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A Cross-Sectional Survey Reporting on the Value of Patient-Centered Ostomy Programs

A Smooth Transition After Ostomy Surgery

Laurie McNichol ◆ Anna Markiewicz ◆ Jimena Goldstine ◆ Thom R. Nichols

ABSTRACT

PURPOSE: The purpose of the study was to evaluate a postsurgical ostomy patient support program in regard to postsurgical experience, education, skin care, pouching system and accessory use, insurance issues, supplier assistance, hospital readmission status, and the benefit of multiple interactions.

DESIGN: Cross-sectional design.

SUBJECTS AND SETTING: Potential respondents were randomly selected from a group of adults 18 years or older who underwent ostomy surgery within 6 months prior to survey completion. Nine hundred seventy-one individuals met inclusion criteria, and 297 were selected for analysis, based on having 1 or more program interactions. Data were collected between the second and third quarters of 2020. All participants were residents of the United States.

METHODS: Participants were contacted by e-mail containing an invitation to participate in a survey; the e-mail also described the intent of the survey. Survey distribution was conducted by the sponsor and linked to a third-party survey management organization for compilation. The survey questionnaire, developed specifically for the purpose of this study, comprised 73 items that queried demographic and pertinent clinical data, participation in an industry-sponsored patient support program, and their post-hospital discharge experiences including unplanned health care provider visits, emergency department visits, and hospital readmissions.

RESULTS: Eighty-three percent (n = 237) of respondents did not have postsurgical ostomy-related emergency department visits, 75% (n = 223) did not have related unplanned physician visits, and 90% (n = 268) did not have related hospitalizations. Participants with 2 or more interactions were more likely to contact a program representative for issues of stoma care, leakage and skin care, ostomy products/accessories, and supplier issues than their single-interaction counterparts.

CONCLUSIONS: Study findings suggest that patients with new ostomies benefited from engagement in an industry-sponsored patient support program. The benefit appears to arise from personal interactions and respondents; 2 or more interactions were shown to have greater benefit than a single interaction.

KEY WORDS: Ostomy, Ostomy education, Ostomy surgery, Patient support program, Self-sufficiency, Transition.

INTRODUCTION

Industry-sponsored patient support programs (PSPs) for persons with a new ostomy are designed to increase their self-care

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knowledge and enhance self-management of their ostomy. These programs are not intended to directly provide health care or replace the role of clinical management programs; instead, they are designed to complement and augment care delivered by health care professionals such as WOC nurses and other ostomy care specialists. In addition to working directly with persons recovering from ostomy surgery, they also often involve family members who must make adjustments to their own lives if they are to effectively assist in patients' care.

The structure and effectiveness of a PSP are influenced by the type of surgical procedure and the ability of patients to adjust to any lifestyle changes occurring as a result of the procedure. For a person who has undergone ostomy surgery, multiple lifestyle changes are necessary including challenges unique to the presence of the ostomy. Issues unique to ostomy surgery include learning to care for the stoma and peristomal skin, obtaining a proper ostomy pouching system fit, mastering use of ostomy accessories and proper product wear time, body image issues, and navigating health insurance. Bare and colleagues² and Colwell and colleagues³ observed that much of the burden associated with recovery from ostomy surgery arises from a lack of knowledge of ostomy care, along with prompt

recognition and management of stomal and peristomal complications. Colwell and colleagues³ reported consensus among an expert ostomy clinician panel that stated successful home health care for new ostomy patients involves knowledge related to pouching system management, peristomal skin, and other aspects essential to learning to live with an ostomy. Additionally, Richbourg and colleagues⁴ found that depression and anxiety, conditions known to reduce learning and knowledge retention, are prevalent following ostomy surgery.

These challenges can be supported or mediated by industry-sponsored postdischarge PSPs. Ganguli and colleagues⁵ reviewed research on the effect of PSPs and found that they exert a positive impact on issues such as patient adherence and clinical and humanistic outcomes such as health-related quality of life and functional status. They also found evidence suggesting that 2 or more interactions were more likely to be successful than a single interaction.

