Research Q2 Evidence Profile

Question 2: Should an ostomy care program or no ostomy care program be recommended?

Population: All adults (18 & over) living with or anticipating an ostomy.
Intervention: Ostomy care program.
Comparison: No ostomy care program.
Outcomes: Patient satisfaction, hospital length of Stay, readmission rates to hospital, staff satisfaction.

Setting: All healthcare settings

Bibliography: 2459, 3016, 3139, 3173, 3180, 3189, 3223, 3351, 3758, 3782, 8109

Quality assessment							Study details		No. of participants		Reported effects/outcomes	Certainty	Reference
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Country	Ostomy care program	Ostomy care program	No ostomy care program			
Patient Satisfaction (measured with surveys made by authors and modified EORTC IN-PATSAT32[1])													
1	RCT	serious [a]	not serious	not serious	serious [b]	none	3782: China	Structured, individualized educational and supportive telephone follow-up program after discharge. Patients were followed up with a series of 2-3 phone calls by ostomy nurses consisting of assessment, management options and evaluation.	52 participants Participants' satisfaction with care was evaluated by a single self-reported item scoring between 1 and 5, with 1 being "very satisfied" and 5 being "very unsatisfied". Baseline average = 1.52 1 month average = 1.44 3 month average = 1.45	51 participants Baseline average = 1.73 1 month average = 2.12 3 month average = 2.04	At 1 month (study group score 1.44 versus control group score 2.12) and 3 months (study group score 1.45 versus control group score 2.04) after discharge, the study group had statistically significant greater satisfaction with care. Overall, the study reported improvement in persons' satisfaction scores with the use of an ostomy care program compared to not using an ostomy care program.	⊕⊕◯◯ LOW	3782: Zhang et al., 2013
3	Quasi-experimental	very serious [c]	serious [d]	not serious [e]	serious [f]	none	3016: Canada	3016: Enhanced Recovery after Surgery (ERAS)	3016: 222 participants	3016: No comparison	Assessment tools varied between studies and different components of	⊕◯◯◯ VERY LOW	3016: Jones et al., 2017

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							3180: US 3351: UK	pathway that included pre-operative education and standard education and information at discharge. <u>3180</u>: Education and management protocol with daily phone call for 3 weeks after discharge. <u>3351</u>: Multidisciplinary team including stoma care nurse specialists providing ongoing support for patients from preoperative consultation through to their community follow-up.	93% satisfied with discharge information; 90% felt ready for discharge; 86% saw their surgeon at 6 weeks and 88% were satisfied with this follow-up plan. <u>3180</u>: 25/32 participants completed the patient satisfaction survey. The average score was 4.69 (CI: 4.51-4.66) on a scale of 1-5, with 1 being poor and 5 being excellent. <u>3351</u>: 56 participants completed survey Please refer to table[f] for survey results.	<u>3180</u>: 23 participants in a historical control cohort. Participants' satisfaction score not provided. <u>3351:</u> No comparison	ostomy care programs were assessed for satisfaction. Overall, all studies demonstrated positive satisfaction rates for most components of ostomy care program interventions. However, it is important to note that no studies had a control group where satisfaction was assessed in usual care.		3180: Iqbal et al., 2017 3351: Edis, 2015

