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Evaluation of low vs high-intensity speciality care staff training on documentation and communication of life-sustaining treatment decisions in the Veterans Health Administration

Submission date
22/08/2018

Recruitment status
No longer recruiting

Registration date
13/09/2018

Overall study status
Stopped

Last Edited
08/11/2019

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Understanding and honoring patient goals and life sustaining treatment preferences is an important part of care for patients with serious illness. Patients with serious illness want to discuss their goals and preferences with their physicians. However, many physicians do not feel prepared to conduct these conversations, and often avoid or delay initiating them. Training physicians and other clinical staff in how to conduct and support these conversations could improve care for patients with serious illness. This project will compare the effects of three staff training approaches on the likelihood that patient life sustaining treatment preferences are documented, discussed in a patient-centered manner, and honored at end of life. Findings will inform decisions about which training approaches to use in the Veterans Health Administration.

Who can participate?
Staff in 48 specialty care clinics participating in the evaluation can participate in the training and interviews.

Adult patients over the age of 18, not enrolled in hospice, who had life sustaining treatment decisions documented by staff in one of the 48 participating clinics can participate in the patient survey.

What does the study involve?
Participating specialty care clinics will be randomly allocated to one of three groups. The first group will receive high-intensity goals of care communication skills training for both physicians and non-physicians. The high-intensity training for physicians will include four to five hours of in-person training about giving serious news, asking about goals, matching care to goals, and talking about life sustaining treatment. The high-intensity training for non-physicians will include seven hours of in-person training about identifying seriously ill patients; preparing them for life

sustaining treatment discussions; and using team strategies to conduct life sustaining treatment discussions in the clinic. The teaching techniques used for the high-intensity physician and non-physician training sessions will include didactic methods, modeling, practice, and feedback.

The second group will receive low-intensity training for both physicians and non-physicians. The low-intensity training includes a one-hour presentation on discussing and documenting life sustaining treatment preferences. It also includes a pocket card conversation guide.

The third group will receive high-intensity training for physicians, and low intensity training for non-physicians.

Six months after the training, we will look at medical records to see how many seriously ill patients in each group had life sustaining treatment preferences documented. We will also survey patients one to nine months after the training to ask how well physicians communicate with them. We will also interview staff one to nine months after the training to ask about their experiences with the training and with talking to patients about life sustaining treatment. Eighteen months after the training sessions we will look at medical records to see how many patients received the life sustaining treatment they said they wanted at end of life.

What are the possible benefits and risks of participating?
All staff participants will receive training in how to conduct and support discussions about care goals and life sustaining treatment preferences. There are no risks of physical injury or harm to participating in the training or interviews. Information obtained from the project may improve staff training programs in the future. Patients mailed a survey will receive a lens cleaning cloth. There are no risks of physical injury or harm to participating in the survey.

Where is the study run from?
Minneapolis Veterans Affairs Health Care System and 12 other Veterans Affairs Medical Centres (USA)

When is the study starting and how long is it expected to run for?
October 2017 to June 2019 (updated 06/06/2019, previously: September 2020).

Who is funding the study?
Veterans Affairs National Center for Ethics in Health Care

Who is the main contact?
Ray Frazier,
Ray.Frazier@va.gov
(updated 06/06/2019, previously:
Melissa Partin
Investigator, Minneapolis Veterans Affairs Health Care System,
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Contact information

Type(s)
Public

Contact name
Mr Ray Frazier

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811 Vermont Avenue
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United States of America
-

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Randomized Evaluation Comparing Low and High-Intensity Specialty Care Staff Training Effects on Life Sustaining Treatment Decision Documentation and Communication in the Veterans Health Administration

Study objectives
1. Documentation of life sustaining treatment decisions will be higher in clinics assigned to high intensity training than in clinics assigned to low intensity training.
2. Documentation of life sustaining treatment decisions will be higher in clinics assigned to received both physician and non-physician training than in clinics assigned to receive only physician training.
3. The quality of physician communication reported by patients will be higher in clinics assigned to receive high intensity training than in clinics assigned to receive low intensity training.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study does not require ethics approval because it has been designated quality improvement /non-research by an official with the authority to make this designation, per Veterans Health Administration Handbook 1058.05. A letter documenting the criteria used to evaluate the appropriateness of this designation can be provided on request. Additionally, we received written concurrence with regard to the appropriateness of this designation from the Minneapolis Veterans Affairs Health Care System Institutional Review Board.

