

Research Article

Mixed-methods exploration of challenges to stoma care for ostomates in four low- and middle-income countries: STomacARe For Improvement reSearch (STARFISH) study

Marie Carmela M. Lapitan^{1,2}, Marie Dione P. Sacdalan¹, Marc Paul J. Lopez¹, Ma. Felina P. Cruz³, Vanessa J. Msosa⁴, Adesoji O. Ademuyiwa⁵, Felix M. Alakaloko⁵, Ritu Jain⁶, Amit Mahajan⁶, Vishal Michael⁶, Dhruva N. Ghosh⁶, Parvez D. Haque⁶, Ashwani Kumar⁷, Manisha Aggarwal⁷, James C. Glasbey⁸

¹ Department of Surgery, University of the Philippines Manila, ² Institute of Clinical Epidemiology National Institutes of Health, University of the Philippines Manila, ³ Department of Surgery, Makati Medical Center, ⁴ Kamuzu Central Hospital, ⁵ Lagos University Teaching Hospital, Lagos, Nigeria, ⁶ Christian Medical College and Hospital Ludhiana, ⁷ Government Medical College Patiala, ⁸ University of Birmingham

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Background

Little is known about the challenges of stoma care and potential solutions for patients in low- and middle-income countries (LMICs). This study aimed to assess the outcomes and experience of care for patients with stomas in LMICs using a mixed methods approach.

Methods

A cross-sectional survey of hospitals assessed health system characteristics relevant to stoma care. A six-month retrospective audit collected data on all patients undergoing new stoma formation, and postoperative complications. Semi-structured interviews with stoma patients and informal caregivers, and key informant interviews with healthcare providers were conducted to gather information on experiences, challenges and coping strategies relating to stoma care. The results were triangulated to develop a questionnaire-based tool to assess patients' and carers' knowledge and attitudes towards stoma and stoma care.

Results

Six hospitals from the Philippines, Malawi, Nigeria and India participated in the study. Data from 446 patients demonstrated diversity case mix, outcomes and postoperative stoma counselling. Interview data from the Philippines highlighted the lack of knowledge on stoma care of the patients and carers, poor access to stoma care and resources and the lack of affordable stoma care supplies. Triangulating these inputs, a 33-item questionnaire was developed to facilitate task sharing of expert stoma care to non-expert nurses and caregivers.

Conclusions

This study highlighted gaps in capacity to provide stoma counselling and poor access to and affordability of stoma care supplies for patients in LMICs. This novel questionnaire can help close these gaps and improve care for new ostomates in resource limited settings.

Registration

The study is registered in the Philippine Health Research Registry PHRR No.210805-003783 (<https://registry.healthresearch.ph/index.php/registry>)

Formation of a stoma is an aspect of surgical treatment for a diverse range of intraabdominal conditions ranging from cancer to inflammation and infection.¹ It is often life-saving, but represents an alteration in body function and

image that patients must self-manage day-to-day for significant periods of time, often permanently.

The primary aim of stoma self-care for patients is to discreetly and safely collect and dispose of body waste, while continuing life as normally as possible. In high income

countries (HICs) the costs of stoma management supplies are commonly supported by state- or insurance-funded health systems. Patients can choose from a range of hygienic, discrete, and reliable disposable collection systems for stoma management. Counselling by stoma care experts is often available pre- and postoperatively.^{2,3} Although better outcomes have been observed in HICs where patients had access to both regular postoperative expert support and appropriate and effective products⁴⁻⁶ many patients still encounter physical, psychological, and social challenges when adjusting to life with a stoma.⁷⁻⁹

Patients with similar indications and reasons for surgery are more likely to have a stoma created in a LMIC than a HIC. This is due to differences in patient conditions, resourcing, training, and access to surgical devices and techniques.¹⁰ In LMICs, many patients do not have access to either stoma nursing care or suitable stoma devices. And since health care is often funded out-of-pocket in such settings, patients who are already at high risk of catastrophic financial impact as a result of their index surgery may be faced with a 'second hit' of ongoing self-funded stoma care.¹¹ Many patients resort to adapting and reusing elements of appliances intended for single-use or creating entirely home-made devices.^{12,13} Despite this huge care need, little research to date has explored patients' experience and outcomes of stoma care in LMICs.^{14,15} This has been recognised as a priority by the World Health Organization's (WHO) Priority Medical Devices project.¹⁶ As the number of ostomates and stoma appliance requirement increases globally,¹⁷ work in partnership with patients to create contextually appropriate and affordable solutions for stoma self-care is much needed.¹⁸

The SToma cARe For Improvement reSearch (STARFISH) study aimed to address this knowledge gap by exploring the current delivery of stoma care and outcomes of stoma surgery in LMIC hospitals, and the challenges of stoma care for patients. By triangulating this knowledge, it aimed to develop a tool for use in clinical settings to assess patients' and carers' knowledge relating to stomas and stoma care and to facilitate effective and timely communication with care providers.

METHODS

This study was conducted in three parts, adopting a sequential explanatory mixed methods design.¹⁹ In the first phase, cross-sectional centre surveys and retrospective audits were conducted to profile the delivery and case-mix of stoma formation surgery and early postoperative outcomes in LMICs. This informed the second phase of semi-structured interviews with patients, carers and stoma care providers seeking to identify challenges to safe, acceptable, and high-quality stoma care in LMICs and explore current and future solutions. These quantitative and qualitative data were then triangulated in the third phase to inform the development of a tool that could strengthen stoma care provision by prompting appropriate communication and knowledge transfer between providers and patients about caring for a stoma and safely and effectively.

All study procedures were conducted in accordance with International Committee on Harmonisation Good Clinical Practice principles.²⁰ Storage, management and cleaning of data were performed in line with best practice recommendations and compliant with EU General Data Protection Regulations (GDPR) and the provisions of the data privacy laws of the participating countries. Written informed consent to participate in interviews was obtained from all patients, carers and healthcare practitioners. The study protocol was reviewed and approved by the University of the Philippines Manila – Research Ethics Board (UPM-REB 2019-316-01) and is publicly registered in the Philippine Health Research Registry (PHRR210805-003783). All other participating institutions obtained local ethical approval in accordance with local requirements. STARFISH was co-designed and co-delivered with patients in LMICs through embedded Community Engagement and Involvement.²¹ It was funded by a grant from NIHR Global Health Research Unit on Global Surgery (NIHR 16.136.79).