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Hospital Length of Stay (*measured objectively*)													
1	Randomized controlled trial	serious [a]	not serious	not serious	serious [g]	none	3223: Norway	3223: Enhanced recovery after surgery (ERAS) program including peri-operative information and patient education	Participants = 61 Length of stay = 6 days	Participants = 61 Length of stay = 9 days	The median length of stay was 6 days for patients in ERAS group. For the control group, the median length of stay was 9 days, demonstrating a difference of 3 fewer days (LOS) for persons in the ostomy care program.	⊕⊕◯◯ LOW	3223: Forsmo et al., 2016
5	Quasi-experimental	serious [h]	not serious	not serious [i]	not serious [j]	none	3180, 8109, 3189, 2459: US 3758: Germany	3180: Education and management protocol with daily phone call for 3 weeks after discharge 3758: Implementation of clinical pathway for enhanced recovery with specific pre-op management + post op care 8109: ERAS program with standardized pathway that guided perioperative management, anesthesia protocol during surgery, and	3180: 32 participants with an average LOS of 3 days 3758: 36 participants with an average LOS of 12.5 days 8109: 279 participants with an average LOS of 4.1 days	3180: 23 patients with an average LOS of 4.2 days 3758: 67 patients with an average LOS of 15 days 8109: 245 patients with an average LOS of 6 days	Among four of the five studies, the LOS was 1 to 2.5 days fewer for persons in the ostomy care program compared to those who were not in an ostomy care program. In one study, the median length of stay was 4 days in the ostomy program group and 5 days in the group that were not in the ostomy care program.	⊕⊕◯◯ LOW	3180: Iqbal et al., 2017 3758:Hardt et al., 2013 8109: Sarin et al., 2016 3189: Shah et al, 2017 2459: Nagle et al., 2012

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								post-op instructions for management 3189: Enhanced recovery protocol from preadmission to discharge 2459: Standardized patient education tools peri-operatively and discharged with flow sheets, supplies for recording intake/output, and visiting nurses services	3189: 324 participants with median LOS of 4 days 2459:42 participants with average LOS of 6.6 days	3189: 383 patients with median LOS of 5 days 2459: 161 patients with average LOS of 7.5 days			
Readmission Rates to Hospital *(Measured objectively)*													
1	Randomized Controlled Trial	serious [a]	not serious	not serious	serious [k]	none	3223: Norway	3223: Enhanced recovery after surgery (ERAS) program including peri-operative information and patient education	13/61	11/61	For every 100 people in an ostomy care program, 3 more will be readmitted (ranges from 8 fewer to 26 more).	⊕⊕◯◯ LOW	3223: Forsmo et al., 2016
7	Quasi-experimental	serious [l]	not serious [m]	not serious [n]	not serious [o]	none	2459 , 3139, 3173, 3180, 3189, 8109: USA 3758: Germany	**2459**: Pre-op education, post-op education, follow-up visits	2459: Any readmission: 9/42 Readmission due to dehydration: 0/42	2459: Any readmission: 57/161 Readmission due to dehydration: 25/161	2459: For every 100 people in an ostomy care program, 14 fewer will be readmitted (ranges from 23 fewer to 4 more). 2459: For every 100 people in an ostomy care program, 15 fewer people will be readmitted	⊕⊕◯◯ LOW	2459 (Q1): Nagle et al. (2012) 3139: Hardiman, Reames, McLeod, & Regenbogen (2016) 3173: Shaffer

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								3139: Post-op education using patient-centered checklist **3173**: Post-op education, multiple home visits after discharge, telephone follow-up **3180**: Post-op education & daily telephone call for first 21 days post discharge **3189**: Enhanced Recovery Protocol with pre-op education, post-op care, telephone call within 72 hours, & follow-up clinic visit **3758**: Implementation of clinical pathway for enhanced recovery with specific pre-op management + post op care **8109**:ERAS program with pre-op + post op education	3139: 21 / 105 3173: 2 / 23 3180: 5 / 32 3189: 38 / 324 3758: 1 / 67	3139: 23 / 70 3173: 5 / 24 3180: 15 / 23 3189: 72 / 383 3758: 1 / 36	due to dehydration (ranges from 16 fewer to 3 more). 3139: For every 100 people in an ostomy care program, 13 fewer people will be readmitted (ranges from 21 fewer to 0 more). 3173: For every 100 people in an ostomy care program, 12 fewer people will be readmitted (ranges from 19 fewer to 2 more). 3180: For every 100 people in an ostomy care program, 49 fewer people will be readmitted (ranges from 58 fewer to 28 fewer). 3189: For every 100 people in an ostomy care program, 7 fewer people will be readmitted (ranges from 11 fewer to 2 fewer). 3758: For every 100 people in an ostomy care program, 1 more person will be readmitted (ranges from 1 fewer to 28 more). 8109: For every 100 people in an ostomy		et al. (2017) 3180: Iqbal et al. (2017) 3189: Shah et al. (2017) 3758: Hardt et al. (2013) 8109: Sarin et al. (2016)