Depending on the sponsoring industry, the focus of a PSP may vary and outcome measures will be unique to the program and should be assessed according to their intent. One such PSP is Secure Start Services (SSS) (Hollister Incorporated, Libertyville, Illinois). This PSP offers customized support for ostomy or catheter product users, regardless of the product brand used, at no cost to the user. The program provides support for people living with an ostomy throughout the continuum of care, that is, those enrolled are matched with a consumer services advisor for long-term personal support as needed. The program offers patients assistance with product needs and options, connects patients to a supplier based on their insurance plan, and offers connections to various support organizations including access to nurses and health education. The primary aim of this study was to evaluate the effects of this PSP in the first 6 months following hospital discharge of patients having undergone ostomy surgery. We also examined knowledge of peristomal skin health, ostomy product knowledge and fit, educational materials, personal guidance, and postsurgery unplanned health care provider visits, emergency department visits, and hospital readmission rates. In addition, we examined the suggestion by Ganguli and colleagues⁵ that 2 or more interactions in a program may offer greater benefit than a single interaction. Specifically, we evaluated hospital readmission status following ostomy surgery and whether 2 or more interactions with a program offered greater benefit than a single interaction.

METHODS

This study was a cross-sectional survey of adults living with a urinary or fecal ostomy (colostomy, ileostomy, or urostomy). Potential respondents were randomly selected from a proprietary database containing e-mail contact information voluntarily provided by persons who resided in the United States, gave permission to be contacted via e-mail, and were 18 years or older. Respondents were required to be able to speak and read English and complete an online survey. Participants were restricted to those undergoing ostomy surgery within 6 months of data collection to reduce the potential for recall bias. Study procedures were reviewed by the Western Institutional Review Board and found to be exempt from individual consent under 45CFR §46.104(d)(2).⁶

Questionnaire

The questionnaire used for data collection was developed specifically for the purpose of this study. The questionnaire

was reviewed by PSP personnel, market access personnel, and health care professionals including a certified WOC nurse, with oversight by a biostatistician. The survey consisted of 73 items that queried the following: (a) participation in the PSP (n=7); (b) demographic and pertinent clinical information (n=13); (c) hospital experience (n=5); (d) experiences during the first 30 days after hospital discharge (n=5); (e) experiences 30 days after hospital discharge (n=5); (f) overall experience after leaving the hospital (n=33); and (g) quality of life as indexed by the EQ-5D (n=5) (EuroQual-5D).

Respondents' health-related quality of life was measured by the EuroQual-5D (EQ-5D; EuroQoL Office, Rotterdam, the Netherlands; https://euroqol.org/eq-5d-instruments) (EQ-5D, n = 5). The EQ-5D assesses mobility, self-care, usual activities, pain and discomfort, and anxiety/depression, has been shown to be a valid and reliable tool, and is responsive over a wide range of populations and disease conditions. A study of 298 family caregivers of patients with leukemia found that agreement among items in the 5 dimensions of the EQ-5D ranged from 86.35% (anxiety/depression) to 94.10% (mobility) and Cohen's κ coefficient exceeded 0.80.7 Response options to individual items were forced-choice answers based on a 5-point Likert-style question, matrix questions, closed-ended questions, multiple-choice questions, and one visual analog question.

The survey was assessed for face validity, that is, the content of the survey appears suitable to its aims, and content validity, that is, it is representative of what it aims to measure. These were nonstatistical assessments relying on the knowledge of subject matter experts who are familiar with the issues being assessed. The subject matter experts were provided with the survey and asked to provide feedback on how well each question appeared suitable and pertinent. Informed decisions were then made about the effectiveness of each question. Upon completion of the survey, the internal consistency of the questionnaire was assessed using the Cronbach α and found to have a coefficient of reliability of 0.781 (standardized alpha), where values of 0.70 or higher are considered acceptable.

Study Procedures

Eligible participants were contacted by e-mail and provided with a 4-paragraph invitation to participate that described the intent of the survey, type of information to be gathered, approximate length of time needed to complete the survey, and investigator contact information (phone number and e-mail) if they had any questions or concerns regarding the survey. They were instructed that participation was voluntary and that opening the survey link and completing the questionnaire indicated consent to participate. Potential respondents were also instructed that at any point they could choose to discontinue the survey. They were advised there would be no financial compensation for participation. Respondents were provided with an electronic nontransferable secured link to the survey. No personal identifying information (names, addresses, or other contact information) was collected. For analysis purposes, survey respondents were identified by a numerical value assigned according to order of survey completion. Participants were informed that their data would be anonymized prior to data analysis and only nonidentifiable aggregate data would be reported in all related publication activities.