PHASE 1. CROSS-SECTIONAL CENTRE SURVEY AND RETROSPECTIVE AUDITS

Hospitals within the UK NIHR Global Health Research Unit on Global Surgery 'hub and spoke' network were invited to participate in Phase 1. Briefly, this is a network of national 'hubs' in seven LMICs with national oversight, leadership and infrastructure with several networked satellite 'spoke' hospitals within each country, each with their own local principal investigator and research infrastructure. This network has demonstrated an ability to deliver both major randomised trials and observational cohort studies of high-quality standards.^{22,23} All hospitals within the network that expressed interest in joining the study and secured ethical approval were included. No restrictions on surgical case load or case mix were used for inclusion in the study.

First, a cross-sectional centre survey of stoma care in the participating hospitals was conducted. The survey was completed by the local principal investigator, or a nominated deputy with a full-time clinical role in the participating hospital. Data were collected on relevant local facility and health system characteristics. These included facility type and size, monthly surgical load, inpatient and outpatient care financing systems, access to stoma care, availability of stoma products, and use of improvised stoma appliance (**See Online Supplementary Document Appendix 1**).

Second, retrospective audits were conducted of consecutive patients undergoing an operation that resulted in the formation of a new stoma in the participating hospitals over any six-month period between December 2018 and December 2020. A six-month period was deemed sufficient to reflect the normal case mix and case load for the participating hospitals. There were no restrictions related to age, surgical specialty, operation type, approach, or indication for surgery. Patients undergoing a revision or re-siting of stoma were excluded. Participating hospitals created a local team to identify all eligible cases from operating theatre logbooks and ward lists. Data were collected from a review of electronic or paper medical records including patient

characteristics, stoma type, and indication for surgery and outcomes during the centres' usual follow-up periods (**See Online Supplementary Document Appendix 2**). Data were inputted into a REDCap²⁴ database hosted at the University of Birmingham, UK, and pseudo-anonymised at the point of data entry. Co-primary outcomes were the rate of provision of preoperative stoma counselling and provision of postoperative stoma nursing care. Secondary outcomes included stoma-related complication rate and types, general complication rate and type, mortality rate and causes of death, and length of hospital stay.

Descriptive data summaries were presented as frequencies and proportions by centre. Means and standard deviations were calculated for normal data, and medians and interquartile range for non-normal data.

PHASE 2. SEMI-STRUCTURED INTERVIEWS WITH PATIENTS AND STOMA CARE PROVIDERS

Semi-structured interviews were conducted with patients with a stoma, caregivers of stoma patients, and stoma healthcare providers. Patients and carers attending the Philippine General Hospital Colorectal Stoma Clinic and hospitalised inpatients identified through referrals from colorectal, paediatric and urologic surgical services were invited to participate. Adult patients of at least 18 years of age who had any type of abdominal wall stoma were eligible, with no restrictions on timing from stoma formation. Informal caregivers of at least 18 years of age were considered for inclusion if they directly provided care for a stoma patient. Stoma health-care providers were defined as any healthcare staff involved directly in stoma care services, including surgeons, specialist stoma nurses, and non-specialist nurses involved in stoma care.

For patient and carer interviews, a topic guide was designed to explore experiences, challenges and coping strategies relating to stoma care, including impact on activities of daily living, community attitudes, and availability, accessibility and affordability of stoma products. A set of probes was created to encourage depth and breadth in open discussion. Development of the topic guide and probe sheet were informed by the findings from Phase 1, with further context provided by a scoping review of existing literature^{5,11,25} and the WHO Priority Medical Devices project's four core areas for design and provision of medical devices: availability, accessibility, appropriateness, and affordability.¹⁶ Invited participants were provided with a Patient Information Sheet explaining the study objectives and procedures. They were given the opportunity to ask questions ahead of giving consent. Prior to the interview, a written informed consent was obtained from each participant after explaining that participation is voluntary, that consent could be withdrawn and that they were able to stop the interview at any time. A target sample size of 20 patients, 5 carers, and 20 stoma care providers was anticipated to reach a point of thematic saturation, and balance quality and pragmatism during the SARS-CoV-2 pandemic. A purposeful maximum variation sampling method based on stoma type, sex, age, and socioeconomic status was employed to explore data from a wide range of perspectives.²⁶

Patients and stoma care providers were interviewed independently by different researchers so the responses from one group could not influence the conduct of the interviews of the other. Interviews were conducted either face-to-face or remotely by telephone or video call and were audio recorded. They took place in settings where privacy and confidentiality were ensured. The interviewer kept written notes and a reflexive journal to aid subsequent interpretation. Interviews were transcribed verbatim, and analysed in the local language by native language speakers. Raw data underwent thematic content analysis with double coding by two investigators. Each distinct concept was marked as a unit and similar units across interviews were grouped into themes. No software was used. Rather, a thematic codebook was iteratively developed from the first two interviews of each group to support consistent and transparent analysis. Where differences arose, the two data analysts resolved these through discussion, documented in reflexive journals. After themes were identified, those expressed in the local language were translated into English by a bilingual lead author.

The study protocol had included focus group discussions after one-to-one interviews to compare and contrast insights, allow member checking, and support co-development of the patient-facing tool but these were not permitted during the SARS-CoV-2 pandemic.

PHASE 3. STOMA PATIENT "ASSISTED COMMUNICATION" TOOL DEVELOPMENT

The findings of phase 1 and phase 2 were triangulated to inform the development, with the involvement of community and patient representatives, of a patient and carer assessment and communication tool. The tool, comprising a series of signalling questions, is intended to be completed by stoma patients and/or their carers to allow the healthcare team to assess initial stoma care literacy and identify any knowledge gaps that need addressed and to give opportunity for patients and carers to ask questions about their care.

First, a longlist list of possible items for inclusion was generated by the study steering group based on Phase 1 data and Phase 2 themes and theory. These items included facts about stoma and stoma care that were recognized as either important yet often not relayed and those that are often misunderstood, and conditions that cause anxiety and worry to ostomates. This list was evaluated item-by-item in a virtual focus group of multidisciplinary experts, including two colorectal surgeons, one urologist, one stoma care nurse and one patient representative with 10-years lived experience of stoma care, along with her carer. Revisions were made by the group based on clarity, understandability and uniqueness of each item, and the completeness and length of the entire tool. Items were either accepted with or without wording changes or rejected, and new items added. The tool was developed in English and then translated into Filipino/Tagalog for local piloting with new ostomates and their informal carers. After completing the questionnaire, the respondents were asked to comment on the importance, relevance and wording of the questions and re-

sponse options using an interviewing-based ('think aloud') approach, with flexibility permitted to allow new concepts, questions, or themes to emerge during the piloting phase. After revision, the tool was piloted in new and old ostomates and finalized.