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									8109: 29 / 279	8109: 64 / 245	care program, 16 fewer people will be readmitted (ranges from 19 fewer to 10 fewer).		

1. EORTC IN-PATSAT32: European Organisation for Research and Treatment of Cancer In-Patient Satisfaction 32-item survey

Explanations

a. Based on the Risk of Bias tool for Randomized Controlled Trials, this study had some serious concerns related to risk of bias due to limitations in how the study was conducted. The study was downgraded by 1.

b. Total number of participants in this study was 103, which is less than the optimal 400 participants. Participants were not blinded to the study and patient satisfaction is subjective outcome. The study downgraded by 1.

c. Based on the ROBINS-I tool for quasi-experimental studies, the studies had very serious concerns related to risk of bias due to limitations in how the studies were conducted. We downgraded by 1.5.

d. The data collection tools varied between all studies, therefore we downgraded by 0.5.

e. All studies did not have a comparison group as per original systematic review research question. We downgraded by 0.25.

f. Total number of participants in these studies was 333, which is less than the optimal 400 participants. The body of evidence downgraded by 1.

3351 – Survey results from 56 respondents

Before operation	After operation	At home (management of stoma at home)	Stoma review clinic
- 28/38 (74%) of patients reported receiving right amount of information before their surgery.	-13/13 (100%) respondents stated that they were satisfied with how stoma specialist explained caring for stoma. - 22/55 (40%) respondents rated ward nurses as 5 or below out of 10 on satisfaction scale related to stoma care.	- 22/53 (42%) responded "very well" - 23/53 (43%) "fairly well" - 4/53 (43%) "okay" - 4/53 (8%) "poorly".	- Only 3 out of 56 participants attended and they were satisfied with the outcome and length of consultation.

g. Total number of participants in this study was 122, which is less than the optimal 400 participants. The study downgraded by 1.

h. Based on the ROBINS-I tool for quasi-experimental studies, the studies had serious concerns related to risk of bias due to limitations in how the studies were conducted. We downgraded by 1.

i. Study 8109 includes patients undergoing ostomy surgery as well as others receiving any colorectal surgery. We did not downgrade as we felt that the intervention and outcomes in relation to all colorectal surgeries were relevant to our research question.

j. Total number of participants among 5 studies is 1, 592 and exceeds the optimal number of participants (400). We did not downgrade.

k. The total number of events (persons who were readmitted) is less than the optimal number of events (300). We downgraded by 0.5.

l. There were serious concerns related to risk of bias due to limitations in how the study was conducted. We downgraded by 1.

m. Out of the 7 studies, 6 studies reported a statistically significant decrease in readmission rates with the use of an ostomy care program ($p<0.05$). Among the 6 studies, reduction in readmission rates ranged from 65% to 9% in post-intervention groups. Overall, studies showed consistent results.

n. Out of the 7 studies, 6 studies looked at readmission rates within 30 days post-discharge. One study (ID # 3758) looked at readmission rates within 14 days post discharge. Also, one study (ID # 8109) that assessed readmission included all colorectal surgeries. However, 6 out of 7 studies addressed readmission rates post discharge for patients who had an ostomy surgery. All studies followed an ostomy care program intervention and compared it to a usual care group. Therefore, indirectness for overall body of evidence was determined to be not serious and no points were deducted.

o. The total number of events (persons who were readmitted) is 367, which is greater than the optimal number of events (300). We did not downgrade.