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HONOREE: ProjectHEAL

Honoree Proposal Description:

Project HEAL is the leading non-profit in the US delivering prevention, treatment financing, and recovery support for people suffering from eating disorders.

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Organization Website:

<https://www.theprojectheal.org/>

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Project HEAL: Communities of HEALing Proposal

Project HEAL, the leading grassroots eating disorder non-profit, is seeking \$100,000 to support a randomized controlled trial to evaluate the effectiveness of peer mentorship as a low cost, high accessibility intervention for patients with eating disorders.

Organization Background and Mission

Treatment resources and insurance coverage for eating disorders are severely lacking, leaving many unable to get the help they need. Project HEAL: Help to Eat, Accept and Live is the largest nonprofit in the U.S. delivering prevention, treatment financing, and recovery support for people suffering from eating disorders. Our goal is to reduce suffering caused by eating disorders.

Project HEAL was conceived when its founders, Liana Rosenman and Kristina Saffran, became aware of the high cost of eating disorder treatment through their own experiences seeking treatment as teenagers. They felt fortunate that their families were able to afford treatment, and they in turn founded Project HEAL at just 15 years old to raise money for others suffering with eating disorders who were unable to afford treatment. Between 2009 and 2017, Project HEAL has provided over 70 life-saving scholarships.

In the last 2 years, Project HEAL has experienced tremendous growth. We currently have over 40 chapters across the globe, partner with over 30 treatment providers, and have 10 of the leading global eating disorder researchers on our advisory board. We are uniquely situated at the intersection of thousands of patients/families/academic/researchers and treatment centers, and we have the ability to unite these groups to create greater impact.

In August, 2016, Project HEAL gathered top researchers in the eating disorder field (including former National Institute of Mental Health director, Tom Insel) for a strategy retreat to discuss how to drive significant change in the field, and released a Priorities for the Eating Disorder Field Report. This meeting solidified our theory that Project HEAL is ready to expand our mission - driven by the desires of the eating disorders community and backed by academic support. Given our massive growth and potential to reach millions of those suffering, and knowledge of gaps in the field, we decided to focus on strengthening lower levels of care and community support. We then piloted Communities of HEALing with 10 mentor-mentee pairs and our preliminary outcomes are promising. Now is therefore an ideal time for us to conduct a pilot study of its effectiveness. Project HEAL has partnered with researchers at The Columbia University Center for Eating Disorders to conduct a randomized controlled trial to evaluate the effectiveness and cost effectiveness of this peer mentorship program.

Should the program demonstrate usefulness, it is scalable and duplicable by virtue of being a volunteer-led, low cost program. Within 12 of our chapters, Project HEAL has developed the infrastructure for providing these mentorship programs by increasing volunteer leadership, building long-term relationships and agreements with partnering organizations and treatment providers, and creating online training and resource tools that are effective and easily accessible for our volunteers.

Problem/ Significance

30 million Americans are estimated to suffer from an eating disorder. Eating disorders are serious psychiatric conditions characterized by heightened medical and psychiatric comorbidity, high relapse rates, and for anorexia nervosa, the highest mortality rate of any psychiatric illness. Adolescents and young adults are at particularly high risk for developing an eating disorder, with peak age of onset between 14 – 19 years (1).

Treatment resources are currently lacking, and a majority of individuals who suffer are unable to access treatment. Even for those who do receive help, the current treatment model consists of intensive and acute stays at residential centers or hospitals, and the relapse rates within the first year of being discharged from a higher level of care are upwards of 50% (2). Adjunctive interventions delivered during these high risk times, designed to bolster patients' motivation and treatment engagement and compliance, may reduce risk of relapse. Adjunctive interventions that can be delivered at lower levels of care (e.g., nursing, community health workers, peer mentors) are also promising by virtue of their potential to remediate deficiencies in care received due to high treatment cost/limited insurance coverage (3), a shared priority for insurers and patients alike.

Project HEAL's new program is a peer mentorship-based adjunctive intervention for individuals with eating disorders participating in outpatient treatment. Peer mentorship involves matching individuals who suffer from eating disorders with fully recovered peers. Peer mentors provide support, accountability, and serve as a model that full recovery from an eating

disorder is possible. Dyads meet weekly in person or online. The content of meetings is focused on the mentee's eating disorder recovery process, including structured topics/activities like examining pros and cons of behavior change and challenging eating disorder thoughts.