RESULTS

PHASE 1. CROSS-SECTIONAL CENTRE SURVEY AND RETROSPECTIVE AUDITS

Six LMIC hospitals participated in phase 1: Philippine General Hospital (PGH) and Makati Medical Center (MMC) in Manila, Philippines; Lagos University Teaching Hospital (LUTH), Nigeria; Kamuzu Central Hospital (KCH), Malawi; and Christian Medical College and Hospital (CMCH) and Government Medical College-Patiala (GMC-P) in India. All are large academic centers with 700-1500 beds, performing more than 300 surgeries annually (Table 1).

Funding arrangements for inpatient and outpatient care varied between centers, from entirely state-funded to wholly out-of-pocket, with some private insurance and charity funding. Only the two hospitals in the Philippines reported stoma care provision by specialized nurses as well as by surgeons; CMCH had a stoma service that catered to patients both in the in- and outpatient settings. All hospitals had stoma care devices stocked in the hospital and clinic pharmacies, as well as available commercially outside the hospital and made available to patients by charitable donations apart from LUTH, where stoma care devices are only available outside the hospital. Respondents from all hospitals were aware of the use of improvised stoma devices by patients, including homemade appliances crafted from plastic caps, garters, polyethylene bags and urine bags, although this was rare in MMC, KCH and GMC-P.

Baseline demographic and clinical characteristics of the retrospective cohort are reported in Table 2. Differences between hospitals reflected differences in hospital specialty intake, staffing, local populations and referral patterns. Although all centers are large academic hospitals, the numbers of consecutive new stoma formation operations identified in the six-month windows varied, from 11 in CMCH to 294 in PGH.

Indications for surgeries resulting in a stoma varied across hospitals with the most common causes overall being colorectal cancer (54.0%), infectious (13.7%), congenital (10.1%), and other benign non-infectious (9.4%) bowel disease. The majority of stoma formed were intended to be temporary (79.2%); 40.7% of patients had a stoma formed involving the small bowel, with a potential risk of high-output effluent.

Provision of preoperative stoma counselling varied widely between hospitals, but was provided to only 13.9% of patients overall: to the majority of patients in two hospitals (MMC: 76.0% and LUTH: 84.0%), to very few in three (GMC 10.9%, CMCH 9.1%, and PGH 0.7%) and to none in one (KCH). Postoperative stoma nursing care was provided to 44.4% patients overall: to all or nearly all patients in all hospitals except for PGH, where only 19.7% received such care (Table 3).

Overall, 23.5% of patients had an in-hospital complication. Stoma-related complications occurred in hospital in 8.6% and post-discharge in 9.1% (Table 3).

PHASE 2. SEMI-STRUCTURED INTERVIEWS

PATIENTS AND CARERS

Nineteen stoma patients and informal carers were interviewed (12 patients, 7 carers) in the Philippines: 11 adult patients were interviewed alone and one alongside their carer (spouse); of six carers interviewed alone, one cared for their spouse and five for children. Of the 18 stoma patients discussed (12 male, 6 female), 12 were enterostomy/colostomy cases and 6 urostomy cases. Index diagnoses included congenital anorectal disease (n=5), bladder cancer (n=6), colorectal cancer (n=5) and benign diseases (Fournier's gangrene, radiation proctitis; n=2) (Table 4, Table 5).

Several major themes emerged from the interviews. Those deemed most relevant to Phase 3 development are outlined below, and further analysis is presented in the **Online Supplementary Document Appendix 3**.

KNOWLEDGE ABOUT HAVING AND CARING FOR A STOMA

Clarity around the need for a stoma as part of surgical treatment and its role was felt to be very important, and while most patients and carers understood what a stoma was and why it was needed, some remained unclear. Commonly, patients' and carers' understanding of the difference between a permanent and a temporary stoma was poor, and some were not made aware of when closure may be possible in case of temporary stoma. Even day-to-day stoma function was often ineffectively relayed to patients:

"Patients are often not informed of what type of (stoma) output to expect, the amount, and how diet can affect the output", colorectal surgeon, 29/F

A recurring theme in the interviews with patients, carers and clinicians was the importance of the knowledge and the skills necessary for proper stoma care. Yet these were often lacking, reflecting the low rates of perioperative stoma counselling and stoma nursing care noted in Phase 1. Healthcare workers expressed concern that many patients and carers have insufficient knowledge at the time of discharge about when and how to change the appliance and the importance of proper cleaning of the stoma and skin care around it. Surgeons commonly mentioned that although they could provide patients and carers with all the necessary instructions and information about stoma care, they do not often have the time to do so.

Poor knowledge persisted in the community, with patients and carers reporting poor understanding of how and when to correctly apply and change appliances, especially in the early days of their condition. In particular, insufficient emphasis had been placed on the importance of cutting the adhesive wafer to a shape and size that provides a good fit, remains securely in place and can prevent dermati-

Table 1. Characteristics of stoma care pathway across hospitals in Phase 1 survey

	Philippine General Hospital (PGH)	Makati Medical Center (MMC)	Lagos University Teaching Hospital (LUTH)	Kamuzu Central Hospital (KCH)	Christian Medical College and Hospital (CMCH)	Government Medical College, Patiala (GMC-P)
Country	Philippines	Philippines	Nigeria	Malawi	India	India
HDI classification (rank)	Medium (116)	Medium (116)	Low (163)	Low (169)	Middle (132)	Middle (132)
Level of care	Tertiary	Tertiary	Tertiary	Tertiary	Tertiary	Tertiary
Facility type	Academic	Academic	Academic	Academic	Academic	Academic
Hospital beds	1500 (200 surgical)	714	756 (200 surgical)	1000	720 (120 surgical)	1200 (210 surgical)
Average total monthly surgical load (elective and emergency)	580	320	240	Not available	377	300
Health care system financing (inpatient care, overall)	State-funded	<ul style="list-style-type: none"> Private insurance Charities Out of pocket 	Out of pocket	State-funded	Mixed	Mixed
Healthcare system financing (outpatient care, overall)	Out of pocket	<ul style="list-style-type: none"> Private insurance Charities Out of pocket 	Out of pocket	State-funded	<ul style="list-style-type: none"> Private insurance Charities Out of pocket 	Mixed
Providers of stoma care (inpatient)	<ul style="list-style-type: none"> Colorectal surgeons Specialized stoma care nurse 	<ul style="list-style-type: none"> Colorectal surgeons Specialized stoma care nurse 	Colorectal surgeons	Colorectal surgeons	<ul style="list-style-type: none"> Colorectal surgeons Specialized stoma care nurse Stoma service Patient support group 	Stoma service
Providers of stoma care (outpatient)	<ul style="list-style-type: none"> Colorectal surgeons Specialized stoma care nurse Patient support group 	<ul style="list-style-type: none"> Colorectal surgeons Specialized stoma care nurse 	Colorectal surgeons	Colorectal surgeons	<ul style="list-style-type: none"> Colorectal surgeons Specialized stoma care nurse Stoma service Patient support group 	Stoma service
Availability / accessibility of stoma products	<ul style="list-style-type: none"> Stocked by hospital or clinic pharmacy Donations from charities / NGO Sources commercially outside the hospital 	<ul style="list-style-type: none"> Stocked by hospital or clinic pharmacy Donations from charities / NGO Sources commercially outside 	Sources commercially outside the hospital	<ul style="list-style-type: none"> Stocked by hospital or clinic pharmacy Donations from charities / NGO Sources commercially outside the hospital 	<ul style="list-style-type: none"> Stocked by hospital or clinic pharmacy Sources commercially outside the hospital Other sources 	<ul style="list-style-type: none"> Stocked by hospital or clinic pharmacy