The survey distribution was conducted by the sponsor of the study through e-mail and linked to Qualtrics (Qualtrics. com, Provo, Utah) for survey management and compilation.⁹ Qualtrics is certified and compliant with the EU-US Privacy Shield Framework (https://www.privacyshield.gov/welcome). Qualtrics is subject to the regulatory enforcement powers of the US Federal Trade Commission. Completed surveys were downloaded to a database and converted to an IBM SPSS Statistics for Windows, Version 25.0 (Armonk, NY: IBM Corp.) format for analysis. An assessment of eligibility for inclusion in the database was made dependent on inclusion criteria. Data were collected from the second quarter of 2020 through the third quarter of 2020.

Data Analysis

Data analyses were completed using IBM SPSS Statistics for Windows, Version 25.0. Descriptive analyses included measures of central tendency and cross-tabulated responses. Chisquare analysis, Fisher's exact test, and chi-square with odds ratios (ORs) were used to analyze differences between groups. Group 1 comprised respondents with one PSP interaction (n = 56), and group 2 comprised participants with 2 or more SSS program interactions (n = 241). Statistical significance was selected at $P \leq .05$ and presented with associated 95% confidence intervals (CIs). Data analysis was performed by a consultant biostatistician. All results were based on the total number of nonmissing responses; missing data imputation was not performed.

RESULTS

In total, 1704 people responded to the survey and 971 met inclusion criteria. Of these, a subset of 297 participants was randomly selected for analysis based on having 1 or more interactions with the SSS program. This provided a margin of error of 5.9%. Of these 297 participants, 138 (46.5%) were male and 159 (53.5%) were female. The majority were between 61 and 80 years of age (n = 165; 55.6%) and had colostomies (n = 151; 50.8%). Approximately 60% (n = 179) of respondents had lived with an ostomy for 3 to 6 months at the time of the survey. Table 1 summarizes demographic and pertinent clinical data.

Post-Surgical Experience

Successful postsurgical recovery from ostomy surgery begins in the hospital with a comprehensive discharge plan for patients to ensure the necessary ostomy education is provided prior to discharge and successful transition from hospital care to home. Upon hospital discharge, many patients also receive an American College of Surgeons Ostomy Home Skills Kit.¹¹ It is intended to support patients with educational and simulation materials required for postoperative recovery. However, not all patients receive such kits. In our study, 216 of 296 (73%) patients (reflecting some missing data for this question) stated they did not receive an Ostomy Home Skills Kit. Among those receiving kits, all but 2 reported using the kits to familiarize themselves with the stoma, ostomy products, and accessories.

A person with an ostomy can be enrolled in the PSP at any time pre- or postsurgery; the majority of study participants (n = 229; 77.1%) enrolled during the first month after surgery. Additionally, upon first contact with the PSP, 259 (87.2%) stated they received a starter kit consisting of a travel bag, an "understanding" booklet, a journal, and product samples. The booklet included in this PSP is page document for persons living with an ostomy. Booklets are customized for persons living with an ileostomy, colostomy, or urostomy. Topics covered in

TABLE 1.	
Responder	nt Profile

			n (%)
Male	Type of stoma	Colostomy Ileostomy Urostomy Multiple or do not know	68/138 (49.3%) 39/138 (28.3%) 26/138 (18.8%) 5/138 (3.6%)
Female	Type of stoma	Colostomy Ileostomy Urostomy Multiple or do not know	83/159 (52.2%) 63/159 (39.6%) 8/159 (5.0%) 5/159 (3.1%)
Male	Length of time since most recent surgery	<1 mo 1-3 mo 3-6 mo	3/138 (2.2%) 52/138 (37.7%) 83/138 (60.1%)
Female	Length of time since most recent surgery	<1 mo 1-3 mo 3-6 mo	5/159 (3.1%) 58/159 (36.5%) 96/159 (60.4%)
Male	Age	18-40 y 41-60 y 61-80 y >80 y	9/123 (7.3%) 27/123 (21.9%) 78/123 (63.4%) 9/123 (7.3%)
Female	Age	18-40 y 41-60 y 61-80 y >80 y	11/159 (6.9%) 53/159 (33.3%) 87/159 (54.7%) 8/159 (5.0%)

the booklet are as follows: "Understanding Your Body, Ostomy Products Explained, Practicing Self Care, Diet and Fluids, Living Daily Life, Relationships and Support." Study findings also indicated that 206 of 295 (69.8%) respondents received 1 or more visits from an independent home health care nurse regarding their stoma within the first month following hospital discharge.