Peer support for other mental illnesses is widespread, effective, and feasible, including in areas of substance use and severe mental illness (4). Although peer mentorship models of care have existed in the mental health field for some time, applying this model to eating disorders is novel, and there are no controlled studies of the efficacy of peer mentorship for patients with eating disorders. One prior observational study provided preliminary evidence in support of peer mentorship, by comparing individuals receiving online mentorship to those waiting for a mentor at a single time point. The between-group comparison showed that individuals receiving mentorship reported better quality of life and missed fewer treatment sessions compared to those who were unmatched (5).

Project HEAL's partners at Columbia University Center for Eating Disorders Columbia University will be studying the effectiveness of peer mentorship in individuals with eating disorders participating in outpatient treatment. The overall objective of the current proposal, therefore, is to evaluate the feasibility and efficacy of peer mentorship in an eating disorder population. The design of the study is a 3-arm randomized clinical trial, comparing a 6-month peer mentorship intervention to active ("social support mentorship") and inactive ("wait list") control conditions. Feasibility, as well as preliminary efficacy for improving eating disorder symptoms and reducing health care costs, will be evaluated. Outcomes will be measured monthly throughout the 6-month intervention period and bi-monthly during a 6-month follow-up period.

Specific Aims

Aim 1. Evaluate the feasibility and acceptability of peer mentorship.

Hyp1a. Among adolescents and adults with eating disorders, peer mentorship will demonstrate greater feasibility, as measured by higher attendance rates in individuals assigned to peer mentorship compared to participants assigned to social support mentorship (the time-matched active control group).

Hyp1b. Peer mentorship will demonstrate greater acceptability compared to both active and inactive control conditions, as measured by higher acceptability ratings.

Aim 2: Evaluate the impact of peer mentorship on eating disorder symptoms.

Hyp2a. Among adolescents and adults with eating disorders, participants in peer mentorship will have greater reductions in eating disorder symptoms, measured using the Eating Disorder Symptom Inventory (EPSI), compared to individuals involved in social support mentorship and wait-list control conditions at post-treatment (6 months) and follow-up (12 months).

Hyp2b: For individuals who meet criteria for current or past anorexia nervosa, individuals assigned to peer mentorship will be more likely to achieve or maintain a BMI ≥ 18.5 , compared to both control conditions at post-treatment (6 months) and follow-up (12 months).

Hyp2c: For individuals who meet criteria for current or past bulimia nervosa or binge eating disorder, individuals assigned to peer mentorship will have greater reductions in the frequency of bingeing/purging and bingeing episodes, respectively, compared to individuals in either control condition at post-treatment (6 months) and follow-up (12 months).

Aim 3: Evaluate the impact of intervention condition on total cost for eating disorder treatment.

Hyp3. Controlling for pre-intervention clinical status, estimated total cost for eating disorder treatment accessed, measured using a Healthcare Utilization Survey, will be lower among peer mentorship participants compared to both control groups at post-treatment (6 months) and follow-up (12 months).

Innovation

1. No study has evaluated the effectiveness of mentorship by non-clinician recovered peers for patients with eating disorders. Although Project HEAL has gathered preliminary data regarding the program's efficacy, peer mentorship for eating disorders has not yet been empirically examined in a controlled study. The goal of the current proposal is to conduct a randomized controlled trial, comparing peer mentorship to a social support intervention led by a Project HEAL volunteer without history of an eating disorder and to a wait-list control group.

2. Focus on tertiary prevention. The effectiveness of structured, behavioral programs delivered at higher levels of care (e.g., hospitalization, residential) for weight gain and stabilization is well established. Yet, *maintaining progress* after discharge is elusive for many patients, with high rates of relapse in the first year following hospitalization. Few studies have explicitly focused on strategies for tertiary prevention, and the current study addresses this gap.

3. Focus on interventions at lower levels of care. There are several reasons to prioritize development of treatment options at lower levels of care. First, such services can serve to bolster the amount of treatment patients receive at high-risk times. Second, many patients are unable to access needed treatment due to high cost, and lower-intensity resources may provide an accessible resource for patients who may otherwise receive no treatment. If peer mentorship shows promise, future research can inform whether it increases service utilization among individuals without access to treatment.

