

15 Quantitative data tabulated by participating centre (B1, B4 and B5).

Table 15.1: Demographic characteristics and past history of randomised participants by centre

Characteristic		NBTG (n=64)		NBTO (n=77)		QEHB (n=112)		UHBR (n=114)		WORC (n=21)		Overall (n=388)	
		n	%	n	%	n	%	n	%	n	%	n	%
DEMOGRAPHY													
Age (years)	Median (IQR)	62	(47.5, 70.7)	33	(30.1, 35.4)	55	(43.9, 68.5)	60	(47.9, 68.7)	52	(45.5, 66.2)	52	(34.7, 66.9)
Male		31/64	48.4%	0/77	0.0%	56/112	50.0%	58/114	50.9%	16/21	76.2%	161/388	41.5%
BMI*	Median (IQR)	27	(23.1, 30.4)	28	(24.1, 33.2)	28	(25.0, 32.5)	27	(24.0, 30.9)	27	(24.0, 31.8)	28	(24.3, 31.6)
Ethnicity	White	61/63	96.8%	54/68	79.4%	100/110	90.9%	107/114	93.9%	19/19	100.0%	341/374	91.2%
	Mixed	1/63	1.6%	4/68	5.9%	0/110	0.0%	4/114	3.5%	0/19	0.0%	9/374	2.4%
	Asian	0/63	0.0%	5/68	7.4%	5/110	4.5%	2/114	1.8%	0/19	0.0%	12/374	3.2%
	Black	1/63	1.6%	4/68	5.9%	5/110	4.5%	1/114	0.9%	0/19	0.0%	11/374	2.9%
	Chinese	0/63	0.0%	1/68	1.5%	0/110	0.0%	0/114	0.0%	0/19	0.0%	1/374	0.3%
MEDICAL HISTORY													
Smoking	Yes	13/62	21.0%	7/77	9.1%	19/112	17.0%	19/114	16.7%	2/21	9.5%	60/386	15.5%
	Ex > 1 month	18/62	29.0%	22/77	28.6%	46/112	41.1%	44/114	38.6%	6/21	28.6%	136/386	35.2%
	No	31/62	50.0%	48/77	62.3%	47/112	42.0%	51/114	44.7%	13/21	61.9%	190/386	49.2%

Characteristic	NBTG (n=64)		NBTO (n=77)		QEHB (n=112)		UHBR (n=114)		WORC (n=21)		Overall (n=388)	
	n	%	n	%	n	%	n	%	n	%	n	%
Current therapeutic oral/IV/IM steroids	2/64	3.1%	7/77	9.1%	8/112	7.1%	6/114	5.3%	2/21	9.5%	25/388	6.4%
Diabetes (any type)	5/62	8.1%	2/77	2.6%	8/112	7.1%	14/114	12.3%	0/21	0.0%	29/386	7.5%
ASA class												
I: Healthy, no medical problems	16/62	25.8%	62/77	80.5%	28/111	25.2%	24/113	21.2%	4/21	19.0%	134/384	34.9%
II: Mild systemic disease	35/62	56.5%	14/77	18.2%	64/111	57.7%	76/113	67.3%	14/21	66.7%	203/384	52.9%
III: Severe systemic disease, not incapacitating	11/62	17.7%	1/77	1.3%	17/111	15.3%	13/113	11.5%	3/21	14.3%	45/384	11.7%
IV: severe systemic disease, constant threat to life	0/62	0.0%	0/77	0.0%	2/111	1.8%	0/113	0.0%	0/21	0.0%	2/384	0.5%

Notes:

NBTG: North Bristol NHS Trust (General surgery), NBTO: North Bristol NHS Trust (Obstetric surgery), QEHB: Queen Elizabeth Hospital Birmingham, UHBR: University Hospitals Bristol NHS Foundation Trust, WORC: Worcestershire Acute Hospitals NHS Trust, BMI: body mass index

Missing data (NBTG, NBTO, QEHB, UHBR, WORC): * 4 patients with missing data (2, 1, 0, 0, 1)

Note that when cell denominator is different to number in column header, the difference arises because of missing data for that variable.