Despite these resources, study findings also revealed that 1.7% (n = 5) did not know what type of ostomy they had, 11.8% (n = 35) did not know if their ostomy was temporary or permanent, and 2.7% (n = 8) did not have health insurance. In addition, 30.2% (n = 89) of respondents stated they did not receive a visit from a home health nurse, and of those who did receive a visit from a home health nurse, 8.3% (n = 17) reported receiving only one visit.

A minority of respondents indicated ostomy-related emergency department visits since their surgery (n = 51; 17.1%), and 24.9% (n = 74) reported ostomy-related unplanned visits to their health care provide. The 30-day hospital readmission rate for respondents was 8.75% (n = 26), and the overall readmission rate (occurring at any time within the first 6 month following ostomy surgery) was 9.8% (n = 29).

Patient Support Program Experience

A vast majority of respondents (n = 224; 78.0%) indicated they contacted a PSP representative more than once to discuss issues of ostomy care, pouch leakage, and peristomal skin irritation (Table 2). Participants with 2 or more interactions were more than 3 times more likely to contact a PSP representative for stoma care issues than their single-interaction counterparts (OR = 3.76; 95% CI, 1.30-10.87; P = .009). Furthermore, they were 2.90 and 4.35 times more likely to discuss pouching system leakage and skin irritation with a PSP representative

TABLE 2.

The Secure Start Services Experience: Associated Health Care

- 1 82.9% (237/286) of SSS clients did not have an ostomy-related ED visit within 6 mo following their ostomy surgery
- 2 90.2% (268/297) of SSS clients did not have an ostomy-related hospitalization within 6 mo following their ostomy surgery
- 3 75.1% (223/297) of SSS clients did not have an ostomy-related unplanned visit to their doctor's office and/or clinic within 6 mo following their stoma surgery

N.B. Response numbers differ due to missing data

Knowledge and Product Use

Those with 2 or more meaningful interactions with an SSS representative when compared with those with 1 interaction are:		95% CI
1	3.76 times more likely to discuss stoma care	1.30-10.87
2	2.90 times more likely to discuss pouch leakage	1.35-6.21
3	4.35 times more likely to discuss skin irritation	1.67-11.36
4	4.27 times more likely to discuss the proper use of ostomy products	2.32-7.87
5	3.09 times more likely to claim knowledgeable on the proper use of ostomy accessories	1.21-7.87
6	3.16 times more likely to be able to achieve a better fit of their products	1.24-8.06
7	4.98 times more likely to call a PSP to find a place to order product from	1.50-16.67
8	2.26 times more likely to find a supplier that works with their health care insurance	1.06-4.48
9	5.56 times more likely to rate the level of support they received as helpful or very helpful	2.91-10.53

Abbreviations: ED, emergency department; PSP, patient support program; SSS, Secure Start Services

(95% CI, 1.35-6.21; P=.005; and 95% CI, 1.67-11.36; P=.001, respectively). Those with 2 or more interactions were also 4.27 times more likely to speak to a PSP representative about the proper use of ostomy products than their single-interaction counterparts (95% CI, 2.32-7.87; P=.001). They were also 3.09 times more likely to claim knowledge of the proper use of ostomy accessories (95% CI, 1.21-7.87; P=.014). The data also indicate that those with multiple interactions were 4.98 times more likely to use the PSP to find a product supplier (95% CI, 1.50-16.67; P=.004), 2.26 times more likely to find a supplier that works with their health care insurance (95% CI, 1.06-4.48; P=.032), and 5.56 times more likely to rate the level of support received as helpful or very helpful (95% CI, 2.91-10.53; P<0.001).

DISCUSSION

This study evaluated an industry-sponsored PSP developed to assist patients acquire the skills and knowledge necessary to living with an ostomy. Study findings suggest that participation in the program reinforces basic knowledge of ostomy care such as the appearance of normal peristomal skin. Study findings also suggest that program participation, and repeated program participation in particular, may be associated with lower unplanned visits to a health care provider, along with lower emergency department and hospital readmission rates.