Study design
un-blinded, cluster-randomised intervention

Primary study design

Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Shared decision making regarding life support care

Interventions
This evaluation randomly assigns 48 specialty care clinics from 12 facilities to receive either:
1. High intensity communication skills training for both physicians who can write life sustaining treatment orders, and non-physicians (nurses, psychologists, social workers, chaplains) who can facilitate and support this process (High Ed-All); or
2. Low-intensity training for physicians and non-physicians (Low Ed-All); or
3. High intensity training for physicians, and low intensity training for non-physicians (High Ed-MD).

We will assign two clinics at each facility to Low Ed-All, one to High Ed-All, and one to High Ed-MD using a modified Latin Square design. This design will balance intervention assignment to clinic types across sites so that there is no confounding of site, clinic, and intervention effects.

Physicians in High Ed-All clinics will receive four to five hours of in-person didactic training, modeling, practice, and feedback, focused on delivering serious news, clarifying patients' goals of care, aligning the care plan with patients' goals, and discussing life sustaining treatment. Non-physicians in High Ed-all clinics will receive seven hours of in-person didactic training, modeling, practice and feedback focused on proactively identifying seriously ill patients; preparing patients for life sustaining treatment discussions; and using team-based strategies to incorporate life sustaining treatment discussions into practice. High Ed training sessions will be administered using a train-the-trainer model, whereby each facility will send three to six representatives to attend a three-day physician communication skills expert training session, and three to six representatives to attend a three-day non-physician expert training session in 2018. Trainers are selected by facilities and are expected to have excellent teaching skills and experience conducting goals of care conversations. All expert training sessions will be conducted by Veterans Affairs National Center for Ethics in Health Care staff at regional training facilities.

Physician and non-physician staff in Low Ed-All clinics will receive a one-hour presentation on discussing and documenting life sustaining treatment preferences, and a pocket card conversation guide. This low intensity presentation will be delivered in-person or via teleconference by a local clinician educator or expert trainer.

Physicians in High Ed-MD clinics will receive the four to five hour high intensity goals of care communication skills training described above. Non-physicians in clinics assigned High Ed-MD training will receive the one-hour low intensity training and pocket card described above.

Participating clinics are expected to train a minimum 80% of eligible staff in the intervention assigned to their clinic over a five-month period. All intervention groups will be followed for 18 months, with outcomes assessed at 6, 9 and 18 months, depending on the outcome.

Intervention Type
Behavioural

Primary outcome measure
1. Life sustaining treatment decision documentation completion will be measured using information on the number of items completed within the 4 fields of a life sustaining treatment progress note template, stored in administrative data over the six months following the clinic training period. We will define documentation completion as presence of a completed progress note in the administrative records. A life sustaining treatment progress note cannot be completed unless the following four fields of the template are filled in: (1) decision making capacity (yes, no), (2) patient reported goals of care (cure, prolonged life, function / independence / quality of life, comfort, obtain caregiving/family support, achieve life goals), (3) code status (full code, do not resuscitate / do not resuscitate except in situations specified), and (4) who provided informed consent (patient, surrogate, other).
2. Life sustaining treatment decision documentation comprehensiveness will be measured using the number of items (out of a total of 8) completed in the life sustaining treatment progress note (total number completed as 1 measure and categorization - none, minimal number completed, more than minimum completed as another measure) over the 6 months following the clinic training period
3. Life sustaining treatment decision documentation timing will be measured using the date of the first visit to an eligible specialty care clinic by an eligible patient and the date of life sustaining treatment progress note completion over the 6 months following the clinic training period
4. Patient-reported quality of provider communication will be measured using a previously validated physician general communication skills scale, administered by mailed patient survey conducted over 1 to 9 months following the clinic training period. This scale includes 6 items asking respondents to rate the quality of physician general communication skills. Response categories for all items range from 0 (the very worst possible) to 10 (the very best possible). The scale is constructed by summing item-specific responses, and higher scores indicate higher quality communication.