Table 15.2: Intraoperative characteristics by centre

Characteristic	NBTG (n=64)		NBTO (n=77)		QEHB (n=112)		UHBR (n=114)		WORC (n=21)		Overall (n=388)		
	n	%	n	%	n	%	n	%	n	%	n	%	
Operation duration (hours)*	Median (IQR)	1	(0.8, 2.4)	1	(0.4, 0.7)	2	(1.0, 2.9)	2	(1.0, 3.0)	2	(0.9, 3.0)	1	(0.7, 2.5)
Grade of surgeon performing skin closure	Foundation Dr	1/63	1.6%	0/76	0.0%	1/111	0.9%	0/107	0.0%	1/21	4.8%	3/378	0.8%
	Core trainee	8/63	12.7%	4/76	5.3%	14/111	12.6%	25/107	23.4%	2/21	9.5%	53/378	14.0%
	Speciality trainee	34/63	54.0%	42/76	55.3%	68/111	61.3%	64/107	59.8%	8/21	38.1%	216/378	57.1%
	Consultant	20/63	31.7%	30/76	39.5%	28/111	25.2%	18/107	16.8%	10/21	47.6%	106/378	28.0%
Number of wounds (excluding drain sites) ^	Median (IQR)	3	(1.0, 4.0)	1	(1.0, 1.0)	3	(1.0, 4.0)	3	(1.0, 4.0)	3	(2.0, 5.0)	2	(1.0, 4.0)
Stoma formed		10/61	16.4%	-	-	14/112	12.5%	18/111	16.2%	4/21	19.0%	46/305	15.1%
Time from randomisation to wound closure (hours)×	Median (IQR)	2	(0.9, 3.5)	1	(0.8, 1.2)	2	(1.6, 3.6)	3	(0.8, 5.2)	3	(1.5, 4.4)	2	(1.0, 3.6)
Delay between wound closure and logging wound closure in randomisation database (minutes)	Median (IQR)	0	(-2.0, 2.0)	0	(0.0, 1.0)	0	(0.0, 1.0)	0	(0.0, 1.0)	1	(0.0, 2.0)	0	(0.0, 1.0)
Day case		21/64	32.8%	2/76	2.6%	20/111	18.0%	38/114	33.3%	1/20	5.0%	82/385	21.3%

Notes:

NBTG: North Bristol NHS Trust (General surgery), NBTO: North Bristol NHS Trust (Obstetric surgery), QEHB: Queen Elizabeth Hospital Birmingham, UHBR: University Hospitals Bristol NHS Foundation Trust, WORC: Worcestershire Acute Hospitals NHS Trust

Missing data (NBTG, NBTO, QEHB, UHBR, WORC):

* 9 patients with missing data (3, 0, 0, 6, 0), ^ 8 patients with missing data (1, 0, 0, 7, 0), × 7 patients with missing data (2, 0, 0, 5, 0).

Note that when cell denominator is different to number in column header, the difference arises because of missing data for that variable.

Table 15.3: Adherence to timing of disclosure of the allocation and the dressing group allocation by centre

Adherence	NBTG (n=64)		NBTO (n=77)		QEHB (n=112)		UHBR (n=114)		WORC (n=21)		Overall (n=388)	
	n	%	n	%	n	%	n	%	N	%	n	%
Adherence to disclosure of dressing category allocation at appropriate time												
Allocated to disclosure before wound closure	30/30	100.0%	38/38	100.0%	57/57	100.0%	50/52	96.2%	11/11	100.0%	186/188	98.9%
Allocated to disclosure after wound closure	23/32	71.9%	32/39	82.1%	49/55	89.1%	51/57	89.5%	10/10	100.0%	165/193	85.5%
Patient adherence to dressing allocation												
Adherence to initial dressing	61/61	100.0%	74/76	97.4%	109/112	97.3%	106/109	97.2%	19/21	90.5%	369/379	97.4%
Adherence to re-dressings (if applicable)	23/23	100.0%	25/26	96.2%	37/47	78.7%	42/52	80.8%	7/7	100.0%	134/155	86.5%
Overall adherence ×	61/61	100.0%	73/76	96.1%	99/112	88.4%	96/109	88.1%	19/21	90.5%	348/379	91.8%
Wound adherence to dressing allocation (wounds/patients)												
Adherence to initial dressing ¹	146/61	100.0%	74/74	97.4%	247/109	97.3%	234/107	98.2%	45/20	95.2%	746/371	97.9%

Adherence to re-dressings (if applicable) ²	67/23	100.0%	77/26	100.0%	113/44	93.6%	122/49	92.5%	21/7	100.0%	400/149	95.5%
Overall adherence ×	213/61	100.0%	151/77	100.0%	360/111	99.1%	356/109	99.1%	66/21	100.0%	1146/379	99.5%
Observer completing face-to-face SSI assessment at 4-8 weeks unblinded	14/39	35.9%	15/61	24.6%	10/89	11.2%	19/98	19.4%	0/15	0.0%	58/302	19.2%
Observer completing 4-8 week WHQ unblinded	7/15	46.7%	1/14	7.1%	9/56	16.1%	11/34	32.4%	0/8	0.0%	28/127	22.0%