Research Strategy

Columbia University's research team will work in collaboration with Project HEAL leadership to implement the study. Project HEAL's primary role is development of the intervention itself and recruitment and training of peer mentors and mentors in the social support condition. Columbia's overarching roles include recruiting, screening, and consenting participants and managing their safety, as well as designing and implementing the RCT and ensuring its fidelity. In the latter role, the research team will develop the active control intervention, provide training in research and safety procedures to all mentors, provide bi-weekly and as-needed supervision to all mentors, and assess intervention fidelity using weekly questionnaires completed by both mentors and mentees.

Sites

Project Heal has community sites in 40 cities across the US and Canada. Sites are locations where one or more individuals has established a local Project HEAL chapter. Chapters range in size from just a few people to over 50. In the past year, 10 sites have been preparing to launch Communities of HEALing programs, where trained mentors carry out peer mentorship and free community support groups with oversight from a National-level Program Director. Moving forward, all peer mentorship will take place in the context of the research study (mentorship will not be offered outside of the study). Study sites will include New York, Philadelphia, Los Angeles, San Francisco, Boston, Chicago, Essex, MA, Southeast Pennsylvania, and Pittsburgh. Interested participants who do not live in the vicinity of an existing Project HEAL site are offered available online peer mentors with whom they may communicate via FaceTime or Skype.

Participants

Participants will be recruited using strategies found to be effective in launching a pilot Communities of HEALing program, including referrals from providers at treatment facilities (with whom Project HEAL has existing collaborations) as well as through Project HEAL's various online platforms (websites, Facebook). Participants will be 14 – 45 year old adolescent and adult women and men who have a current (or within the past 6 months) diagnosis of anorexia nervosa, bulimia nervosa, or binge eating disorder. In order to target patients during a critical window of susceptibility to relapse, all participants will have been recently (within the past 6 months) discharged from an inpatient, residential, or partial hospitalization program and now be involved in outpatient treatment at an appropriate level of care (based on clinician documentation). Exclusion criteria include medical instability (e.g., acute hypotension, bradycardia, electrolyte imbalance) *as reported by the participant's primary eating disorder treatment provider* or evidence of needing specialized treatment for another major medical or mental health condition or substance use.

Procedure

There are three primary components of the study: (1). Screening/randomization (pre-treatment), (2). Randomized treatment phase (months 1-6), and (3). Follow-up phase and "open label" treatment during which wait-list participants will receive peer mentorship (months 6 – 12). Assessments will occur monthly throughout the 6-month randomized treatment phase and bi-monthly throughout the 6-month follow-up phase. Each component is described in detail below.

1). Screening and randomization: Participants will be screened by telephone by an EDRU (Eating Disorders Research Unit) study team member, during which inclusion/exclusion criteria will be assessed. Potential participants who are interested will be consented by telephone. For participants who are 14 – 17 years old, parental consent and adolescent assent will be documented. Prior to study enrollment, participants will complete baseline questionnaires assessing eating disorder and comorbid psychiatric symptoms using Recovery Record®, a HIPAA compliant application accessible by computer or smart phone. Assessment measures are described in detail below in the Assessment Instruments section.

Participants will also provide consent for the research team to contact their primary eating disorder treatment provider, who will in turn provide documentation of their patient's medical stability and engagement in treatment. After a participant has signed consent and completed baseline screening measures, he or she will be randomized to either peer mentorship, social support mentorship, or wait-list. Participants in both mentorship conditions will then be matched with an available mentor. Participants will enter the study on a rolling basis.

2). Randomization phase (months 1 – 6): Participants and mentors meet weekly for one hour in person (for those from the locations listed above) or online (for those who live outside of commutable distance from the identified sites) for six

months. Matching between mentees and mentors will be determined based upon location. We will also attempt to honor participant preferences (e.g., similar age). To evaluate fidelity, the mentors will keep track of which principles, topics, and activities addressed in each mentee meeting using a post-meeting mentor rating form completed after each meeting.