	Philippine General Hospital (PGH)	Makati Medical Center (MMC)	Lagos University Teaching Hospital (LUTH)	Kamuzu Central Hospital (KCH)	Christian Medical College and Hospital (CMCH)	Government Medical College, Patiala (GMC-P)
Frequency of use of improvised stoma appliance	Sometimes	Rare	Sometimes	Rare	Sometimes	Rare
Types of improvised stoma appliance reported	Plastic cap, garters, plastic icebags	Diaper	Polyethylene bags Urine bags	None reported	Romson kit (ring type) Home made (polythin) Hosepipe Ordinary plastic bags	Polyethylene bag with panty hose

Table 2. Patient and stoma characteristics in Phase 1 cohort study

		Philippines		Nigeria	Malawi	India		Total
		PGH	MMC	LUTH	KCH	CMCH	GMC-P	
	New stoma cases	n = 294	n = 43	n = 25	n = 27	n = 11	n = 46	N = 446
Age (years)	Mean (SD)	49.5 (20.9)	54.9 (22.5)	30.0 (27.1)	41.7 (15)	15.4 (24.1)	40.2 (17.3)	46.7 (22.1)
Age group	≤18 years	31 (10.5%)	4 (9.3%)	10 (40.0%)	1 (3.7%)	7 (63.6%)	4 (8.7%)	57 (12.9%)
	19-60	159 (54.1%)	19 (44.2%)	12 (48.0%)	23 (85.2%)	3 (27.3%)	33 (71.7%)	249 (55.8%)
	61-70	75 (25.5%)	11 (25.6%)	1 (4.0%)	2 (7.4%)	0 (0.0%)	6 (13.0%)	95 (21.3%)
	71-80	21 (7.1%)	7 (16.3%)	1 (4.0%)	1 (3.7%)	1 (9.1%)	3 (6.5%)	34 (7.6%)
	81-90	8 (2.7%)	2 (4.7%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	11 (2.5%)
Sex	Female	119 (40.5)	19 (44.2%)	10 (40%)	1 (3.7%)	5 (45.5%)	12 (26.1%)	166 (37.2%)
	Male	175 (59.5%)	23 (53.5%)	15 (60%)	26 (96.3%)	6 (54.5%)	34 (73.9%)	279 (62.6%)
	Missing data	0 (0.0%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
Urgency	Elective	176 (59.9%)	35 (81.4%)	0 (0.0%)	1 (3.7%)	5 (45.5%)	5 (10.9%)	222 (49.8%)
	Emergency	118 (40.1%)	8 (18.6%)	25 (100%)	26 (96.3%)	6 (54.5%)	41 (89.1%)	224 (50.2%)
Indication	Colorectal cancer	203 (69%)	26 (60.5%)	7 (28.0%)	2 (7.4%)	0 (0.0%)	3 (6.5%)	241 (54.0%)
	Congenital bowel disease	27 (9.2%)	4 (9.3%)	8 (32.0%)	0 (0.0%)	6 (54.5%)	0 (0.0%)	45 (10.1%)
	Benign non-infectious	16 (5.4%)	3 (7.0%)	1 (4.0%)	17 (63.0%)	1 (9.1%)	4 (8.7%)	42 (9.4%)
	Gastrointestinal trauma	4 (1.4%)	0 (0.0%)	2 (8.0%)	2 (7.4%)	2 (18.2%)	0 (0.0%)	10 (2.2%)
	Intraoperative bowel injury	4 (1.4%)	1 (2.3%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (1.3%)
	Infectious bowel disease	8 (2.7%)	6 (14.0%)	2 (8.0%)	4 (14.8%)	1 (9.1%)	40 (87.0%)	61 (13.7%)
	Pelvic malignancy	11 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	11 (2.5%)
	Other intraabdominal malignancy	6 (2.0%)	6 (14.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	13 (2.9%)
	Urological cancer	4 (1.5%)	2 (4.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (1.3%)
	Congenital urological	4 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	5 (1.1%)
	Urological trauma	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.2%)
	Other	12 (4.1%)	0 (0.0%)	3 (12.0%)	2 (7.4%)	0 (0.0%)	2 (4.3%)	19 (4.3%)
Type of surgery	Colonic diversion	97 (33.0%)	17 (39.5%)	17 (68.0%)	5 (18.5%)	4 (36.4%)	8 (17.4%)	148 (33.2%)
	Small bowel diversion	71 (24.1%)	6 (14.0%)	5 (20.0%)	14 (51.9%)	2 (18.2%)	16 (34.8%)	114 (25.6%)
	Bowel repair with protecting diversion	5 (1.7%)	3 (7.0%)	1 (4.0%)	0 (0%)	1 (9.1%)	11 (23.9%)	21 (4.7%)

