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Evaluating the Effectiveness of the SPIKES Model to Break Bad News – A Systematic Review

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Abstract

Introduction: Breaking bad news to patients and families can be challenging for healthcare providers. The present study conducted a systematic review of the literature to determine if formal communication training using the SPIKES protocol improves learner satisfaction, knowledge, performance, or system outcomes. **Method**: MEDLINE, Embase, CINAHL Plus (Nursing & Allied Health Sciences), and PsycINFO Databases were searched with keywords BAD NEWS and SPIKES. Studies were required to have an intervention using the SPIKES model and an outcome that addressed at least one of the four domains of the Kirkpatrick model for evaluating training effectiveness. The Cochrane Risk of Bias Tool was used to conduct a risk of bias assessment. Due to heterogeneity in the interventions and outcomes, meta-analysis was not undertaken and instead, a narrative synthesis was used with the information provided in the tables to summarise the main findings of the included studies. **Results**: Of 622 studies screened, 37 publications met the inclusion criteria. Interventions ranged from the use of didactic lecture, role play with standardised patients (SPs), video use, debriefing sessions, and computer simulations. Evaluation tools ranged from pre and post intervention questionnaires, OSCE performance with rating by independent raters and SPs, and reflective essay writing. **Conclusions**: Our systematic review demonstrated that the SPIKES protocol is associated with improved learner satisfaction, knowledge and performance. None of the studies in our review examined system outcomes. As such, further educational development and research is needed to evaluate the impact of patient outcomes, including the optimal components and length of intervention.

Keywords

breaking bad news, communication skills, SPIKES protocol, systematic review, learner satisfaction, learner knowledge, learner performance, system outcome

Background and Objective

Breaking bad news to patients and families can often be a challenging communication endeavour for healthcare providers. Bad news can be defined as any information that negatively changes expectations about the future[1,2] and healthcare providers may have to communicate bad news more than once throughout the trajectory of a patient's illness. As such, the skill of communicating bad news is essential to providing high quality patient-centred care.

How healthcare providers communicate bad news impacts the patient's life including their illness understanding, satisfaction with care, level of hope, and psychological adaptation.[3-5] Breaking bad news also impacts the healthcare provider who is delivering it. Stress, anxiety, burnout, and alienation from the clinical situation have all been cited as outcomes of communicating bad news.[1,5-10] When apprehension arises in breaking bad news, important conversations can be delayed until a possible crisis situation.[11-15] From the perspective of the healthcare provider, barriers to delaying or inappropriately delivering bad news range and include a healthcare provider's difficulty in dealing with patients'

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emotions, a fear of taking away hope and their own feelings of helplessness.[1,3-5,16]

A lack of skills training in communicating bad news has been met with increasing urgency to develop and implement tools and formal training for healthcare providers.[1,3,4,16-18] Certainly, the COVID-19 pandemic has compounded this urgency with the need to also adapt communication skills and tools to communicate bad news in circumstances where social distancing and isolation are required.[19] The SPIKES Protocol[1,6,7] developed by Baile et al in 2000, is a common communication tool designed and used to help healthcare providers approach breaking bad news in a systematic way. Although initially developed by oncologists to break bad news to patients with cancer,[20] the SPIKES protocol is widely used in various health care specialities.[21,22] The acronym SPIKES, stands for Setting up, Perception, Invitation, Knowledge, Emotions with Empathy, and Strategy or Summary and is intended to be used in a stepwise manner to support information flow and address patient distress. Use of the SPIKES protocol for complex communication tasks, such as delivering poor prognosis, has been shown to improve clinician confidence and capacity, reduce anxiety, avoid miscommunications, and increase the patient's decision-making engagement.[2,9,23-25]

Given the widespread awareness of the SPIKES protocol, the objective of this systematic review was to determine if formal communication training using the SPIKES protocol improves learner satisfaction, knowledge, performance, or system outcomes. These outcome measures are according to the Kirkpatrick Model,[26] which is a standard model used to evaluate the effectiveness of any form of training. The model consists of four levels to evaluate the effectiveness of training and education programs and has been widely used. These four levels include learner satisfaction towards the training, learner knowledge acquired after the training, learner performance in the workplace as a result of the training, and targeted systems outcomes as a result of the training acquired.[26]

Methods

Search Strategy

Four electronic databases were searched from January 1, 2000, to September 30, 2022: MEDLINE; Embase; CINAHL Plus (Nursing & Allied Health Sciences); PsycINFO Databases. The keywords BAD NEWS and SPIKES were used for the search, combined with the Boolean operator AND. The reference lists of the included studies were scanned to identify additional relevant articles.

Inclusion and Exclusion Criteria

To be included in the review, studies needed to meet the following criteria: they must be published in the English language; they must be published after the inception of the SPIKES model (since 2000); the target population must be a healthcare provider; there must be an intervention using the SPIKES model; and the outcome must address one of the four domains of the Kirkpatrick model for evaluating training effectiveness. The four domains are learner satisfaction, knowledge, performance, and system outcomes. There was no exclusion based on the age of the participants. The inclusion criteria are shown in Table 1. Commentaries, conference abstracts, letters to the editor, correspondence, commentaries, literature reviews and unpublished studies were excluded. Duplicated studies were not included.

Study Selection

The systematic review of mixed method studies was conducted and reported following Preferred Reporting Items for Systematic Reviews and Meta-Analyses protocols (PRISMA-P)[27] as shown below (Figure 1). The literature review was carried out by two independent reviewers (MM and GP). Any disagreements were discussed to arrive at a consensus between the reviewers. No inter-rater reliability was reported. The initial search identified 760 articles. After removing duplicate citations, there were 622 non-duplicate citations. The titles and abstracts of the 622 articles were reviewed for relevance, and 52 articles were retrieved after applying the inclusion and exclusion criteria. After reviewing the full text of the 52 articles, 16 were then excluded. From the remaining 36 articles, the references and citations were manually searched, and 1 additional article was identified, thus providing 37 articles in this review (RCT n = 9, Case Report n = 1, Prospective Cohort Studies = 26, Cross-Sectional Studies n = 1). The 16 articles excluded after full text review were either due to a lack of a formal training intervention or a lack of evaluating the SPIKES intervention.

Data Extraction

The following data were extracted for each included study using Excel: (1) study & country of origin, (2) setting, (3) study

Table 1. Inclusion Criteria.

Population – Any health care provider
Setting – Any health care setting
Intervention – SPIKES training
Outcomes (Kirkpatrick Model)
1. Learner satisfaction
2. Change in learners' knowledge or attitudes
3. Change in learners' performance or behaviour
4. Change in systems outcomes
Language – English
Time – January 1, 2000 to September 31, 2022