Notes:

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¹ Reasons for non-adherence of initial dressing (NBTG, NBTO, QEHB, UHBR, WORC):

Wound problem (0, 0, 1, 0, 0), standard dressing applied (0, 1, 1, 0, 0), surgeon preference (1, 0, 5, 6, 1), allocated dressing not available (0, 0, 0, 1, 0), other (0, 1, 4, 1, 0)

² Reasons for non-adherence of re-dressings (NBTG, NBTO, QEHB, UHBR, WORC):

Problem with wound (0, 0, 12, 15, 0), surgeon preference (0, 0, 3, 1, 0), participant/family request (0, 1, 0, 0, 0), nurse preference (0, 0, 0, 3, 0), other (0, 0, 1, 6, 0)

× Note that numbers in the denominator may differ in these two rows as patients can only appear in the patient adherence to dressing allocation row if their dressing allocation was adhered to for all wounds at all times, however they can appear in the wound adherence to dressing allocation row if their dressing allocation was adhered to for at least one wound at all times.

Note that when cell denominator is different to number in column header, the difference arises because of missing data for that variable. This is only the case for tabulated summaries and not those presented as (wounds/patients).

Table 15.4: Co-interventions by centre

Outcome	NBTG (n=64)		NBTO (n=77)		QEHB (n=112)		UHBR (n=114)		WORC (n=21)		Overall (n=388)	
	n	%	n	%	n	%	n	%	N	%	n	%
Type of wound closure methods												
Sutures (wounds/patients)	144/61	100.0%	77/77	100.0%	217/93	83.0%	226/105	97.2%	45/19	90.5%	709/355	93.7%
Clips (wounds/patients)	0/0	0.0%	-	-	34/23	20.5%	5/3	2.8%	4/2	9.5%	43/28	9.2%
Steri-strips (wounds/patients)	4/2	3.3%	1/1	1.3%	13/8	7.1%	7/3	2.8%	3/1	4.8%	28/15	4.0%
Glue (unplanned) (wounds/patients)	0/0	0.0%	-	-	3/3	2.7%	7/3	2.8%	0/0	0.0%	10/6	2.0%
Prescription of prophylactic antibiotics	45/63	71.4%	77/77	100.0%	69/112	61.6%	84/112	75.0%	21/21	100.0%	296/385	76.9%
Classification of surgery^												
Clean	9/64	14.1%	77/77	100.0%	23/112	20.5%	21/114	18.4%	9/21	42.9%	139/388	35.8%
Clean-contaminated	43/64	67.2%	0/77	0.0%	89/112	79.5%	90/114	78.9%	12/21	57.1%	234/388	60.3%
Contaminated	11/64	17.2%	0/77	0.0%	0/112	0.0%	2/114	1.8%	0/21	0.0%	13/388	3.4%
Dirty-infected	1/64	1.6%	0/77	0.0%	0/112	0.0%	1/114	0.9%	0/21	0.0%	2/388	0.5%

Notes:

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^ Note that this was not collected on the CRFs but was classified by a surgeon based on the type of surgery and whether it was elective or unplanned.

Note that when cell denominator is different to number in column header, the difference arises because of missing data for that variable. This is only the case for tabulated summaries and not those presented as (wounds/patients).

Table 15.5: Completeness of data for outcomes anticipated to be measured in the main trial by centre

Event type	NBTG (n=64)		NBTO (n=77)		QEHB (n=112)		UHBR (n=114)		WORC (n=21)	
	n	n (%)	n	n (%)	n	n (%)	n	n (%)	n	n (%)
	expected	complete	expected	complete	expected	complete	expected	complete	expected	complete
OCCURRENCE OF AN SSI 4-8 WEEKS AFTER RANDOMISATION										
Reference SSI assessment at 4-8 weeks	64	39 (60.9%)	75	62 (82.7%)	111	89 (80.2%)	109	98 (89.9%)	18	15 (83.3%)
Abscess or other evidence of infection found during re-operation	39	38 (97.4%)	62	62 (100.0%)	89	89 (100.0%)	98	98 (100.0%)	15	15 (100.0%)
Aspirated fluid/swab of surgical site yields organisms and pus cells present	39	39 (100.0%)	62	62 (100.0%)	89	89 (100.0%)	98	98 (100.0%)	15	15 (100.0%)
Clinician's diagnosis	39	39 (100.0%)	62	61 (98.4%)	89	89 (100.0%)	98	98 (100.0%)	15	15 (100.0%)
Fever	39	39 (100.0%)	62	62 (100.0%)	89	89 (100.0%)	98	98 (100.0%)	15	15 (100.0%)
Heat	39	39 (100.0%)	62	61 (98.4%)	89	89 (100.0%)	98	98 (100.0%)	15	15 (100.0%)