		Philippines		Nigeria	Malawi	India		Total
		PGH	MMC	LUTH	KCH	CMCH	GMC-P	
Type of stoma	Small bowel resection with stoma formation	5 (1.7%)	0 (0%)	1 (4.0%)	0 (0%)	1 (9.1%)	8 (17.4%)	15 (3.4%)
	Colonic resection with stoma formation	71 (24.1%)	17 (39.5%)	1 (4.0%)	8 (29.6%)	1 (9.1%)	3 (6.5%)	101 (22.6%)
	Colonic resection with protecting diversion	4 (1.4%)	0 (0%)	0 (0%)	0 (0%)	1 (9.1%)	0 (0%)	5 (1.1%)
	Laparoscopic colonic diversion	27 (9.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	27 (6.1%)
	Laparoscopic colonic resection with stoma formation	3 (1.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (0.6%)
	Robotic colonic resection with stoma formation	5 (1.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	5 (1.1%)
	Cutaneous vesicostomy	3 (1.0%)	0 (0%)	0 (0%)	0 (0%)	1 (9.1%)	0 (0%)	4 (0.9%)
	Radical cystectomy with ileal conduit	3 (1.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (0.6%)
	Ascending colostomy	0 (0.0%)	1 (2.3%)	0 (0.0%)	1 (3.7%)	0 (0.0%)	0 (0.0%)	2 (0.5%)
	Descending colostomy	27 (9.2%)	0 (0.0%)	0 (0.0%)	11 (40.7%)	5 (45.5%)	0 (0.0%)	43 (9.7%)
	Transverse colostomy	81 (27.7%)	11 (25.6%)	8 (32.0%)	0 (0.0%)	0 (0.0%)	3 (6.5%)	103 (23.2%)
	Sigmoid colostomy	70 (24.0%)	18 (41.9%)	13 (52.0%)	1 (3.7%)	1 (9.1%)	8 (17.4%)	111 (25.0%)
	Ileostomy	106 (36.3%)	9 (20.9%)	4 (16%)	14 (51.9%)	3 (27.3%)	35 (76.1%)	171 (38.5%)
	Jejunostomy	5 (1.7%)	4 (9.3%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	10 (2.3%)
	Ileal conduit	5 (1.7%)	2 (4.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (1.6%)
	Vesicostomy	3 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	4 (0.9%)
Other / Unknown	1 (0.3%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.5%)	
Stoma configuration**	Loop stoma	136 (46.3%)	24 (55.8%)	7 (28.0%)	11 (40.7%)	6 (54.5%)	35 (76.1%)	219 (49.1%)
	Double barrel stoma	60 (20.4%)	1 (2.3%)	14 (56.0%)	3 (11.0%)	3 (27.3%)	9 (19.6%)	90 (20.2%)
	End stoma	94 (32%)	18 (41.9%)	4 (16.0%)	13 (48.1%)	1 (9.1%)	2 (4.3%)	132 (29.6%)
	Distal mucous fistula	32 (10.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	32 (7.2%)
	Urostomy	7 (2.4%)	2 (4.7%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	10 (2.2%)
Intention to reverse	Permanent	26 (8.8%)	21 (48.8%)	4 (16.0%)	0 (0.0%)	0 (0.0%)	2 (4.3%)	53 (11.9%)
	Temporary	220 (74.8%)	22 (51.2%)	21 (84.0%)	24 (88.9%)	11 (100.0%)	42 (91.3%)	340 (79.2%)
	Unknown / Not reported	48 (16.3%)	0 (0.0%)	0 (0.0%)	3 (11.1%)	0 (0.0%)	2 (4.3%)	53 (11.9%)

PGH – Philippine General Hospital; MMC – Makati Medical Center; LUTH - Lagos University Teaching Hospital; KCH – Kamuzu Central Hospital, CMCH – Christian Medical College and Hospital; GMC-P – Government Medical College – Patiala, SD=Standard deviation.

*Except for Age(years), values are n(%)

**Patients with more than one type of stoma could select more than one stoma configuration type (e.g., end stoma with distal mucous fistula).

Table 3. Stoma care provision and postoperative outcomes of patients included in Phase 1 cohort study

		Philippines		Nigeria	Malawi	India		
		PGH	MMC	LUTH	KCH	CMCH	GMC-P	TOTAL
		N = 294	N = 43	N = 25	N = 27	N = 11	N = 46	N = 446
Stoma information								
Preoperative stoma counselling	Yes	2 (0.7%)	33 (76.6%)	21 (84.0%)	0 (0.0%)	1 (9.1%)	5 (10.9%)	62 (13.9%)
	No	292 (99.3%)	10 (23.3%)	4 (16.0%)	27 (100%)	10 (90.9%)	41 (89.1%)	384 (86.1%)
Postoperative stoma nursing care	Yes	55 (19.7%)	38 (88.4%)	23 (92.0%)	27 (100%)	9 (81.8%)	46 (100%)	198 (44.4%)
	No	239 (81.3%)	5 (11.6%)	2 (8.0%)	0 (0.0%)	2 (18.2%)	0 (0.0%)	248 (55.6%)
In-hospital status								
In-hospital complications	Yes	66 (22.4%)	4 (9.3%)	10 (40%)	8 (29.6%)	4 (36.4%)	13 (28.3%)	105 (23.5%)
	No	228 (77.6%)	39 (90.7%)	15 (60%)	19 (70.4%)	7 (63.6%)	33 (71.7%)	341 (76.5%)
Stoma-related	Stomal retraction	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	1 (1.0%)
	Dermatitis	0 (0.0%)	0 (0.0%)	1 (10%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	2 (1.9%)
	Stenosis	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)
	Necrosis	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Others	3 (4.5%)	0 (0.0%)	2 (20%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (4.8%)
General	Anastomotic leak	5 (1.7%)	0 (0.0%)	0 (0.0%)	2 (7.4%)	0 (0.0%)	0 (0.0%)	7 (1.6%)
	Cardiopulmonary	19 (6.5%)	1 (2.3%)	0 (0.0%)	2 (7.4%)	1 (9.1%)	0 (0.0%)	23 (5.2%)
	SSI	8 (2.7%)	1 (2.3%)	7 (70.0%)	4 (14.8%)	2 (18.2%)	11 (23.9%)	33 (7.4%)
	Haemorrhage	4 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (3.8%)
	Sepsis	9 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (2.0%)
	Others	18 (6.1%)	3 (7.0%)	1 (10.0%)	1 (11.1%)	1 (9.1%)	2 (4.3%)	26 (5.8%)
Length of stay	Mean (SD)	8.61 (8.6)	17.4 (23.3)	14.7 (15.5)	7 (6.4)	7.8 (7.2)	8.7 (8.8)	
Post-discharge status								
Post-discharge complications	Yes	12 (4.1%)	6 (14.0%)	5 (20.0%)	0 (0.0%)	1 (9.1%)	9 (19.6%)	33 (7.4%)
	No	187 (63.8%)	33 (76.7%)	19 (76.0%)	4 (14.8%)	9 (81.9%)	23 (50%)	275 (61.8%)
	Missing	94 (32.1%)	4 (9.3%)	1 (4.0%)	23 (85.2%)	1 (9.1%)	14 (30.4%)	137 (30.8%)
Stoma-related	Parastomal hernia	0 (0.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)
	Bleeding	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	2 (6.1%)