Peer Mentorship

The mentorship intervention includes mentorship of patients with an eating disorder by those who have recovered from an eating disorder. All mentors have a history of an eating disorder but identify as recovered for at least two years. The peer mentorship program being studied was developed by Project HEAL. It is adapted from a program designed by Carolyn Costin, a pioneer in the eating disorder field and founder of the first group of treatment centers utilizing recovered therapists. Per the Project HEAL Mentor Training Handbook, mentors will act as a support person and role model for the mentee, through providing interpersonal support, guidance, and sharing of wisdom from personal experiences. Interactions between mentors and mentees are guided by eight core principles used to promote eating disorder recovery, each of which has suggested objectives (e.g., help those still struggling to examine the cost/benefits of recovering) and activities (e.g., write ten goals for treatment, write about a day in my life when I am recovered). Between weekly meetings, mentees and mentors may connect by calling, texting, etc., if both parties agree. Meetings will take place in public or semi-public locations, including those on college campuses (e.g., library, coffee shop, common spaces in dormitories/apartments).

Social support (active control condition)

The active control condition is termed “social support mentorship,” and will involve matching between mentees and volunteer mentors who have no history of an eating disorder. Social support mentors coordinate social activities within Project HEAL and the community, such as participating in advocacy (e.g., writing a letter to a congressperson) or attending a leisure activity (e.g., a museum). Mentees engage in one activity per week (lasting about one hour), with the Project HEAL volunteer, and in some cases, one to three other mentees. Interactions are centered around the week’s activity. Meeting location will depend on the designated activity.

Wait-list control (inactive control condition)

Wait-list control participants will be evaluated monthly throughout the randomized treatment phase during which they will not receive study interventions. Waitlist participants will subsequently receive peer mentorship following completion of the wait-list study period. To promote retention during the randomized phase, participants will be contacted at two and five months by Project HEAL staff members.

Common intervention components

Recovery Record: Participants in all arms of the study will be asked to utilize Recovery Record®, a HIPPA-compliant smart phone application used by over half a million participants with eating disorders, in order to complete study assessments at baseline, monthly throughout treatment, and at post-treatment. The application was designed to provide support to eating disorder patients and includes a number of features aimed to promote recovery (e.g., meal tracking prompts for completing meals/snacks). In addition to completing study assessments using the application, participants in the peer mentorship condition only will also be encouraged to utilize the application’s support features and communicate with mentors using this feature. Mentors are able to see mentee symptoms and behaviors in real time and provide in app feedback.

Community support groups: All participants in the study are invited to attend Communities of HEALing support groups, which are offered by Project HEAL but are not part of the proposed study. Groups may include members of the community who are not involved in research. Participants will be informed at the onset of groups that there are members in the group who are not participating in the research study and it is up to their discretion whether they choose to attend. Mentors will lead the support groups.

Fidelity monitoring and supervision: Mentors will be supervised by the PI (Dr. Ranzenhofer) or other EDRU clinician. Supervision will occur in a group format, by telephone, twice-monthly. Between scheduled supervision, mentors may contact an EDRU clinician and/or psychiatrist on call. Supervision will focus on both clinical issues that arise during meetings with participants as well as treatment fidelity and adherence to the content of the intervention. Mentors and mentees will complete weekly reports of session number and content, which will be used to inform supervisory discussions and evaluate intervention fidelity.

3). Follow-up phase (months 6 – 12). Outcomes will be assessed bimonthly in participants formerly assigned to active conditions, and monthly in participants formerly assigned to wait-list. Participants initially assigned to wait-list will be matched with a peer mentor and receive the peer mentorship intervention as described above.

Measures

On a monthly basis throughout the six month randomized phase and then bi-monthly during the follow-up phase, participants will complete assessments of eating disorder symptoms, co-morbid psychiatric symptoms, and health care cost. Participants assigned to the wait-list condition will complete *monthly* (rather than bi-monthly) assessments during the “open label” phase in which they are receiving peer mentorship, to be consistent with the procedures completed by participants in active conditions. Patients’ treatment providers will be contacted in order to obtain the patient’s current height/weight measurements according to the same schedule.