Event type	NBTG (n=64)		NBTO (n=77)		QEHB (n=112)		UHBR (n=114)		WORC (n=21)	
	n	n (%)	n	n (%)	n	n (%)	n	n (%)	n	n (%)
	expected	complete	expected	complete	expected	complete	expected	complete	expected	complete
Incision spontaneously dehisces or opened by surgeon	39	39 (100.0%)	62	61 (98.4%)	89	89 (100.0%)	98	98 (100.0%)	15	15 (100.0%)
Localised pain and tenderness	39	39 (100.0%)	62	61 (98.4%)	89	89 (100.0%)	98	98 (100.0%)	15	15 (100.0%)
Localised swelling	39	39 (100.0%)	62	61 (98.4%)	89	89 (100.0%)	98	98 (100.0%)	15	15 (100.0%)
Purulent drainage	39	39 (100.0%)	62	61 (98.4%)	89	89 (100.0%)	98	98 (100.0%)	15	15 (100.0%)
Redness	39	39 (100.0%)	62	61 (98.4%)	89	89 (100.0%)	98	97 (99.0%)	15	15 (100.0%)
Type of SSI	39	39 (100.0%)	62	61 (98.4%)	89	89 (100.0%)	98	98 (100.0%)	15	15 (100.0%)
WOUND COMPLICATIONS ARISING IN-HOSPITAL AND UP TO 4-8 WEEKS POST-RANDOMISATION										
Post-operative wound complications (CRF D2)	64	48 (75.0%)	77	76 (98.7%)	112	101 (90.2%)	114	82 (71.9%)	21	19 (90.5%)
Wound complications [4-8 weeks] (CRF F7)	64	42 (65.6%)	75	62 (82.7%)	111	92 (82.9%)	110	104 (94.5%)	18	15 (83.3%)

Event type	NBTG (n=64)		NBTO (n=77)		QEHB (n=112)		UHBR (n=114)		WORC (n=21)	
	n	n (%)	n	n (%)	n	n (%)	n	n (%)	n	n (%)
	expected	complete	expected	complete	expected	complete	expected	complete	expected	complete
MEASURES OF RESOURCE USE										
Surgery date	64	64 (100.0%)	77	77 (100.0%)	112	112 (100.0%)	114	114 (100.0%)	21	21 (100.0%)
Time of knife-to-skin	64	61 (95.3%)	77	77 (100.0%)	112	112 (100.0%)	114	111 (97.4%)	21	21 (100.0%)
Time of skin closure	64	62 (96.9%)	77	77 (100.0%)	112	112 (100.0%)	114	109 (95.6%)	21	21 (100.0%)
Level 3 – patient admitted to area?	64	47 (73.4%)	77	71 (92.2%)	111	111 (100.0%)	114	114 (100.0%)	21	19 (90.5%)
Date of initial admission	1	1 (100.0%)	0	-	2	2 (100.0%)	2	2 (100.0%)	0	-
Time of initial admission	1	1 (100.0%)	0	-	2	2 (100.0%)	2	1 (50.0%)	0	-
Readmitted to this area?	1	1 (100.0%)	0	-	2	2 (100.0%)	2	2 (100.0%)	0	-
Date of re-admission	0	-	0	-	1	0 (0.0%)	1	1 (100.0%)	0	-
Time of re-admission	0	-	0	-	1	0 (0.0%)	1	0 (0.0%)	0	-