		Philippines	Nigeria	Malawi	India		
General	Anastomotic leak	1 (0.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)
	Intraabdominal infection	2 (0.6%)	1 (2.3%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	4 (12.1%)
	SSI	3 (1.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	6 (18.2%)
	Other infections	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (27.3%)
	Haemorrhage	1 (0.3%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.1%)
	Cardiopulmonary	0 (0.0%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.2%)
	Others	7 (2.3%)	49.3%	2 (8.0%)	0 (0.0%)	0 (0.0%)	13 (39.4%)
Reoperation for stoma complication	Yes	3 (0.9%)	0 (0.0%)	0 (0.0%)	1 (3.7%)	0 (0.0%)	6 (1.3%)
	No	291 (91.9%)	43 (100%)	25 (100%)	26 (96.3%)	11 (100%)	440 (98.7%)
Mortality	Yes	18 (6.1%)	8 (18.6%)	2 (8.0%)	4 (14.8%)	1 (9.1%)	51 (11.4%)
	No	276 (93.9%)	43 (100%)	23 (92.0%)	23 (85.2%)	10 (90.9%)	395 (88.6%)
Cause of death*	Infection	10 (55.6%)	2 (25%)	2 (100%)	1 (25.0%)	1 (100%)	18 (35.3%)
	Cardiopulmonary	6 (33.3%)	8 (100%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	26 (51.0%)
	End of life cancer	1 (5.6%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.9%)
	Others	1 (5.6%)	0 (0.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	12 (23.5%)
	Unknown	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	1 (2.0%)

SSI=Surgical site infection. SD=Standard deviation. *More than one cause of death could be selected per patient where appropriate.

*Except for Length of Stay (mean), values are n (%)

tis. Most reported that they had learned most of what they were currently doing by trial and error.

Whilst the rate of early stoma-related complications seen in Phase 1 was reasonably low, these can have significant impact on long-term quality of life and survival for these patients, a factor that was highlighted as a key area for improvement. Care providers were worried about poor patient and carer knowledge about signs, symptoms and early management of emerging complications such as stoma prolapse and peristomal dermatitis, and when to seek help:

“We often send patients home failing to explain to them the signs and symptoms of stoma complications that should prompt them to seek early consultation”, urologist, 40/F

UNDERSTANDING THE PSYCHOSOCIAL IMPACT OF A STOMA

Having a stoma should not leave a patient debilitated or prevent them from going back to work or school or doing their usual activities, but can impact lives significantly. Patients reported reduced quality of life, low self-esteem and other psychosocial problems. Although surgeons reported that many patients, especially those with cancer, worry more about their underlying condition and prognosis than about having a stoma, they also described patients reporting discrimination against them, unwillingness or unavailability of someone to help them care for their stoma, and problems returning to work. Surgeons may try to provide counselling and emotional support, but do not feel trained to do so:

“Some patients get depressed and develop psychological problems and I feel helpless. I do not think I have the proper training and knowledge to properly counsel them. I am a surgeon and not a psychologist.” Colorectal surgeon, 37/M

A stoma care nurse highlighted how emotional responses to a newly placed stoma can even inhibit patients' and carers' ability to learn about stoma care in the early stages, especially those who were not properly counselled preoperatively:

“Sometimes it is not about having difficulty in understanding but more of refusing to listen and refusing to understand. Because they have not yet accepted having a stoma and are scared of having one, so much that they do not even want to look at it or touch even the bag.” Stoma care nurse, 62/F

The important role of patient support groups in providing social, educational and emotional support for ostomates was acknowledged, and it was suggested that these could be supported by both the government and manufacturers and suppliers.

AFFORDABILITY, AVAILABILITY AND ACCESSIBILITY OF STOMA APPLIANCES

Phase 1 revealed variability of availability, accessibility and affordability of stoma appliances and accessories. While some products were generally available in pharmacies and hospitals, these were basic products with little choice or variety in brands or types. Patients complained about not being able to get the correct size or type of product, especially in rural areas, although online stores with home delivery were improving this. Some patients reported obtaining products from relatives abroad or sourcing donated products from hospitals, doctors or patient support groups.

Poor availability and affordability often lead to changing stoma appliances less frequently than recommended. To contain cost, some would assess how well the appliance was still functioning and delaying changing until signs of malfunction, a practice that could predispose patients to complications, particularly peristomal dermatitis.

Most respondents reported adaptations of stoma devices in the face of poor product affordability and availability, a phenomenon also reported in Phase 1. Some reported using adhesive tape or a garter belt to prevent a commercial wafer from coming off, washing and re-using products intended for single use, particularly bags, and using baby diapers temporarily when supplies ran out. Some used entirely improvised appliances made from bottle caps, plastic bags and elastic garter.

SOURCES OF STOMA CARE KNOWLEDGE

The majority of the surgeons said that they were the principal provider of knowledge for their stoma patients. Some expressed regret that they do not have on hand patient educational materials on stoma care and stoma appliances. When available, stoma care nurses can become the main source of information in an institution:

“The residents are always busy and rely on me to teach their patients about stoma care.” Stoma care nurse, 62/F

The majority of the patients and carers reported that their principal source of knowledge and help relating to stoma care were their own doctors and nurses. Other potential sources of knowledge include the internet, other patients, local or online patient/carer support groups and representatives of stoma appliance companies.

PHASE 3. STOMA PATIENT “ASSISTED COMMUNICATION” TOOL DEVELOPMENT

Based on the information and insights gained in Phases 1 and 2, a questionnaire was developed that aimed to gauge the knowledge and understanding of patients and carers about stoma care and stoma appliances, and to support effective communication with care providers.

A longlist of 45 candidate items was created by the investigators. The questions covered key knowledge areas including the nature of the stoma, stoma care, sourcing of supplies and expenses, problems and complications, and support and resources. Examples are “Do you know why you

Table 4. Characteristics of patients and carers interviewed in Phase 2 (N=18)