Life with an ostomy can be psychologically, socially, and physically challenging. ^{12,13} People with a new ostomy must learn to cope, adapt, and develop a new sense of normality. Multiple interventions have been designed to provide patients with new ostomy knowledge and resources needed to cope with and adapt to life with an ostomy. Education about living with an ostomy optimally begins prior to surgery via consultation with a certified WOC nurse; ideally, this education begins prior to surgery, progresses through the hospital course, and extends to follow-up visits in an ambulatory care setting. Many patients also receive a "kit" from the American College of Surgeons.

This kit is an interactive program developed by the American College of Surgeons, in collaboration with the American Society of Colon and Rectal Surgeons, American Urological Association, Wound Ostomy and Continence Nurses Society, United Ostomy Associations of American, American Pediatric Surgical Association, American Pediatric Surgical Nurses Association, and the American Cancer Society's Commission on Cancer. 14-21 Following hospital discharge, many patients with a new ostomy also experience 1 or more visits by a home health care nurse. Additionally, they may have access to an industry-sponsored postsurgical PSP.

Prinz and colleagues²² assert that best practice for patients with a new ostomy includes education related to basic skills of ostomy and pouch management, ordering supplies, available manufacturers of ostomy products and accessories, nutrition, potential complications, and medications prior to hospital discharge. Despite this multiple pronged approach to care for patients with a new ostomy, findings from our study suggest that a significant minority of patients receive only part of these resources and some respondents indicated a lack of even basic knowledge of the type or ostomy they have or whether it was intended to be permanent or temporary.

Industry-funded PSPs are designed to engage and support the patient by extending services offered by more formal clinical care in which the traditional health care experience focuses on clinical outcomes. The PSP we evaluated is a patient-centric infrastructure overlapping one-on-one guidance with health and product knowledge, education, insurance, technology, and health-related quality-of-life issues. The lack of knowledge transfer and supportive contact in a minority of respondents further reinforces the need for postsurgical programs. While patients' need for additional information varies, findings of our study suggest that patients will use the PSP to access information most important to their individualized needs regarding transition to life with a new ostomy. Specifically, analysis of study findings revealed that not all respondents accessed the benefits offered by the PSP for all issues. Rather, users selectively

accessed information they deemed most pertinent to their needs at the time they made contact with a PSP representative.

A potential benefit of PSP is prevention of stomal and peristomal complications, resulting in less utilization of emergent health care services. Specifically, the ability to promptly identify a problem with peristomal skin or ostomy-related complication may prevent or mitigate more serious sequelae, reducing unplanned visits to a health care provider, emergency department visits, or hospital readmissions, particularly within the first 30 days following stoma surgery. While the cross-sectional design of this study does not allow us to draw conclusions related to efficacy of the PSP, several findings suggest that program participation provides the knowledge needed to prevent or promptly recognize complications before they led to use of emergent services. For example, the 30-day hospital readmission rate in our study was 8.75%. Our rate compares favorably to published incidence rates reported in prior studies that vary from 11% to 39%.^{23,24} Our results are also comparable to a comparison cohort study of 493 participants that found participation in a PSP following creation of a new ostomy was associated with a lower risk of hospital readmission both within the first 30 days and first 18 months following ostomy surgery when compared to patients who did not participate in a support program (OR = 0.45; 95% CI, 0.27-0.73; and OR = 0.37; 95% CI, 0.22-0.64, respectively).²⁵

We assert that much of the effect of the PSP is derived from interactions between PSP representatives and study participants that focused on the daily routine of ostomy care and stoma product management. We also questioned, in light of the wealth of information provided before and following stoma surgery and during home health care nurse visits, whether these additional interactions are of benefit to the person with a new stoma. Study findings indicated that respondents, and particularly those engaging in 2 or more interactions, obtained benefit from PSP participation. This finding underscores the need for an iterative process of teaching for patients with a new ostomy. While not all participants sought out additional contact with a PSP representative, study findings indicate that 8 out of every 10 respondents found the level of support they received to be helpful or very helpful.