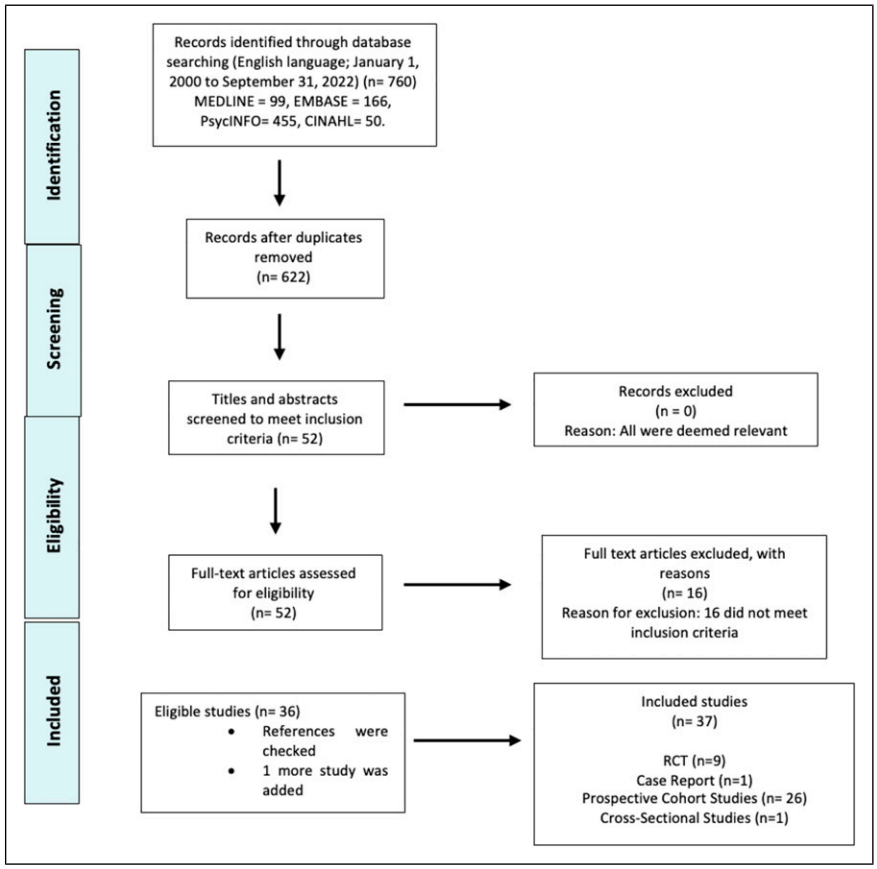

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow chart for study selection.

design, (4) participants, (5) intervention (SPIKES), (6) evaluation tools, (7) outcomes (learner satisfaction, knowledge, performance, and system outcomes), and (8) quality (strong, moderate, weak). M.M. and G.P. independently extracted data on outcomes. Discrepancies were resolved by discussion and consensus between the two. An academic clinician acted as a referee in case of any disagreement between the findings of the two initial reviewers.

Data Synthesis, Analysis and Quality Appraisal

Due to heterogeneity in interventions and outcomes, data were not pooled in a meta-analysis. Instead, the outcomes of the interventions were presented separately in a table with an indication of whether the effects of the intervention were statistically significant. The available data did not allow us to calculate effect sizes. Hence, we presented data in the way it was reported in the study (eg, *P* values). A narrative synthesis was used with the information provided in the Table 2 to summarise the main findings of the included studies. With respect to quality appraisal of the data, the Cochrane Risk of Bias Tool was applied to assess the risk of bias in RCTs (Table 3) and non-randomized studies (Table 4).[28,29]

Ethical Issues

This is secondary research, which means there are no participants involved and it was not subject to an ethical approval process.

Results

The present review found 37 studies from the literature that examined the impact of interventions utilising the SPIKES framework in communication skills training among health care professionals. Of the 37 studies examined, 9 were randomised control trials with control groups, 22 were experimental studies with control groups, 1 was a cross-sectional study and 1 was a case study with no control groups (Table 2). Interventions ranged from the use of didactic lecture, role play with standardised patients (SPs), video use, debriefing sessions, and computer simulations. The majority of the studies took place in the United States (n = 18). These studies were conducted with medical students (n = 13), interns/fellows (n = 10), nursing students (n = 4), midwife students (n = 1), physicians (n = 4), pharmacists (n = 1), and nurses (n = 3). Most studies included used a convenience sampling method, with the main eligibility criteria being a trainee in a specific setting. The settings where the included studies took place also

Table 2. Description of Included Studies.

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Bowyer et al, (2010, United States)[7]	3rd year Introduction to Surgery Clerkship Curriculum; Formative Clinical Skills Laboratory.	Experimental Study- RCT.	553 third-year medical students.	Video training on SPIKES protocol (15 min) OR Didactic lecture plus demonstration (45 min) OR both.	Pre/Post intervention questionnaire, simulated patient evaluation.	All groups rated the experience as helpful (4.□ on Likert Scale).	All four groups had highly significant improvement (*P* value range <1.3 ×10-15 to 2.4 × 10041) over baseline on self-assessment of ability to break bad news.	Simulated patient rated students in groups that received training as superior to the group who had no training on the encounter on the following four checklist items: the student appeared to have a plan for the encounter; assessed how much I knew; was aware of my ability to discuss the news; and prepared me for receiving the bad news.	N/A
Wolfe et al, (2014, United States)[8]	American Family Children's Hospital in Madison, Wisconsin (61-bed free standing children's hospital).	Prospective Cohort Study.	159 multidisciplinary paediatric team members (physician, resident, RN, SW, PT/OT).	1 hr training module with a didactic session introducing guidelines, group critique of video role-play scenarios demonstrating SLAI encounters, and videotaped parent recollections. To note, the SPIKES framework was central to the development of the SLAI (sharing life-altering information) guidelines.	Pre/post intervention questionnaire.	N/A	All respondents in aggregate demonstrated statistically significant increases ($P < .001$) in the mean item responses for the four training objectives; Medical Trainees in particular demonstrated the largest difference in all objectives.	N/A	N/A
Setubal et al, (2018, Brazil)[10]	Obstetrics & Paediatrics Programs at a Medical School in Sao Paulo, Brazil.	RCT.	61 obstetrics and paediatrics residents.	1-2.5 hr training session with reflection, didactic teaching around SPIKES model and video review of the residents' first simulated encounter.	Post-intervention questionnaire with Likert Scale for evaluating SPIKES model and 1 open-ended question reserved for comments.	94.6% rated it as helpful, 100% believed it was valuable training.	>80% reported perceived improvement in knowledge/ability/understanding of BBN.	N/A.	N/A.
Pereira et al, (2017, Brazil)[11]	Research Center.	Prospective Cohort Study.	100 physicians and 100 nurses.	Didactic lecture followed by role-play. Instrument used was based on a model adapted from the SPIKES protocol.	Post-Intervention Questionnaire.	97% of participants consider the protocol appropriate and useful in BBN.	N/A.	N/A.	N/A.

(continued)

Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Haubner et al, (2010, United States)[12]	Tampa General Hospital-Emergency Department, Grand Rounds/ Conference Time Frame.	Prospective Cohort Study.	14 emergency medicine residents.	5 hr grand rounds with didactic lectures, video, role-play, and simulation based on SPIKES protocol.	Post-intervention questionnaire.	Overall usefulness rated as 4.73/5, educational quality rated as 4.86/5.	Ability to improve patient care after intervention was rated as 4.79/5.	N/A.	N/A.
Bonnaud-Antig et al (2010, France)[14]	University of Nantes Medical School.	Prospective Cohort Study.	108 fifth year medical students in Clerkship Rotation Medical Oncology.	Session 1: Didactic lecture with introduction of SPIKES protocol (mandatory). Session 2 took place 1-8 weeks later and involved video-taped simulation with assessment by psychologist. (voluntary). Session 3 was individual feedback of simulation from Session 2 with senior physician and took place 1-2 weeks later. (voluntary).	Pre/post intervention questionnaire, expert assessment using SPIKES protocol & formal examination by psychologist + senior physician.	N/A.	Self-assessed improvement in communication techniques in 77% of participants, 100% in those who completed all three sessions.	Less than half recalled the "PI" part of SPIKES in formal testing, only a few students were able to complete the IE portion of SPIKES according to the psychologist assessment. More than 30% of students experienced difficulty in adjusting to patients' reactions.	N/A.
Baghdari et al, (2017, Iran)[15]	Mashad University of Medical Sciences.	Double-Blind RCT.	90 midwifery students.	Multimedia (45 minute PowerPoint on SPIKES, 15 minute video) **OR** Role-play (45 minute didactic lecture with 30 minute simulation/feedback).	Expert evaluation using OSCE.	N/A.	N/A.	Statistically significant difference in mean skill score of role play and multimedia groups pre/post intervention compared to control group.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Szmulewicz (2021, France)	Bicetre Hospital, France- Simulation Center	Prospective Cohort Study	80 Obstetrics & Anaesthesia Residents.	Video Demonstration with Pre-Test Knowledge Questionnaire and Simulation/Role Play Scenario that was video-recorded followed by debriefing session.	Self Evaluation Questionnaire, External Evaluation by Trainers, Self-Assessment Questionnaire 3-6 months after intervention.	Satisfaction regarding the simulation training was high (9.1/10 [8.9-9.3]). Overall satisfaction, perception that the simulation session was useful and that it will help them change their practice were highly scored (respectively 9.1/10 [8.9-9.3], 9.3/10 [9.1-9.5], and 8.5 [8.2-8.8]).	Residents believed that the session was useful to improve their skills.	Most steps were poorly performed & scored. Among the parts, which were easiest to perform, describing the patient's condition and providing medical information were well done as well as providing this information with empathic behaviour. The fields "setting up the interview" and "closing the encounter" were the most difficult steps to apply and had the lowest scoring values. Residents had indeed difficulties to close the interview in 20 scenarios (45%). Assessing the patient's perception and getting the patient's invitation were not spontaneously performed in most cases. Finally, psychosocial support was rarely offered.	N/A.

(continued)

Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
De Moura Villela et al (2020, Brazil).	Mid-Western Brazilian Public Medical School.	Experimental Study using Qualitative Approach. Prospective Cohort Study.	30 third-year medical students undergoing a formative clinical skills training.	6-month elective course: Participated in activities 4h/week involving didactic lecture involving reflection on SPIKES protocol, role-playing/ simulation strategies and debriefing.	Two focus groups were conducted before the training on BBN and 2 focus groups were conducted after intervention was completed with 15 medical students each. Questionnaires administered to assess the importance of training about BBN and their favourite strategy after intervention.	Fifty percent (n = 15) reported they face a real-life situation during their integrative practices with real patients in the same semester, in which they could use what they had learned in the BBN training and that it made a difference. The videotaping analysis of their own performance during class-based role playing reportedly helped 76% (n = 23) of the students to realize they need improvement such as body posture, gestures and verbal and nonverbal language.	The results of the post intervention focus group indicated that 90% of student participants (27/30) recognized the relevance of BBN and reported they were able to apply the protocols in their clinical training situations.	N/A.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Sekar et al (2021, United States).	Large urban academic institution (IM Residency Program at the University of Texas Southwestern Medical Center).	Prospective Cohort Study.	163 Internal Medicine postgraduate year 1-2-and-2 residents.	Weekly half-day didactic sessions during a course of 5 weeks 2.5-hour curriculum with two major components: interactive discussion lecture and faculty-guided small-group-case based discussions on communication skill frameworks including SPIKES. To standardize the learner experience, we developed a resident worksheet and faculty facilitator guide surrounding the three cases used for small group-discussion. Also conducted a one-time 1-hour faculty development session before implementing curriculum and spent 15 minutes debriefing with the facilitators after each of the 5 resident training sessions.	Immediate and anonymous pre-and post intervention surveys.	N/A.	Total of 109 (response rate of 67%) residents reported improvement in overall confidence in goals of care discussion skills (3.6+/−.9 vs 4.1+/− .6, P < .001) responding to emotions (3.5+/− .9 vs 3.9 +/− .6, P = .004), making care recommendations (3.5+/−1.0 vs 3.9 +/− .7, P < .001) and quickly conducting a code status discussion (3.6+/−1.0 vs 4.0+/− .7, P < .001).	N/A.	N/A.
Coutinho & Ramessur (2016, Portugal).	Faculty of Health Sciences of University of Beira Interior in Covilha (Portugal).	Cross-Sectional Study.	Participating students were in the last 2 years of their Master Degree of Medicine (5th and 6th grade). 260 students total, 120 related to 5th year and 140 linked to 6th year were invited to participate in online questionnaire if they attended lecture. However, only 54 students attended and completed the online survey, representing 21% of the total number of students.	45 minute lecture "Breaking Bad News" using SPIKES protocol training was given.	Online questionnaire consisting of Likert-type questions and few open questions provided after lecture/ intervention.	83% of students admitted that delivering bad news performs an essential role in daily medical practice. 83% of students were pleased to have the presentation in a main auditorium and 20 students of them have expressed themselves very satisfied with respect to the schedule time to the presentation. One of the main results was that most of the students were convinced that solely a lecture may not be an effective teaching method for communication of bad news.	N/A.	N/A.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Ellis et al (2021, United States).	State university classroom for the educational modules and role-play activities.	Prospective Cohort Study.	44 Family Nurse Practitioner Students.	Classroom, lecture style education followed by 1 hour role play of case study for all students in the Advanced Assessment course. Role play with timeframe for each case of 10-15 minutes + debriefing discussion with time for reflections. Classroom communication training using evidence-based end-of-life nursing education consortium materials & role-play opportunities. One month later, simulation experience in a high-fidelity simulated medical office environment with SP. Debriefing session thereafter with feedback. Cameras captured audio/video feed.	4 weeks after: National League for Nursing Student Satisfaction and SElf-Confidence in Learning measurement tool. (13-item questionnaire self-reported on a Likert type scale from 1-5) + Knowledge pretest and posttest.	The NLN SSCS scale Cronbach for the satisfaction section was .928. Satisfaction was reported as a mean of 18.14 (SD, 2.11) (95% confidence interval, 17.50-18.78; median 19; with range between 13 and 20).	Knowledge test results were significantly greater after the education intervention (median, 21) than before (median, 20) ($z = 4.165$) ($P = .000$) with a medium size effect ($r = .444$).	Standardized patients rated student communication skills during simulation overall as excellent, 54.7%; good, 37.7% and fair, 7.5%. Communication regarding withholding/ withdrawing life support was rated as excellent, 41.5%; good, 45.3% and fair, 13.2%.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Rivet et al (2021, United States).	Tertiary Care Center in Central Virginia.	Single arm, unblinded, feasibility study. Prospective Cohort Study.	Surgical interns (categorical and preliminary), surgical residents, and surgical faculty from General, Neuro, Pediatric, Plastics, Oncology, Urology and Vascular surgical specialties; 33 surgical learners participating in the training and 28 completing evaluation surveys.	Didactic Lecture with video prior to simulation with SP + 10 minute video mediated communication encounter +5 minutes of feedback and reflection. This training program was based on SPIKES and aimed to teach surgical residents and faculty how to disclose difficult news via video-mediated communication.	Electronic Survey post workshop assessing demographics, reactions to the workshops, usability of VMC platform.	Out of 28 responses, 22 learners (79%) agreed objectives were clearly described and 25 (86%) agreed the activity was a valuable learning experience. Moreover, 24 learners (89%) agreed the SFM portrayed the role realistically and agreed that feedback from the SFM and faculty would be helpful for their communication skills in practice. Nineteen (68%) learners agreed the training videos helped prepare for the activity with PREP-SPIKES review and examples of emotional responses.	Only three respondents (11%) did not feel adequately prepared to deliver bad or serious news with patients/ families via VMC after the workshop.	N/A.	N/A.
Tobler, Grant, & Marczinski (2014, Canada).	University of Calgary.	Experimental Study. Prospective Cohort Study.	39 Residents in their 2nd-5th year of Postgraduate Paediatric Training at the University of Calgary.	5-hour workshop led by physicians and bereavement social workers was developed to teach subjects how to communicate difficult information or "bad news" to parents with description given of SPIKES tool. Simulation with SPs with rest of group observing through 1 way mirror; debriefing.	2 questionnaires at end of workshop; rate skills before/after workshop & second asked them to evaluate various elements of the workshop and provide written feedback. Two -physician experts and two parents who personally experienced receiving bad news evaluated resident performance using previously validated communication evaluation tool in an OSCE where they were required to give bad news.	Residents' ratings of the workshop were very high for all items.	100% of the residents reported improvement in their ability to deliver bad news after the workshop. Statistically significant improvement in confidence ratings were found with $P < .009$ for all items.	Statistically significant improvements in communication skills were obtained before and after the workshop ($Ps < .02$) in all but 3 items as follows: explains the nature of the interview, encourages the parents to contribute reaction, and provides support. However, mean preworkshop and postworshop scores were high for these items and seemed to be close to ceiling values.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Yazdanparast et al (2021, Iran).	Educational Hospitals of Birjand, Iran.	RCT.	60 nurses. Participants were selected using convenience sampling method and based on the inclusion criteria from among nurses working in two educational hospitals in Birjand; allocated participants randomly to intervention and control groups using a lottery method.	Integrated workshop on communication skills (principles of communication, communication process, purpose of communication, types of communication, barriers to effective communication, models of communication and strategies of improving communication and guidelines for successful therapeutic interactions) in the hospital. Teaching method was a combination of lecture, question and answer, group discussion, role-playing and film presentation. Each session lasted 2 h with a total of four sessions in 2 weeks (twice a week). Researcher-made educational posters were installed and educational booklets were placed in the hospitals for other participants 4 weeks after intervention.	3 Part Questionnaire including a demographics characteristics questionnaire, the Breaking Bad News Skills Questionnaire and the Questionnaire of Participation in Breaking Bad News. Questionnaires were completed by subjects before the intervention and 4 weeks after intervention.	N/A.	Independent t-test showed a significant difference between the two groups in the mean (SD) of breaking bad news skills after the intervention. In addition, according to paired t-test results, this increase was statistically significant only in the intervention group. The mean (SD) of breaking bad news skills after the intervention was 57.42 (10.13) in the control group and 65.12 (6.68) in the experimental group and the between-group difference was statistically significant ($P < .001$).	After the intervention, the mean score of nurses' participation in delivering bad news increased in both groups. According to paired t-test results, this increase was statistically significant only in the intervention group.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Oliveira et al (2020, Brazil).	Department of Obstetrics and Gynecology, Hospital das Clinicas, Faculdade de Medicina FMUSP, Universidade de Sao Paulo.	Prospective Cohort Study.	111 physicians who work in the Obstetrics Department of HC-FMUSP.	Theoretical Training (didactic lecture 50 minutes based on SPIKES protocol) + Practical Training with Simulations (90 minutes) + Debriefing.	Pre and post questionnaires with 14 month interval between them.	The participants positively valued the proposed training model (median 10/10) and perceived that they were better prepared to break bad news after the training (a median of 5/10 before training and 8/10 after training).	After training, there were significant improvements in knowing how to prepare the environment before delivering bad news ($P = .010$), feeling able to transmit bad news ($P < .001$) and to discuss the prognosis ($P = .026$), feeling capable of discussing ending the pregnancy ($P = .003$) and end-of-life issues ($P = .007$) and feeling confident about answering difficult questions.	N/A.	N/A.
Servotte et al (2019, Belgium).	?	RCT.	68 participants including medical students following a 1-month ED internship and first year EM residents.	Traditional 156-hour ED Rotation and 4 hours of BBNSBT (BBN simulation-based training). n = 37. BBNSBT involved two components: 1) a one-hour theoretical course on BBN, SPIKES and communication skills with a 15-minute video illustrating SPIKES components and 2) a three-hour simulation including six role-plays. During the first week of internship, participants underwent a pre-test of their ED BBN self-efficacy and skills. During the second week, participants assigned to the TG participating in the BBNSBT.	Pre and post questionnaires (four weeks later). Two blinded raters assessed the BBN process with the SPIKES competence form and communication skills with the modified BBN Assessment Schedule.	N/A.	Group by time effects adjusted by study year revealed a significant improvement in TG as compared with CG on self-efficacy ($P < .001$), the BBN process ($P < .001$) and communication skills ($P < .001$). At post-test, we found a statistically significant ($P = .02$) difference for the SPIKES cut-off score: the TG had a higher number of participants passing the cut-off score (27 students passed; 73%) than the CG (14 passed; 45%.2%).	After the training students with limited clinical experience prior to the rotation showed BBN performance skills equal to that of students in the CG who had greater clinical experience.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Rivet et al (2021, United States)	Single institution- during internship years.	Experimental Study. Prospective Cohort Study.	38 4th year medical students participated in BBN telehealth Covid-19 case as a mandatory part of the curriculum for graduating medical students matched into surgical specialties.	Video chat room to discuss rationale for telehealth practice and review SPIKES and NURSE models- paired with SP in virtual breakout room to start 10 minute encounter (simulation) + feedback/reflection + debrief.	Survey at completion of course to measure student reaction to the simulation, self-reported readiness for BBN independently using an adapted supervisory scale and the impact of VMC compared with face-to-face via open-ended questions.	Students rated the overall experience positively and found the feedback provided both by faculty and the SFM to be helpful. Most respondents rated the session beneficial (96%) and felt they could express empathy using the VMC format (83%).	Only 57% felt ready to deliver bad news independently after the training and 52% reported it was more difficult to communicate without physical presence. A significant group (39%) indicated they would like direction "from time to time"	N/A.	N/A.
Ghoneim et al (2019, United States).	3-year Baylor College of Medicine Neonatal-Perinatal Medicine fellowship program in 2013-2014 academic year.	Experimental Study. Prospective Cohort Study.	15 fellows in the 3-year Baylor College of Medicine Neonatal-Perinatal Medicine fellowship program	Simulation involved video-recorded encounters between each fellow and a SP involving communication of difficult news + debriefing session. Specifically, the intervention day was approximately 4.5 hours and first involved orientation and two 1 hour didactic sessions on SPIKES protocol before simulations began. Follow-up sessions took place 3-4 months later and were approx. 40 minutes and included one simulation with an SP per fellow. The follow-up scenarios were designed to be at a complexity level appropriate for NICU fellows b/c all fellows by the time of the follow-up sessions had had NICU clinical experience.	Each fellow was evaluated before, immediately after, and 3-4 months after intervention (i.e. pre/post/follow up) with evaluation of video recorded sessions by two expert raters blinded to timing of encounter (BRE), self-assessment questionnaire and content test evaluating knowledge of concept and SP evaluation.	N/A.	Content Test scores increased significantly at postinternvetion compared with preintervention ($Z = -2.65$, $P = .008$) and a follow up vs baseline ($Z = -3.07$, $P = .002$).	Although all fellows displayed improved Self-Assessment and Content Test Scores at Postintervention with retention at the follow-up assessment, the BREs showed no statistically significant improvement in post intervention scores and showed a decline in follow-up scores. First year fellows had higher BRE post intervention scores than the senior fellows.	N/A.