Event type	NBTG (n=64)		NBTO (n=77)		QEHB (n=112)		UHBR (n=114)		WORC (n=21)	
	n	n (%)	n	n (%)	n	n (%)	n	n (%)	n	n (%)
	expected	complete	expected	complete	expected	complete	expected	complete	expected	complete
Level 2 – patient admitted to area?	64	47 (73.4%)	77	71 (92.2%)	111	111 (100.0%)	114	114 (100.0%)	21	19 (90.5%)
Date of initial admission	2	2 (100.0%)	0	-	17	17 (100.0%)	14	14 (100.0%)	3	3 (100.0%)
Time of initial admission	2	2 (100.0%)	0	-	17	17 (100.0%)	14	5 (35.7%)	3	3 (100.0%)
Readmitted to this area?	2	1 (50.0%)	0	-	17	17 (100.0%)	14	14 (100.0%)	3	3 (100.0%)
Date of re-admission	0	-	0	-	0	-	2	2 (100.0%)	0	-
Time of re-admission	0	-	0	-	0	-	2	1 (50.0%)	0	-
Level 1 – patient admitted to area?	64	51 (79.7%)	77	76 (98.7%)	111	111 (100.0%)	114	114 (100.0%)	21	19 (90.5%)
Date of initial admission	35	34 (97.1%)	74	74 (100.0%)	111	111 (100.0%)	76	76 (100.0%)	11	11 (100.0%)
Time of initial admission	35	15 (42.9%)	74	71 (95.9%)	111	111 (100.0%)	76	18 (23.7%)	11	11 (100.0%)

Event type	NBTG (n=64)		NBTO (n=77)		QEHB (n=112)		UHBR (n=114)		WORC (n=21)	
	n	n (%)	n	n (%)	n	n (%)	n	n (%)	n	n (%)
	expected	complete	expected	complete	expected	complete	expected	complete	expected	complete
Readmitted to this area?	35	29 (82.9%)	74	74 (100.0%)	111	111 (100.0%)	76	76 (100.0%)	11	11 (100.0%)
Date of re-admission	0	-	0	-	5	4 (80.0%)	7	4 (57.1%)	0	-
Time of re-admission	0	-	0	-	5	4 (80.0%)	7	2 (28.6%)	0	-
Date of discharge/death	64	64 (100.0%)	77	76 (98.7%)	111	111 (100.0%)	114	114 (100.0%)	21	20 (95.2%)

Notes:

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Note that the number of patients with fields expected will differ due to patients withdrawing at different times during the study.

Table 15.6: Potential trial outcomes by centre

Summary	NBTG (n=64)		NBTO (n=77)		QEHB (n=112)		UHBR (n=114)		WORC (n=21)		Overall (n=388)	
	n	%	n	%	n	%	n	%	n	%	n	%
EQ-5D score - median (IQR)												
Baseline*	0.89	(0.75, 1.00)	0.94	(0.87, 1.00)	0.93	(0.83, 1.00)	0.92	(0.84, 0.95)	0.94	(0.87, 1.00)	0.92	(0.83, 1.00)
15 days^	0.82	(0.69, 1.00)	0.84	(0.79, 0.94)	0.82	(0.75, 0.89)	0.86	(0.75, 0.89)	0.89	(0.79, 0.92)	0.84	(0.75, 0.90)
4-8 weeks ×	0.84	(0.77, 1.00)	0.94	(0.89, 1.00)	0.89	(0.80, 0.95)	0.91	(0.84, 1.00)	0.89	(0.87, 1.00)	0.89	(0.82, 1.00)
SSI in-hospital	1/49	2.0%	0/76	0.0%	0/102	0.0%	3/101	3.0%	0/19	0.0%	4/347	1.2%
SSI at 4-8 week reference assessment												
None	33/39	84.6%	49/61	80.3%	68/89	76.4%	89/98	90.8%	14/15	93.3%	253/302	83.8%
Superficial	6/39	15.4%	11/61	18.0%	20/89	22.5%	7/98	7.1%	1/15	6.7%	45/302	14.9%
Deep	0/39	0.0%	1/61	1.6%	1/89	1.1%	1/98	1.0%	0/15	0.0%	3/302	1.0%
Organ/space	0/39	0.0%	0/61	0.0%	0/89	0.0%	1/98	1.0%	0/15	0.0%	1/302	0.3%
Any SSI (overall)	6/31	19.4%	12/61	19.7%	21/85	24.7%	11/89	12.4%	1/15	6.7%	51/281	18.1%

Notes:

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Missing data (NBTG, NBTO, QEHB, UHBR, WORC):

* 3 patients with missing data (1, 0, 0, 2, 0), ^ 120 patients with missing data (23, 30, 32, 26, 9), × 149 patients with missing data (24, 34, 41, 44, 6).

Note that when cell denominator is different to number in column header, the difference arises because of missing data for that variable.