Study findings suggest multiple benefits from program participation. For example, 78% of people with ostomies in our study could identify what healthy peristomal skin should look like. Recognizing healthy peristomal skin becomes of primary importance when it is realized that peristomal skin issues are not simply physical issues. The published literature provides empirical evidence that social interactivity in an ostomy population is influenced by peristomal skin condition that acts as a health stressor and can be debilitating and costly affecting health utility and quality-adjusted lifetimes.²⁶⁻²⁸ When provided with support material relevant to this issue, the majority (182 of 210; 86.7%) of respondents surveyed stated that such material was helpful. For those stating they had peristomal skin issues, approximately 9.5 out of 10 respondents stated information received on this topic was helpful or very helpful. These findings strongly suggest that the teaching-learning process in the person with a new ostomy is iterative; repetition reinforces and expands the knowledge base required to successfully transition to a life with a stoma. Fundamental topics such as stoma care, pouch leakage, skin irritation, and the proper use of ostomy products and accessories become life lessons benefitting the daily routine of the person with an ostomy.

Colwell and colleagues³ described anticipated changes in the size and shape of a new stoma over time. During the increasingly brief amount of time a patient remains in hospital after ostomy creation, nursing education necessarily focuses on ensuring the most basic skills such as pouch emptying are mastered. Despite teaching patients that the pattern used to fit a pouching system in the immediate postsurgical period will evolve over time, many patients with a new ostomy do not recall this instruction as the aperture size they use in pouching becomes larger than required over time. Reinforcement of stoma measurement and skin barrier preparation can prevent peristomal skin complications caused by a poorly fitting pouching system.

Similarly, during the provision of ostomy education in the acute care setting, patients with a new ostomy are instructed that they may bathe and shower with the ostomy pouching system on or off and written materials reinforce this concept. Due to an incision or wound left open to heal, however, occasionally surgeons may recommend delayed return to showering or bathing based on wound-healing priorities. A coauthor of this article (L.M.), a WOC nurse, reports it is not uncommon to discover that people with ostomies who have received education about resumption of bathing with an ostomy fail to resume this activity for many months following surgery and completion of wound healing. Interactions with a PSP provide reinforcement for this nonclinical lifestyle activity and promote a prompt return to normalcy.

LIMITATIONS

The cross-sectional study design provides a broad description of patient experiences during the first 6 months following ostomy surgery, but it does not enable conclusions about the effects of the program on the prevention of adverse outcomes such as visits to an emergency department or hospital readmission. We did not evaluate secondary features such as health care cost reduction, which is difficult to measure in a survey and unlikely to be attributed solely to the effect of a program. The survey had established face and content validity by expert review; more rigorous psychometric evaluation was not undertaken. Additionally, not all industry-sponsored PSPs are similar and outcomes of this study may not apply to other PSPs.

CONCLUSIONS

For life-altering surgeries such as ostomy surgery, postsurgical patient engagement is essential for a return to a life of self-sufficiency. This study evaluated an industry-sponsored PSP developed to assist patients learn the skills and knowledge necessary to life with an ostomy. The PSP we evaluated provides a lifetime of free, customized support on many levels. Study findings suggest that participation in the program reinforces basic knowledge of ostomy care such as the appearance of normal peristomal skin. Study findings also suggest that program participation, and repeated program participation in particular, may be associated with lower unplanned visits to a health care provider, along with lower emergency department and hospital readmission rates. We assert that these outcomes are linked to reinforcement of knowledge and skills needed to manage an ostomy, select and use an ostomy pouching system and accessory products essential to ensuring a good product fit, prevent undermining and leakage from the pouching system, prevent

peristomal skin complications, and help connect patient with ostomy product suppliers.

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Call for Authors: Ostomy Care

- Original research reports comparing surgical outcomes for patients who undergo preoperative stoma site marking by a WOC nurse compared to patients who do not.
- Case studies, case series or original research reports focusing on stomal or peristomal complications.
- Case studies, case series or original research reports focusing on other potential sequelae of ostomy surgery
 including physical manifestations such as low back pain or psychosocial manifestations such as depression,
 altered sexual function or embarrassment.
- Original research reports confirming or challenging the assertions of the ongoing WOCN Ostomy Consensus Session including ostomy pouch wear time and minimum standards for immediate postoperative education of patient and family.