(continued)

Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Schmitz et al (2018, Switzerland).	Medical School, Bern University, Switzerland.	RCT.	67 fourth-year medical students at Bern University, Switzerland, enrolled in a mandatory clinical communication course with SPs.	They worked through an e–learning module that introduced the SPIKES protocol for delivering bad news to patients. There were 3 types of groups- one with worked example presented in text version vs video version vs video version enriched with text hints denoting SPIKEs steps.	Overall Performance Assessment Instruments: Self-developed five point scale with six items (each addressing a SPIKES step) and published five-point 'global Breaking Bad News Assessment Scale'.	N/A.	N/A.	Intraclass correlations were solid for SPIKES ratings (ICC = .89) and glBAS rating (ICC = .85), indicating that the three assessors scored the overall communication performance similarly. SPIKES scores differed significantly among the three learning conditions; relevant pairwise comparisons revealed that participants shown the video with hints achieved significantly better scores than participatns shown text ($z = 3.21$, Bonferroni-corrected $P < .01$, $r = .53$) or the plain video ($z = 2.43$, Bonferroni-corrected $P < .05$, $r = .38$). The groups glBAS scores also differed significantly; pairwise comparisons revealed that participants shown the video with hints performed significantly better than participants shown either text ($z = 2.89$, Bonferroni-corrected $P < .05$, $r = .47$) or the plain video ($z = 2.47$, Bonferroni-corrected $P < .05$, $r = .39$).	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Schildmann et al (2012, Germany).	Friedrich-Alexander-University Erlangen-Nuremberg Medical School.	Experimental study. Prospective Cohort Study.	Thirty-seven medical students took part in the teaching sessions; All 74 videotaped medical interactions of SPs and third-year medical students were included for analysis.	Course involved initial encounter with SP and cancer diagnosis disclosure, followed by teaching module on BBN (presented information on guidance of SPIKES protocol), and ended with second student SP interaction after teaching.	Rating by independent raters was conducted with modified breaking bad news assessment scale/mBAS and global rating scale versionof mBAS, the gIBAS.	N/A.	N/A.	The detailed analysis of pre-post scores indicates significant improvement in four of the five domains of breaking bad news competency covered by mBAS. The medical students' overall breaking bad news competency also improved significantly after the course; compared with prior to the cours on all five domains of the gIBAS.	N/A.
Grassi et al (2005, Europe).	Project spanned a period of 2 years and took place in the hospitals of the 3 centers participating in the study (located in Italy, Spain, Portugal).	Experimental Study. Prospective Cohort Study.	30 oncologists.	3 types of learning activities involved in the 12 hour workshop, spread over 2 days: didactic lectures using SPIKES algorithm, interactive discussion and role playing.	Post-intervention Questionnaire/ Evaluation of the Workshop.	Half of the doctors (n = 15) believed their clinical communication techniques were improved by participating in the workshop, and the remaining half thought that their abilities to communicate with cancer patients had improved.	N/A.	N/A.	N/A.

(continued)

Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Hanya et al (2017, Japan).	Within Aichi Prefecture/ Pharmaceutical Association.	Experimental Study. Prospective Cohort Study.	20 pharmacists working in the insurance-covered pharmacies within Aichi Prefecture.	Role-playing sessions with standardized patients before and after communication skill training. The communication skills training involved discussion of SPIKES protocol.	Post-Intervention Evauation sheet completed by SP to assess pharmacists' management & Roter Interaction Analysis System was used to analyze dialogues of participants during SP encounters.	The rate of each category, representing the pharmacists' conversation styles when dealing with the patients, changed after communication skill training as follows: [Giving information] decreased from 37.0 to 27.6%; [Empathy statements]; increased from 12.0 to 17.2%; and [Data gathering]; increased from 19.0 to 23.3%. The results of pharmacist assessment by the patients including their levels of overall satisfaction showed significant correlations with [Empathy statements] and [Building relationships].	N/A.	N/A.	N/A.
Dunning & Laidlaw (2015, United Kingdom).	Medical School-University of St. Andrews.	Case Study.	One third-year medical student.	First consultation with SP followed by didactic training with Practitioners in Applied Practice Model (PAPM) alongside SPIKES Framework along with use of video clips & reflective discussion. After this training, participants were able to engage in a second consultation and review theri video footage and carry detailed self-analysis of their own communication behaviour.	Roter Interaction Analysis System (RIAS) was used to analyze the behaviour of both participant and SP.	N/A.	N/A.	The patient centred scores and patient clinical communication satisfaction rating was highest in Consultation 2 and 3.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Sanchez-Reilly et al (2007, United States).	University of Texas Health Science Center.	Experimental Study. Prospective Cohort Study.	25 fourth-year medical students.	8 hour curriculum (1 day per week for 4 weeks) as an elective rotation- This involved didactic lecture involving discussion about SPIKES model, consultations with patients, and personal reflections from students.	Pre and Post-Intervention Questionnaires.	Mean scores on communicated oriented variables on posttest reflected high comfort and confidence in communication and low communication apprehension with dying persons.	N/A.	Despite a significant increase in knowledge about geriatric and palliative medicine ($F = 24.80$; $P < .001$), there were no significant changes in students' self-reported behaviours when applying curriculum-based communication strategies.	N/A.
Williams et al (2011, United States).	Internal Medicine Residency Program at Thomas Jefferson University Hospital.	Experimental Study. Prospective Cohort Study.	33 First Year internal Medicine residents participated in workshop but complete data were only available for 24.	Program consisted of three sessions including an interactive workshop flanked by pre and post workshop evaluation in simulated encounter and clinical vignette formats. Program materials for the workshop included lecture materials on SPIKES protocol along with video clips. Simulated encounters were recorded on video and residents' performances were rated by two independent observers.	Two raters evaluated each resident's performance in the baseline and final assessment using a 23-item checklist.	N/A.	N/A.	Of the 23 total communication checklist items for simulated encounters, 12 showed statistically significant improvement. Only 6 of the 18 skills for the clinical vignettes showed statistically significant improvement after the workshop session.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Schmitz et al (2017, Switzerland)	The learning environment was computer-based with instructions, questionnaires, and learning materials integrated on online survey tool on standard PC; trials conducted in a study room at Medical Faculty of University of Bern.	RCT.	Thirty-six first-year nursing students.	Randomly assigned to one of two experimental groups (correct v. erroneous examples) or to control group (no examples). All groups were provided an identical introduction to learning material on breaking bad news (discussion and integration of SPIKES protocol). Experimental group also received set of video-based work examples. Each example was accompanied by self-explanation prompt and elaborated feedback.	Prior knowledge test to assess baseline understanding of PIKE model along with cognitive assessment and behavioural assessment conducted by trained assessor.	N/A.	Strong implication that participants with erroneous examples developed and cognitively used PIKE-related communication schemas at a higher level than participants with correct examples ($z = -1.64$, one-tailed $P = .051$, $r = .33$).	Participants presented with erroneous examples broke bad news to a simulated patient significantly more appropriately than students in the control group. Additionally, they tended to outperform participants who had correct examples, while participants presented with correct examples tended to outperform the control group.	N/A.
Westmoreland et al (2018, Southern Africa)	Princess Marina Hospital in Gaborone.	Experimental Study. Prospective Cohort Study.	Forty-two medical students attended the workshop and 35 completed the survey.	3-hour small group workshop with curriculum including overview of communication basics and introduction of validated (SPIKES) protocol for breaking bad news- used didactic lecture, handouts, role-playing cases, and open forum discussion.	Pre-and post-training surveys assessed prior exposure to breaking bad news using multiple choice questions and perception fo skill about BBN using 5-point Likert Scale. OSCE was conducted as a standardizing BBN skills assessment on students- scores compared two medical student classes before and after workshop was implemented.	Self-perceived skill and confidence increased from 23% to 86% of those who reported feeling "good" or "very good" with their ability to BBN after workshop. Feedback after workshop demonstrated htat 100% found the SPIKES approach helpful and planned to use it in clinical practice, found role-playing helpful and requested more sessions.	Competency for delivering bad news increased from a mean score of 14/25 (56%, SD = 3.3) at baseline to 18/25 (72%, SD = 3.6) after the workshop ($P = .0002$).	N/A.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Rosenzweig et al (2008, United States).	The Patient CommSim Lab was symbolically given during class days with other skills laboratories emphasizing the proficiency component of communication skills at the University of Pittsburgh, School of Nursing.	Experimental Study. Prospective Cohort Study.	ACNP students enrolled in a didactic course with laboratory component.	Students participated in a didactic session and then completed a 2-hour communication simulation in the laboratory with SPs. Each scenario with SPs involved communication skills including SPIKES, deemed appropriate for the case and were part of a checklist when providing feedback to students. Content and simulation concentrated on breaking "bad news", empathetic communication, motivational interviewing and the "angry" patient.	Survey completion before, immediately after simulation lab and 4 months after. Students self-reported confidence and perceived skill in communication were measured using a LIkert Scale.	Overall students rated the laboratory simulation experience highly beneficial.	Compared with baseline findings (Before the lecture and simulation), students' confidence in initiating difficult conversations increased significantly both immediately ($P < 0001$) and 4 months after ($P = .001$) the laboratory simulation. Students' self-ratings of overall ability to communicate were also significantly greater immediately ($P < .001$) and 4 months ($P = .001$) after the simulation.	N/A.	N/A.
Eid et al (2009, United States).	Encounters were conducted simultaneously in 4 rooms equipped with a video camera in Clinical Skills Center at the University of Arkansas for Medical Sciences.	Experimental Study.	8 Hematology Oncology Fellows (HOFs) and 2 Advanced Practice Nurses (APNs). Of the fellows, 3 were in their 3rd year and 5 were in theri 2nd year of a 3-year accredited hematology oncology fellowship program. Each APN had more than 5 years of experience in cancer care. To note, a total of 6 HOFs and 2 APNs participated in the preintervention test and a total of 5 HOFs and 1 APN participated in the postintervention test 1 week later.	Breaking Bad News Standardized Patient Intervention (BBNSPI)- 2 scenarios with SPs with a 21-item checklist to assess the learners which was designed based on SPIKES methodology in breaking bad news. Preintervention test consisted of encounters with SPs. The preintervention encounters were followed by a 45 minute interactive lecture given by an educator experienced in communication skills and involved discussion on SPIKES methodology. A total of 1 week after intervention, subjects had their postintervention encounters with SPs.	Each encounter in pre and post intervention sessions were scored using same 21-item checklist and scored by 3 different scoring teams: SP inside room and at end of each encounter, trained faculty member or SP watching encounter remotely on video monitor screen and investigator who retrospectively watched the recorded encounters. In addition, a total of 5 months later, subjects were asked to fill out long-term postintervention survey.	The long-term intervention perception survey showed that all 6 subjects (100%) thought the intervention improved their communication skills in breaking bad news to cancer patients ($P < .048$).	The average test score of the participants improved from 56.6% in the preintervention test to 68.8% ($P < .005$) in the postintervention test.	N/A.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Williams-Reade et al (2018, United States).	Major Academic Teaching hospital.	Experimental Study. Prospective Cohort Study.	Convenience sample of 15 surgery residents.	Each resident participated in two 30-min simulations and received feedback from observers. Training was presented in eight 2-hr educational seminars; held in the MedFT training clinic in two adjacent rooms that included a two-way mirror and an audio feed system. Training was created utilizing an established communication framework for BBN called SPIKES.	Self-assessments completed before, immediately after, and 6 months after simulation.	Statistically significant change with medium to large effect sizes in participant self-reported perceptions of skill and confidence were documented and maintained over 6 months. Questionnaires included 5-point Likert scale questions.	N/A	Significant improved with large effect sizes was found in residents' delivery of bad news after analysis of the SPIKES evaluation from the first to the second role play, as rated by residents ($t(14) = -3.97$, P = .001, Hedge's g = = 1.18; simulated family members, $t(14) = -8.09$, P < .001, Hedge's g = 1.72; and observers, $t(14) = -5.913$, P < .001, Hedge's g = 1.84.	
Annadurai et al (2021, United States)	4 hospitals in New York and Connecticut.	RCT	22 oncologists.	Communication Skills Training INT which consisted of an interactive training session and four joint visits with communication coaches.	Baseline survey included questions that assessed oncologists' beliefs about end-of-life discussions and their prior communication training and level of comfort with specific communication skill topics. Audiotapes were reviewed by three blinded coders who were each trained as a VitalTalk communication skills teacher. Each coder evaluated performance using a validated assessment tool, a checklist of the most important communication skills that shown to be feasible and reliable in another study.	N/A.	There was no significant difference between the summary scores evaluating seven or eight skills. There was no significant difference in oncologists' skills pre INT between trial arms.	In the post-INT audiotaped visits, INT oncologists were significantly more likely to elicit patient values (55% vs 0%; P = .01).	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Kiluk et al (2012, United States).	Interdisciplinary Oncology Clerkship at the University of South Florida, College of Medicine.	Experimental Study. Prospective Cohort Study.	4th year medical students (n = 112).	Spent 2-3h partaking in a small group session going over techniques of conveying difficult news, they were then videotaped during a 15-min encounter with a SP. Following the encounter, students gather in groups of three to five to review videotaped interactions with SPs and physician specialized in cancer care.	Initial Questionnaire on medical school experience and comfort in breaking bad news. Follow-Up questionnaire about small group session.	Following the small group interaction, students overwhelmingly "agreed/strongly agreed" (98.3%) that the exercise was helpful and that the SPs were "very realistic/somewhat realistic" (94.7%). 57.2% of students agreed the discussion was the most advantageous feature.	Following the completion of the CDN session, students "agreed/ strongly agreed" that their knowledge of best practices had increased (97.3%). Increased knowledge about best techniques for discussion these situations (66.9% to 94.6%).	N/A.	N/A.
Kron et al (2017, United States).	Three US Medical Schools: Eastern Virgina Medical School, University of Michigan Medical School, University of Virginia School of Medicine.	Single-blinded, mixed methods, randomized multisite trial; RCT	Second-year medical students (n = 421).	In MPathic-VR intervention, students assumed role of intern in two thematically linked scenarios; Learning objectives for the scenarios were guided by CRASH principles for cultural competence and by SPIKES protocol for delivering bad news.	Communication scores during repeat interactions with MPathic-VR's intercultural and interprofessional communicaiton scenarios and scores on a subsequent advanced communication skills OSCE. Secondary outcomes included student attitude surveys and qualitative assessment of their experiences (using reflective essays) with MPathic-VR or computer based learning.	Attitudes and experiences were more positive among students trained with MPathic-VR who valued its providing immediate feedback, teaching non-verbal communication skills and preparing them for emotion-charged patient encounters.	Students in the MPathic VR successfully learned how to improve their communication skills for both intercultural and interprofessional scenarios.	MPathic-VR trained students achieved significantly higher composite scores on the OSCE than computer-based learning trained students.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Vermylen et al (2019, United States).	Northwestern University Feinberg School of Medicine, Chicago Illinois.	Experimental Study. Prospective Cohort Study.	Fourth year medical students (n = 10).	For BBN SBML curriculum, a clinical case was developed to assess learner BBN skills at pretest and post-test. At the start of the workshop, learners received focused feedback about their pretest performance. Lecture then focused on SPIKES protocol to deliver bad news and included a demonstrated of BBN encounter was given. Then participants completed three hours of deliberate practice of BBN skills. Pilot testing was completed after to confirm improvement in skill acquisition.	Breaking Bad News assessment tool containing a 15-item checklist and six scaled items was developed.	N/A.	N/A.	Students Checklist performance improved significantly at post-test compared to baseline (mean 65.33%, SD = 12.09% vs mean 88.67%, SD = 9.45%, P < .001).	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Rosenzweig et al (2007, United States).	Acute Care Nurse Practitioner Program from large urban university; workshop sessions were conducted in 4 conference rooms within School of Nursing each with a video camera.	Experimental Study. Prospective Cohort Study.	4 nurse practitioners and 2 clinical nurse specialist students specializing in cancer care.	Communication skills workshop using standardized patients (SPs) was planned for oncology nurse practitioner students. Three patient cases using SPs were developed to represent a specific communication skill. The third scenario, in particular focused on breaking bad news with didactic session used to present SPIKEs protocol. After each encounter, SP provided feedback. Students then spent 20 minutes writing progress note to document communication issue and self-reflect. Videotapes of these encounters were reviewed by faculty. Further feedback and review of 3 cases + key communication skills was provided.	Postworkshop evaluative survey, simulated patient feedback to students, videotapes of actual communication scenarios and student's comments on open-ended questions. In addition the students evaluated the overall workshop and components of the teaching methodology through Likert scale and open-ended question methodology.	Four methods of evaluation revealed a high level of satisfaction with the course. Confidence in communication skills increased following the workshop.	Four methods of evaluation revealed a high level of communication skills demonstrated during course.	N/A.	N/A.