Secondary outcome measures
1. Physician end of life communication skills will be measured using patient responses will be measured using 4 additional questions about provider communication not included in the physician general communication skills scale over 1 to 9 months after the clinic training period
2. Staff experiences with the training and perspectives on barriers and facilitators to documenting life sustaining treatment decisions will be measured using 30-minute qualitative phone interviews, conducted with 24 staff from the 12 participating facilities at one to nine months after the clinic training period
3. Concordance between life sustaining treatments preferred and received by patients with documented life sustaining treatment decisions will be measured using a manual chart review at 18 months after the clinic training period

Overall study start date
01/10/2017

Completion date
30/06/2019

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Facilities.
1. Veterans Health Administration medical center with complexity level 1a or 1b
2. Have not yet trained specialty care staff in the interventions evaluated

Clinics:
1. Cardiology, nephrology, oncology and pulmonology clinics agreed to participate in the evaluation.

Staff.
1. Physicians, physician assistants, advance practice registered nurses, and fellows in one of the participating clinics

Patients:
1. Life sustaining treatment decision documented by staff in one of the participating clinics after the completion of the clinic training period.
2. Life sustaining treatment decision consented by patient
3. Age 18 or older

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12 facilities; 48 clinics, 24 staff interviews, 576 patient survey respondents.

Total final enrolment
120

Key exclusion criteria

Patients:
1. Deceased
2. Enrolled in hospice
3. Life sustaining treatment decision consented by surrogate
4. Recently recruited to one of the Veterans Health Administration’s patient satisfaction surveys

Date of first enrolment
01/04/2018

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
United States of America

Study participating centre
Atlanta Veterans Affairs Health Care System
1670 Clairmont Road
Decatur
United States of America
30033

Study participating centre
Birmingham Veterans Affairs Medical Center
700 S. 19th Street
Birmingham
United States of America
35233

Study participating centre
Veterans Affairs Boston HealthCare System
150 South Huntington Avenue
Jamaica Plain
United States of America
02130

Study participating centre
Veterans Affairs Connecticut HealthCare System
950 Campbell Avenue
West Haven

United States of America
06516

Study participating centre
Edward Hines Jr Veterans Affairs Hospital
5000 South 5th Ave
Hines
United States of America
60141

Study participating centre
Michael E. DeBakey Veterans Affairs Medical Center
2002 Holcombe Blvd
Houston
United States of America
77030-4298

Study participating centre
Clement J. Zablocki Veterans Affairs Medical Center
5000 West National Avenue
Milwaukee
United States of America
53295-1000

Study participating centre
Oklahoma City Veterans Affairs Health Care System
921 N.E. 13th Street
Oklahoma City
United States of America
73104

Study participating centre
Tennessee Valley HealthCare System
1310 24th Avenue South
Nashville
United States of America
37212

Study participating centre

Veterans Affairs Palo Alto Health Care System
3801 Miranda Avenue
Palo Alto
United States of America
94304-1290

Study participating centre
Philadelphia Veterans Affairs Medical Center
3900 Woodland Avenue
Philadelphia
United States of America
19104

Study participating centre
Veterans Affairs Puget Sound Health Care System
1660 S. Columbian Way
Seattle
United States of America
98108

Sponsor information

Organisation
Veterans Affairs National Center for Ethics in Health Care

Sponsor details
810 Vermont Ave., N.W.
Washington, DC
United States of America
20420

Sponsor type
Government

Website
https://www.ethics.va.gov/

ROR
https://ror.org/05rsv9s98

Funder(s)

Funder type
Not defined

Funder Name
U.S. Department of Veterans Affairs

Alternative Name(s)
Department of Veterans Affairs, United States Department of Veterans Affairs, US Department of Veterans Affairs, U.S. Dept. of Veterans Affairs, Veterans Affairs, Veterans Affairs Department, VA, USDVA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journal in 2021

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
Data sharing is not required by our funder and currently we are not able to share participant level data outside of the Veterans Health Administration. We will likely make deidentified participant level-data available to interested Veterans Health Administration employees at a future, as of yet undetermined, date.

IPD sharing plan summary
Not expected to be made available