Eating Disorder Symptoms: Eating disorder symptoms will be assessed monthly using the Eating Pathology Symptoms Inventory (6). The Eating Pathology Symptoms Inventory (EPSI) is a self-report questionnaire that includes 45 items covering 8 subscales (e.g., body dissatisfaction, binge eating). Each item is scored on a five-point Likert-style scale. The EPSI is part of the Phynx Toolkit, a NHGRI/NIDA-sponsored catalog of recommended standard measures of phenotypes (symptoms) for use in biomedical research.

Weight and height: Before enrolling in the study, participants will provide permission for the study team to contact their primary eating disorder treatment provider, who will in turn inform the study team of the patients’ *measured* height and weight, on a monthly basis throughout the randomized phase of treatment.

Binge and purge episode Frequency: Frequency of bingeing and purging episodes will be assessed by asking participants to report the number of bingeing and/or bingeing/purging episodes experienced within the past week. Questions from the Eating Disorder Examination will be adapted to be assessed via Recovery Record.

Health Care cost: Estimated total health care costs related to the patient’s eating disorder will be assessed using the Health Care Cost and Utilization Survey, developed by the research team. The survey asks participants to report the types and frequencies of a range of health services received including hospitalizations, residential treatment, outpatient visits (e.g., primary care, registered dietician) and tests (e.g., urine test, blood test), and mental health treatment (e.g., individual therapy, family therapy).

Statistical analyses

Aim 1: Each individual’s attendance rate will be calculated based upon proportion of weekly meetings attended. ANOVAs will be used to compare average attendance rates and acceptability ratings by treatment condition.

Aim 2: Linear mixed models with total EPSI score as the dependent variable will be used to evaluate the associations among time (IV), condition (IV), and the condition x time (IV) interaction and EPSI scores (DV). Controlling for baseline BMI, a generalized estimating equation with BMI >18.5 (yes/no) as the dependent variable will be used to examine the association between condition and BMI outcome. Linear mixed models with episode frequency as the dependent variable will be used to evaluate the associations among time (IV), condition (IV) and the condition x time (IV) interaction and episode frequency.

Aim 3: Linear mixed models will be used to evaluate the associations among time (IV), condition (IV), and the condition x time interaction (IV) and total health care cost (DV).

Conclusion

Project HEAL’s goal is to reduce suffering caused by eating disorders by delivering prevention, treatment financing, and recovery support for people suffering from these conditions. We are proposing to deliver a new model of care, peer mentorship, to individuals in eating disorder recovery, in the context of a randomized study that will allow us to also examine how effective it is. We expect that individuals receiving mentorship and general social support through our programs will experience improvements in eating disorder symptoms, other psychiatric symptoms, and reductions in their need for health care over time, and we expect that the outcomes for those in the mentorship program will be better than those receiving general social support. We hope to in turn generate an evidence base that will provide a basis for dissemination and a rationale to support insurance coverage for these disorders.

The need for empirically based and cost effective eating disorder interventions at lower levels of care cannot be overstated. Peer mentorship may meet this need, but has not yet been evaluated in a rigorous way. Our integration of an RCT into an existing program will allow us to evaluate peer mentorship’s effectiveness with comparably low additional cost. We hope to partner with your foundation to conduct this study.

References

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2. Khalsa SS, Portnoff LC, McCurdy-McKinnon D, Feusner JD. What happens after treatment? A systematic review of relapse, remission, and recovery in anorexia nervosa. J Eat Disord. 2017;5:20. doi: 10.1186/s40337-017-0145-3. PubMed PMID: 28630708; PubMed Central PMCID: PMC5470198.
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6. Forbush KT, Wildes JE, Pollack LO, Dunbar D, Luo J, Patterson K, et al. Development and validation of the Eating Pathology Symptoms Inventory (EPSI). Psychological assessment. 2013;25(3):859-78.

Grant Budget template

Grantee Legal Name:

Project HEAL: Help to eat, accept and live.

A novel peer-mentorship and social support program for reducing relapse in outpatients with eating disorders

Project Name:

Project Dates (1 year): October 1, 2017 - September 30, 2018

Amount requested (MUST match the figure in your grant application):

Project/Program funding expected from other sources:

Total project budget:

	100,000
	145,000
	245,000

Please add more rows within the budget categories as needed.

Please be as detailed and specific as possible in your break-down of the one-year project budget.