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Table 2. (continued)

Study and Country of Origin	Setting	Study design	Participants	Intervention (SPIKES)	Evaluation tools	Learner satisfaction	Learner knowledge	Learner performance	System outcomes
Yakhforoshha et al (2019, Iran).	Two teaching hospitals of Tehran University of Medical Sciences.	Experimental Study- Quasi Experimental Methods, Interrupted Time Series. Prospective Cohort Study.	Oncology fellows (n = 19).	Trained through workshop, followed by engaging participants with different types of art-based teaching methods. Specifically, multifaceted intervention for all fellows (n = 19) was developed based on 1-day workshop of consisting of a) interactive lectures about teh essential sub-skills of BBN, b) small group discussions followed by presenting different art approaches such as films, music, and telling story, c) scenario-based learning, d) writing reflective essay, and e) role playing. After this, all fellows gather in groups of 3-5 to discuss the art engagement and interactions with SPs. Educational content and material were developed based on key sub-skills of BBN with a focus on SPIKES model.	In order to assess effectiveness of integrating model, fellows' performance was rated by two independent raters (SPs and faculty members) using BBN assessment checklist. Assessment tool measured 7 different domains of BBN skill.	N/A.	N/A.	Based on SP ratings, fellows' performance scores in post-training showed significant level changes in three domains of BBN checklist (B = 1.126, F = 3.221, G = 2.241; P < .05). Similarly the significant level change in fellows' score rated by faculty members in post-training was B = 1.091, F = 3.273, G = 1.724; P < .05. There was no significant change in trend of fellows' performance after the intervention.	N/A.

Table 3. Risk of Bias in Randomized Control Trials.

Study	Bias arising from randomization process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result	Overall Bias
Bowyer et al, (2010, United States)	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias
Setubal et al, (2018, Brazil)	Lower risk of bias	Lower risk of bias	Some concerns- selection bias	Lower risk of bias	Lower risk of bias	Some concerns- re; selection bias
Baghdari et al, (2017, Iran)	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias
Yazdanparast et al (2021, Iran)	Lower risk of bias	Some concerns	Lower risk of bias	Some concerns	Lower risk of bias	Some concerns
Servotte et al (2019, Belgium)	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk
Schmitz et al (2018, Switzerland)	Lower risk of bias	Lower risk of bias	Some concerns	Some concerns	Lower risk of bias	Some concerns
Schmitz et al (2017, Switzerland)	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias
Annadurai et al (2021, United States)	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias
Kron et al (2017, United States)	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias	Lower risk of bias

ranged from medical schools (n = 11), university-affiliated teaching hospitals (n = 11), academic research centres (n = 5), and universities (n = 7). Specific specialties involved included paediatrics (n = 4), surgery (n = 3), obstetrics/gynaecology (n = 3), emergency medicine (n = 2), oncology (n = 7), anaesthesia (n = 1), midwifery (n = 1), internal medicine (n = 1) and pharmacy (n = 1). Interventions ranged in length from 1.5 hours to a 6-month elective course and a few studies had a follow-up post-intervention encounter. Finally, evaluation tools ranged from pre and post intervention questionnaires, OSCE performance with rating by independent raters and SPs, and reflective essay writing.

Discussion

Our systematic review is the first of its kind to evaluate the SPIKES protocol according to the Kirkpatrick Model[28] which is a standard model to evaluate the effectiveness of training, specifically, learner satisfaction, knowledge, performance, and system outcomes. Overall, the majority of studies showed improvements in learner satisfaction, learner knowledge, and learner performance that were all of statistical significance. None of the studies examined system outcomes. These findings are in alignment with the literature. Specifically, a review and meta-analysis of 17 studies conducted by Johnson & Panagioti[30] highlighted that those interventions based on the SPIKES framework for breaking bad news were associated with significant improvement in observer-rated communication skills compared to interventions that uses frameworks other than SPIKES.

Despite these overarching findings, our study found that there was some variability in the results based on the intervention used. For instance, a study by Sanchez-Reilly et al[18] involved 25 fourth-year medical students undergoing an 8-hour curriculum involving didactic lecture on the SPIKES framework, consultations with patients, and personal reflections from students. Despite a significant increase in the knowledge about geriatric and palliative medicine ($F = 24.80$; $P < .001$) among participants, the study found no significant changes in students' self-reported behaviours when applying the curriculum-based communication strategies. Specifically, their results showed students lacked true application of the communication skills training conducted in the course. Similarly, Coutinho & Ramessur[31] gave a 45-minute lecture using the SPIKES framework to 160 medical students and conducted a post-intervention survey. Reports from their survey demonstrated that students felt a lecture alone may not be an effective teaching method for communication of bad news and preferred a theoretical-practical educational program. This was seen in our review as per findings from several studies which demonstrated simulation and practical components in the various SPIKES- based interventions were deemed most helpful by participants. For instance, an experimental study conducted by Park et al[9] reported that 43% of

Table 4. Risk of Bias in Non-randomized Studies.

