_ _ . _  (1-99)						
40. If insulin given intra-op and in PACU, how was it given? *	<input type="radio"/> Variable rate IV <input type="radio"/> Fixed rate (inc. GKI) <input type="radio"/> SC bolus <input type="radio"/> Other						
41. Glucose (g): Total dose administered*	_ _ _  (0-999)						
42. Blood loss: Total volume (mL)*	_ _ _ _ _  (0-10 000)						

43. NSAID given? *	<input type="radio"/> Yes <input type="radio"/> No
44. Duration of surgery (mn)*	_ _ _  (1-750)
<b>Section 5: PACU DATA AND POSTOPERATIVE DAY 1 (if in-hospital stay)</b>	
45. Glucose First recorded in PACU* <input type="radio"/> No <input type="radio"/> mmol/L (1-70) <input type="radio"/> mg/dL (1-999)	_ _ _ . _
46. Total crystalloid during anaesthesia and PACU (ml)*	_ _ _ _ _  (0-25 000)
47. Total colloid during anaesthesia and PACU (ml)*	_ _ _ _ _  (0-10 000)
48. Blood products IV: Total volume of any blood product administered (mL)*	_ _ _ _
49. Estimated number of episodes of Hypotension defined as SAP <90 for >10 min Intra-Op + PACU combined*	_ _ _  (0-100)
50. Any Vasopressor/inotropic use during anaesthesia and PACU: *	<input type="radio"/> Yes <input type="radio"/> No Boluses number  _ _ _  (0-100)
50.2 Infusion*	<input type="radio"/> Yes <input type="radio"/> No
51. Discharge destination*	<input type="radio"/> Home <input type="radio"/> Ward <input type="radio"/> HDU <input type="radio"/> ICU <input type="radio"/> Death
51.1/2/3 If discharge at Ward, HDU or ICU, was Discharge Destination Planned?	<input type="radio"/> Planned <input type="radio"/> Unplanned
<b>CRF2: Discharge and Outcome</b>	
<b>Section 1: POSTOPERATIVE DAY OF DISCHARGE</b>	
52. Did patient stay in hospital overnight? *	<input type="radio"/> Yes <input type="radio"/> No
53. Date of discharge from the hospital*	d   d   -   m   m   m   -   2   0   2   y
54. Highest recorded glucose since PACU* <input type="radio"/> Not available <input type="radio"/> mmol/L (1-70) <input type="radio"/> mg/dL (1-999)	_ _ _ . _
55. Lowest recorded glucose since PACU* <input type="radio"/> Not available <input type="radio"/> mmol/L (1-70) <input type="radio"/> mg/dL (1-999)	_ _ _ . _
56. Total insulin given or taken since discharge from PACU*	_ _ _  (0-500)
57. Was any extra (more than usual) insulin given since discharge from PACU?*	<input type="radio"/> Yes <input type="radio"/> No
58. QoR-15 Score*  _ _ _ _  (0-150)	Please refer to patient survey: MOPED Appendix 13
59. Was non-routine insulin given since discharge any day? *	<input type="radio"/> Yes <input type="radio"/> No
60. CCI Score at Day of Discharge  _ _ _ _  (0-100)	Please refer to appendix 14
61. Was the Postop creatinine level measured? * If, yes, please provide highest Post op Creatinine value.	<input type="radio"/> No <input type="radio"/> µmol/L  _ _ _ _ . _ _ _  (20-999) <input type="radio"/> mg/dL  _ _ . _ _ _ _  (0.1-15)
<b>Section 2: OUTCOME DATA 30 days</b>	
62. When was follow-up performed? *	d   d   -   m   m   m   -   2   0   2   y
63. How was follow up performed? *	<input type="radio"/> In hospital - at discharge or at day 30, whichever came first <input type="radio"/> By phone or by mail - at Day 30 or up to 14 days after day 30
64. Did patient die? *	<input type="radio"/> Yes <input type="radio"/> No
64.1 if yes date of death*	d   d   -   m   m   m   -   2   0   2   y

65. DAH 30: Number of days at home in first 30 days since date of surgery*  _ _  (0-30)
66. Discharge to rehabilitation or other non-home care different from preop* <input type="radio"/> Yes <input type="radio"/> No
67. Readmission to hospital < 30 days* <input type="radio"/> Yes <input type="radio"/> No
68. Dindo Clavien Scale: highest score <b>Please see definitions of the grades below.</b> <input type="radio"/> Grade I <input type="radio"/> Grade II <input type="radio"/> Grade IIIa <input type="radio"/> Grade IIIb <input type="radio"/> Grade IVa <input type="radio"/> Grade IVb <input type="radio"/> Grade V
<p><b>GRADE I:</b> Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions (Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside)</p> <p><b>GRADE II:</b> Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.</p> <p><b>GRADE III:</b> Requiring surgical, endoscopic or radiological intervention.</p> <p>- <b>IIIa:</b> Intervention not under general anesthesia</p> <p>- <b>IIIb:</b> Intervention under general anesthesia</p> <p><b>GRADE IV:</b> Life-threatening complication (including CNS complications) * requiring IC/ICU-management</p> <p>- IVa: single organ dysfunction (including dialysis)</p> <p>- IVb: multiorgan dysfunction</p> <p><b>GRADE V:</b> Death of a patient</p>
69. Complications in 30 days [tick all that apply] <input type="checkbox"/> Surgical Site Infection <input type="checkbox"/> MI <input type="checkbox"/> MINS <input type="checkbox"/> Dysrhythmia <input type="checkbox"/> PPC <input type="checkbox"/> CVA <input type="checkbox"/> VTE <input type="checkbox"/> AKI <input type="checkbox"/> Other Please try to find out (through their records or asking the patient directly) if patient had any of these since surgery
70. CCI score: highest  _ _ _  (0-100) Please refer to appendix 14
71. Hypoglycaemic episodes: number in last 30 days*  _ _  (0-30)
72. Ketoacidosis episodes: number in last 30 days*  _ _  (0-20)
73. Diabetic medication requirements* <input type="radio"/> Increased <input type="radio"/> Decreased <input type="radio"/> Unchanged