Total Project Budget should include h&g budget plus other funding, if applicable.

Please note that you may budget up to 10 percent of the grant amount for activities to support the grant reporting and evaluation requirements.

Proposed Project Budget	Grand Funded Budget 10/1/2017 - 9/30/2018	Total Project Budget 10/1/2017 - 9/30/2018
Salaries		
Program Director	30,000	60,000
Director of Volunteer Services	20,000	60,000
	<u>50,000</u>	<u>120,000</u>
Direct Program Costs		

<i>Training Supplies</i>	1,000	2,000
<i>Travel for Site Inspections</i>	2,000	10,000
<i>Online Training Module Support</i>	5,000	15,000
<i>Background Check for Volunteers</i>	2,000	2,000
<u><i>Support Group Meeting Space</i></u>	<u>20,000</u>	<u>40,000</u>
	30,000	-
Consultant Fees		
Contract with Columbia Eating Disorders Research Unit	20,000	85,000
	<u>20,000</u>	
Other		
<u>Subtotal</u>		<u>85,000</u>
Total Project/Program Budget	100,000	245,000

Budget Narrative

Salaries

- Program Director- \$30,000 is 50% of the Program Manager's annual salary who will spend 100% of her time working on the Communities of HEALing. Program Manager is responsible for creating and updating online training module, program marketing, program supervision of all volunteers and participants, program compliance, site visits and working directly with Columbia Research Unit to ensure research compliance is met in the peer-to-peer mentorship program.
- Director of Volunteer Services- \$20,000 is 33% of the Director of Volunteer Services annual salary who spends 50% of her time working on Communities of HEALing. Director of Volunteer Services is responsible for assisting in program management as needed, building chapter capacity to support Communities of HEALing, assisting with volunteer management and vetting, and working directly with Columbia Research Unit to ensure research compliance is met in the social support mentor control study.

Direct Program Costs

- Training Supplies- \$1000 is 50% of the annual training supply costs for Communities of HEALing. (25 workbooks \$500, 25 curriculum guides \$500, 15 support mentorship booklets \$400, 40 binders \$400, additional printing \$200= \$2000)
- Travel for Site Inspections- \$2000 is 20% of the annual travel costs for site inspections for Communities of HEALing. Funds are needed for 1 site visit per year to these sites. (Flight \$600, Hotel \$200 x 2 nights (\$400), Meals/Incidentals \$425) x 7 sites= \$10,000). Travel allows for quality assurance of the program through in-person assessments and giving feedback.

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- Online Training Module Support- \$5000 is 33% of the cost to create and implement the online mentor training program. Total cost is \$15,000. This online training will allow for mentors to access training and ongoing education sessions with ease and for Project HEAL to monitor and evaluate mentor training performance and frequency of module participation for additional learning tools.
 - a. Peer mentorship training includes 23 hours of training in an online “classroom” which includes completing readings, watching lectures, videos, film clips, and role plays, as well as completing writing assignments and webinars with facilitated conversations.
 - b. Social support mentor training is 4-5 hours, also delivered in an online format. In both groups, 2.5 hours of the mentor training is devoted to recognizing and responding to urgent/emergency situations. Training is coordinated by Project HEAL staff. The PI and Co-I will develop and lead training regarding research components.

 - Background Check for Volunteers- \$2000 is the entire cost to background check 40 volunteers in one year. Project HEAL is using Verified Volunteer which costs \$40 per background check with an initial set-up fee of \$400.

 - Support Group Meeting Space-\$20,000 is 50% of the estimated annual costs for meeting space for weekly support groups. Although, Project HEAL intends to get donated space as much as possible, the average space is \$150 per meeting based on pilot programming in NYC and Philadelphia. We expect that each of seven sites will need approx. \$5700 a year for meeting space for 38-40 meetings (approx. \$40,000 total).

Consultant Fees

- Contract with Columbia Eating Disorders Research Unit- \$20,000 is 24% of the annual Columbia Eating Disorders Research Unit fees of \$85,000. Columbia’s research unit will oversee and manage all aspects of the research, including screening and enrollment, randomization, intervention fidelity, and data collection, management and analysis, and publication/dissemination of findings in scientific and lay communities.