Parameter	Characteristic	Number (%) N= 18 patients
Type of interview	Face to face	10 (55.6%)
	Phone	8 (44.4%)
Type of respondent *	Patient	12 (63.2%) *
	Carer	7 (36.8%) *
Relationship of carer to patient	Mother	5 (71.4%)
	Wife	2 (29.6%)
Educational attainment of respondent	Postgraduate	1 (5.6%)
	College level	8 (44.4%)
	High school / Secondary level	7 (38.9%)
	Grade school / primary level	1 (5.6%)
	None	1 (5.6%)
Age of patient at time of interview	<18 years	5 (27.8%)
	19-39	1 (5.6%)
	40-60	7 (38.9%)
	61-75	5 (27.8%)
Age of patient at time of stoma creation	< 18 years	5 (27.8%)
	19-39	2 (35.7%)
	40-60	9 (50.0%)
	61-75	2 (11.1%)
Sex of patient	Male	12 (67.8%)
	Female	6 (33.3%)
Diagnosis	Bladder cancer	6 (33.3%)
	Colorectal cancer	5 (27.8%)
	Congenital anorectal disease	5 (27.8%)
	Benign colorectal disease	2 (11.1%)
Stoma type	Urostomy	6 (33.3%)
	Enterostomy/Colostomy	12 (67.8%)
Civil status	Single	5 (27.8%)
	Married	12 (66.7%)
	Widowed	1 (5.6%)
Family size	2	3 (16.7%)
	3-4	8 (44.4%)
	5-6	6 (33.3%)
	>6	1 (5.6%)
Residence	National Capital Region	12 (67.8%)
	Outside NCR	6 (33.3%)
Type of residence	House	15 (83.3%)
	Apartment	1 (5.6%)
	Room	2 (11.1%)
No of residents in home	Lives alone	1 (5.6%)
	2-4	5 (27.8%)
	5-10	9 (50.0%)
	> 10	3 (16.8%)
Wage earners in the household	0	3 (16.8%)

Parameter	Characteristic	Number (%) N= 18 patients
	1	5 (27.8%)
	2	7 (38.9%)
	3	3 (16.8%)
Health financing	Philhealth	18 (100%)
	HMO	4 (22.2%)

* both the carer and the patient were interviewed at the same time in one instance

Table 5. Characteristics of stoma care providers interviewed in Phase 2 (N=31)

Parameter	Types	N (%)
Participant type	General surgeon	2 (6.5%)
	Colorectal surgeon	19 (61.3%)
	Paediatric surgeon	3 (9.7%)
	Urological surgeon	6 (19.4%)
	Enterostomy nurse	1 (3.2%)
Years in practice	Mean (range)	8.1 (1 - 36)
	1-2 years	9 (29.0%)
	3-5 years	10 (32.3%)
	6-10	4 (12.9%)
	>10	7 (22.6%)
	Missing	1 (3.2%)
Hospital location	Urban	12 (38.7%)
	Rural	4 (12.9%)
	Mixed	4 (12.9%)
	Missing	11 (35.5%)
Hospital funding	Private	3 (9.7%)
	Government	3 (9.7%)
	Both	16 (51.6%)
Hospital type	Teaching/training Hospital	7 (22.6%)
	Non-teaching hospital	2 (6.5%)
	Both	12 (38.7%)
	Missing	10 (32.3%)
Average number of new stomas patients per month	1 to 3	19 (61.3%)
	4 to 5	5 (16.1%)
	6-10	3 (9.7%)
	>10	3 (9.7%)
Average number of ostomates followed-up per month	1 to 3	10 (32.3%)
	4 to 5	4 (12.9%)
	6-10	8 (26.7%)
	>10	8 (25.8%)
	Missing	1 (3.2%)

*Except for Years in practice (mean), values are n(%)

have a stoma?”, “Do you know how to empty the stoma bag?”. The questions may be answered by “yes”, “no”, or “not sure”. An additional 13 questions on potential areas of concern for patients were also included. These questions

are framed as “Are these areas of concern or anxiety to you?”, to which the respondent can answer “yes”, “a little” or “no”. The list was reviewed by two colorectal surgeons and one stoma care nurse for content and language. After

Table 6. StomaSurg communication assistance tool (STARFISH Questionnaire): topic domains and elements

Domain	Knowledge elements assessed
Nature of stoma	Reason for stoma Nature of stoma output Whether stoma is permanent or temporary Expected reversal date if temporary
Stoma care	How to clean a stoma How to empty a stoma bag How to change a stoma appliance When to change an appliance How to cut a wafer to the correct size How a stoma should fit in a wafer (with illustrations) What supplies to have on hand when changing a stoma appliance
Obtaining stoma appliances	What type or size of appliance to buy Where to buy appliance and other stoma care supplies How many wafers and bags will be needed each month Estimated monthly cost of stoma care supplies
Stoma-related complications and support	Awareness of possible problems that should be reported to a doctor/nurse Awareness of sources of support other than doctors/nurses Areas in which more information is needed Perceived ability to advise other ostomates or carers
Persisting areas of concern relating to having a stoma	Its appearance Visibility of a bag under clothes Smell / odor Leakage of bag contents Accidental detachment of an appliance Bag bursting, tearing or leaking Returning to work or school with a stoma Normal daily activities Social activities / activities in public Sexual relations Changes in sleeping habits Ability to take care of the stoma Financial burden

two revisions, a first draft questionnaire of 56 items was developed (see **Online Supplementary Document Appendix 4**).

The first draft was pilot-tested on four patients, two of whom were assisted by their carers in their responses, and on one mother of a pediatric ostomate. Taking into consideration the comments and suggestions on the phrasing of some of the questions and to ensure that the time to complete the questionnaire should not exceed 15 minutes, the questionnaire was trimmed down to 20 knowledge items and 13 potential problem areas. Testing of the revised tool was performed on another three patients and two carers, with no further recommendations for improvement. The tool was considered easily understood, straightforward and easily completed. The tool's main topic domains and elements are presented in **Table 6**. The full version of the final tool, the StomaSurg Communication Tool is available in <http://tinyurl.com/StarfishStudyTool>.

DISCUSSION

Over the three phases of the study, within- and between-country variations in the case mix of stoma patients and in the delivery of stoma care were observed, challenges unique to stoma care in LMICs highlighted, poor levels of counselling and knowledge transfer relating to stoma

care and subsequent low levels of understanding and skills amongst patients and carers explored. A tool for use in clinical settings to assess patients' and carers' knowledge and to facilitate effective communication with care providers was developed.

There was wide variation between the six centers in four countries in the nature and number of stoma cases, treatment funding models (from entirely state-funded to wholly out-of-pocket), the provision of pre- or post-surgical counselling, the availability of specialized nursing care and the availability of stoma care supplies.

Stomas in the LMIC centers involved often resulted from indications and reasons for surgery that may not result in a stoma in a high income setting (HIC) setting, likely because of differences in patient population, resources, training and availability of surgical equipment and techniques. In addition, a significant proportion of surgeries resulting in a stoma were performed on an emergency basis. These may not be reversed when they could be, if at all, given challenges in funding, access, resources and staffing for elective surgical care, and even poor communication about when or if closure may be possible. Subsequently, the burden of ongoing stoma care is potentially higher in LMICs.