Study	Pre-Intervention: Bias due to confounding	Pre-Intervention: Bias in Selection of Participants into the study	At Intervention: Bias in classification of interventions	Post-Intervention: Bias due to deviations from intended interventions	Post-Intervention: Bias due to missing data	Post-Intervention: Bias in measurement of outcomes	Post-Intervention: Bias in selection of the reported result
Wolfe et al, (2014, Unted States).	Low Risk	Moderate Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Pereira et al, (2017, Brazil).	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Haubner et al, (2010, United States).	Low Risk	Moderate Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Bonnaud-Antig et al (2010, France).	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Szmulewicz (2021, France).	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Low Risk
De Moura Villela et al (2020, Brazil).	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Sekar et al (2021, United States).	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Low Risk	Low Risk
Coutinho & Ramessur (2016, Portugal).	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Low Risk	Low Risk
Ellis et al,(2021, United States).	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Rivet et al, (2021, United States).	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Tobler, Grant, Marczinski (2014, Canada).	Low Risk	Moderate Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Oliveira et al (2020, Brazil).	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Low Risk	Low Risk
Rivet et al (2021, United States)	Low Risk	Moderate Risk	Low Risk	Low Risk	Moderate Risk	Low Risk	Low Risk
Ghoneim et al (2019, United States).	Moderate Risk	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Low Risk
Schildmann et al (2012, Germany).	Low Risk	Moderate Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Grassi et al (2005, Europe).	Low Risk	Moderate Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Hanya et al (2017, Japan).	Low Risk	Moderate Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Dunning & Laidlaw (2015, United Kingdom).	Low Risk	Moderate Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk

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Table 4. (continued)

Study	Pre-Intervention: Bias due to confounding	Pre-Intervention: Bias in Selection of Participants into the study	At Intervention: Bias in classification of interventions	Post-Intervention: Bias due to deviations from intended interventions	Post-Intervention: Bias due to missing data	Post-Intervention: Bias in measurement of outcomes	Post-Intervention: Bias in selection of the reported result
Sanchez-Reilly et al (2007, United States).	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Williams et al (2011, United States).	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Moderate Risk	Low Risk
Westmoreland et al (2018, Southern Africa)	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Low Risk	Low Risk
Rosenzweig et al (2008, United States).	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Moderate Risk	Low Risk
Eid et al (2009, United States).	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Low Risk	Low Risk
Williams-Reade et al (2018, United States).	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Moderate Risk	Low Risk
Kiluk et al (2012, United States).	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Vermylen et al (2019, United States).	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Low Risk	Low Risk
Rosenzweig et al (2007, United States).	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Low Risk	Low Risk
Yakhforoshha et al (2019, Iran).	Low Risk	Low Risk	Low Risk	Low Risk	Moderate Risk	Low Risk	Low Risk

participants rated the simulation portion of the SPIKES-intervention to be the most useful. Moreover, open-ended responses from participants in a study conducted by Bonnaud-Antignac et al[32] suggested that participants wished for opportunities to practice their communication techniques as part of the intervention to improve their skills in breaking bad news. Similarly, de Moura Villela et al[33] also found that participants found the role-playing component of their teaching to be the most impactful. These findings highlight that lecture-based, didactic interventions based on the SPIKES framework alone may not be sufficient for skills acquisition.

Our review is one of the first on communication skills training that looked at the utility of 'worked examples' in these teaching interventions. The worked example effect is the step-by-step demonstration of how to solve a problem and is a notable construct within human cognition that is often embedded in interventions to support initial skills learning.[34] These worked examples and the use of erroneous examples (a subtype of worked examples that include one or more errors) have been found to reduce cognitive load, increase learner attention, and encourage critical thinking.[34] The benefits of this construct have been cited extensively in medical education literature where case-based work examples have improved clinician's diagnostic competencies and procedural skills.[35,36] In terms of communication skills training, our review found the worked examples in the SPIKES interventions helped to bolster participant skills and performance as participants whose interventions involved worked examples outperformed those participants whose interventions did not.[37,38] Specifically, a study conducted among nursing students found that those students who were presented with video-based erroneous worked examples with guided explanation of the case broke bad news to simulated patients more appropriately than those students who were presented with video-based correct worked examples and guided explanation and those with no worked examples in the control group.[37] As such, our review suggests that incorporating

worked examples in interventions for future studies on communication skills training may be useful.

Our review is also one of the first to look at teaching interventions within the COVID-19 pandemic context. Rivet et al[39] used a telehealth training program based on SPIKES to teach surgical interns how to break bad news through video-mediated communication. Although 96% of the interns expressed that the session was beneficial, a significant proportion of students felt breaking bad news was more challenging when not in the same physical space as their patient (n = 12, 52%). Furthermore, some students expressed concern about their ability to express non-verbal cues, setting the scene using video-mediated communication, and possible concerns with weak internet connection (n = 12). Despite this, 83% of interns felt they were able to empathize with patients during this encounter successfully, lending to the notion that video-mediated communication and the use of telehealth workshops can be helpful and feasible ways to teach these skills. Previous reviews on communication skills training have also discussed such similar feasibility and economic concerns about teaching interventions and how practical they may be for health care professionals to attend given work schedules and potential costs.[40] Our review addresses and expands on these concerns. Specifically, Bowyer et al[41] found that observation of a video on the SPIKES protocol offered the most efficient way of teaching breaking bad news skills when there were significant time constraints set in place. In addition, a study by Westmoreland et al[42] found that training of health care professionals in a resource limited hospital in sub-Saharan Africa was done best through the use of standardized role-playing communication workshops which they felt could be easily integrated into medical school curriculum at low-cost. As such, our results highlight practical ways in which communication skills training interventions can be conducted when there are significant cost and time restraints.

Apart from these new findings and insights, our review's further strengths include being quite generalizable as several of our studies were conducted in a variety of countries and institutions with a plethora of health care professionals. The importance of this has been highlighted in the literature given the strong cultural influence that can impact the process of breaking bad news for patients and their families.[43] This review is also the first of its kind to focus specifically on the SPIKES framework within teaching interventions and its impact on communication skills teaching.

In summary, our systematic review highlights only 9 RCTs that have investigated the SPIKES intervention. The prospective and retrospective studies included were all short-term, with small sample sizes and without standardised reporting of outcomes. There is a lack of controlled studies and as such, we can only draw limited conclusions due to the low-quality of available evidence. Despite this, our systematic review highlights four main limitations in the current evidence base which could be addressed in future research. First, none of the studies in our review analysed patient outcomes, patient satisfaction, or patient perception. This dearth in the literature has been highlighted before in previous reviews which have also found a gap in assessing both patient and health care provider mental and physical health in response to these interventions.[40,44,45] Although a few studies in our review did report on health care provider satisfaction and level of confidence in their skills post-intervention, future studies should focus on specific outcomes that assess for these constructs bearing in mind the possible distress healthcare providers and patients can feel in having these difficult conversations. Second, there continues to be poor understanding of the impact of the 'ceiling effect' whereby, those health care professionals who have had previous communication skills training may respond differently to these training interventions in comparison to those health care practitioners who have not. While our review found studies that identified disparities in performance among trainees who had received previous formal communication skills training, there remains a need to further elucidate and delineate this impact, specifically by investigating the type of previous training, its format, and length and impact on knowledge and skill acquisition.[46-49] Third, only one of our studies had an additional evaluation which took place 3-4 months after the intervention and found that participants experienced a significant decline in their content and knowledge test scores.[48] As such, there remains a large need to explore how to maximize long-term retention of knowledge and skill from these teaching interventions.[40,44,45] Finally, our review did not find any studies that explored system outcomes and thus, future studies should analyse the impact of these teaching interventions on an institutional level. Furthermore, other potential interesting questions that remain unanswered include the potential utility of consolidation courses and the impact of compulsory vs voluntary training in these interventions.

Conclusion

The importance of clinicians being able to communicate bad news is imperative, especially given the recent challenges caused by social distancing as a result of the COVID-19 pandemic. Our systematic review suggests that the SPIKES protocol is associated with improved learner satisfaction, knowledge and performance, however no study examined system outcomes. Further research is needed to evaluate the impact of patient outcomes, including the optimal components and length of intervention.

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