When stomas are formed in emergency circumstances, preoperative counselling about stoma care is not possible. However, in some of the hospitals, provision of stoma care

education was inconsistent even with elective cases, and in the postoperative period. This is a worrying finding, particularly in the light of the importance placed on sufficient knowledge about stoma care by healthcare workers, patients and carers, and given that better outcomes have been observed where patients have access to regular expert support postoperatively.^{4,5,27} Patients and carers reported insufficient knowledge about all aspects of stoma care, especially in the early days after discharge. Communication was poor around practical considerations: choosing and using appropriate products; the importance of hygiene; signs, symptoms and early management of emerging complications. The observation that shock, revulsion and denial affect some patients' ability to engage in effective communication perioperatively emphasizes the importance of the availability of ongoing postoperative expert support.

The audit and interview phases of the study highlighted effective and timely communication as a feasible and potentially impactful area for care improvement. In these LMIC settings, the surgeon is currently regarded as the main source of knowledge about stoma and stoma care by the surgeons themselves as well as by the rest of the healthcare staff and the patients and carers. Hence, surgeons should be prepared to acquire and share appropriate and sufficient information and materials on stoma care, despite undoubted time limitations and perceived lack of training and expertise in psychosocial factors. This role needs to be emphasized to surgical trainees who may need to exert extra effort during their training to gain the levels of knowledge and understanding of stoma care required to effectively serve their patients. Indeed, stoma care counselling should be part of the curriculum of surgical training programs.

The questionnaire-based communication assistance tool developed in this study is intended to be a starting point for effective communication and patient and carer education. It is hoped that its routine administration to patients and carers prior to hospital discharge and analysis of its results by surgeons and other care providers can highlight strengths and weaknesses in knowledge and understanding, and facilitate the efficient and timely provision of focused education and support. Hospitals should provide the requisite training, personnel and resources to allow counselling on stoma formation and training on stoma care prior to surgery when possible, and mandate this prior to a patient's discharge.

Governments and health systems can improve the provision of initial and ongoing stoma-related education and support by mandating stoma clinics in all public hospitals and community health care facilities. The patients in hospitals in Malawi and Nigeria in this study would be well served by such a policy and lessen the burden of the colorectal surgeons.

Higher educational institutions must be encouraged to create more training opportunities and promote the elevation of stoma care provision as a distinct profession in the field of healthcare. This lack of trained stoma care providers in the Philippines and India may have contributed to the inconsistent provision of stoma care counselling among their

patients despite the declared availability of stoma care services in the participating hospitals.

The stoma industry should be required to provide education and information materials appropriate for patients and carers in the countries where their products are marketed. It should also be encouraged to support professional training through educational grants.

Accessibility and affordability of appliances is a major issue in LMICs. Patients and carers reported extending the time between changing appliances to contain cost and reusing products intended for single use, and the adaptation or improvisation of stoma devices by patients were commonplace, all practices that may lead to poor appliance performance and increased risk of stoma-related complications. Governments can play a role in ensuring the availability, accessibility and affordability of stoma supplies. Ostomates and their carers may be supported by removal of taxes from appliances, provision of subsidies for people with ongoing stoma-related expenses, and ensuring inclusion of stoma care in national health insurance programs. For example, in El Salvador the issue of access was addressed by the implementation of a law ensuring ostomates receive monthly supplies.²⁸ Incentives and support for local manufacturing of stoma appliances could reduce their cost and improve availability and access. Marketing licensing for new stoma products must include assurance of sufficient quantity, variety and wide distribution by the suppliers.

The study has several limitations. The study involved only tertiary hospitals in urban settings, and findings may not reflect rural hospital experience and the levels of care available among more marginalized communities. Levels of missing audit data were uncertain for some elements. These may provide inaccurate estimates of the stoma formation and the challenges of stoma care provision. The COVID pandemic necessitated restrictions in some qualitative elements, although enhanced in-hospital infectious disease prevention measures and modern communication platforms and technologies allowed many of the activities to proceed as planned. Patient and provider perspectives from only one country guided the development of the communication assistance tool, but it may be considered sufficiently representative of the LMIC context based on shared problems and priorities seen in Phase 1. However, beliefs, attitudes, values and preferences and challenges relating to stoma care may vary between countries so that the content of the tool may need to be adjusted to optimise its effectiveness in other settings. The study did not implement best practice guidelines for questionnaire development. However, the tool is not intended to be a research instrument, but rather a quality improvement resource. The effectiveness of the communication tool in improving efficient knowledge transfer has yet to be tested in practice. Testing and validation in different LMICs and care settings, with future development for cross-cultural and cross-language equivalence work, should be performed to ensure its utility and effectiveness.

Other avenues for future research on stoma care include: (1) describing the characteristics, outcomes and needs of

patients who receive a stoma due to conditions not commonly seen in HICs such as infectious bowel disease or congenital anomalies, (2) identifying stoma care requirements in LMICs and searching for affordable, effective interventions and programs to address these requirements, (3) developing and testing locally-adapted patient educational and training materials and strategies, and (4) evaluating the short- and long-term impact of different educational, quality improvement programs and policy interventions on stoma care on patient outcomes and quality of life in LMICs.

CONCLUSIONS

This study done in six hospitals in LMIC highlighted the diversity in the types of cases resulting in stoma creation, stoma outcomes, and the variability in stoma care delivery. Patients, carers, and healthcare providers raised concerns regarding stoma care delivery including the lack of knowledge regarding stoma and stoma care pre and post stoma creation, and poor access to affordable stoma care products. Since this study involved only tertiary hospitals in urban settings, the findings may not reflect the experience in the rural setting in LMIC.

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DISCLAIMER

The views expressed in this paper are the authors' own and not the official position of their respective institutions or the funder.

ETHICS STATEMENT

Written informed consent to participate in interviews was obtained from all patients, carers and healthcare practitioners. The study protocol was reviewed and approved by the University of the Philippines Manila – Research Ethics Board (UPM-REB 2019-316-01)

DATA AVAILABILITY

The anonymised dataset and the StomaSurg communication tool are available upon request to corresponding author at <http://tinyurl.com/StarfishStudyTool>

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AUTHORSHIP CONTRIBUTIONS

State the individual contributions of all named authors, using the [ICMJE authorship criteria](#).

DISCLOSURE OF INTEREST

None of the authors have any conflict of interest to disclose.

ADDITIONAL MATERIAL

Available as **ONLINE SUPPLEMENTARY DOCUMENT**

CORRESPONDENCE TO:

Marie Carmela M. Lapitan
Department of Surgery, Philippine General Hospital
Taft Ave, Manila 1000
Philippines
mmlapitan@up.edu.ph

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SUPPLEMENTARY MATERIALS

Online Supplementary Document

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